Shook, Hardy & Bacon L.L.P.

Product Liability Litigation Report

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STATE APPEALS COURT FINDS GENERIC DRUG LABELING NOT PREEMPTED BY FEDERAL LAW

A California court of appeal has ruled that a woman who claimed that a generic prescription drug maker failed to adequately warn of the risk of a condition she contracted after taking the drug should be allowed to proceed with her claim. *McKenney v. Purepac Pharm. Co.* No. F052606 (Cal. Ct. App., 5th Dist., decided September 25, 2008). So ruling, the court rejected the defendant's federal preemption argument, which is similar to the one that the U.S. Supreme Court will consider during its 2008-2009 term in *Wyeth v. Levine*, No. 06-1249 (U.S., *cert*. granted January 18, 2008).

The case involved the generic version of a heartburn drug which carried the same label that the Food and Drug Administration (FDA) had approved for use with its brand-name counterpart. The plaintiff allegedly contracted involuntary muscle movements after taking the drug and claimed that its label "substantially understated and downplayed the risks of tardive dyskinesia."

The drug's manufacturer argued that it could not use any labeling that was not FDA-approved, "and that therefore it cannot be held liable under state law for failing to use whatever different labeling McKenney may contend Purepac should have used." The court found this application of implied preemption theory too broad. Citing a 1988 California Supreme Court decision which found that Congress did not intend to preempt all state tort liability for injuries from prescription drugs, particularly in cases involving a failure to warn of known or reasonably scientifically knowable risks, the court noted that nothing in the law had changed since then, not even changes in FDA's approach to preemption. Because the plaintiff did not allege that the defendant "should have given warnings about the use of metoclopramide that the FDA expressly precluded Purepac from giving," the court found that the trial court erred in sustaining the company's demurrer.

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JUSTICE DEPARTMENT REACHES PLEA AGREEMENT WITH DRUG MAKER OVER OFF-LABEL PROMOTIONS

The U.S. Department of Justice charged Cephalon, Inc. with promoting some of its prescription drugs for off-label uses not approved by the Food and Drug Administration. The company has agreed to plead guilty to one misdemeanor count of introducing misbranded drugs into interstate commerce and pay $50 million in criminal fines and forfeiture obligations. The company has also agreed to pay $375 million as part of a separate settlement of civil proceedings against it that were filed in several federal courts as *qui tam* actions involving claims that Cephalon sought payment for its drugs through various government-funded programs, such as Medicaid and Medicare, which do not allow reimbursements for unapproved uses of prescription drugs.

According to the criminal indictment against Cephalon, the company trained its sales force to promote the drugs for off-label uses and visit doctors who would not normally prescribe the drugs and convince them to use it for their patients. The company also allegedly established sales quotas and a bonus program to encourage the off-label promotions and instructed its sales force "to coach the physicians on what diagnostic codes to record in their documentation," when submitting reimbursement claims to third-party payors such as Medicaid. The company was also charged with sending physicians "to lavish resorts for supposed 'consultant' meetings to hear discussions about off-label uses of its drugs."

TRIAL CONSULTANTS TRAWL ONLINE PROFILES TO VET JURORS

"In the age of MySpace, Facebook, cyberspace sales pitches and blogging, the Internet is proving a treasure trove of insight into the thinking and values of those called for jury duty," according to a September 28, 2008, article in *The Los Angeles Times,* which reported that trial consultants have increasingly turned to the World Wide Web to perform background checks on prospective jurors.

Several consultants interviewed for the article noted that any personal information gleaned from the Web is "fair game" in contentious cases. They estimated that although only 10 percent of jurors have a substantial online presence, this number is "growing exponentially" and allowing consultants to augment or altogether bypass traditional investigative routes, such as interviews. "We're really getting an opportunity to find out where the skeletons are hidden," said one jury selection expert, adding that law firms and companies request these types of services in particularly difficult cases.

Some trial consultants, however, expressed reservations about using online profiles to accurately vet jurors. "Most of this information is what I would describe as noise," another trial consultant was quoted as saying. "And it's so very difficult amongst all that noise to find anything that can be useful."

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AMERICAN COLLEGE OF TRIAL LAWYERS CALL DISCOVERY SYSTEM "BROKEN"

A survey of American trial lawyers, representing both plaintiff and defendant interests, complained about the civil discovery system and cited electronic discovery as an expensive "morass" that denies access to justice for many litigants. Conducted by the American College of Trial Lawyers (ACTL) and Institute for the Advancement of the American Legal System, the survey elicited nearly 1,500 responses. According to the survey overview, four major themes emerged: "Although the civil justice system is not broken, it is in serious need of repair."; "The discovery system is, in fact, broken"; "Judges should take more active control of litigation from the beginning;" and "Local Rules are routinely described as 'traps for the unwary' and many think they should either be abolished entirely or made uniform."

While the respondents aired numerous complaints, nearly two-thirds agreed that the civil justice system works well for personal injury torts and product liability cases. Sixty-five percent do not believe that the Federal Rules of Civil Procedure are conducive to meeting the goal of a "just, speedy and inexpensive determination of every action." Half said there are too many rules, and half said they are too complex. More than 87 percent indicated that the discovery of electronically stored information increases the costs of litigation and 63 percent say that e-discovery is being abused by counsel. The survey also explored lawyer attitudes about the effectiveness of notice pleading, initial disclosures, dispositive motions, and alternative dispute resolution, among other matters. According to an ACTL spokesperson, "The costs and burdens of discovery are driving litigation away from the court system and forcing settlements based on the costs, as opposed to the merits." *See U.S. Law Week,* September 16, 2008.

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INSURANCE COMPANY TO EXCLUDE COVERAGE FOR NANOTECHNOLOGY-RELATED INJURY AND PROPERTY DAMAGE

Continental Western Group of Des Moines, Iowa, has announced that it plans to "exclude coverage of bodily injury and property damage caused by nanotubes and nanotechnology," according to a September 26, 2008, report in *Greenwire,* which questions "whether such exclusions could be the start of a trend." Effective November 15, the policy draws on a recent study comparing the purported health risks of carbon nanotubes to those posed by asbestos. "It would not be prudent for us to knowingly provide coverage for risks that are, as of yet, unknown and unquantifiable," stated the insurance company. "We are all too aware of what happened to companies involved with asbestos-related exposures in the past and see this as a very similar issue."

A policy associate with the Woodrow Wilson Center Project on Emerging Technologies reportedly noted that Continental Western's decision reflects a reluctance to take "unknown financial risks" in untested scientific waters. Other experts, however, argued that the insurance group will have difficulty defending the policy if challenged. "Treating nanotechnology as if it is monolithic makes no sense," said a spokesperson for the NanoBusiness Alliance. "A technology itself does not have risks and benefits–only the embodiments of the technology in the form of products do. Furthermore, the definitions were sufficiently broad that almost any business [could] be subject to the exclusions."

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ALL THINGS LEGISLATIVE AND REGULATORY

CPSC Announces Requirements to Accredit Third Party Children's Product Testing Labs

The Consumer Product Safety Commission (CPSC) has published a notice of its requirements for the accreditation of third party laboratories that will be testing children's products to conform to the agency's lead paint ban. Effective September 22, 2008, the requirements incorporate ISO Standard ISO/IEC 17025:2005—General Requirements for the Competence of Testing and Calibration Laboratories. Third party laboratories must also "be accredited by an ILAC-MRA signatory accrediting body and the accreditation must be registered with, and accepted by, the Commission." The CPSC will maintain a listing of those labs "whose accreditations it has accepted and the scope of each accreditation."

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Firewalled laboratories, that is, those owned, managed or controlled by a manufacturer or private labeler of a children's product to be tested by the laboratory, must also "submit to the Commission copies of their training documents showing how employees are trained to notify the Commission immediately and confidentially of any attempt by the manufacturers, private labeler or other interested party to hide or exert undue influence over the laboratory's test results." The CPSC notice outlines additional accreditation requirements for laboratories owned or controlled in whole or in part by a government. *See Federal Register*, September 22, 2008.

New California Green Chemistry Laws Could Require Additional Product Labeling

California Governor Arnold Schwarzenegger (R) has signed into law two bills (A.B. 1879, S.B. 509) that would establish a "green chemistry" program in the state to reduce "chemicals of concern" in consumer products and the environment. Both the California Department of Toxic Substances Control and the Office of Environmental Health Hazard Assessment will have new authority under the legislation to identify and prioritize toxic chemicals, analyze their alternatives and increase consumer knowledge about their purported hazards.

The Assembly bill also requires the adoption of regulations that (i) impose "requirements on the labeling or other type of consumer product information"; (ii) impose "a restriction on the use of the chemical of concern in the consumer product"; (iii) prohibit "the use of the chemical of concern in the consumer product"; (iv) impose "requirements that control access to or limit exposure to the chemical of concern in the consumer product"; or (v) impose "requirements for the manufacturer to manage the product at the end of its useful life, including recycling or responsible disposal of the consumer product."

Under the legislation, chemicals of concern will be evaluated in terms of their life-cycle emissions, environmental contamination, worker safety, and public health impacts. When the governor signed the bills, he was quoted as saying

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that the bipartisan package created "the most comprehensive Green Chemistry program ever established" and would "spur a new era of research and innovation." He also reportedly said that toxics "will be something that can be removed from every product in the design stage—protecting people's health and our environment." *See BNA Daily Environment Report*, September 30, 2008.

THINKING GLOBALLY

Ninth Circuit Dismisses Alien Tort Claims in Pesticide Suit

Plaintiffs living and working on fruit plantations in the Ivory Coast lost their appeal to the Ninth Circuit from orders dismissing their claims against the makers, distributors and users of DBCP for genocide and crimes against humanity under the Alien Tort Claims Act. *Abagninin v. AMVAC Chem. Corp.*, No. 07-56326 (9th Cir., decided September 24, 2008). Claiming that exposure to the agricultural pesticide causes male sterility and abnormally low sperm counts, plaintiffs alleged that defendants continued making, selling and using DBCP on Ivory Coast plantations despite knowing about its toxicity since the 1950s. They contended that this conduct supports alien tort claims because the conduct was undertaken with knowledge of the chemical's effects and pursuant to a state or organizational policy.

The district court dismissed the claims with prejudice, ruling that genocide requires specific intent to destroy a particular group of victims and that crimes against humanity require an element of state action, neither of which, according to the court, had been or could be alleged. The Ninth Circuit agreed, analyzing the claims under the guidance of *Sosa v. Alvarez-Machain*, 542 U.S. 692 (2004), which clarified "that any claim based on the law of nations must 'rest on a norm of international character accepted by the civilized world and defined with a specificity comparable to the features of the 18th-century paradigms.'" According to the court, general knowledge about the purported risks of a chemical does not equate to specific genocidal intent under the law of nations.

The court also found that plaintiffs' crimes against humanity claim failed because one of its elements is a course of conduct "pursuant to or in furtherance of a State or organizational policy to commit such attack." While the defendants were business organizations, the court determined that the expression "organizational policy" refers to the actions of "political organizations," like the "unofficial militias loosely affiliated with the State and unaffiliated civilians [who] perpetrated the crimes in Bosnia and Rwanda." Political organizations, according to the court, exercise de facto control over a defined territory by, for example, erecting checkpoints on main roads, developing civilian structures and holding a substantial percentage of territory. Thus, the court concluded, "Merely purchasing and providing DBCP for use on the plantations does not suffice, and the district court correctly found that the facts as alleged do not support [plaintiffs'] conclusory statement that the use of DBCP was carried out pursuant to a State or organizational policy."

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LEGAL LITERATURE REVIEW

Dan Markel, "How Should Punitive Damages Work?," *University of Pennsylvania Law Review* **(forthcoming 2009)**

This article analyzes the distinct purposes of punitive damages, that is, retribution, deterrence or vindication of dignity interests, and explains how certain procedural protections that defendants enjoy should be linked to which purpose is being served. Florida State University College of Law Associate Professor Dan Markel also addresses other implications of this approach as to insurance, settlement and taxation. The article is intended as a companion to an article that Markel is publishing in a forthcoming issue of the *Cornell Law Review* titled *Retributive Damages: A Theory of Punitive Damages as Intermediate Sanction.* Markel's concern is that, by improperly characterizing punitive damages, courts run the risk of both under- and over- protecting various defendants. He also considers the subject from the perspective of meeting constitutional mandates.

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Alexandra Klass, "Tort Experiments in the Laboratories of Democracy, *William & Mary Law Review* **(forthcoming 2009)**

University of Minnesota Law School Associate Professor Alexandra Klass explores tort-law trends in the states, Congress and the U.S. Supreme Court and concludes that an emerging public law view of tort at the federal level has allowed the displacement of state tort reforms. She suggests that giving sufficient attention to the private law goals that tort law serves makes it easier to value the role the states play in our federalist system. Klass discusses a few of the state tort law "experiments" that have occurred over the past two decades, such as limitations on damages, new statutes of limitations and the establishment of regulatory compliance defenses. She also shows how the U.S. Supreme Court has applied preemption and due process doctrine to limit such experiments and calls for allowing states "to serve their role as 'laboratories of democracy'" in the tort arena.

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LAW BLOG ROUNDUP

FASB Reporting Rules on Hold

"In demanding more detailed reporting of the potential losses resulting from litigation, FASB was going to force companies to show their legal hand to the very people suing them, violate attorney-client privilege, and in the process, require highly speculative commentary that could damage a company's reputation with investors." National Association of Manufacturers senior advisor Carter Wood, noting that the Financial Accounting Standards Board has delayed, at least until December 2009, the implementation of its proposal for fuller disclosures about loss contingencies in public company financial statements. A storm of protest followed the proposal's release, and FASB has adopted a "plan for redeliberations," as well as an "alternative model" that it will field test.

PointofLaw.com, September 25, 2008.

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Court's Ruling May Not Be Entirely Authoritative

"[I]t is not clear that international law requires 'State-like' action in order for a prohibited act committed as part of a widespread or systematic attack directed against a civilian population to constitute a crime against humanity." Hastings College of Law Associate Professor Chimène Keitner, blogging about the Ninth Circuit's decision in *Abagninin v. AMVAC Chemical Corp.* Keitner opines that the "court's cursory analysis, based largely on the parties' unexamined assumptions, should not be considered authoritative on this point." Keitner has authored an article titled "Conceptualizing Complicity in Alien Tort Cases," that will be published in a forthcoming issue of the *Hastings Law Journal*.

Opinio Juris, September 26, 2008.

Tulane Law School Issues Apology for Errors in Data Underlying Law Review Article

"A professor-written law review article suggesting that the Louisiana Supreme Court justices tend to decide cases in favor of litigants and lawyers who contribute to their campaigns contained 'numerous errors,' according to a recent letter of apology sent to the Louisiana Supremes by Tulane Dean Lawrence Ponoroff." *The Wall Street Journal's* legal writer Dan Slater, discussing the apparent errors that led Tulane Law Professor Vernon Valentin Palmer and his co-author to conclude that the justices voted in favor of their contributors 65 percent of the time and two justices did so 80 percent of the time. Palmer, who has apparently corrected the errors, claims that the study's conclusions have not, broadly speaking, changed. The law review article was discussed in the January 24, 2008, issue of this Report.

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WSJ Law Blog, September 18, 2008.

THE FINAL WORD

Sara Stefanini, "3 Ways to Prepare for E-Discovery," *Product Liability Law 360,* **September 26, 2008**

This article discusses three ways that companies can prepare for electronic discovery to meet requirements added to Federal Rules of Civil Procedure in December 2006. E-discovery attorneys told *Law360* that when faced with a potential lawsuit, companies should (i) immediately save all relevant electronic data by issuing legal hold notices to employees and disabling automatic deletion and recycling programs; (ii) start talking with the opposition to determine what electronic information will be at stake in the litigation; and (iii) learn from companies sanctioned by courts for their failure to adequately comply with the new e-discovery rules.

In particular, the article cites a Deloitte Financial Advisory Services LLP study claiming that 17.5 percent of more than 500 chief executives surveyed last month "said their companies were not yet ready to handle complex discovery

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requests," while 39 percent of CEOs stated that their company's data burden had reached an "unmanageable size." "People don't know exactly what they're doing, they don't know the intricacy of the rules, they don't properly preserve or identify the information, they don't properly produce the information or they don't initiate the dialog with the other side, so they get into troublesome situations," one special master for federal courts was quoted as saying. "Transparency is really the way to go on both sides, so the old rules of hiding and gamesmanship don't apply in e-discovery."

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UPCOMING CONFERENCES AND SEMINARS

Juris Conferences, London, England – October 2, 2008 – "Second Annual Electronic Evidence Disclosure in International Arbitration." Shook, Hardy & Bacon Tort Partner John Barkett joins a faculty of arbitrators, consultants, vendors, and e-discovery experts to discuss issues ranging from the Sedona principles and IBA Rules on Taking Evidence to privilege, protocols, costs, and future e-disclosure developments.

American Bar Association, Rockville, Maryland – October 8, 2008 – "Third Annual Biotech Institute and Regional CLE Workshop." Shook, Hardy & Bacon Intellectual Property Partner Peter Strand will participate on a panel discussing "Intellectual Property Case Law Update and Resulting Litigation Issues."

American Conference Institute, Scottsdale, Arizona – October 28, 2008 -- "Positioning the Class Action Defense for Early Success." Joining a faculty that includes federal and state judges, Shook, Hardy & Bacon National Product Liability Litigation Partner Gary Long will participate in a panel discussion titled "Foregoing Settlement and Taking the Class Action to Trial."

Practicing Law Institute (PLI), Chicago, Illinois – October 29, 2008 – "PLI's Electronic Discovery and Retention Guidance for Corporate Counsel 2008." Shook, Hardy & Bacon Tort Partner Amor Esteban will join a distinguished faculty of presenters addressing "Judicial Insight into How Evidentiary Hearings Are Decided Under the Amended Federal Rules." The panel will focus on how the courts handle claims that electronically stored information is inaccessible.

American Conference Institute, Chicago, Illinois – October 29-30, 2008 – "Defending and Managing Automotive Product Liability Litigation." Shook, Hardy & Bacon Tort Partner H. Grant Law will serve on a panel discussing "Preemption: Examining the Current Viability of the Defense in Auto Product Liability Cases."

American Bar Association, New York, New York – November 7, 2008 – "12th Annual National Institute on Class Actions." Shook, Hardy & Bacon Tort Partner Laurel Harbour and Pharmaceutical & Medical Device Litigation Partner James Muehlberger will join panels addressing the latest developments in class action law. Harbour will discuss "Class Actions Sans Frontières," while Muehlberger will explore the "Rigorous Analysis" standard that courts apply when evaluating whether to certify a class.

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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.

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 Madeleine McDonough 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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