Shook, Hardy & Bacon L.L.P.

JULY 19, 2012

PRODUCT LIABILITY LITIGATION REPORT

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U.S. SUPREME COURT DISMISSES APPEAL, PLAINTIFF LACKING INJURY MAY SUE FOR STATUTORY VIOLATION

The U.S. Supreme Court issued an order dismissing as improvidently granted the writ of certiorari filed in a case asking whether a company can be sued for a statutory violation even if the plaintiff alleged no direct harm from the violation. ***First Am. Fin. Corp. v. Edwards*, No. 10-708 (U.S., order entered June 28, 2012)**.

Thus, the Court let stand a Ninth Circuit Court of Appeals determination that the plaintiff had standing to seek monetary damages on behalf of a class against her title insurer, which had allegedly provided millions of dollars in kickbacks to her title agency, even though she had not been charged more for her title insurance and did not allege any shortcomings in the service she was provided. Consumer advocates were apparently watching the case closely, concerned that if the Court had ruled against the plaintiff, a wide range of consumer protection laws could have been undermined. *See The Washington Post*, June 28, 2012.

FIRED WORKER SEEKS SCOTUS REVIEW OF PUNITIVE DAMAGES QUESTION

A former UPS employee who alleges retaliatory discharge has filed a petition for certiorari, seeking U.S. Supreme Court review of a Tenth Circuit decision overturning as excessive a jury's $2 million punitive damages award. ***Jones v. United Parcel Serv., Inc.*, 12-27 (U.S., petition for certiorari filed July 3, 2012)**.

The Tenth Circuit held that because the employer's misconduct resulted solely in economic injury and because the jury awarded Jones a substantial compensatory damage award, the punitive award was "grossly excessive" and violated the employer's due process rights.

According to Jones's petition, "The jury's punitive damage verdict was approximately 3.1 times the actual damage verdict, a relatively low single-digit ratio, and one that has historically been considered to be constitutionally acceptable. Nevertheless, the Tenth Circuit held that the 3.1-to-1 ratio was 'grossly excessive,' and that the punitive damages award in this case could not constitutionally exceed a 1-to-1 ratio, even though there was no component of the jury's actual damage verdict which

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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was duplicated in the punitive damage verdict." Jones contends that a reviewing court should not be permitted to substitute its "own subjective judgment[] as to the appropriate amount of punitive damages, in lieu of a jury's assessment of the appropriate amount."

SECOND CIRCUIT RULES FAILURE TO INSTITUTE "LITIGATION HOLD" DOES NOT CONSTITUTE GROSS NEGLIGENCE PER SE

In the context of an employment discrimination dispute, the Second Circuit Court of Appeals has determined that a district court did not abuse its discretion in denying an adverse inference instruction despite the defendant's failure to preserve personnel files after receiving notice of the plaintiffs' Equal Employment Opportunity charge in 2001. ***Chin v. The Port Auth. of NY & NJ,* Nos. 10-1904-cv(L), 10-2031-cv(XAP) (2d Cir., decided July 10, 2012)**.

Thus, the court rejected the plaintiffs' contention that "a failure to institute a 'litigation hold' constitutes gross negligence *per se*." Instead, the court indicated that "'the better approach is to consider [the failure to adopt good preservation practices] as one factor' in the determination of whether discovery sanctions should issue." This determination, according to the court, must be made on a case-by-case basis.

TASER HAD NO DUTY TO WARN ABOUT METABOLIC ACIDOSIS

The Ninth Circuit Court of Appeals has determined that a company which manufactures electronic-control devices, or "tasers," did not know, when the product was made and distributed, that repeated exposure could lead to fatal levels of metabolic acidosis and thus, under California law, had no duty to warn about this risk. ***Rosa v. TASER Int'l, Inc.,* No. 09-17792 (9th Cir., decided July 10, 2012)**. So ruling, the court affirmed the district court's grant of the defendant's motion for summary judgment.

The lawsuit was filed by the surviving family members of a man killed during a police confrontation that resulted in officers repeatedly deploying their tasers in an effort to incapacitate him. According to the court, his death was "subsequently linked to metabolic acidosis, a condition under which lactic acid—a byproduct of physical exertion—accumulates more quickly than the body can dispose of it, causing the pH in the body to decrease. The condition makes sudden cardiac arrest more likely."

California law places a duty on manufacturers to warn of a particular risk if it is "known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution." The plaintiffs relied on four peer-reviewed scientific studies published before the tasers were made in December 2003. Finding that none of the articles specifically

linked the use of electronic-control devices to acidosis and the risk of ventricular fibrillation, the court ruled that the plaintiffs failed to "establish a triable issue of fact that the risk of metabolic acidosis was knowable at the time of distribution."

AMOUNT IN CONTROVERSY STANDARD UNDER CAFA, TENTH CIRCUIT RULING WIDENS SPLIT

The Tenth Circuit Court of Appeals has joined seven other circuits and ruled that a defendant must show by a preponderance of the evidence that the amount in controversy exceeds the minimum under the Class Action Fairness Act (CAFA) to prevent a remand to state court. ***Frederick v. Harford Underwriters Ins. Co.*, No. 12-1161 (10th Cir., decided June 28, 2012)**. Two other circuit courts require that defendants show to a "legal certainty" that the minimum amount has been met.

The issue arose in the context of a putative class action filed in state court alleging that the defendant failed to disclose important information about the insurance policies it sold to class members. The plaintiff asserted in his complaint that the damages did not exceed the jurisdictional limit of $5 million, and the district court to which the case had been removed remanded the matter to state court agreeing that a complaint requesting damages of less than $5 million "should be taken at face value irrespective of the evidence advanced by the defendant."

The Tenth Circuit, which had not previously decided what burden the defendant faces to prevent remand, noted that the "legal certainty" standard has been adopted in the Ninth and Third Circuits only. The First, Second, Fourth, Sixth, Seventh, Eighth, and Eleventh Circuits in both published and unpublished opinions have adopted the preponderance of the evidence standard "regardless of whether the complaint alleges an amount below the jurisdictional minimum."

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Choosing to align itself with the majority, the Tenth Circuit agreed that "there is 'no logical reason why we should demand more from a CAFA defendant' than other parties invoking federal jurisdiction. … By adopting the preponderance standard, we ensure that defendants seeking removal face the same burden regardless of whether they are invoking simple diversity jurisdiction or CAFA jurisdiction. To hold otherwise would confuse courts and litigants alike, and contradict the clear weight of authority." Accordingly, the court vacated the district court's remand order and remanded with instruction to apply the preponderance of the evidence standard.

PUTATIVE CLASS CHALLENGES HEALTH-BENEFITS CLAIMS FOR FIVEFINGERS® RUNNING SHOES

Seeking to certify a state-wide class of product purchasers, a California resident has filed a consumer fraud action against the company that makes running shoes

marketed with "health benefit" claims. *Safavi v. Vibram USA Inc.*, No. CV12-5900 (U.S. Dist. Ct., C.D. Cal., filed July 9, 2012).

The company apparently launched its FiveFingers® running shoes in 2006, claiming that "you get all the health benefits of barefoot running combined with our patented Vibram® sole." According to the complaint, such claims convey "reliable scientific proof" of health benefits despite the lack of any such evidence. Among other matters, the company allegedly claims that the shoes will strengthen muscles in the feet and lower legs; improve the range of motion in ankles, feet and toes; stimulate neural function; eliminate heel lift to align the spine and improve posture; and allow the foot and body to move naturally. The plaintiff alleges that reasonable consumers would not have paid the amounts charged for the shoes or would not have purchased them at all had they known that scientific evidence does not support the company's health-benefit representations.

Alleging violations of California's Business & Professions Code and Consumers Legal Remedies Act, as well as breach of express warranty, the plaintiff seeks restitution and disgorgement, injunctive relief, a corrective advertising campaign, attorney's fees, costs, and interest.

ALL THINGS LEGISLATIVE AND REGULATORY

CRS Report Examines FDA's Authority to Regulate Cosmetics and Personal Care Products

The Congressional Research Service (CRS) has issued a report titled "FDA Regulation of Cosmetics and Personal Care Products," which addresses statutory limitations on the Food and Drug Administration's (FDA's) ability to ensure the safety and efficacy of these products. Noting that the agency's "authority over cosmetics is less comprehensive than its authority over other FDA-regulated products," the July 9, 2012, report questions whether continued self-regulation and flexible guidelines are "still appropriate" in light of serious health and safety issues that can arise in this sector.

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CRS explores the extent of FDA authority over other products, such as food, drugs and medical devices, with regard to registration; testing; premarket notification, clearance, or approval; good manufacturing practices; mandatory risk labeling; adverse event reports; and recalls. And while CRS acknowledges that the manner in which a cosmetic product could or should be regulated is not always clear, the report raises questions about oversight shortcomings given the ingredients, ranging from toxic chemicals to nanomaterials, that are often used in cosmetics.

CPSC Approves Play Yard Rule

The Consumer Product Safety Commission (CPSC) has unanimously approved a mandatory safety standard "to improve the safety of play yards and to prevent injuries and deaths to children." The new rule, which will take effect six months after publication in the *Federal Register*, apparently incorporates provisions in ASTM's voluntary F 406-12a standard and includes stability testing requirements, latch and lock mechanisms to prevent a play yard from folding on a child when in use, entrapment and floor-strength tests, and minimum side-height requirements. According to the agency, more than 2,100 incidents involving play yards were reported to CPSC between November 2007 and December 2011; 60 resulted in fatalities. *See CPSC News Release*, June 29, 2012.

Statement of Policy on Animal Testing Published; Method of Testing Hazardous Substances Amended

The Consumer Product Safety Commission (CPSC) has **proposed** codifying its statement of policy on animal testing, as amended. Under the statement, CPSC urges product manufacturers subject to the Federal Hazardous Substances Act (FHSA) "to find alternatives to animal testing and reduce the number of animal tests under the FHSA." The policy, when finalized, will take effect on publication in the *Federal Register*. The agency has also issued a **notice of proposed rulemaking** outlining its proposal to update regulations on CPSC's FHSA animal-testing methods. "All of the proposed amendments to 16 CFR part 1500 clarify or add language to explain that alternative test methods exist that avoid or reduce animal testing." Comments on both proposals are requested by September 12, 2012. *See Federal Register*, June 29, 2012.

U.S., EU and China Product-Safety Officials Begin Talks on Consumer-Product Surveillance

During their third biennial consumer product safety trilateral summit, product-safety officials from the United States, European Union (EU) and China laid the foundation for strengthening cooperation and continued an exchange of "opinions and information concerning seamless surveillance of consumer products, consumer product tracking and traceability, as well as consumer product safety information dissemination." Officials with the U.S. Consumer Product Safety Commission, the European Commission's Health and Consumers Directorate General and Enterprise and Industry Directorate General, and China's General Administration of Quality Supervision, Inspection and Quarantine participated in the talks.

According to a **joint statement** released at the summit's close, the participating agencies will, among other matters, (i) address ways to move toward a "seamless surveillance" model of product-safety enforcement and (ii) "continue research on relevant standards in the field of consumer products of shared concern by Tripartite Participants, exchange information on technical regulations and standards for these products and explore jointly the possible convergence of safety requirements." The

participants also committed to improving information exchange, as permitted by the countries' respective laws, and to communicating major safety issues as early as possible. The next summit will be held in 2014 in the EU.

EPA, CDC Officials Claim No Safe Level of Lead for Children

The Senate Committee on Environment and Public Works recently held a hearing devoted to "The Latest Science on Lead's Impacts on Children's Development and Public Health." Among those speaking during the July 12, 2012, hearing were officials with the Environmental Protection Agency (EPA) and Centers for Disease Control and Prevention (CDC) who testified that no safe blood lead level for children has been identified. In her prepared remarks, Senator Barbara Boxer (D-Calif.) noted that proposed fiscal year (FY) 2013 budget cuts will cut funding for CDC programs that address indoor lead hazards just when CDC has halved the blood lead level in children at which action is triggered to address exposures.

According to CDC National Center for Environmental Health Director Christopher Portier, Congress already reduced the FY 2012 lead poisoning prevention program to $2 million from the FY 2011 funding level of $29.2 million. EPA's John Vandenberg, who serves as director of the division responsible for identifying and evaluating the scientific literature that provides the foundation for decisions about the national ambient air quality standards for lead, testified that many lead effects, "including effects on learning and memory, are found in populations of young children at very low blood lead concentrations."

OSHA Finalizes Whistleblower Rules Under Consumer Product Safety Act Amendments

The Occupational Safety and Health Administration (OSHA) has issued a **final rule** that took effect July 10, 2012, to implement the protections provided to employees under the Consumer Product Safety Improvement Act of 2008 "against retaliation by a manufacturer, private labeler, distributor, or retailer, because they provided to their employer, the Federal Government or the attorney general of a state, information relating to any violation of, or any act or omission the employees reasonably believe to be a violation of, any provision of an Act enforced by the Consumer Product Safety Commission, or any order, rule, regulation, standard, or ban under any such Act." The new rule explains what constitutes retaliation for engaging in protected activity pertaining to consumer product safety and provides a complaint mechanism that begins with OSHA, includes a hearing before an administrative law judge and review by a federal circuit court of appeals. The rules also allow an employee to bring an action at law or equity for de novo review before a federal district court. *See Federal Register*, July 10, 2012.

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NHTSA Seeks Comments on Forward-Looking Sensor and Lighting-Performance Reports

The National Highway Traffic Safety Administration (NHTSA) has issued a **request** for comments on a research report involving advanced braking technologies that rely on forward-looking sensors to supplement driver braking or to actuate automatic breaking in response to an impending crash. NHTSA is soliciting comments by September 4, 2012, on the results of its research to date "to help guide its continued efforts in this area." *See Federal Register*, July 3, 2012.

NHTSA also **requests** comments on a technical report that evaluates "new approaches for the regulation of motor vehicle lighting performance." According to the agency, Federal Motor Vehicle Safety Standard No. 108, Lamps, reflective devices, and associated equipment, "is a complex motor vehicle standard that has been in effect for several decades." NHTSA contracted for the preparation of a technical report, "Feasibility of New Approaches for the Regulation of Motor Vehicle Lighting Performance," and seeks comments on whether these approaches would increase or decrease safety for "the traveling public." Comments are requested by September 10, 2012. *See Federal Register*, July 11, 2012.

EPA Issues for Comment Nanomaterial Case Study Involving Flame-Retardant Coatings for Upholstery Textiles

The U.S. Environmental Protection Agency (EPA) is **seeking** comments on an external review draft document titled "Nanomaterial Case Study: A Comparison of Multiwalled Carbon Nanotubes and Decabromodiphenyl Ether Flame-Retardant Coatings Applied to Upholstery Textiles." While the document does not apparently "draw conclusions regarding potential environmental risks or hazards of multiwalled carbon nanotubes, … it aims to identify what is known and unknown about [them] to support future assessment efforts." The agency will also conduct a public information exchange meeting to receive comments and questions on the case study on October 29, 2012. Comments are requested by August 31, 2012. *See Federal Register*, July 2, 2012.

LEGAL LITERATURE REVIEW

Steven Thomas & Jennifer Stonecipher Hill, "*Conte* Reeling in the Wake of California Supreme Court Decision," *DRI, RX for the Defense*, July 11, 2012

Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partner **Steve Thomas** and Associate **Jennifer Stonecipher Hill** suggest in this article that a recent California Supreme Court ruling "may signal the end of so-called 'innovator liability' under *Conte v. Wyeth*," a 2008 appellate court ruling allowing brand-name prescription-drug manufacturers to be held liable for injuries allegedly caused by generic-equivalent drugs. The California Supreme Court has refused to extend such liability, stating that the brand-name manufacturer "had no duty to warn of

risks arising from *other manufacturers'* products." Thomas and Stonecipher Hill also analyze the ruling in light of *PLIVA v. Mensing*, 131 S. Ct. 2567 (2011) (federal law preempts failure-to-warn claims against generic drug makers), in which the U.S. Supreme Court understood that consumers may have no recourse under current law when injured by a generic medication, and conclude that nothing in that opinion "requires imposing a new duty on name-brand manufacturers."

Sergio Campos, "Proof of Classwide Injury, Brooklyn Journal of International Law (2012)

University of Miami School of Law Associate Professor Sergio Campos contends that requiring proof of class-wide injury to certify a class "arises from three fallacies about the class action": (i) "class actions require a court to resolve all issues in one fell swoop"; (ii) "the class action is an extraordinary remedy that, like a preliminary injunction, requires the plaintiffs to show a likelihood of success on the merits"; and (iii) "in the absence of proof of classwide injury, individual trials are required to accurately determine each individual plaintiff's injury, and thus prevent uninjured plaintiffs from recovering." Campos discusses and corrects these purported fallacies and concludes that "common questions, not common answers, should be the standard for class certification, both in the United States and abroad."

LAW BLOG ROUNDUP

Federal Pleadings Are Not Press Releases

"I am not a fan of this sort of over-the-top pleading, but it is becoming more common. So while I am surprised by the order, I am glad to see a judge halting these practices. Perhaps this is judicial order as press release." Florida International University College of Law Professor Howard Wasserman, blogging about cyclist Lance Armstrong's lawsuit, which sought to halt a doping investigation and was promptly *sua sponte* dismissed under the U.S. Supreme Court's plausibility pleading standard. Characterizing the complaint as a "lengthy and bitter polemic against the named defendants," the court said it was "not inclined to indulge Armstrong's desire for publicity, self-aggrandizement, or vilification of Defendants," and that "pleadings filed in the United States District Courts are not press releases, internet blogs, or pieces of investigative journalism."

PrawfsBlawg, July 10, 2012.

Early Offer Law Should Have Salutary Effects

"There is reason to hope that those who request the offer have already decided they prefer the certainty of economic loss delivered quickly and the offers that are made will be accepted at a substantial rate, but only time will tell." Widener University School of Law Associate Professor Christopher Robinette, discussing

New Hampshire's early offer law. According to one of its sponsors, a claimant who requests an early offer, rejects it and then fails to receive at least 125 percent of that offer from the tort system will pay the health-care provider's attorney's fee for the early offer process only. According to Robinette, "That will likely be quite cheap. This obviously ameliorates the fear of those who have been arguing that the scheme was too draconian."

TortsProf Blog, July 16, 2012.

THE FINAL WORD

FDA Tracked E-mails Sent by Disgruntled Scientists to Congress, Intercepted Communications Leaked to Internet

According to *The New York Times*, the Food and Drug Administration (FDA) launched a surveillance action against its own scientists and outside critics of FDA's medical-review process, gathering more than 80,000 pages of computer documents representing private communications to Congress, lawyers, journalists, and President Barack Obama (D). FDA had apparently claimed that the operation was limited to five scientists the agency suspected of leaking confidential material containing trade secrets related to medical device safety and design. The software FDA used reportedly tracked their keystrokes, captured screen images, intercepted personal emails, and copied documents on their personal thumb drives.

All of the documents compiled in the investigation were accessed by *The New York Times* from a public Web site where FDA's contractor apparently posted them by mistake. The surveillance was purportedly undertaken as part of a long-running dispute between FDA scientists and their agency bosses over the approval of medical imaging devices that allegedly exposed mammogram and colonoscopy patients to unsafe radiation levels. While the scientists have complained in a lawsuit that their emails were intercepted, the scope of the operation, with a wide range of targets in Washington, D.C., and the volume of computer information monitored were not known until recently.

While the scientists have complained in a lawsuit that their emails were intercepted, the scope of the operation, with a wide range of targets in Washington, D.C., and the volume of computer information monitored were not known until recently.

Some have reportedly suggested that FDA's surveillance may have exceeded legal authority by seizing information specifically protected under the law, such as attorney-client communications, whistleblower complaints to Congress and workplace grievances. The White House Office of Management and Budget has evidently responded to the situation by issuing a memo to government agencies to emphasize that monitoring employee communications is legal, but cannot be used to intimidate whistleblowers and must be done in ways that "do not interfere with or chill employees' use of appropriate channels to disclose wrongdoing." Congressional representatives and staff targeted by FDA's surveillance operation called it unacceptable for FDA to spy on its employees. *See The New York Times*, July 14, 2012.

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UPCOMING CONFERENCES AND SEMINARS

Carmel Valley eDiscovery Retreat, Monterey, California – July 22-25, 2012 – "eDiscovery in the Cloud." Shook, Hardy & Bacon Data Security & Privacy Partner **Amor Esteban** will serve on a panel titled "Mitigating and Managing Risks Associated with the Cloud," which will focus on compliance issues as well as reducing security, privacy and intellectual property loss risks.

ACI, New York, New York – October 2-3, 2012 – "National Forum on Pharmaceutical Pricing Litigation." Shook, Hardy & Bacon Pharmaceutical & Medical Device Partner **Michael Koon** will join a distinguished continuing legal education faculty to present during a panel discussion on "Preparing Defenses to Allegations of False Claims Act Violations."

ACI, Chicago, Illinois – October 3-4, 2012 – "FDA & USDA Compliance Boot Camp: An In-Depth and Comprehensive Course on Regulatory Requirements for the Food and Beverage Industry." Shook, Hardy & Bacon Agribusiness & Food Safety Practice Co-Chair **Madeleine McDonough** will address "Preemption Fundamentals: Overview of Recent Case Decisions and How to Successfully Assert Federal Preemption."

ACI, Philadelphia, Pennsylvania – October 22-24, 2012 – "Drug Safety, Pharmacovigilance and Risk Management Forum." Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partner **Hildy Sastre** will serve on a panel with Food and Drug Administration Associate Chief Counsel Carla Cartwright to discuss "Assuaging Agency Concerns About Safety: Developing a REMS Strategy and Successfully Negotiating with the FDA." ■

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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 95 percent of our more than 470 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).