Shook, Hardy & Bacon L.L.P.

MARCH 17, 2011

PRODUCT LIABILITY LITIGATION REPORT

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SEVENTH CIRCUIT AFFIRMS DEFENSE VERDICT IN DEFECTIVE RV STEP-CONTROLLER SUIT

The Seventh Circuit Court of Appeals has determined that a district court properly barred the plaintiff from arguing during trial that her recreational vehicle (RV) as a whole was the defective product at issue. ***Aldridge v. Forest River, Inc.*, No. 10-2193 (7th Cir., decided March 8, 2011)**. The plaintiff was allegedly injured when she stepped from her RV and the step controller unexpectedly retracted. Because the plaintiff's complaint alleged that the step controller was defective and the plaintiff responded to interrogatories by identifying the step controller as the product at issue, the court granted the defendants' motion barring her from arguing to the jury that the RV was the product at issue.

According to the appeals court, the district court did not abuse its discretion; its "ruling was consistent with the nature of the litigation from the beginning of the case and it prevented surprise to the defendants regarding the nature of the case that they had been defending throughout the litigation." The court also opined, "Plaintiff's counsel would have this court believe that just as his client's feet were pulled out from beneath her as she stepped out of her recreational vehicle, so was her case at trial when she was not allowed to present her theory of liability to the jury. The record does not support his argument." The plaintiff evidently sought to change her theory after the trial court precluded her expert from testifying, finding him unqualified to offer an opinion as to the step controller's purportedly defective design.

CPSC SUES COMPANY FOR SELLING LAWN DARTS IN MISSOURI

The Consumer Product Safety Commission (CPSC) is seeking a permanent injunction to stop a company and an individual from selling lawn darts, which the agency has banned as a hazardous substance because they "present a mechanical hazard and an unreasonable risk of injury to children." *United States v. Lawn Dart Parts, LLC*, No. n/a, (U.S. Dist. Ct., E.D. Mo., E. Div., filed March 15, 2011). According to the complaint, an investigator posing as a consumer purchased a set of lawn darts online from the defendants in 2009 and 2010. In addition to injunctive relief, the agency seeks costs and authorization "to inspect Defendants' places of business and all records relating to the sale, offering for sale, manufacturing for sale, distributing in commerce, or importing into the United States any lawn darts to ensure compliance with the terms of the injunction."

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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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FTC SETTLES ENFORCEMENT ACTION, COMPANY SANCTIONED FOR TRACKING ONLINE CONSUMER ACTIVITY

The Federal Trade Commission (FTC) has entered an agreement to resolve an enforcement action against a company that serves as a channel for advertisers and media buyers to target online consumers. *In the Matter of Chitika, Inc.*, No. 1023087 (FTC Consent Order, March 14, 2011). The agreement requires that the company not misrepresent "the extent to which consumers may exercise control over the collection, use, disclosure, or sharing of data collected from or about them, their computers or devices, or their online activities."

Apparently, when consumers asked not to receive targeted ads, the opt-out expired after 10 days, and they would have had to repeatedly renew the request despite the company's promise that the opt-out would expire after 10 years. According to the company, a faulty computer mechanism that existed from May 2008 through February 2010 was responsible for the problem. The company has also promised to (i) place a clear notice on the homepage of its Website stating "We collect information about your activities on certain websites to send you targeted advertisements. To opt out of Chitika's targeted ads, click here"; (ii) provide an opt-out mechanism that remains in effect for at least five years; (iii) not use in any way consumer information obtained before March 1, 2010; and (iv) permanently destroy information stored in Chitika users' cookies and all IP addresses and unique identifiers in log files and backup tapes. *See Law360*, March 15, 2011.

COMPANY TO PAY PENALTY FOR FAILING TO REPORT DRAWSTRINGS IN CHILDREN'S JACKETS

The Consumer Product Safety Commission (CPSC) has **announced** that Ms. Bubbles, Inc. will pay a $40,000 civil penalty for failing to immediately report to the agency that it sold children's hooded jackets with drawstrings through the hood. The California-based company has denied knowingly violating the law or that the jackets contained drawstrings. The allegations that the company agreed to resolve were based on 1996 CPSC guidelines and a 2006 CPSC Office of Compliance announcement "that children's upper outerwear with drawstrings at the hood or neck would be regarded as defective and a substantial risk of injury to young children." Drawstrings are considered to pose a strangling hazard.

CPSC Commissioner Nancy Nord issued a statement accompanying her approval of the penalty to express her "continuing concern that the agency needs to promulgate a rule with respect to drawstrings on children's clothing rather than just continuing to address this risk on an ad hoc enforcement basis." She called for a vote to be scheduled to finalize a proposed rule addressing the matter "so industry and consumers are officially on notice about the serious consequences of this hazard."

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OFFICE SUPPLY STORE AGREES TO SETTLE PROP. 65 CLAIMS OVER LEAD IN PENCILS

A company that sells pencils and other office supplies has entered a consent judgment with an environmental health organization that claimed the company violated a California law requiring warnings for products posing a cancer or reproductive risk (Prop. 65). *Ctr. for Envtl. Health v. Staples, Inc.*, No. 09-493397 (Cal. Super. Ct., judgment entered March 8, 2011). Without admitting liability, the company agreed to comply with federal lead-content limits that are currently set at 0.03 percent lead by weight (300 parts per million (ppm)) and will be reduced to 0.01 percent lead by weight (100 ppm) on August 14, 2011. If the Consumer Product Safety Commission determines "that it is not technically feasible for manufacturers of [pencils] to meet a 100 ppm limit," the company agreed to comply with the 300 ppm standard.

The agreement also requires supplier specifications and testing, and indicates that the environmental health organization intends to conduct periodic product testing. The company agreed to make a $55,000 settlement payment, most of which will be paid to the organization for its attorney's fees and costs. The agreement does not require the company to provide Prop. 65 warnings to consumers.

ALL THINGS LEGISLATIVE AND REGULATORY

CPSC's Consumer Product Safety Information Database Goes Live

The Consumer Product Safety Commission (CPSC) recently launched the database mandated by Congress to allow consumers to search for or submit complaints about the safety of certain products. **SaferProducts.gov** will provide public access to the injury and death reports and hazard complaints that CPSC has gathered for years. As of March 11, 2011, consumers were able to file reports on the site and browse product recalls. Consumer complaints will be accepted for all consumer products except food, drugs, cosmetics, cars, and guns.

The database provides consumers with an outlet to submit reports of harm or risks of harm that are "true and accurate to the best of their knowledge," according to CPSC. After reviewing all online reports, the commission will have five business days to transfer qualifying reports to manufacturers for a response. Although the database is currently considered live, reports submitted by consumers will not be available until early April because of a 10-day response period provided to manufacturers.

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"I believe an informed consumer is an empowered consumer," CPSC Chair Inez Tenenbaum said. "The ability for parents and consumers to search this database for incidents involving a product they already own or are thinking of purchasing will enable them to make independent decisions aimed at keeping their family safe." *See The New York Times,* March 10, 2011; *CPSC News Release,* March 11, 2011.

CPSC Advisory Panel to Study Health Effects of Phthalates in Children's Toys, Care Products

The Consumer Product Safety Commission (CPSC) has **announced** a meeting of the Chronic Hazard Advisory Panel (CHAP) on phthalates and phthalate substitutes. The March 30-31, 2011, meeting in Bethesda, Maryland, represents the fourth time CHAP has met "to study the effects on children's health of all phthalates and phthalate alternatives as used in children's toys and child care articles, pursuant to section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA)." No opportunity will be provided during this meeting for public comment; the panel expects to discuss its progress toward analyzing potential phthalate risks.

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CPSIA permanently prohibits the sale of any children's toy or child care article that contains more than 0.1 percent of each of three specified phthalates—di-(2-ethyl-hexyl) phthalate (DEHP), dibutyl phthalate (DBP) and benzyl butyl phthalate (BBP). It also prohibits on an interim basis the sale of any "children's toy that can be placed in a child's mouth" or child care article that contains more than 0.1 percent of each of three additional phthalates—diisononyl phthalate (DINP), diisodecyl phthalate (DIDP) and di-*n*-octyl phthalate (DNOP).

Requiring CHAP to fully examine the range of phthalates used in children's products, CPSIA also mandates that the panel consider issues including (i) "the potential health effects of each of these phthalates, both in isolation and in combination with other phthalates"; (ii) "the likely levels of children's, pregnant women's, and others' exposure to phthalates, based upon a reasonable estimation of normal and foreseeable use and abuse of such products"; (iii) "the cumulative effect of total exposure to phthalates, from children's products and from other sources, such as personal care products"; (iv) "all relevant data, including the most recent, best available, peer-reviewed, scientific studies of these phthalate alternatives that employ objective data-collection practices or employ other objective methods"; (v) "the health effects of phthalates not only from ingestion but also as a result of dermal, hand-to-mouth, or other exposure"; and (vi) "the level at which there is a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals and their offspring." *See Federal Register,* March 15, 2011.

FDA Advisory Committee on Vaccines and Related Biological Products to Meet

The Food and Drug Administration's (FDA's) Vaccines and Related Biological Products Advisory Committee has **announced** an upcoming meeting that will include updates on research programs concerning bacterial polysaccharides and matters relating to groups of meningococcal vaccines. FDA plans to make background material available to the public no later than two business days before the April 6-7, 2011, meeting in Washington, D.C., and Gaithersburg, Maryland.

Agenda items will include (i) "updates of the research programs in the Laboratory of Bacterial Polysaccharides, Division of Bacterial, Parasitic, and Allergenic Products, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, FDA"; (ii) briefings "on the use of immunological markers for demonstration of effectiveness of meningococcal serogroups A, C, Y, and W-135 conjugate vaccines administered to children less than 2 years of age"; and (iii) "approaches to licensure of meningococcal serogroup B vaccines."

House Judiciary Subcommittee Considers Rule 11 Changes to Reduce Lawsuit Abuses

The House Subcommittee on the Constitution recently conducted a **hearing** on a bill (H.R. 966) that would amend Federal Rule of Civil Procedure 11 to impose more stringent sanctions on those who file frivolous lawsuits. The current version of the rule provides that a federal district court "may" impose an appropriate sanction on a lawyer, law firm or party that files any paper in court without an attorney's signature, which certifies that, after reasonable inquiry, it is not presented for any improper purpose, it is not frivolous, and the factual contentions or defenses have evidentiary support. The proposed "Lawsuit Abuse Reduction Act of 2011" would make sanctions for violations mandatory and would include attorney's fees and costs in the penalties assessed.

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Among those testifying in favor of the bill was Shook, Hardy & Bacon Public Policy Partner **Victor Schwartz**, speaking on behalf of the U.S. Chamber Institute for Legal Reform. Schwartz discussed the challenges small businesses face when required to defend frivolous lawsuits. Claiming that "the current version of Rule 11 permits attorneys to file the lawsuit first and try to back up their claims with law and fact later," Schwartz discussed the history of the rule and its amendments, noting that a previous, more stringent version was amended over the objection of two U.S. Supreme Court justices. Justice Antonin Scalia said of that amendment that it would "render the Rule toothless by allowing judges to dispense with sanction," and allow parties "to file thoughtless, reckless, and harassing pleadings, secure in the knowledge that they have nothing to lose: If objection is raised, they can retreat without penalty."

Federal Case Filings Continue to Grow

According to **data** released March 15, 2011, by the Administrative Office of the U.S. Courts, case filings continued to increase in fiscal year 2010. "This continues a decade-long trend of growth in these filings," said an office news release. New product liability cases increased from 59,504 in 2009 to 64,367 in 2010. The vast majority of the 41,133 personal injury cases filed in federal court in 2010 involved asbestos claims.

Overall, civil case filings in the U.S. district courts increased 2 percent in 2010, which represents "417 civil filings per authorized judgeship." According to the report, filings in the Southern District of Illinois more than quadrupled mostly due to multidistrict

litigation (MDL) involving contraceptives. Filings in the District of Minnesota increased 30 percent due to multiple MDL personal injury/product liability claims.

New York Agency Issues Draft Proposal on Ingredient Disclosures for Household Cleansers

The New York State Department of Environmental Conservation (DEC) has issued a **draft proposal** that would require manufacturers to disclose both the main ingredients in household cleaning products and those present in trace amounts. Evidently backed by a coalition of environmental groups, the proposal will ask manufacturers to provide this information to the agency, as well as the estimated content by weight and whether the ingredient is an "asthmagen, carcinogen, reproductive toxin, mutagen, persistent bioaccumulative toxin, ozone-depleting compound, or chemical of concern."

Implementing provisions in the state's 1976 chemical right-to-know law, the final proposal, which is expected in the next several months, will not apparently result in regulations or formal policy, but will build on stakeholder consensus. "This is a different approach," said DEC spokesperson Michael Bopp, adding that the proposal brings "everybody to the table to work out a deal that will play itself out in a nongovernmental way."

According to the proposal, DEC is not seeking confidential business information from manufacturers or research findings regarding human health or environmental effects. "However, we do propose to request that manufacturers post information on their websites regarding the nature and extent of investigations and research performed by or for the manufacturer concerning the effects on human health and the environment of their products or the chemical ingredients of such products," DEC said. *See Product Safety & Liability Reporter,* March 14, 2011.

LEGAL LITERATURE REVIEW

Madeleine McDonough & Jennifer Stonecipher Hill, "Learning from our neighbors about regulation of biosimilar drugs," *The National Law Journal,* March 14, 2011

In this article, Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Attorneys **Madeleine McDonough** and **Jennifer Stonecipher Hill** discuss the approaches that other nations have taken to approve biosimilars, which are follow-on versions of biological medicinal products. As the U.S. Food and Drug Administration considers what information biosimilar makers must provide to demonstrate safety and efficacy, the authors explore the regulatory frameworks adopted abroad and note how some vary the level and type of data required depending on how closely related the biosimilar is to the reference product. The key to an abbreviated approval process appears to be a demonstration of similarity based on in-depth comparisons of the properties of each product.

The key to an abbreviated approval process appears to be a demonstration of similarity based on in-depth comparisons of the properties of each product.

Victor Schwartz & Christopher Appel, "Exporting United States Tort Law: The Importance of Authenticity, Necessity, and Learning from Our Mistakes," *Pepperdine Law Review*, 2011

Prepared for an April 2010 law review symposium, this article focuses on tort law principles, such as strict products liability, punitive damages, contingency fees, and class actions, to explain to other countries why importing U.S. tort or procedural law must not be undertaken lightly. According to Shook, Hardy & Bacon Public Policy Attorneys **Victor Schwartz** and **Christopher Appel**, "It requires thorough research, careful evaluation, and meticulous execution to accomplish in a manner in which the importer obtains not only the correct, authentic version of the American law, but also learns from the benefits and failures of the tort rule or civil procedure process in the United States." They contend that the "authentic tort law product" is not easy to obtain.

Patrick Luff, "Risk Regulation and Regulatory Litigation," *Working Paper Series*, March 10, 2011

This paper explores the development of regulatory litigation, provides an overview of the scholarly literature addressing regulatory litigation theory and endeavors to define the concept to "serve as foundational scholarship for the still-young area of regulatory litigation scholarship." According to Oxford University D. Phil. Candidate Patrick Luff, regulatory litigation "emerged not because of greedy lawyers or plaintiffs, but rather because of unaddressed social demands for risk regulation." He cites asbestos litigation as an example of regulatory litigation that developed because the federal government did not issue prospective rules to prevent injuries from exposure or establish a compensatory scheme for those exposed and injured. Luff observes that such litigation uses legal remedies to influence future, risk-producing behaviors and notes that critics "view the presence of regulatory gaps as policy decisions on the part of agencies and the legislature, and … prefer the decisions on the appropriate scope of regulatory protection to be left to these politically accountable actors."

LAW BLOG ROUNDUP

U.S. Supreme Court Fails to Cite *Twombly* or *Iqbal* in Discussing Sufficiency of Pleading. Discuss.

"[T]he Court did not cite *Twombly* or *Iqbal*. What does that mean? … perhaps it is Justice [Ruth Bader] Ginsburg's way of trying to walk back *Twiqbal* a little bit, but in a quiet way where the pleading standard and pleading details were not at the heart of the case. Thoughts?" Florida International University College of Law Associate Professor Howard Wasserman, blogging about a recent U.S. Supreme Court decision which noted that, under a sufficiency analysis, a complaint "need not pin plaintiff's claim for relief to a precise legal theory. Rule 8(a)(2) of the Federal Rules of Civil Procedure generally requires only a plausible 'short and plain' statement of the plaintiff's claim, not an exposition of his legal argument."

PrawfsBlawg, March 11, 2011.

THE FINAL WORD

Debate over the Future of Mass Torts

The *University of Pennsylvania Law Review's* online "PENNumbra" project has published a **debate** between two law professors considering the viability of the mass-tort litigation device. University of Miami School of Law Associate Professor Sergio Campos opens the discussion with a negative view of mass tort actions and calls for mandatory class actions or multidistrict litigation to resolve disputes involving a large number of plaintiffs. Fordham University Law School Professor Howard Erichson provides the rebuttal, questioning whether anything is gained by compelling collectivization through mandatory class actions. His principal objection to doing away with mass tort actions is that it would "deprive claimants of control over whether to release their claims in settlement."

UPCOMING CONFERENCES AND SEMINARS

MoBar CLE, Interactive Webinar – March 30, 2011 (Noon – 2 p.m., Central Time) – "International and Multinational Litigation – Management and Trends." Shook, Hardy & Bacon International Litigation & Dispute Resolution Partner **Gregory Fowler**, who chairs the International Law Committee of The Missouri Bar, is the planning chair for this program. He will serve as moderator and speaker. Also participating as a speaker is Shook, Hardy & Bacon International Litigation & Dispute Resolution Partner **Simon Castley**.

ABA, Phoenix, Arizona – March 30 – April 1, 2011 – "2011 Emerging Issues in Motor Vehicle Product Liability Litigation." Shook, Hardy & Bacon is a conference co-sponsor. Tort Partner **H. Grant Law** is on the CLE planning committee and will serve as moderator for a panel discussing "Developments in Litigation Involving Component Manufacturers. Tort Associate **Amir Nassihi** is serving as CLE co-chair and will also participate in a panel that will discuss "Recent Developments in Products Liability Consumer Class Actions and Mass Torts." Shook, Hardy & Bacon Tort Partner **Willie Epps** will participate as the moderator of a session titled "Meet You in the Middle? The Art of Mediating a Catastrophic Injury Case." The distinguished faculty for this program includes general counsel for the National Highway Traffic Safety Administration and major corporations, a member of the National Transportation Safety Board, as well as a federal court judge and other experienced litigators.

ACI, Chicago, Illinois – April 27-28, 2011 – "Reducing the Legal Risks in the Sales and Marketing of Medical Devices: Fortifying Domestic and International Fraud and Abuse Compliance Efforts in the Face of Increasing Scrutiny." Shook, Hardy & Bacon Government Enforcement & Compliance Practice Co-Chair **Carol Poindexter** will conduct a half-day "master class" that will focus on region-specific compliance strategies and best practices in "high-risk emerging markets," such as Latin America, China and India.

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DRI, Chicago, Illinois – May 5-6, 2011 – "Drug and Medical Device Seminar." Co-sponsored by Shook, Hardy & Bacon, this 27th annual CLE program will include a presentation by Pharmaceutical & Medical Device Litigation Partner Matthew Keenan, who will discuss "Rambo vs. Atticus Finch: Ethical Consideration and the Preservation of Professionalism in Drug and Medical Device Litigation." ■

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ABOUT SHB

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

Shook attorneys have unparalleled experience in organizing defense strategies, developing defense themes and trying high-profile cases. The firm is enormously proud of its track record for achieving favorable results for clients under the most contentious circumstances in both federal and state courts.

The firm's clients include many large multinational companies in the tobacco, pharmaceutical, medical device, automotive, chemical, food and beverage, oil and gas, telecommunications, agricultural, and retail industries.

With 93 percent of our more than 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).