Shook, Hardy & Bacon L.L.P.

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PRODUCT LIABILITY LITIGATION REPORT

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FIRM NEWS

SHB-Authored Article Explores Punitive-Damages Trend

Shook, Hardy & Bacon Public Policy attorneys Mark Behrens, Cary Silverman and Christopher Appel have published an article in the *Wake Forest Law Review* examining whether awards of attorney's fees, prejudgment interest and other costs to a plaintiff may be included in the ratio calculation for determining a punitive-damage award. A growing number of courts have been asked by plaintiffs' counsel to include these extra-compensatory damages to increase the maximum amount of punitive damages that may be awarded in a case, while still adhering to the U.S. Supreme Court's constitutional limitations on punitive-damage awards. Titled "Calculating Punitive Damages Ratios with Extracompensatory Attorney Fees and Judgment Interest: A Violation of the United States Supreme Court's Due Process Jurisprudence?," the article analyzes relevant case law and concludes that the practice would offend the Supreme Court's due process framework and adversely affect litigation's general dynamics.

Schwartz & Behrens Publish on Asbestos Plaintiffs' Search for Solvent Defendants

Shook, Hardy & Bacon Public Policy Partners Victor Schwartz and Mark Behrens have co-authored an article titled "Asbestos Litigation: The 'Endless Search for a Solvent Bystander'" in a mass-torts symposium edition of the *Widener Law Journal*. They discuss how plaintiffs' lawyers have sought to expand asbestos litigation by asserting liability claims against solvent defendants that, under accepted tort law principles, owe them no duty for exposures caused by others. Among the legal theories discussed are market-share liability, enterprise liability, alternative liability, and premises owner liability for "take home" exposure claims.

CASE NOTES

First Circuit Dismisses Products Claims Against Clog Maker, Insufficient Probative Evidence

The First Circuit Court of Appeals has affirmed a district court's grant of summary judgment following pretrial discovery, agreeing that the plaintiff failed to demonstrate, under Massachusetts law, that CROCS® shoes present a heightened risk of

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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escalator entrapment. ***Geshke v. Crocs, Inc.*, No. 12-2204 (1st Cir, decided January 17, 2014)**. The plaintiff's 9-year-old daughter was allegedly injured when her right foot, clad in a CROCS® resin sandal, became entrapped in the side of an escalator. At issue on appeal was whether the plaintiff could carry her burden of proving the breach of a cognizable duty as to failure to warn and breach of implied warranty of merchantability.

The court determined that the "evidentiary pillars" the plaintiff adduced were insufficient to "permit a rational jury to find that CROCS sandals pose a heightened risk of elevator entrapment." The evidence included (i) "cryptic incident reports" from the company's files regarding previous complaints about children and escalator entrapment; according to the court, these reports constituted "meager anecdotal history" that "sheds no light on whether this quantum of complaints is atypical of the shoe industry"; (ii) an unauthenticated Japanese ministry report comparing escalator entrapment tests for a variety of shoe types including resin sandals made by seven unidentified manufacturers; (iii) the company's response to that report, i.e., the design of a new sandal model for the Japanese market, characterized by the court as "not, in and of itself, sufficient to warrant a conclusion that the regulator's concern is justified"; and (iv) the company's decision to include "a generalized escalator safety warning on the hangtag of its sandals." As to the latter, the court noted that the warning label "makes no mention of any special danger posed by CROCS. It speaks, in the most general terms, about escalator safety."

In the court's view, "To conclude from this evidence that CROCS posed a heightened risk of escalator entrapment would require a surfeit of speculation and surmise far beyond the outer limits of the summary judgment standard."

Alcoholic Beverage Makers Owe No Duty to Warn About Alcoholism

Finding that "the dangers of alcohol, including the risk of becoming an alcoholic, are obvious, regardless of whether one is predisposed to that disease," a federal court in Idaho has dismissed a tort action filed by state department of correction inmates seeking to hold alcoholic beverage makers liable for failing to warn the plaintiffs that consuming alcohol can be habit-forming or addictive. ***Brown v. Miller Brewing Co.*, No. 12-0605 (D. Idaho Jan. 17, 2014)**. Because Idaho views the purported dangers of alcohol as obvious, the court dismissed with prejudice a complaint that sought $1 billion in damages and new labeling.

Among the plaintiffs' allegations was that a label warning the public that even reasonable drinking can lead to alcohol addiction "due to the possibility of a predisposition" to the disease would have stopped them from taking their first drink as youths. They argued that this predisposition is not a commonly known danger. Acknowledging that Idaho courts had not yet addressed this precise issue, the court found that the state has adopted the *Restatement (Second) of Torts* § 402A, which provides that products safely designed and manufactured can be dangerously defective if the manufacturer has reason to know of its dangerous propensities

but fails to provide adequate warnings to purchasers or users. Still, "the duty to warn of a product's dangerous propensities 'is limited to situations wherein the danger is not obvious.'"

Finding nothing in state law to support the plaintiffs' claims, the court explored decisions from other jurisdictions and found persuasive case law and commentary rejecting prior invitations to widen the scope of warnings for alcohol. In this regard, the court states, "It would be next to impossible to create an effective warning label that would warn of the myriad combinations of alcohol use and of human characteristics that might contribute to alcoholism. And, even if it could be done, it would be unnecessary, because the danger of alcoholism is subsumed in the general dangers of alcohol commonly known to the public." The court further rejected claims that advertising focusing on the "pleasurable nature" of the products supports "a higher duty to warn against the perils of alcoholism."

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Biomedical Device Maker Enters Plea, Failed to Provide Information to FDA

San Diego-based Valor Medical, Inc., a biomedical device manufacturer, and four of its employees have reportedly pleaded guilty to counts of failing to provide the Food and Drug Administration (FDA) with required information on unfavorable safety tests for Neucrylate, a product developed to treat aneurysms. The company, which faces a February 19, 2014, sentencing hearing, entered a guilty plea to a felony violation that carries a maximum penalty of five years' probation, a $500,000 fine and a $400 special assessment. A federal magistrate judge has already sentenced former Valor CEO H. Clark Adams, who pleaded guilty to a misdemeanor charge, to one year of probation and a $5,000 fine. Valor's Regulatory and Clinical Manager Cathy Bacquet drew a sentence of one year of probation and a $2,500 fine. Two additional defendants reportedly faced a February 3 status hearing.

According to U.S. Attorney Laura Duffy, "Our nation's system of evaluating medical device safety and effectiveness depends upon the submission of truthful data to the FDA. When manufacturers like these defendants place their profits above their duty to honestly report the results of product testing, they place the American public's health and safety in jeopardy. This office will continue to vigorously enforce laws designed to protect the health and safety of our citizens through cases like this."

Court records show that the company filed two investigational device exemption (IDE) applications, which must be obtained to perform the human clinical trials that would provide the data needed to support an application for premarket approval. IDE applicants must submit "reports of all prior clinical, animal and laboratory testing of the device." Valor allegedly sent Neucrylate samples to a lab for testing and, when the lab found that all of the chromosomes in the chromosomal assay (CAA) were destroyed by initial contact with the device, Valor declined to retest the samples,

which would have been standard protocol. Preliminary results of the mouse lymphoma assay (MLA) were similarly unfavorable, with the "test article" found to be "mutagenic." The company provided neither the CAA nor the MLA test results to FDA. On later investigation, Bacquet allegedly told the agency that the CAA and MLA tests were inadvertently left out of the IDE application and that company management and regulatory staff were unaware of the results. Emails apparently contradicted these representations. *See U.S. Attorney News Release*, January 30, 2014.

ALL THINGS LEGISLATIVE AND REGULATORY

CPSC Considers Changes to Rules on Public Disclosure of Product-Related Information

Scheduled to meet February 12, 2014, the U.S. Consumer Product Safety Commission (CPSC) will **discuss** proposed changes to 16 C.F.R. part 1101, which interprets Section 6(b) of the Consumer Product Safety Act (CPSA) governing CPSC's disclosure of information to the public. Under the law, CPSC must notify manufacturers or private labelers about consumer product information that will be disclosed, if the information "will permit the public to ascertain readily the identity of [the] manufacturer or private labeler." The law also requires CPSC to "take reasonable steps to assure" that the information to be disclosed "is accurate, and that [its] disclosure is fair in the circumstances and reasonably related to effectuating the purposes of [the CPSA]."

The proposed changes to the regulatory text would update it to account for advances in information technology since its initial adoption in 1983, streamline relevant procedures and refine provisions addressing information subject to certain legal privileges. The Consumer Product Safety Improvement Act of 2008 is apparently driving some of the proposed changes because it shortened the advance notice period from 30 to 15 days, eliminated a required *Federal Register* notice when CPSC finds that public health and safety necessitate public disclosure in a lesser period of time and broadened statutory exceptions. The proposed regulatory revisions would also reflect Section 6(b) changes that allow CPSC to publish product information without notifying manufacturers when the information is already public.

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If approved, the proposal would be published the *Federal Register*, triggering a 60-day public comment period. *See CPSC Staff Notice of Proposed Rulemaking*, January 14, 2014; *Federal Register*, February 6, 2014.

CPSC Launches Contest to Promote Consumer Safety Awareness

The U.S. Consumer Product Safety Commission (CPSC) has **announced** its "Safer Products App Challenge," a contest under section 105 of the America COMPETES

Reauthorization Act of 2011, which calls on innovators to create application (apps) and tools that raise awareness of consumer product safety reports and recalls of consumer products submitted through the agency's Website, SaferProducts.gov. CPSC will award $1,000 to one winner in each of the following four categories: "Best Mashup with Online Auction Sites," "Best Mashup with Online Product Reviews," "Best Mashup with Search," and "Most Innovative." Entries will be accepted until April 28, 2014, and judging will be complete on or around June 30. Winners are expected to be announced during an awards ceremony in July or August. *See Federal Register*, January 22, 2014.

Time and Cost Burdens Estimated for CPSC Consumer Opinion Forum Surveys

The U.S. Consumer Product Safety Commission (CPSC) has **requested** comments on the time and cost burdens associated with surveys of participants in its Consumer Opinion Forum. According to CPSC, the information collected helps "inform the Commission's identification and evaluation of consumer products and product use, by providing insight and information into consumer perceptions and usage patterns. This information may also assist the Commission in its efforts to support voluntary standards activities, and help CPSC identify consumer safety issues requiring additional research." The information is also apparently used to help with proposed revisions to warning labels and manuals, as well as the effectiveness of product recall communications. Nearly 3,500 have registered to participate in the forum, and staff estimates the aggregate burden to all respondents at 73 hours at an annual aggregate cost of $4,560. Comments are requested by March 31, 2014. *See Federal Register*, January 28, 2014.

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NHTSA Issues NPR for Child-Restraint Systems

The U.S. National Highway Traffic Safety Administration (NHTSA) has **issued** a notice of proposed rulemaking (NPR) to amend Federal Motor Vehicle Safety Standard (FMVSS) No. 213, "Child restraint systems," to adopt side-impact performance requirements for all child restraint systems designed to seat children up to 40 pounds. With an aim to ensure that child restraint systems "provide a minimum level of protection in side impacts by effectively restraining the child, preventing harmful head contact with an intruding vehicle door or child restraint structure, and by attenuating crash forces to the child's head and chest," the agency also hopes to fulfill the statutory requirement of the "Moving Ahead for Progress in the 21st Century Act" of July 6, 2012, requiring that NHTSA issue new rules to protect children during side-impact crashes. Comments will be accepted until April 28, 2014. *See Federal Register*, January 28, 2014.

NHTSA Invites Comments on Burdens of Data Requests as to Older Adult Drivers

The U.S. National Highway Traffic Safety Administration (NHTSA) has **requested** comments on the proposed time burdens for states to complete questionnaires about medical review guidelines and practices they may use to help evaluate older adults referred to state motor vehicle licensing agencies for reexamination over concerns about unsafe driving performance due to suspected age or medical condition-related impairments. The five-hour estimate to complete the questionnaire includes the preparation of a short narrative and possible follow-up for clarification. Comments are requested by March 3, 2014. *See Federal Register*, January 30, 2014.

FDA Modifies List of Recognized Standards

The U.S. Food and Drug Administration (FDA) has **announced** the availability of its publication, "Modifications to the List of Recognized Standards, Recognition List Number: 034," which outlines modifications the agency is making to the list of standards it recognizes for use in premarket submissions and other requirements for medical devices. FDA says the guide will help manufacturers that choose to declare conformity with consensus standards to meet certain requirements for medical devices and notes that it will incorporate the modifications in its searchable database. *See Federal Register*, January 30, 2014.

LEGAL LITERATURE REVIEW

Kyle Graham, "Strict Products Liability at 50: Four Histories," January 26, 2014

Santa Clara University School of Law Assistant Professor Kyle Graham offers four different perspectives on "the strict products-liability 'revolution' that climaxed a half-century ago." Viewing this history through conventional, populist, functionalist, and contingency lenses, Graham is able to provide a more in-depth explanation of how and why products liability emerged, developed and "swept" the nation. According to Graham, "Accounts of doctrinal movement in tort law tend to overlook the prosaic groundwork laid by prospective plaintiffs and their attorneys; ignore case tropes as a profitable unit of analysis; and downplay the fortuitous circumstances associated with the diffusion of almost every successful new idea in this area of the law. By pulling these subjects out of the shadows and according them the attention they deserve, one can better understand the complexities inherent in the processes of doctrinal change."

Suja Thomas, "How Atypical, Hard Cases Make Bad Law," *Wake Forest Law Review*, 2013

In a just-published article, University of Illinois College of Law Professor Suja Thomas examines recent U.S. Supreme Court rulings, including *Bell Atlantic Corp. v. Twombly*, to argue that the Court, unconstrained by "sufficient effective doctrines of judicial restraint," made legal change motivated by extraordinary facts. Thomas calls for the adoption of a judicial restraint method, "the atypical doctrine," to avoid making bad law from hard cases. The doctrine, which would apply to cases with atypical facts involving legal changes inappropriate for typical cases, would advocate judicial restraint through a refusal to grant certiorari, narrower decisions, or changes accomplished in other cases or through a different institution, such as Congress or a rulemaking body. Thomas contends that legal change motived by extraordinary facts "threatens the legitimacy of the Court, interferes with the authority of other institutions, and adds unaccounted-for costs to the justice system."

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LAW BLOG ROUNDUP

Opponents to Proposed FRCP Amendments Fill Docket

"We reported on January 1 that approximately 86% of the commenters at that time opposed the amendments. As of January 21, approximately 80% opposed." St. Thomas University School of Law Professor Patricia Moore, writing about the response to proposed Federal Rule of Civil Procedure amendments that would address purported costs and delays engendered by the current rules. Moore apparently submitted her own comments directing the rules committee to (i) a 2009 Federal Judicial Center study, "which shows neither out-of-control costs nor an increase in costs over time"; (ii) an Administrative Office of the Courts statistic showing that "the median disposition time for a civil case (from case filing to final disposition) has maintained stability for twenty-five years, from 7 months in 1986 to a still-brisk 7.8 months in 2012, a difference of about 24 days"; and (iii) the awareness of lawyers and judges of "proportionality" in discovery and their frequent application of the concept.

Civil Procedure & Federal Courts Blog, January 31, 2014.

More Explanation Needed for Reliance on or Rejection of Judicial Statements

"Calling something dicta, or dismissing it as merely 'descriptive' and thus unworthy of deference, isn't enough. There needs to be a better explanation—be it pragmatic, historical, or otherwise—for why a particular type of statement isn't worthy of deference. Only upon making that transition can the caselaw move toward something like internal coherence in defining the scope of precedent." University of Notre Dame Law School Associate Professor, blogging about his draft article "The Scope of

Precedent" and discussing why a simplistic distinction between a case holding and dicta "can overshadow more fundamental debates about why some judicial statements deserve deference while others don't."

PrawfsBlawg, February 4, 2014.

THE FINAL WORD

Appropriations Law to Allow Public Access to Half of Taxpayer-Funded Research

According to a news source, the Consolidated Appropriations Act of 2014, approved by Congress on January 16, 2014, includes a provision requiring the federal agencies under the Labor, Health and Human Services and Education parts of the legislation with research budgets exceeding $100 million to give the public online access to the research they fund within 12 months of publication in a peer-reviewed journal. The Scholarly Publishing and Academic Resources Coalition said in a news release that the provision will make some $31 billion of the total $60 billion annual U.S. taxpayer-funded research openly accessible. U.S. Sen. Tom Harkin (D-Iowa), who helped launch a National Institutes of Health public access program in 2008, reportedly said, "Expanding this policy to public health and education research is a step toward a more transparent government and better science." Increased accessibility to this information could help products-liability litigants who rely on scientific research to support their general-causation claims. *See The Washington Post*, January 17, 2014. ■

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