Shook, Hardy & Bacon L.L.P.

SEPTEMBER 27, 2012

PRODUCT LIABILITY LITIGATION REPORT

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LAW FIRM NEWS

SHB Partners to Speak During IBA Annual Conference in Dublin

Shook, Hardy & Bacon Partners **Gregory Fowler**, International Litigation & Dispute Resolution, **William Martucci**, Employment Litigation & Policy, and **Marc Shelley**, Global Product Liability, will participate in this year's International Bar Association (IBA) Annual **Conference** in Dublin, Ireland, September 30-October 5, 2012.

Fowler, who serves as vice-chair of IBA's Product Law & Advertising Committee, will speak during a "moderated speed-dating" roundtable on "hot topics" relevant to product law. Participants will share the latest developments in the law with their table members before moving on to another hot topics table. Among other matters, the topics during this popular session will include aggregated product litigation and compliance requirements for suppliers in supply chain agreements.

Martucci will speak about issues involved in "Post-merger integration," focusing on employment and labor factors essential to successful M&A transactions. Shelley is serving as co-chair of a session on "Selling regulated products across borders: discussions and case studies on the sale of booze, drugs and other regulated products." His panel will focus on alcoholic beverages and cross-border issues relating to distribution and government restrictions. Speakers will also address common trends and issues for regulated product sales in general, disputes that may arise and how to prevent them.

Wajert Provides Comments on Upcoming SCOTUS Class Action Docket

Shook, Hardy & Bacon Global Product Liability Partner **Sean Wajert**, who authors the *Mass Tort Defense Blog*, provided commentary for a September 21, 2012, *Missouri Lawyers Media* article on the upcoming U.S. Supreme Court term, including a case asking, "Whether a district court may certify a class action without resolving whether the plaintiff class has introduced admissible evidence, including expert testimony, to show that the case is susceptible to awarding damages on a class-wide basis." According to Wajert, "It's such a huge issue that the courts have been struggling with."

In *Comcast Corp. v. Behrend*, No. 11-864 (U.S., cert. granted June 25, 2012), the Third Circuit Court of Appeals declined to consider "merits arguments" at the class-certification stage on damages despite the defendant's assertions that the arguments were

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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directly relevant to the certification analysis. The plaintiffs' bar apparently contends that such a standard of proof imposed near the outset of litigation would result in an inefficient trial before trial. Wajert countered, "If you have a large class, you are going to have discovery issues, you may have factual disputes, you will have another mini-trial [at the end] on the issue of damages. Where's the efficiency in that?"

Newstead Authors Part 1 of Two-Part Briefing on Product-Recall Risks

Shook, Hardy & Bacon Global Product Liability Partner **Alison Newstead** has authored an **article** titled "Risks following a product recall, part 1: disclosure and freedom of information requests," published in the September 2012 issue of *The In-House Lawyer*. This part of a two-part series addresses the documentation that occurs during a product recall and how sensitive and confidential information can reach external parties through disclosure or as a result of Freedom of Information Act requests. Newstead recommends resisting disclosures of privileged material in litigation, but where this is not successful, she suggests that companies may want to weigh whether settling a small number of claims is preferable to disclosures that could go beyond the litigants in a particular lawsuit. She also discusses the types of materials that are generally disclosed during a recall investigation by public authorities, noting that certain exemptions under the Freedom of Information Act will protect some of it.

CASE NOTES

FDA Urges SCOTUS to Reject Review in Ear Candles Case, Says Warning Letters Are Not Reviewable in Court

The Food and Drug Administration (FDA) has **urged** the U.S. Supreme Court to reject the petition for review filed by the Holistic Candlers and Consumers Association and companies making ear candle products from a D.C. Circuit Court of Appeals ruling dismissing their challenge to FDA's warning letters about their products. *Holistic Candlers & Consumers Ass'n v. FDA*, No. 11-1454 (U.S., opposition to cert. petition filed September 10, 2012). Additional information about the *certiorari* petition appears in the June 14, 2012, **issue** of this *Report*.

FDA argues that "[t]he decision of the court of appeals that the warning letters are not final agency action subject to judicial review is correct and does not conflict with any decision of this Court or any other court of appeals." FDA contends that warning letters do not mark the consummation of a decision-making process; rather, they give a company the opportunity to correct a violation before the agency takes action to enforce the law.

Jury Awards Colorado Man $7.2 Million for "Popcorn Lung"

A federal jury has reportedly awarded $7.2 million to a man who claimed that he developed *bronchiolitis obliterans*, a debilitating lung disease also known as popcorn lung, from consuming two to three bags of microwave popcorn every day for six years. *Watson v. Dillon Cos., Inc.*, No. 08-cv-00091-WDM-CBS (U.S. Dist. Ct., D. Colo., decided September 19, 2012). Details about the case appear in Issue **244** of Shook, Hardy & Bacon's *Food & Beverage Litigation Update*. The settlement that the plaintiff reached with one of the defendants, a flavoring manufacturer, is discussed in Issue **331** of the *Update*.

According to a news source, the jury found that Gilster-Mary Lee Corp., which manufactured the popcorn, and a retailer were negligent for failing to warn that diacetyl, the butter flavoring chemical in the product, was dangerous. The manufacturer was found liable for 80 percent of the damages, and the supermarket chain was found liable for 20 percent. The retailer has indicated that it will appeal the verdict. The plaintiff was represented by Kenneth McClain, a Missouri-based attorney, who has brought successful occupational exposure claims since 2004 on behalf of popcorn and flavoring workers who also developed the disease. *See Thomson Reuters* and *The Kansas City Star*, September 19, 2012.

The retailer has indicated that it will appeal the verdict.

Weight Loss Company Agrees to $3.7-Million Penalty to Settle FTC Charges

A weight-loss company that was ordered by the Federal Trade Commission (FTC) in 1992 to cease from "making certain representations about the efficacy of its weight loss products, programs, or services without sufficient scientific substantiation," has agreed to settle claims that it has since violated that order. *United States v. Jason Pharms., Inc.*, No. 1:12-cv-01476 (U.S. Dist. Ct., D.D.C., filed September 7, 2012). The company has not admitted or denied any of FTC's allegations concerning its Medifast low-calorie meal substitute products and services, which are available online, from health coaches or through physicians who carry the company's products.

If approved by the court, the agreement requires the company to pay a $3.7-million civil penalty and to stop claiming in product advertising that people can generally expect to achieve certain results, including the loss of a particular amount of weight, by using the company's Medifast program, unless the company has "competent and reliable scientific evidence that substantiates that the representation is true." The company would also be enjoined from making any health or safety representations about the program in the absence of scientific evidence and may not misrepresent that doctors recommend its products, programs, services, drugs, or dietary supplements. According to the Commission, the company represented that the experiences of the people endorsing its program in its advertisements were typical and that consumers would lose more than 30 pounds, or up to two to five pounds each week. *See FTC News Release*, September 10, 2012.

Federal Court Narrows Claims Against Pet Chew Toy Maker

A federal court in Maryland has dismissed a number of claims filed by a pet owner whose French bulldog allegedly ingested part of a Nylabone chew toy that subsequently caused intestinal injury. *Stanley v. Cent. Garden & Pet Corp.*, No. CCB-11-2401 (U.S. Dist. Ct., D. Md., decided September 19, 2012). Because the warning accompanying the product was adequate under state law, the court dismissed the plaintiff's claims for strict liability and negligence based on failure to warn. The court also dismissed her breach of express warranty claim for failure to point to "any specific statement of fact or promise by the defendants" that she alleged was false. The court denied the defendants' request to dismiss the plaintiff's claim for fraudulent concealment, finding that her allegations were sufficient.

The court also allowed the plaintiff's unjust enrichment claim to proceed, finding that Maryland law permits claims for both legal and equitable relief. The court dismissed the corporate parent from the suit because, in her efforts to pierce the corporate veil, the plaintiff had failed to allege that "the corporate cloak has been used to perpetuate fraud" or that the companies had disregarded the proper corporate formalities.

As for the plaintiff's claims for damages, the court agreed with the defendants that Maryland limits compensatory damages in cases of tortious injury to pets to the reasonable and necessary cost of veterinary care. While that limitation would not affect the plaintiff's claims for implied warranty, unjust enrichment and consumer protection, the court determined that she had "not demonstrated that she is entitled to recover non-economic damages under these claims either" in the absence of allegations that she experienced a specific physical or emotional injury. The court also ruled that the plaintiff could not recover treble or punitive damages.

The plaintiff had sought to represent a nationwide class of consumers, but conceded that the class should be confined to Maryland consumers. The defendants sought to strike all class allegations, arguing that the plaintiff could not satisfy Rule 23. The court agreed to strike allegations in support of a Rule 23(b)(2) class, finding that the plaintiff's request for injunctive relief "appears incidental to her claim for money damages." But the court refused to strike class allegations as to the plaintiff's strict liability, negligence, fraud, unjust enrichment, and consumer protection claims because she had not yet sought to certify the class and thus there was a "need for further factual development before resolving the close issues," such as predominance and whether strict liability, fraud and consumer-based claims are suitable for class treatment.

The court agreed to strike allegations in support of a Rule 23(b)(2) class, finding that the plaintiff's request for injunctive relief "appears incidental to her claim for money damages."

Still, the court agreed to strike the class allegations for breach of implied warranty, finding that Maryland law imposed a notification prerequisite and the plaintiff "has made no allegations that she or other potential class members gave notice either to the defendants or to the immediate sellers from whom the chew toys were purchased."

ALL THINGS LEGISLATIVE AND REGULATORY

House Bill Would Require CPSC to Adopt Standards for Drywall

The U.S. House of Representatives has passed a bill (**H.R. 4212**) titled "The Drywall Safety Act of 2012" that would require the Consumer Product Safety Commission (CPSC) to adopt standards for domestic and imported drywall, including limitations on the sulfur content and a labeling provision for traceability purposes. The bill also sets forth "the sense of Congress" that Chinese companies which sold purportedly contaminated drywall in this country should submit to the jurisdiction of U.S. courts currently considering property damage and personal injury suits against drywall makers and installers and provide remedies to homeowners "that have problematic drywall in their homes."

Blender Importer Agrees to Settle CPSC Allegations for $850,000

The Consumer Product Safety Commission (CPSC) **seeks** comments on a provisional settlement with a company that imports and distributes electric blenders over a purported defect, i.e., "the nut holding the blade assembly can dislodge during use, allowing the blade assembly pieces to break apart, and/or crack the Blenders' glass jar, posing a laceration hazard to consumers." Some 56 incident reports were apparently submitted to the company, which allegedly delayed reporting the defect to the Commission. Without admitting any liability as to notification violations or defect, the company has agreed to pay a civil penalty of $850,000. It states that it "was (and is) aware of only one report of a minor cut to a consumer's hand, associated with the reported issue, which did not require medical attention." The company voluntarily recalled the product to replace the blade assembly. Comments are requested by October 4, 2012. *See Federal Register*, September 19, 2012.

FDA Issues Warning over Cosmetics Company's Marketing Claims

The Food and Drug Administration (FDA) recently **issued** a warning letter to a cosmetics company, citing marketing claims that allegedly violate the Federal Food, Drug, and Cosmetic Act (the Act). According to FDA, "Greek Island Labs" makes several statements on its Websites indicating that its products are "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or articles intended to affect the structure or any function of the human body, rendering them drugs under the Act." The statements highlighted by FDA as violations of the Act include claims about the use of organic essential oils and herbal remedies as antimicrobials and as treatments for hair loss and alopecia, scarring, inflammation, "plague and fevers," and other infections.

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"Your products are not generally recognized among qualified experts as safe and effective for the above referenced uses and, therefore, the products are new drugs as defined in section 201(p) of the Act [21 U.S.C. § 321(p)]," states the warning letter. "Under section 505(a) of the Act (21 U.S.C. § 355(a)) a new drug may not be legally marketed in the U.S. without prior approval from FDA in the form of an approved New Drug Application (NDA)."

FDA has given the company or its agent, Radcliff Consultants, LLC, 15 days to address all violations and respond to the warning letter. "Failure to do so may result in enforcement action without further notice. The Act authorizes injunctions against manufacturers and distributors of illegal products and seizure of such products," concludes FDA. "If you do not believe that your products are in violation of the Act, include your reasoning and any supporting information for our consideration. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be implemented."

Research Integrity Roundtable Offers Ideas to Improve Regulatory Decisionmaking

A non-profit organization that convenes leaders in the public, private and civic sectors has issued a **report** prepared by a working group, the Research Integrity Roundtable, to suggest ways to improve the regulatory process, particularly in regard to the selection of panels that review scientific literature and how that literature is reviewed and evaluated. Titled "Improving the Use of Science in Regulatory Decision-Making: Dealing with Conflict of Interest and Bias in Scientific Advisory Panels, and Improving Systematic Scientific Reviews," the report addresses (i) "How should panels be composed and the qualifications of prospective advisory panelists be vetted?"; (ii) "How should concerns about biases and conflicts of interest of advisory panelists be handled?"; (iii) "Which studies should agencies review when examining the scientific literature related to a regulatory policy issue?"; and (iv) "How should contending views regarding the relevance of particular scientific results to a regulatory issue and the credibility of those results be addressed?"

Roundtable members, who represented their personal views in the dialog that culminated in the report, included individuals affiliated with industry and government as well as advocacy organizations such as the Natural Resources Defense Council and Union of Concerned Scientists. An appendix to the report compares the conflict of interest policies of a number of agencies, such as the National Academies, International Agency for Research on Cancer, Food and Drug Administration, and National Institutes of Health. The report also includes references to the systematic review frameworks used by several organizations and agencies, providing guidelines for the use of scientific information and data.

LEGAL LITERATURE REVIEW

Adam Steinman, "The Meaning of *McIntyre*," *Southwest Journal of International Law* Symposium, 2012

Seton Hall University School of Law Professor Adam Steinman has contributed an essay on the U.S. Supreme Court's *J. McIntyre Machinery, Ltd. v. Nicastro* ruling to the *Southwestern Journal of International Law's* 2012 symposium "Our Courts and the World: Transnational Litigation and Procedure." Steinman explores how the high court's fragmented ruling on jurisdiction over foreign defendants has been applied by state and federal courts, noting that some "have mistakenly interpreted *McIntyre* as establishing new constitutional restraints on state court exercises of personal jurisdiction, or as resolving previously open questions in favor of a more restrictive approach." According to Steinman, the courts should read Justice Anthony Kennedy's plurality opinion in conjunction with the concurring opinion authored by Justice Stephen Breyer, who took a "narrow view of the factual record," which explains "how he was able to reach the conclusion that J. McIntyre had not even 'delivered its goods in the stream of commerce with the expectation that they will be purchased by New Jersey users.'"

Steven Shavell, "A Fundamental Enforcement Cost Advantage of the Negligence Rule over Regulations," *Harvard Public Law Working Paper*, September 2012

According to Harvard Law School Professor of Law and Economics Steven Shavell, "because the negligence rule is triggered by harm, the rule enjoys a fundamental enforcement advantage over regulation[, which evaluates conformance with regulations whether or not harm has occurred]. The advantage flowing from this characteristic of the negligence rule often renders the rule a cheaper, more efficient method of enforcing socially desired behavior than regulation." Relying on a stylized model of law enforcement that incorporates certain assumptions about behavior, Shavell concludes that the negligence rule "involves lower enforcement costs than regulation" because "the cost of evaluating compliance is experienced only with the probability that harm occurs." Still, because some defendants may be judgment proof or plaintiffs may face difficulties establishing causation, Shavell suggests "in theory as in reality, it will generally be desirable for society to employ regulation along with the negligence rule."

Herbert Kritzer & Robert Drechsel, "Local News of Civil Litigation: All the Litigation News That's Fit to Print or Broadcast," *Judicature*, July/August 2012

University of Minnesota Law School Professor Herbert Kritzer and University of Wisconsin-Madison School of Journalism and Mass Communication Professor Robert Drechsel examine how local print and TV news coverage of civil litigation may tend to influence the tort reform debate. They found that the most often discussed areas of torts in that debate, "product liability and medical malpractice,

actually constitute a minority of the reports within the category of torts. A substantial number of reports concern intentional torts (assault and abuse) or injuries and deaths arising from fires and explosions." The authors also found that "relatively few reports on local television news deal with case resolution, [and a]mong case resolutions reported, many more deal with settlements than with adjudicated outcomes." While dollar figures are not apparently featured prominently, "when amounts of money are mentioned they tend to be fairly large figures."

The authors suggest that such TV reporting could lead civil justice reform proponents and opponents to conclude that (i) a "large number of suits are without merit," i.e., "lots of suits get filed but few seem to reach resolution"; (ii) "the typical case is considerably larger than it actually is," due to the greater news coverage devoted to larger verdicts; and (iii) "juries are out of control," for the same reason. They note that countervailing reporting on consumer issue lawsuits or problems created by consumer products and services could lead citizens to conclude that "although many cases seem unwarranted, many others are clearly justified, and may be the only way ordinary individuals can obtain redress from powerful corporations." The article concludes that "the message from local news reporting of civil litigation is mixed for those who would place limits on lawsuits, whether those would be limits on the amount that can be recovered, limits on legal fees, or direct limits on the cases that can be brought. . . . at least at the local media level, much is reported that cuts against the limits proponents would impose. And it is on local market television and newspapers that people seem to rely most heavily for their news."

THE FINAL WORD

DRI National Poll Uncovers Perceptions of Flaws in U.S. Civil Justice System

DRI-The Voice of the Defense Bar recently issued a **report** titled "The DRI National Poll on the Civil Justice System," in which it found, on the basis of a random sample of 1,020 U.S. adults, that a significant percentage (41) of respondents indicated that they were not confident that the civil law system produces just and fair results. A vast majority of respondents (83 percent) indicated that "the side with the most money for lawyers usually wins." About two-thirds said that they preferred juries over judges to decide disputes. Questions probing bias toward litigants revealed that 54 percent would favor an individual in litigation against a large corporation. Only 11 percent said that they would favor business, and 23 percent said they would be neutral. If the defendant were "a small business located in your community," the preference for individual plaintiffs faded away, however, with 32 percent indicating they would favor the plaintiff.

A vast majority of respondents (83 percent) indicated that "the side with the most money for lawyers usually wins."

According to DRI, the poll was "the first major research effort of DRI's new Center for Law and Policy which, in addition to conducting objective research, will provide expertise to the courts and policymakers, and conduct public education on important civil justice issues." Center Chair Marc Williams noted, "This data indicates that

we have some public education work to do. No matter how much affinity one might have with one side or another, a basic premise of justice is that cases will be tried before an unbiased judge and jury who then make their decisions based upon the law and the facts presented." Other matters addressed in the poll included the respondents' involvement in class action suits. Four out of 10 Americans have apparently been invited to participate in a class action, and 15 percent of them did so. *See DRI Press Release*, September 19, 2012.

UPCOMING CONFERENCES AND SEMINARS

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).