Shook, Hardy & Bacon L.L.P.

OCTOBER 11, 2012

PRODUCT LIABILITY LITIGATION REPORT

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LAW FIRM NEWS

Newstead Addresses the Risk of Criminal Liability Following a Product Recall

Shook, Hardy & Bacon Global Product Liability Partner **Alison Newstead** has authored an **article** titled "Risks following a product recall, part 2: criminal offences for the company and directors," appearing in the October 2012 issue of *The In-House Lawyer*. The second in a two-part series, this article discusses potential criminal liability for a company and its directors following the recall of an unsafe product.

Newstead focuses on the General Product Safety Regulations of 2005 and the Corporate Manslaughter and Corporate Homicide Act of 2007. Their provisions and potentially wide-ranging penalties raise questions about the timing of notification to regulatory authorities about defective products and the level of culpability (e.g., gross negligence) in allowing such products to continue to be sold. Newstead concludes, "While there have been many such individual prosecutions in respect of health and safety offences, so far no such prosecutions have been based on badly managed product recalls or indeed failure to instigate such recall. However, the legal framework is in place and the possibility of such a prosecution remains."

SHB Center for Excellence in Advocacy to Co-Host Federal Rules Conference

Shook, Hardy & Bacon's Center for Excellence in Advocacy and the *Kansas Law Review* will co-host a continuing legal education **conference** titled "Advocacy Under the Federal Rules of Civil Procedure After 75 Years," on November 9, 2012, at the University of Kansas.

Among those scheduled to present during the program are University of California Hastings College of the Law Professor Richard Marcus, who serves as associate reporter to the Judicial Conference Advisory Committee on Civil Rules; Shook, Hardy & Bacon Partner **John Barkett**, who serves as the American Bar Association Section of Litigation's liaison member to the civil rules advisory committee; U.S. District Court Judge Lee Rosenthal, who chairs the Judicial Conference Committee on the Rules of Practice and Procedure and formerly served as chair of the Judicial Conference Advisory Committee on Civil Rules; former Colorado Supreme Court Justice Rebecca Kourlis; and U.S. District Court Magistrate Judge and former Shook, Hardy & Bacon Partner David Waxse, who formerly chaired the Kansas Commission on Judicial Qualifications.

Shook, Hardy & Bacon L.L.P.

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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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Behrens' White Paper Considers Plaintiff Forum Shopping in Philadelphia

Shook, Hardy & Bacon Public Policy Partner **Mark Behrens** has authored a **white paper** published by the Federalist Society titled "Philadelphia Tort Litigation: Forum Shopping and Venue Reform." Noting that the American Tort Reform Foundation named Philadelphia to the top of its "Judicial Hellhole" lists in 2010 and 2011, Behrens discusses how the city's courts became a magnet for civil litigation by forum-shopping plaintiffs, efforts that have been undertaken to reduce the number of mass tort claims filed there and additional steps that lawmakers and courts could take to help refocus "Pennsylvania litigation on Pennsylvania citizens and … ensure that claims are heard in the county with the most logical connection to the case."

CASE NOTES

SCOTUS Opens Term with Additional Argument on Alien Tort Claims Issues

During the first day of its new term, the U.S. Supreme Court heard a second round of arguments in ***Kiobel v. Royal Dutch Petroleum Co.*, No. 10-1491 (U.S., restored to the calendar for reargument March 5, 2012)**. The parties had been directed to address "Whether and under what circumstances the Alien Tort Statute, 28 U.S.C. § 1350, allows courts to recognize a cause of action for violations of the law of nations occurring within the territory of a sovereign other than the United States."

According to court observers, the Court's more liberal wing, including Justices Ruth Bader Ginsburg, Stephen Breyer, Sonia Sotomayor, and Elena Kagan, appeared to favor allowing at least some claims under the statute for incidents involving foreign litigants occurring outside the United States, while the more conservative wing, that is, Chief Justice John Roberts and Justices Antonin Scalia and Samuel Alito, seemed inclined to favor a more restrictive view. Justice Clarence Thomas did not apparently speak during re-argument, and Justice Anthony Kennedy's position was difficult to ascertain. Additional information about the case appears in the **October 27, 2011, issue** of this *Report*. *See Law 360*, October 1, 2012.

Ninth Circuit Determines Statute of Repose Inception Date in Aircraft Defect Suit

The Ninth Circuit Court of Appeals has upheld a district court's determination that the statute of repose under the General Aviation Revitalization Act began to run when an allegedly defective part, "along with the aircraft in which it was installed originally, was delivered to its first purchaser." ***U.S. Aviation Underwriters, Inc. v. Nabtesco Corp.*, No. 11-35440 (9th Cir., decided October 2, 2012)**. At issue was whether the Act's first "trigger" date applies to component parts.

The component part at issue was originally installed in a Cessna 550 aircraft that was delivered to its first purchaser in October 1990—more than 18 years before the accident—and then removed, overhauled and reinstalled in a Cessna 560, the aircraft involved in the accident, in April 2007. The plaintiff filed a subrogation claim

against the part's manufacturer in May 2010 for damage to the Cessna 560, which was involved in a runway accident in August 2009. The statute has two "trigger" dates; the second, a rolling trigger date, "occurs when a new component, which is alleged to have caused the accident, replaces an existing component of the aircraft or is added to the plane." Because the part was not new and the trial court correctly held that the rolling trigger date did not therefore apply, the plaintiff did not appeal this part of the lower court's ruling.

The first trigger date specifically applies to the delivery date of "the aircraft" and does not expressly mention component parts. The Ninth Circuit found this part of the statute ambiguous and cited legislative history to hold that "the 'date of delivery of the aircraft' in § 2(1)(A) refers to the accident aircraft, including its constituent parts." According to the court, "it is more natural to construe 'the aircraft' to mean the aircraft including its component parts" and suggested that its broader definition also "comports with the language and design of the statute as a whole." Thus, the court affirmed the lower court's grant of the component-part manufacturer's motion for summary judgment.

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Federal Court Finds Navy Ship Is Not a "Product" Under Product Liability Law

In the context of asbestos-exposure litigation, a federal court in Pennsylvania has determined that under maritime product liability law, a ship is not a product, and thus the shipbuilder cannot be held strictly liable for the various products aboard the ship that may have caused personal injury. *Mack v. Gen'l Elec. Co.*, MDL No. 875, 2:10-78940-ER (U.S. Dist. Ct., E.D. Pa., decided October 3, 3012).

The plaintiff alleged that he had been exposed to asbestos aboard a number of Navy ships during the 1960s and 1970s while employed as a welder by the Department of Defense. He alleged both negligence and strict product liability against the defendants, claiming that they were liable for failing to warn him about asbestos-exposure hazards. The court allowed his negligent failure-to-warn claims to proceed, finding that he was not a sophisticated user of asbestos insulation. But the court granted the defendants' motion for summary judgment as to the plaintiff's strict liability claim because a ship is not a product.

The latter was an issue of first impression for the court, and it concluded on the basis of policy considerations that to hold a shipbuilder liable for "the thousands (if not tens of thousands) of products assembled in a Navy ship pursuant to Navy specifications, would be an undue, unmanageable, and cumulative burden likely to discourage the activity of shipbuilding." The court also observed that the entity most knowledgeable about each of the products incorporated into a ship is its manufacturer and that "the role of the builder of Navy ships appears to be more like a provider of a service (assembly of an assortment of products) than a manufacturer or supplier of a product."

FDA Seeks Dismissal of Whistleblower Retaliation Claims

In an ongoing dispute between scientists critical of the Food and Drug Administration's (FDA's) medical-device review process, FDA has sought to dismiss claims of adverse employment action allegedly taken in retaliation for whistleblowing. *Hardy v. Hamburg*, No. 1:11-cv-01739-RBW (U.S. Dist. Ct., D.D.C., motion filed October 1, 2012). Details about allegations that the agency tracked the scientists' computer keystrokes, captured screen images, intercepted their personal emails, and copied documents on their personal thumb drives appear in the **July 19, 2012, issue** of this *Report*.

FDA contends that most of the employment-related claims are already the subject of administrative complaints filed with the Office of Special Counsel, most of which are still pending, and are precluded by the Civil Service Reform Act. The agency also argues that the remaining causes of action "must be dismissed for lack of standing and because the statute cited does not provide a private right of action." FDA further indicates that the Office of Special Counsel is "currently investigating this matter pursuant to plaintiffs' administrative complaints, including investigating allegations that the FDA 'used covert surveillance as a tool to retaliate against whistleblowers.' Indeed, a recent OSC news release indicated that the Office had 'broadened' its investigation into allegations that the FDA 'monitored the communications of employees who were suspected of blowing the whistle on FDA's approval of unsafe medical devices.'"

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Putative Class Challenges "Super Stay" Lipstick Advertising Claims

Plaintiffs from three states have filed a putative class action against Maybelline, LLC, alleging that the company's marketing and promotions highlighting the long-lasting qualities of its lipstick are misleading, inaccurate and deceptive. *Leebove v. Maybelline, LLC*, No. 12-cv-7146 (U.S. Dist. Ct., S.D.N.Y., filed September 21, 2012). Specifically, the plaintiffs allege that the defendant's Super Stay 10HR Stain Gloss® and Super Stay 14HR Lipstick® do not, as represented, last for 10 and 14 hours respectively. Seeking to certify a nationwide class and Michigan, New Jersey and New York subclasses of product purchasers, the plaintiffs allege unjust enrichment, breach of express warranty and violations of state consumer protection laws. They seek injunctive relief, disgorgement of profits, reimbursement, punitive and treble damages, attorney's fees, and costs.

ALL THINGS LEGISLATIVE AND REGULATORY

GAO Report Highlights Medical Device Information Security

The U.S. Government Accountability Office (GAO) recently released an August 2012 **report** urging the Food and Drug Administration (FDA) to expand its consideration

of information security for certain medical devices. According to GAO, wireless medical devices are at risk for both unintentional and intentional threats, including those "with the potential to adversely affect operations, assets, or individuals by means to unauthorized access, destruction, disclosure, modification of information, denial of service or a combination of these." In particular, the report cites research demonstrating the ability to exploit vulnerabilities in implantable cardioverter defibrillators and insulin pumps, raising questions about the need to address such information security loopholes.

To date, FDA has apparently focused on unintentional threats such as electromagnetic interference when conducting premarket reviews of medical devices with known vulnerabilities. "Specifically, FDA considered risks from unintentional threats for four of the eight information security control areas GAO selected for its evaluation—software testing, verification, and validation; risk assessments; access control; and contingency planning," states the report, which notes that the agency did not view intentional tampering as a realistic issue until recently. "However, the agency did not consider risks from intentional threats for these areas, nor did the agency provide evidence of its review for risks from either unintentional or intentional threats for the remaining four information security control areas—risk management, patch and vulnerability management, technical audit and accountability, and security-incident-response activities."

GAO has thus urged FDA to reassess its approach for evaluating the information security of medical devices, as well as provide post-market opportunities to report vulnerabilities. "For example, the agency's adverse event reporting system relies upon reports submitted by entities, such as manufacturers, that are more closely related to clinical risks than to information security risks," concludes the report. "Because information security in active implantable medical devices is a relatively new issue, those reporting might not understand the relevance of information security risks."

HHS Report Criticizes Dietary Supplement Claims

The U.S. Department of Health and Human Services' (HHS') Office of the Inspector General (OIG) recently issued two reports critical of the dietary supplement industry. Titled *Dietary Supplements: Structure/Function Claims Fail to Meet Federal Requirements,* the first **report** sought to determine whether manufacturers could support claims describing "the role of a dietary supplement in the structure or function of human bodies." To this end, OIG apparently assessed structure/function claims "for a purposive sample of 127 dietary supplements marketed for weight loss or immune system support" to establish their compliance with Food and Drug Administration (FDA) regulations. The department also reviewed the documents used to substantiate these claims as well the manufacturers' notification letters.

OIG reportedly found that substantiation documents for structure/function claims "were not consistent with FDA guidance," as only 34 percent of the 1,624 documents reviewed were based on human studies and "none met all of FDA's recommendations for competent and reliable evidence." The report further noted that 56 percent of these substantiation documents "would be considered background information according to FDA guidance" and thus are not sufficient to support structure/function claims. In addition, 7 percent of the supplements allegedly lacked the required disclaimer indicating that FDA did not evaluate the product's claims, while 20 percent featured prohibited claims purporting to treat diseases, "such as influenza, the common cold, herpes, and HIV," reduce cholesterol or prevent diabetes.

"These results raise questions about the extent to which structure/function claims are truthful and not misleading," concluded OIG, which urged FDA to seek "explicit statutory authority to review substantiation for structure/function claims to determine whether they are truthful and not misleading." The Inspector General further recommended revamping the notification system for these claims "to make it more organized, complete, and accurate," and expanding market surveillance "to enforce the use of disclaimers for structure/function claims and to detect disease claims."

"These results raise questions about the extent to which structure/function claims are truthful and not misleading," concluded OIG, which urged FDA to seek "explicit statutory authority to review substantiation for structure/function claims to determine whether they are truthful and not misleading."

Meanwhile, the second **report** focused on the ability of FDA to contact dietary supplement companies in an emergency. Using the same data set for 127 weight loss and immune support supplements, OIG found that 20 percent of labels did not provide the required telephone numbers or addresses for reporting adverse events. The Inspector General also compared the contact information that manufacturers provided to FDA upon registration with "information obtained during structured interviews with company representatives." The results apparently revealed that 28 percent of contacted companies "had facilities that failed to register with FDA as required." Of those companies with registered facilities, 72 percent allegedly did not give complete and accurate information.

OIG has thus called on FDA to (i) "improve the accuracy of information in the registry," (ii) "seek authority to impose civil monetary penalties on companies that do not comply with registration requirements," and (iii) "educate the dietary supplement industry about registration and labeling requirements." FDA has apparently concurred with these three recommendations and agreed to improve its adverse event notification system and market surveillance in accordance with the first report's conclusions. The agency also indicated that it would consider OIG's request to seek explicit statutory authority to assess the documents provided in support of structure/function claims.

LEGAL LITERATURE REVIEW

Jill Curry & Matthew Alex Ward, "Are *Twombly* & *Iqbal* Affecting Where Plaintiffs File? A Study Comparing Removal Rates by State, *Texas Tech Law Review* (forthcoming July 2013)

Authored by a University of Maryland Ph.D. candidate and a University of Maryland School of Law graduate, both of whom clerked with the Federal Judicial Center, this article analyzes data the Center compiled to assess the effect of the U.S. Supreme Court's rulings in *Bell Atlantic Corp. v. Twombly* and *Ashcroft v. Iqbal* on civil litigation in the U.S. federal courts. The Court adopted a more stringent "plausibility" pleading standard for cases filed in the federal courts, and the authors predicted that this heightened standard "would encourage plaintiffs in cases with federal and state claims, especially plaintiffs alleging a violation of their civil rights, to file in state courts to benefit from the liberal notice pleading standard." To the contrary, however, "the results demonstrate that these expectations were not met. There was no systematic increase in the rate of removal after *Twombly* and *Iqbal,* and the effect was not more pronounced in notice pleading states compared to fact pleading states, questioning the assertion that cases are being diverted from federal court to state courts due to heightened pleading standards."

Louis Kaplow, "Multistage Adjudication," *Harvard Law Review* (forthcoming)

In this article, Harvard Law School Professor of Law and Economics Louis Kaplow sets forth a "conceptual framework for analyzing how decisions are optimally made at each juncture in multistage legal proceedings." He focuses on motions to dismiss and motions for summary judgment as among the significant stages in U.S. civil litigation and attempts to "examine systematically how decisions at different procedural stages should ideally be made in light of the legal system's objectives." Complicating the analysis, according to Kaplow, is that "current legal standards, as stated in the Federal Rules of Civil Procedure and elaborated by the Supreme Court, are unclear, question-begging in key respects, and at bottom open-ended." He suggests that any meaningful reform requires consideration of the interplay between the decision criteria he outlines and the legal system's effects on behavior, i.e., "deterrence of harmful conduct and the chilling of desirable activity," as well as its total costs.

LAW BLOG ROUNDUP

Stakes High in *Kiobel*?

"Thus re-framed, the *Kiobel* case has the potential to substantially redefine prevailing understandings about how open the U.S. courts are to claims under international law." Cornell University Law School Professor Michael Dorf, blogging about one of the cases argued before the U.S. Supreme Court on the first day of

its new term. Involving an interpretation of the Alien Tort Statute, the plaintiffs in *Kiobel* initially asked the court whether the law authorized suits against corporate defendants, but the Court directed re-argument to address whether the law allows U.S. courts to hear cases involving violations of the law of nations occurring outside the United States. Dorf suggests that a court majority could go so far as to determine that the statute does not confer substantive rights to sue and thus to preclude federal courts from converting international law norms into domestic federal common law.

Dorf on Law, October 1, 2012.

When Jurisdiction Gives Way to Other SCOTUS Concerns

"Having read the argument transcripts in *Kiobel* and *Lozman,* SCOTUS' early-term jurisdictionality cases, I am somewhat at a loss. Nothing in either case should have had anything to do with jurisdiction. The arguments both seemed rife with the mixing of jurisdiction and cause of action that I thought the Court had cleaned up fairly well over the past several years. And I am a bit worried that these cases will muck things up a bit." Florida International University College of Law Professor Howard Wasserman, discussing the first cases argued in the new term before the U.S. Supreme Court, including *Kiobel v. Royal Dutch Petroleum Co.* According to Wasserman, the re-argument in *Kiobel* did not focus on jurisdiction v. merits; rather, the "discussion was largely about what international norms are."

Concurring Opinions, October 3, 2012.

THE FINAL WORD

Uptick in U.S. Traffic Fatalities Linked to Economy

With traffic fatalities up 9 percent in the first half of 2012 over the same period in 2011, some researchers have linked any previous decreases in fatalities to economic downturns. A University of Michigan researcher claims that the recent increase could continue as the economy recovers. In his report "Road Safety in the United States: Are the (Relatively) Good Times Over?," Michael Sivak claims that the 26 percent reduction in roadway fatalities between 2005 and 2011 can be attributed in large part to a decrease in discretionary driving, changes in driving patterns and reduced freight shipments.

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Among other matters, Sivak cautions policy makers to "[b]e very cautious in assuming that any sudden, large drop in fatalities is in response to interventions related to vehicle design. The main reason for this is that it takes about 20 years to turn over the fleet. Do not expect most regulatory actions aimed at drivers to produce a sudden, huge drop in fatalities. Be aware that most rapid, underlying

changes are transient, and therefore their effects are mostly transient too." His findings agree with data analyzed by the Advocates for Highway & Auto Safety, showing a clear correlation between U.S. recessions since 1971 with reduced motor vehicle fatalities.

The National Highway Traffic Safety Administration (NHTSA) compiled the data on which these studies rely, but it was more cautious in attributing the trends to any particular contributing factors. According to a spokesperson for the AAA Foundation for Traffic Safety, NHTSA's most recent traffic fatalities report is based on preliminary data, and the apparent 9 percent increase in fatalities may not hold up nor may it presage results for the remainder of the year. *See Bloomberg BNA Product Safety & Liability Reporter,* October 5, 2012.

UPCOMING CONFERENCES AND SEMINARS

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).