Shook, Hardy & Bacon L.L.P.

JUNE 27, 2013

PRODUCT LIABILITY LITIGATION REPORT

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LAW FIRM NEWS

Victor Schwartz Honored as One of "The Most Influential Lawyers in America"

The National Law Journal (*NLJ*) recently honored Shook, Hardy & Bacon Public Policy Partner **Victor Schwartz** as one of "The 100 Most Influential Lawyers in America" during a June 13, 2013, award ceremony in New York City. Recognizing "the crème de la crème of lawyers," the ceremony highlighted legal leaders who continue to shape the world "through their work in the courtroom, at the negotiating table, in the classroom or in government."

Described as "the patron saint of the tort reform movement," Schwartz was singled out for authoring "the leading law school text on torts" and for his stint as chair of the federal inter-agency task force on product liability at the Department of Commerce. "For decades, he has shaped [the tort reform movement's] strategy, crafted its legislative proposals and coined its phrases—such as 'judicial hellhole,' the label for plaintiff-friendly jurisdictions," noted *NLJ*. "In January, he argued before the Texas Supreme Court against compensation for the sentimental value of pets. And he still does a mean imitation of the voice of former President Bill Clinton."

Last compiled in 2006, "The 100 Most Influential Lawyers in America" are selected by the journal's editorial staff with input from the legal community.

CASE NOTES

SCOTUS Rules Design-Defect Claims Involving Generic Drugs Are Preempted

The U.S. Supreme Court, in a 5-4 ruling, has determined that state-law design-defect claims that "turn on" the adequacy of a generic drug's warnings are preempted by federal law under *PLIVA, Inc. v. Mensing*. ***Mut. Pharm. Co., Inc. v. Bartlett*, No. 12-142 (U.S., decided June 24, 2013**. So ruling, the Court reversed a First Circuit decision upholding a $21.06-million jury award to a woman who developed permanently crippling toxic epidermal necrolysis from using the generic version of a nonsteroidal anti-inflammatory drug for shoulder pain. Additional details about the First Circuit's ruling appear in the May 10, 2012, **issue** of this *Report*.

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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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According to the Court's majority, New Hampshire imposes design-defect liability where "the design of the product created a defective condition unreasonably dangerous to the user." The state's courts use a "risk-utility approach" to decide whether a product is "unreasonably dangerous." Under that approach, "a product is defective as designed if the magnitude of the danger outweighs the utility of the product." Three factors are considered as part of the risk-utility inquiry: "the usefulness and desirability of the product to the public as a whole, whether the risk of danger could have been reduced without significantly affecting either the product's effectiveness or manufacturing cost, and the presence and efficacy of a warning to avoid an unreasonable risk of harm from hidden dangers or from foreseeable uses."

Finding that redesign was not possible, because federal law requires a generic drug "to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based," and that the jury determined that the drug maker breached its duty to adequately label the generic drug "so as to render the drug not 'unreasonably dangerous,'" the Court held that the only way for the defendant to avoid liability in New Hampshire would be to strengthen the warning label, something that federal law prohibits.

The Court directly addressed the First Circuit's reasoning that the defendant "could escape the impossibility of complying with both its federal- and state-law duties by 'choos[ing] not to make [the drug] at all." It stated, "We reject this 'stop-selling' rationale as incompatible with our pre-emption jurisprudence. Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be 'all but meaningless.'"

In his dissenting opinion, joined by Justice Elena Kagan, Justice Stephen Breyer opined, "It is not literally impossible here for a company like petitioner to comply with conflicting state and federal law. A company can comply with both either by not doing business in the relevant State or by paying the state penalty, say damages, for failing to comply with, as here, a state-law tort standard." In her dissenting opinion, joined by Justice Ruth Bader Ginsburg, Justice Sonia Sotomayor said, "Today, the Court unnecessarily and unwisely extends its holding in *Mensing* to pre-empt New Hampshire's law governing design-defects with respect to generic drugs" and did so "by concluding that petitioner Mutual Pharmaceutical was held liable for a failure-to-warn claim in disguise, even though the District Court clearly rejected such a claim and instead allowed liability on a distinct theory."

In a related development, six U.S. senators and representatives responded to the *Bartlett* ruling by calling on Food and Drug Administration (FDA) Commissioner Margaret Hamburg "to expedite its consideration of revisions to the FDA's drug labeling regulations to enable manufacturers of generic drugs to update patient safety labeling in appropriate circumstances. These changes are critically important to ensure that the public is adequately informed of the risks and benefits of

prescription drugs, and that consumers who are injured by generic drugs have the same legal rights as those who are injured by the brand-name versions of the same drugs." The June 24, 2013, letter is signed by Sens. Patrick Leahy (D-Vt.), Tom Harkin (D-Iowa) and Al Franken (D-Minn.), and Reps. Chris Van Hollen (D-Md.), Bruce Braley (D-Iowa) and Henry Waxman (D-Calif.).

Meanwhile, consumer advocacy organization Public Citizen, which petitioned FDA in 2011 to request that the agency amend its regulations to permit generic drug makers to use the same procedures for updating product labels available to brand-name manufacturers, released a report on June 24 titled "Generic Drug Labeling: A report on serious warnings added to approved drugs and on generic drugs marketed without a brand-name equivalent." The report discusses drugs to which black-box warnings were added "calling attention to serious or life-threatening risks … after generic market entry.… The data show that new safety issues commonly arise after generics have entered the market, and underscore the public health imperative of maintaining an incentive for generic manufacturer surveillance of safety concerns."

Public Citizen also contends that generic competition "frequently leads the brand-name manufacturer to cease production of the brand-name drugs. For these drugs, patients and physicians cannot rely on the brand-name manufacturer to monitor reports of adverse effects and update the labeling." The report characterizes generic companies' inability "under current regulations to update the labeling of their products a threat to the safety of prescription drugs, creating unnecessary risks to patients."

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Colorado Supreme Court Confirms Active Judicial Role in Managing Discovery

The Colorado Supreme Court has determined that Rule 26 of the Colorado Rules of Civil Procedure (C.R.C.P.) requires "active judicial management to control excessive discovery" and, to resolve a dispute over the proper scope of discovery, "the trial court should, at a minimum, consider the cost-benefit and proportionality factors set forth in C.R.C.P. 26(b)(2)(F)." ***In re DCP Midstream, LLP v. Anadarko Petroleum Corp.*, No. 12SA307 (Colo., decided June 24, 2013)**.

The court concluded that the trial court abused its discretion by not taking an active role managing discovery and returned the case for it to determine "the appropriate scope of discovery in light of the reasonable needs of the case" and "to tailor discovery to those needs." The issue arose in a contract dispute; one of the parties sought to compel the production of documents, and the trial court granted the motion without holding a hearing, addressing the scope-of-discovery objections or providing any analysis. Later, during a telephone conference, the trial court apparently suggested that the parties confer to narrow the scope of discovery, given the millions of documents involved, and stated that it did not "have the power to make you do that."

Shook, Hardy & Bacon Public Policy Attorneys **Mark Behrens** and **Jonathan Gregor** submitted an *amicus* brief on behalf of the National Association of Manufacturers and American Tort Reform Association to support the party resisting the motion to compel. They argued that trial courts must take an active, hands-on role in managing discovery and should consider the C.R.C.P.'s cost-benefit and proportionality factors to control excessive discovery.

ALL THINGS LEGISLATIVE AND REGULATORY

Senator Rockefeller Decries Delay of Rearview Camera Rule

Sen. Jay Rockefeller (D-W.Va.) has issued a statement in response to Transportation Secretary Ray LaHood's announcement that the National Highway Traffic Safety Administration will not finalize a rule requiring rearview cameras to be installed in passenger vehicles until 2015. The rule was required under bipartisan legislation enacted in 2008 and was supposed to be finalized by February 2011, although the law allowed the deadline to be extended. The latest delay marks the third extension for the rule.

According to Rockefeller, "I am deeply disappointed by the Administration's foot dragging over a rule that could help save the lives of hundreds of young children and prevent thousands of heartbreaking injuries. The fact is simple—installing rear cameras in cars will prevent injury and death. The Administration needs to move forward with this common sense safety measure because children's lives are in jeopardy." Rockefeller has indicated that he will press the new secretary, once confirmed, to finalize the rule before the 2015 deadline. *See U.S. Senate Committee on Commerce, Science, & Transportation Press Release*, June 20, 2013.

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Administrative Conference Calls for Cost-Benefit Analysis by Independent Agencies

The Administrative Conference of the United States (ACUS) has adopted a **recommendation** that independent agencies, such as the Federal Trade Commission and Consumer Product Safety Commission (CPSC), prepare cost-benefit analyses as part of their rulemaking process. While CPSC is required by statute to prepare a regulatory analysis statement describing expected costs and benefits before issuing certain rules, the ACUS recommendation is somewhat broader, calling for the development of written guidance on the preparation of such analyses, updating the cost-benefit analysis as a rulemaking proceeds and changes are made to the rule, and applying the analysis to the proposed rule and its primary alternatives. ACUS is "an independent federal agency dedicated to improving the administrative process through consensus-driven applied research, providing nonpartisan expert advice and recommendations for improvement of federal agency procedures."

Meanwhile, Sens. Rob Portman (R-Ohio), Mark Warner (D-Va.) and Susan Collins (R-Maine) have introduced a bill (**S. 1173**) that would authorize the president to require independent agencies to conduct a cost-benefit analysis for any rule with an annual economic impact greater than $100 million. It would also require that these agencies design rules in the "most cost-effective manner to achieve the regulatory objective" and "tailor rules to impose the least burden on society." According to Portman, "This bill would close the loophole for independent agencies by authorizing the president to bring them within the same regulatory review framework that applies to other agencies. This is a bipartisan, consensus reform with broad support, and it will promote a more stable regulatory environment for economic growth and job creation." *See Sen. Rob Portman News Release*, June 18, 2013.

CPSC to Hold Public Hearing on FY2014/2015 Agenda and Priorities

The Consumer Product Safety Commission (CPSC) has slated a July 10, 2013, public **hearing** in Bethesda, Maryland, to "receive views from all interested parties about its agenda and priorities for fiscal year 2014 [FY2014], which begins on October 1, 2013, and for fiscal year 2015, which begins on October 1, 2014." Requests to present during the hearing and oral presentation texts must be submitted by July 1, 2013. CPSC seeks comments on the priorities it should consider emphasizing, activities it should consider deemphasizing and whether the commission should "consider making any changes or adjustments to its education, safety standards activities, regulation, and enforcement efforts in fiscal years 2014 and/or 2015." *See Federal Register*, June 24, 2013.

Safety Standards for Infant Walkers and Swings Finalized

The Consumer Product Safety Commission (CPSC) has issued a direct final **rule**, revising its standards for infant walkers and infant swings "to incorporate by reference the more recent versions of the applicable ASTM standards." The rule will take effect October 7, 2013, unless CPSC receives "significant adverse comment by July 24." If timely significant adverse comment is received, the commission will withdraw the rule before its effective date.

The move follows legislation enacted by Congress in 2011that established a process for updating standards that the Commission issues under the authority of the Consumer Product Safety Improvement Act of 2008. CPSC has determined that the most recent revisions to ASTM F977, Standard Consumer Safety Specification for Infant Walkers, and ASTM F2088, Standard Consumer Safety Specification for Infant Swings, "make these revised ASTM standards nearly the same as the CPSC-mandated standards for these products." *See Federal Register*, June 24, 2013.

Ross Stores to Pay $3.9 Million for Selling Children's Clothing with Drawstrings

The Consumer Product Safety Commission (CPSC) has entered a settlement **agreement** with Ross Stores, Inc. to resolve staff allegations that the retailer committed prohibited acts by failing to inform CPSC about the company's continued sale of children's garments with drawstrings. Under the agreement, the company will pay $3.9 million, said to be the highest civil penalty ever assessed by the agency for drawstring violations and a reflection of the company's purported status as a "repeat violator." The company will also institute measures to reduce the risk of future noncompliance, including enhanced compliance procedures and internal controls. *See CPSC Chair Inez Tenenbaum Statement*, June 21, 2013; *Bloomberg BNA Product Safety & Liability Reporter*, June 24, 2013.

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NHTSA to Hold Crash Data Upgrade Meeting

The U.S. Department of Transportation's National Highway Traffic Safety Administration (NHTSA) has scheduled a listening **session** for July 18, 2013, in Washington, D.C. According to NHTSA, the meeting is the next phase of the agency's effort to modernize the National Automotive Sampling System (NASS) and improve NHTSA's crash database, which has not received "significant revision" since its creation in the 1970s. The listening session aims to solicit information and comments about what should be added, deleted or changed regarding the current NASS and recommendations for improving the data collection methodology. Pre-registration is required by July 11. *See Federal Register,* June 18, 2013.

ASTM Committee Agrees to Develop Voluntary Standard for Adult Portable Bed Rails

A newly formed ASTM committee has reportedly agreed to establish a voluntary standard for adult portable bed rails. Committee members, including large and small manufacturers and safety organization representatives, will apparently start with ASTM F2085, a children's bed rail standard, and make changes to it. The process to develop a usable standard, according to at least one participant in the group's first conference call, could take six to 10 years. A recent Consumer Product Safety Commission (CPSC) report linked adult portable bed rails to nearly 37,000 emergency room visits and 155 deaths between 2003 and 2011. Some of the consumer safety groups that called on CPSC to ban the products will be part of the ASTM standards committee. *See Bloomberg BNA Product Safety & Liability Reporter*, June 24, 2013.

LEGAL LITERATURE REVIEW

Keith Hylton, "Toward a Regulatory Framework for Third-Party Funding of Litigation," *Boston University School of Law, Law and Economics Research Paper*, June 2013

Boston University School of Law Professor Keith Hylton focuses on the economics and ethics of third-party litigation funding, which although prohibited in most jurisdictions is occurring in many through a fairly robust litigation-loan business. He explores the forms under which legal rights are transferred, such as settlements, waiver agreements and subrogation, to gain insight into the legal basis for regulating third-party funding.

LAW BLOG ROUNDUP

Disturbing U.S. Supreme Court Ruling on Generic Design-Defect Case?

"We were critical of the First Circuit decision in *Bartlett v. Mutual Pharm. Co.*, and called for Supreme Court review. The Supreme Court today reversed the horrifically bad decision—but disturbingly, did so only on a 5-4 vote." Manhattan Institute Center for Legal Policy Adjunct Fellow Ted Frank, blogging about the Court's ruling insulating generic drug makers from liability under state law for design-defects.

PointofLaw.com, June 24, 2013.

THE FINAL WORD

Civil Jury Trials Drop to 40-Year Low in Texas

A combination of factors, including tort reform, a more conservative appellate bench, arbitration agreements, and increasing discovery costs, has apparently resulted in a significant decrease in resort to the civil jury trial in Texas. Trials in state court have reportedly decreased 67 percent since 1997, and U.S. district courts conducted just 135 civil jury trials in 2012, down from 360 in 1997. Product liability jury trials fell 50 percent between 2011 and 2012. While plaintiffs' lawyers have expressed concern about the trend for more than 10 years, some defense counsel have begun calling the decline "unhealthy" and "profoundly negative." One attorney said, "People get very upset when other constitutional rights are taken away or limited, but we are witnessing our Seventh Amendment right to a civil jury severely attacked, and people don't seem to care." Another said he counsels his business clients to bring their civil lawsuits in other states, noting that the Texas appellate courts so favor defendants that a good jury verdict "fully supported by the facts and the law" is likely to be reversed on appeal. *See The Dallas Morning News*, June 22, 2013.

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UPCOMING CONFERENCE AND SEMINARS

DRI, Washington, D.C. – July 25-26, 2013 – "2013 DRI Class Actions Conference." Shook, Hardy & Bacon Class Actions & Complex Litigation Partners Tim Congrove and Jim Muehlberger will participate in this event. Congrove, who is also serving as program vice-chair, will moderate a panel of distinguished in-house counsel discussing "Inside and Out: A Wide-Ranging Discussion of Class Actions from the Client's Perspective." Muehlberger "will discuss the current state of issue classes, techniques for addressing them, and his experience in trying a case involving a Rule 23(c)(4) class" during a presentation titled "Making an Issue Out of It: The Trial of a 23(c)(4) Class." SHB is a conference co-sponsor. ■

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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 440 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).