Shook, Hardy & Bacon L.L.P.

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PRODUCT LIABILITY LITIGATION REPORT

CONTENTS

SEVENTH CIRCUIT REVERSES VERDICT, JURY IMPROPERLY ALLOWED TO EXAMINE LADDER EXEMPLAR

The Seventh Circuit Court of Appeals has determined that a district court abused its discretion by allowing an exemplar ladder, introduced as a "demonstrative exhibit" by the defendant at trial in a product liability action, to be provided to the jury during deliberations and further found that the error was not harmless. ***Baugh v. Cuprum S.A. de C.V.*, No. 12-2019 (7th Cir., decided September 13, 2013)**. So ruling, the court reversed the judgment in favor of the defendant and remanded for a new trial.

The plaintiff was cleaning the gutters at his home when the ladder allegedly collapsed, causing his severe brain injury. No one saw the incident, and the plaintiff could not testify about what happened. Some two years after discovery closed, the defendant indicated that it intended to use an exemplar of the ladder during its expert's trial testimony. It was new, but constructed with the same specifications as the ladder the plaintiff had used. The defendant marked the ladder as an exhibit "for Demonstrative Purposes." The plaintiff objected to its use because it had not been included in the defendant's expert disclosures, but the court permitted it to be displayed and used in the courtroom because the ladder was "being offered only as a demonstrative exhibit."

During its deliberations, the jury asked to see the ladder several times. Each time, the plaintiff objected because the ladder had never been admitted as an exhibit, but the court pressed counsel to explain how allowing the jury to see the ladder would prejudice the plaintiff. Ultimately, the court overruled the plaintiff's objections and allowed jury members to enter the courtroom by themselves and look at the ladder. After they asked if they could step on it, the court allowed the ladder to go into the jury room. Several hours later, the jury returned a verdict for the defendant.

Noting some ambiguity in the term "demonstrative," the Seventh Circuit declined to reconcile all of its uses, but clarified that a jury may not consider an exhibit that has not been admitted into evidence absent the parties' agreement to allow this use of the exhibit. It explained how demonstrative exhibits are generally used to "persuade the jury to see the evidence in a certain light favorable to the advocate's client" and, because such exhibits are not admitted into evidence, the designation allows the parties and court "to avoid protracted disputes regarding the admissibility of

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demonstrative exhibits that might arise if such an exhibit were being offered as substantive evidence." The parties and court, in the court's view, understand that demonstrative exhibits are argumentative and persuasive in nature. The court noted, "we would not allow a lawyer to accompany the jury into the deliberation room to help the jurors best view and understand the evidence in the light most favorable to her client. The same goes for objects or documents used only as demonstrative exhibits during trial."

Observing that the plaintiff had no "opportunity to plan for, mitigate, or rebut the effects of the ladder's introduction into jury deliberations," the court found that he "was prejudiced by his inability to respond to the ladder as substantive evidence." Because the jury deliberated for three days and reached a verdict shortly after being given the opportunity "to examine, step on, and manipulate the exemplar ladder," the trial court's error "may well have been decisive; we cannot say it was harmless," the court said.

TENTH CIRCUIT FINDS INDUSTRIAL MACHINE NOT UNREASONABLY DANGEROUS IN AMPUTATION SUIT

The Tenth Circuit Court of Appeals has affirmed the dismissal of strict product liability and negligence claims brought against the manufacturer of a hydraulic press brake, a machine tool used to shape sheet metal, by a press operator who lost his hand after reaching into the machine to remove a jammed piece of metal and accidentally stepping on the foot pedal that activated the machine. ***Braswell v. Cincinnati Inc.*, No. 12-5128 (10th Cir., decided September 23, 2013)**.

The plaintiff had argued that the machine was defective because, despite all of its safety features, many of which had been disabled by previous owners, "it was not equipped with an anti-trip footswitch, which requires a complete depression of the pedal each time the operator wants to reinitiate the machine's movement." He also argued that the subsequent alterations did not insulate the defendant from liability because the alterations were reasonably foreseeable.

In the absence of any Oklahoma case law on the issue, the court did not address "what constitutes a reasonably foreseeable modification," finding that the case could be resolved on the third strict-liability element: unreasonable dangerousness. Oklahoma courts continue to apply the Restatement (Second) of Torts' "consumer expectations test," so the court determined that the machine was not unreasonably dangerous as to a trained operator—the ordinary consumer or user of the press brake—who is aware of the "extreme danger and risk of reaching into the machine while having one's foot remain anywhere near the footswitch, at least without disengaging or blocking the ram." The ordinary operator "would also heed the warnings on the machine and in the instruction manual." According to the court, the plaintiff "knew of the exact danger he faced. He admitted in his deposition that when a piece

is jammed '[y]ou take your foot off of the pedal' before reaching into the machine. Unfortunately, [the plaintiff] neglected to do just that."

The court further declined to reverse the trial court's dismissal of the plaintiff's negligence claims, finding that he had waived both of the arguments on which he based his challenge.

SECOND CIRCUIT RULES CAFA'S HOME STATE EXCEPTION NOT JURISDICTIONAL

Aligning with the Seventh and Eighth Circuits, the Second Circuit Court of Appeals has determined that the Class Action Fairness Act's (CAFA's) "home state exception," which "requires district courts to 'decline to exercise' jurisdiction over class actions in which two-thirds or more of the class, and the primary defendants, are citizens of the state in which the action was filed," is not jurisdictional and is not waived if invoked within a reasonable time. ***Gold v. N.Y. Life Ins. Co.*, No. 12-2344 (2d Cir., decided September 18, 2013)**. The issue arose in the context of a wage dispute filed by a former life insurance agent in 2009. The defendant did not invoke the CAFA exception until class discovery, begun in 2011 under the court's scheduling order, revealed that more than two-thirds of the class consisted of New York citizens.

While the Second Circuit was not prepared to rule that the district court abused its discretion by finding nearly three years a reasonable time for the defendant to invoke the exception, it noted "that there are numerous instances where the home state exception was raised much more promptly than it was in this case, and without full blown class discovery." According to the Second Circuit, the district court was in the better position to evaluate when the defendant's motion could have been made, "based on its greater familiarity with the course of the litigation, especially scheduling and discovery matters."

PENNSYLVANIA HIGH COURT CONFIRMS REJECTION OF "EVERY BREATH" THEORY IN ASBESTOS SUIT

The Pennsylvania Supreme Court has reinstated a trial court's grant of the motion for summary judgment filed by the manufacturer of products containing asbestos after the plaintiffs conceded that the court would not allow them to "prove that a plaintiff's exposure to a particular asbestos-containing product is substantially causative of disease by the use of affidavits in which the expert's methodology is founded upon a belief that every single fiber of asbestos is causative." ***Howard v. A.W. Chesterton Co.*, No. J-7A-C-2013 (Pa., decided September 26, 2013)**. An intermediate appellate court had reversed the lower court ruling, reasoning, among other matters, that "a plaintiff bears a diminished burden of meeting a frequency, regularity, and proximity threshold of exposure in cases of mesothelioma, since the disease may be caused by limited exposure to asbestos."

One of the manufacturing defendants also requested that the court reaffirm certain governing principles "in view of [the company's] status as a defendant in other cases and the time and expense of litigation." The court agreed to do so and confirmed the following: (i) "The theory that each and every exposure, no matter how small, is substantially causative of disease may not be relied upon as a basis to establish substantial-factor causation for diseases that are dose-responsive"; (ii) "Relatedly, in cases involving dose-responsive diseases, expert witnesses may not ignore or refuse to consider dose as a factor in their opinions"; (iii) "Bare proof of some *de minimus* exposure to a defendant's product is insufficient to establish substantial-factor causation for dose-responsive diseases"; and (iv) "Relative to the testimony of an expert witness addressing substantial-factor causation in a dose-responsive disease case, some reasoned, individualized assessment of a plaintiff's or decedent's exposure history is necessary."

ALL THINGS LEGISLATIVE AND REGULATORY

Drug Compounding Oversight Bill Advances in House

The U.S. House of Representatives has reportedly passed by voice vote a bill (**H.R. 3204**) to strengthen the Food and Drug Administration's (FDA's) oversight of human drug compounding and the pharmaceutical supply chain. Known as the Drug Quality and Security Act, the legislation seeks to address concerns raised about the manufacturing and distribution of compounded drugs after an investigation linked a fungal meningitis outbreak to tainted steroid injections from a Massachusetts facility.

Negotiated by the Senate Health, Education, Labor and Pensions Committee and House Energy and Commerce Committee, the measure, if enacted, would clarify "FDA's authority over the compounding of human drugs" and directs the agency to engage in two-way communication with state regulators. In addition to eliminating "unconstitutional provisions of Section 503A of the Federal Food, Drug, and Cosmetic Act (FFDCA) that created uncertainty regarding the laws governing compounding," the new rules would permit drug compounding entities to register as "outsourcing facilities" subject to FDA oversight while preserving "the practice of traditional pharmacy compounding occurring in community pharmacies." The legislation would also create "a uniform national standard for drug supply chain security to protect Americans against counterfeit drugs."

"With the passage of this bill, the FDA will have the authority it needs, but we have to also make sure that they have the fortitude to take action on any compounding pharmacy that they see not up to the high level of standards the FDA sets, that all citizens expect," said House Oversight and Investigations Subcommittee Chair Tim Murphy (R-Penn.). "The Drug Quality and Security Act will end these problems, we hope, end these inspection holidays, and reassure the American public that these medications, wherever they are manufactured, and most by compounding pharma-

cies, who do a superb job of maintaining sterile conditions, but in all cases the FDA will have the authority to make sure they have the inspections and they have the team that can go in there and take solid action when these centers do not adhere to those high standards." *See House Energy and Commerce Committee Press Release and Facts Sheet,* September 28, 2013.

CRS Publishes Report on Drug and Medical Device Claim Preemption

The Congressional Research Service (CRS) has prepared for Congress a report titled "Preemption of Drug and Medical Device Claims: A Legal Overview." It provides a background on preemption doctrine, the types of claims plaintiffs have brought under state tort law against medical device and prescription drug makers, an overview of federal law regulating these products, and recent U.S. Supreme Court preemption rulings. The report concludes by considering proposed changes to Food and Drug Administration regulations and pending bills that either raise policy questions or may not alter the results of the high court's rulings. It also suggests that certain related issues were not addressed in the preemption cases and could find their way to the U.S. Supreme Court's docket in the near future.

CPSC to Hold Public Meeting on Magnet Set Standards

The Consumer Product Safety Commission (CPSC) has **announced** an October 22, 2013, public meeting in Bethesda, Maryland, to receive oral comments on a notice of proposed rulemaking (NPR) seeking "to reduce the risk of injury associated with children ingesting magnets that are part of a magnet set." Issued September 4, 2012, the **NPR** would set standards requiring magnet sets with magnets that fit in CPSC's small parts cylinder to have a flux index of 50 or less according to ASTM F963-11, the Standard Consumer Safety Specification for Toy Safety. The rules would ban any magnet set that failed to meet these specifications. CPSC will accept oral presentation requests until October 15. *See Federal Register,* September 24, 2013.

CPSC Considers Guidelines for Voluntary Recall Press Releases

The Consumer Product Safety Commission (CPSC) staff has **drafted** a notice of proposed rulemaking (NPR) that would "set forth principles and guidelines for the content and form of voluntary recall notices that firms provide as part of corrective action plans under Section 15 of the Consumer Product Safety Act (CPSA)." Still under consideration by the agency, which has scheduled a decisional meeting for October 23, 2013, the draft NPR seeks to standardize voluntary recall notices to achieve (i) "greater efficiencies during recall negotiations," (ii) "greater predictability for the regulated community in working with the agency to develop voluntary recall notice content," and (iii) "timelier issuance of recall announcements to the public."

The proposed NPR would establish a new subpart in 16 C.F.R. 1115 and expand 16 C.F.R. 1115.20 to include key principles for voluntary recall notices in line with those

already required for mandatory recall notices. According to CPSC, these guidelines would ensure that voluntary recall notices help consumers (i) identify the products recalled, (ii) understand the hazards associated with the product, (iii) "understand the remedies available to consumers concerning the product," and (iv) "take appropriate action in response to the notice." In addition, the NPR would address the use of electronic media—such as radio and video, social media and blogs—as general forms for voluntary recall notices, as well as create new provisions concerning the possible contents of corrective action plans negotiated under 16 CFR 1115.20(a).

"Believe it or not, when we're negotiating recalls and press releases, we spend a lot of time negotiating the recall notice headline, and we don't think that's an efficient process," said Howard Tarnoff, senior counselor to the director of CPSC's Office of Compliance and Field Operations. "We want to try to standardize it to the greatest extent possible." *See Bloomberg BNA Product Safety & Liability Reporter,* September 26, 2013.

NHTSA Adds Rearview Video Systems to U.S. New Car Assessment Program

The National Highway Traffic Safety Administration (NHTSA) has issued a final **decision** indicating that it will update the U.S. New Car Assessment Program with recommendations to consumers about those "vehicle models that have rearview video systems that the agency believes (based on currently available data) will decrease the risk of backover crashes." NHTSA's determination to do so preceded by one day the filing of a **petition** in the Second Circuit Court of Appeals for a writ of mandamus to declare that the Department of Transportation (DOT) has unreasonably delayed issuing a backover rule as required under the Gulbransen Act. One of the petitioners, Greg Gulbransen, is a pediatrician who lost his 2-year-old son in a backover crash in 2002; he was driving the car that struck the child and could not see him with existing mirrors and even looking over his shoulder. He advocated for the law, enacted in 2008, that bears his name and required DOT to issue within three years a final rule that would "expand the required field of vision to enable drivers of motor vehicles to see better behind their vehicles." *See Federal Register*, September 30, 2013.

California Names Dozens of Chemicals That Consumer Product Manufacturers May Need to Replace

California's Department of Toxic Substances Control issued an "informational 'initial' **list** of candidate chemicals and chemical groups" as the Safer Consumer Products initiative took effect on October 1, 2013. Based on this list, which includes chemicals such as formaldehyde, bishphenol A, acrylamide, aluminum, benzene, toluene, and arsenic, the department will, by April 2014, identify up to five "priority products" containing at least one of the chemicals. Their manufacturers will be asked to evaluate the product's design and replace the chemicals with safer, feasible alternatives. According to the department, factors considered in selecting the products include

"the extent of their use, the potential for public exposure to the toxic ingredient, and how the products eventually are disposed." Public comment will be solicited "since the selection will be finalized via the regulation adoption process." *See California EPA Department of Toxic Substances Control Press Release*, September 26, 2013.

LEGAL LITERATURE REVIEW

Laura Hines, "The Unruly Class Action," *George Washington Law Review* (forthcoming)

University of Kansas School of Law Professor Laura Hines explores how some courts have come to use and, in fact, "widely embrace" the "issue class action" allowed by Federal Rule of Civil Procedure 23(c)(4) as an alternative to the (b)(3) class action with its "daunting predominance requirement." Hines contends that this practice "can only be sustained by imprudent (and arguably hypocritical) endorsement of outcome-oriented rulemaking by adjudication rather than by statutorily prescribed procedures." She calls for rulemaking under Rules Enabling Act procedures to provide "legitimacy, both statutory and democratic" that would also permit "extensive deliberations by Committee members with superior expertise, divergent perspectives, and access to empirical data unavailable to the court" on the potential "risks and benefits of creating a stand-alone issue class action."

Herbert Kritzer, et al., "An Exploration of 'Non-Economic' Damages in Civil Jury Awards," *William & Mary Law Review* (forthcoming 2014)

Scholars from the University of Minnesota Law School and Duke University – School of Law have presented an analysis of empirical data to determine if non-economic damages—those damages awarded for losses without a specific monetary valuation, such as pain and suffering, loss of society, emotional distress, loss of consortium, disfigurement, and loss of enjoyment of life—can be predicted by the economic damages that juries award. They found "a mixture of consistent and inconsistent patterns across our various datasets. One fairly consistent pattern was the tendency for the ratio of non-economic to economic damages to decline as the amount of economic damages increased." The authors also observed that "there tends to be considerably more variability in the relationship between non-economic and economic damages than between punitive and compensatory damages." They conclude that this variability "is problematic as evidence regarding the need to limit non-economic damages."

Donald Gifford & William Reynolds, "The Supreme Court, CAFA and *Parens Patriae* Actions: Will It Be Principles or Biases?," *North Carolina Law Review*, 2013

University of Maryland Carey School of Law professors discuss a case on the U.S. Supreme Court's upcoming docket asking whether defendant manufacturers can

remove a *parens patriae* action, one brought by a state government to protect the health and welfare of its citizens, to federal court on diversity grounds under the Class Action Fairness Act (CAFA). They posit that the case "promises an unusual test of whether the Justices will follow their own preferred principles of statutory interpretation or their pro- or anti- business biases." In their view, a textualist, or "plain-meaning," approach, favored by the Court's conservatives "will lead to a pro-consumer outcome," while "a genuine application of the purposive approach by Justice Breyer will probably lead to a pro-business and anti-consumer outcome." The authors ask "So for both the conservatives and the more progressive members of the Court, which shall it be? A principled application of their preferred approach to statutory interpretation? Or a result consistent with their ideological preferences?"

LAW BLOG ROUNDUP

Civil Litigation Will Be Low Priority for DOJ During Government Shutdown

"Most Civil Division employees will be subject to furlough because their activities do not relate to 'emergencies involving the safety of human life or the protection of property,' or meet some other category or exemption." St. Thomas University School of Law Professor Patricia Moore, reporting on the Department of Justice's (DOJ's) Contingency Plan for FY 2014, which took effect October 1, 2013, and accounted for the possibility that the U.S. Congress would fail to pass a continuing resolution to fund the federal government.

Civil Procedure & Federal Courts Blog, September 30, 2013.

Wrongful Death Damages at Issue for Tort Scholars

"Premature death is normally the harm we fear most. But the law of torts provides no redress for that harm. Legal economists have found this particularly disturbing." Yale Law School Visiting Professor Gregory Keating, discussing a law journal article titled "Lost Life and Life Projects" that tackles the purported inadequacy of wrongful death damages. Keating posits, "Tort provides poor redress for, and little protection against, the worst harm that we can suffer."

Jotwell: Torts, September 27, 2013.

THE FINAL WORD

Federal Courts to Continue Operations for 10 Business Days Under Government Shutdown

In advance of Congress's ongoing failure to resolve differences over a short-term spending resolution, the Administrative Office of the U.S. Courts issued the following notice: "In the event of a government shutdown on October 1, 2013, the federal judiciary will remain open for business for approximately 10 business days. On or

around October 15, 2013, the Judiciary will reassess its situation and provide further guidance. All proceedings and deadlines remain in effect as scheduled, unless otherwise advised. Case Management/Electronic Case Files (CM/ECF) will remain in operation for the electronic filing of documents with courts." The government has begun shutting down, and some 800,000 employees will be furloughed.

The U.S. Supreme Court has posted a separate notice on its Website indicating that while it will continue to conduct normal operations through October 4 and the building will be open to the public, "[f]urther notice will be provided in the event a lapse of appropriations continues beyond October 4." The first day of the Court's 2013-2014 term is set for October 7. *See Bloomberg BNA, The United States Law Week*, September 27, 2013; *Law360*, October 1, 2013.

UPCOMING CONFERENCES AND SEMINARS

ACI, New York, NY – October 7-9, 2013 – "5th Annual Forum on: Sunshine Act Compliance & Aggregate Spend Reporting, HCP Reporting Risk Mitigation and Compliance Strategies for Biopharmaceutical and Medical Device Manufacturers." Shook, Hardy & Bacon Government Enforcement & Compliance Partner Carol Poindexter will join a distinguished faculty to discuss "Mastering the Challenges of Identifying and Tracking Research and Pre-clinical Related Payments."

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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).