

PRODUCT LIABILITY LITIGATION REPORT



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FIRM NEWS

Law360 Features Shook's Win in Pelvic Mesh Trial

Law360 recently [featured](#) Shook, Hardy & Bacon's successful representation of Boston Scientific Corp. in "the first product liability lawsuit involving the company's pelvic mesh product to go to trial." Led by Global Product Liability Partner [Rob Adams](#) and Pharmaceutical & Medical Device Litigation Partner [Jon Strongman](#), the Shook team obtained a defense verdict in Massachusetts state court following a three-week trial and one day of jury deliberation. The plaintiff claimed that the company did not adequately warn her physicians and claimed that its Pinnacle Pelvic Floor Repair Kit was allegedly defectively designed before surgical implantation.

"The verdict could have a substantial impact on similar lawsuits consolidated in Middlesex Superior Court," reports *Law360*. "More than 500 pelvic mesh cases relating to Boston Scientific's products are pending before Justice Diane M. Kottmyer, according to court filings." A recent *Bloomberg* [article](#) also noted that previous jury trials involving pelvic-mesh manufacturers have resulted in damages totaling more than \$13 million for purported injuries. See *Law360* and *Bloomberg*, July 29, 2014.

SHB Partner Authors U.S. Chamber ILR Report on Legal Trends in Latin America

Shook, Hardy & Bacon Global Product Liability Partner [William Crampton](#) has prepared a U.S. Chamber Institute for Legal Reform (ILR) [report](#) titled "Following Each Other's Lead: Law Reform in Latin America" that "reviews some of the significant trends in Latin America that could significantly affect potential defendants."

According to Crampton, change in one country is often adopted regionally, thus changes to procedural rules and the adoption of class-action mechanisms in Brazil have established a model that others have followed. He describes the reforms, both adopted and pending, in some detail. While acknowledging that access to justice could be improved in some countries by creating a class-action mechanism, Crampton argues that "it is fair and appropriate to oppose class action systems that change the meaning of justice under the guise of creating access to it." He recommends that the business sector participate in the discussion "to ensure that a level playing field is maintained for both plaintiffs and defendants."

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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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CASE NOTES

Eleventh Circuit Rules Exclusion of Expert Testimony on Basis of Industry Standards Was Abuse of Discretion

The Eleventh Circuit Court of Appeals has revived negligence claims filed against Laboratory Corp. of America for allegedly failing to identify abnormalities in the plaintiff's Pap smears thus causing a delayed cancer diagnosis, finding that the district court erroneously excluded the plaintiff's expert testimony. [*Adams v. Lab. Corp. of Am., No. 13-10425 \(11th Cir., decided July 29, 2014\)*](#). The expert had been retained to testify about whether the lab's employees breached the standard of care for cytotechnologists when reviewing the plaintiff's slides.

The appeals court determined, among other matters, that the district court erred when ruling that the expert's methodology in reviewing the slides was unreliable because she did not conduct a blinded review as recommended by the College of American Pathologists (CAP) and American Society of Cytopathology (ASC) in their litigation guidelines. Finding that the expert's methodology was reliable under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and Federal Rule of Evidence 702, the court disagreed that the guidelines set the standard for the profession.

In this regard, the court stated, "As far as we are aware, this is the first time that an industry group has promulgated a set of guidelines that attempts to define and limit the evidence courts should accept when the group's members are sued. The members of the CAP and ASC have a substantial interest in making it more difficult for plaintiffs to sue based on alleged negligence in their Pap smear screening, and their guidelines do just that."

According to the court, while the guidelines would require plaintiffs' experts to conduct a "blind" review, they do not impose the same obligation on the defendant's reviewers and, more importantly, impermissibly require an expert witness to eliminate any potential "review bias" in her opinion, which is "usually a credibility issue for the jury." The court further stated, "[T]he 'acceptance' to which *Daubert* refers is the acceptance that the technique or theory has in the community's own field of practice when the science is being applied outside the litigation context, not the scientific community's opinion about the standard or type of proof that should be required in litigation."

The court suggested that if such organizations could define what constitutes admissible expert testimony, nothing would stop pharmaceutical companies, for example, from adopting "guidelines setting high standards of proof for establishing that a plaintiff's injury was caused by a given drug and justify[ing] doing so based on their experience with the complex nature of pharmacology and their expertise in the field."

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A concurring panel member would also have vacated the lower court's summary judgment ruling, but would have done so because the issue was not the methodology the expert used. Rather, it was a matter of the application of professional judgment and scientific knowledge. "Because the admissibility of Dr. Rosenthal's testimony hinges on the reliability of her knowledge of a cytotechnologist's standard of care rather than the reliability of any 'methodology,' her competence renders her testimony admissible under *McDowell v. Brown*, 392 F.3d 1283 (11th Cir. 2004)," in this jurist's view. Under this approach, "the competency of a standard-of-care expert satisfies the demands of Rule 702 and *Daubert*."

Federal Court Dismisses Strict Liability Claims Against Drug Maker

Citing a recent Pennsylvania Supreme Court decision reaffirming a long-standing bar on strict liability claims for prescription drugs under the *Restatement (Second) of Torts* § 402A cmt. k (1965), a federal court has granted in part the summary judgment motion filed by a drug maker in litigation seeking to hold it liable for injury allegedly caused by the use of a prescription medication that the company designed, manufactured and marketed to manage metastatic bone cancer. *Rowland v. Novartis Pharm. Corp.*, Nos. 12-1474, -1476, -1715 (U.S. Dist. Ct., W.D. Pa., decided July 28, 2014). The court also dismissed the plaintiffs' claims for breach of express warranty and implied warranty, finding "all non-negligence based claims asserted against a manufacturer of prescription drugs" barred under a broad interpretation of state-law precedent.

At issue were the claims of three plaintiffs who were part of multidistrict litigation (MDL) pre-trial proceedings in the Middle District of Tennessee. They alleged strict liability, negligence and breach of warranty against the pharmaceutical company, claiming that its drug caused them or their spouse to develop osteonecrosis of the jaw. In addition to its strict-liability ruling, the court rejected the plaintiffs' claim that Pennsylvania's learned intermediary doctrine, which considers whether a warning that was given to the prescribing physician was proper and adequate thus discharging the company's duty to the consumer, also encompasses other treating professionals such as dentists and oral surgeons. While the *Restatement (Third) of Torts: Products Liability* may extend the learned intermediary doctrine to other health-care providers, the court noted confusion as to whether the state's high court has adopted Sections 1 and 2 of the *Third Restatement*. The court determined on the basis of existing case law that the state would not extend a manufacturer's duty to warn beyond the prescribing physician. The court further determined that it was bound by the MDL court's ruling that the adequacy of the drug's warnings was a question of fact for the jury to consider.

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Minnesota Supreme Court Rejects Plausibility-Pleading Standard

While Minnesota's civil-pleading rule mirrors the federal rule, the state's high court has determined that it would not, without a "compelling reason to depart from the traditional pleading standard for civil actions in Minnesota," adopt the plausibility-pleading standard established by the U.S. Supreme Court in *Twombly* and *Iqbal*. [*Walsh v. U.S. Bank, N.A., No. A13-0742 \(Minn., decided August 6, 2014\)*](#). The issue arose in the context of litigation seeking to vacate a foreclosure sale of residential property. Two concurring judges agreed that the complaint survived a motion to dismiss even under the plausibility-pleading standard, but wrote separately because they did not believe that the majority was called on to decide whether to adopt the standard.

In effect since the court adopted it in 1951, the state's rule provides that "[a] pleading which sets forth a claim for relief . . . shall contain a short and plain statement of the claim showing that the pleader is entitled to relief." According to the majority, given the rule's plain language, purpose, history, and procedural context, "A claim is sufficient against a motion to dismiss for failure to state a claim if it is possible on any evidence which might be produced, consistent with the pleader's theory, to grant the relief demanded."

Here, the complaint alleged ineffective service of foreclosure-related documents because neither the homeowner nor her roommate was served with the documents and they were the only residents of the property on the date of attempted service. They admitted that a Jane Doe was served with the documents, but Jane Doe was not the plaintiff. The court found it reasonable to infer that Jane Doe did not reside at the property—a requirement for effective service—which was consistent with the report of the bank's process server who described Jane Doe as a property "occupant." So ruling, the court affirmed an intermediate appellate court decision, which found that the district court had erred by dismissing the complaint.

ALL THINGS LEGISLATIVE AND REGULATORY

House Members Call on CPSC to Act on CHAP Phthalate Safety Report

Three Democratic House members have [urged](#) the U.S. Consumer Product Safety Commission (CPSC) to act on the Chronic Hazard Advisory Panel (CHAP) report on phthalates, discussed in the July 31, 2014, [issue](#) of this *Report*, and preserve existing bans on their use in consumer products, while making "those that have been interim permanent." While congratulating CPSC Chair Elliot Kaye on his recent confirmation, Reps. Henry Waxman (D-Calif.), Frank Pallone (D-N.J.) and Jan Schakowsky (D-Ill.) address the "serious risks" that CHAP identified relating to specific phthalates, calling its findings "alarming." In particular, the August 1, 2014, letter focuses on the purported risks to the liver, thyroid, immune system, and kidneys, as well as adverse reproductive effects. They conclude, "Although the statute requires CPSC to act within 180 days, we urge you to move forward on these actions without delay."

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High-Power Magnet Maker Agrees to Product Recall

According to the U.S. Consumer Product Safety Commission (CPSC), Star Networks USA LLC has agreed to recall its Magnicube Spheres and Magnicube Cubes, high-powered magnet sets that CPSC alleges cause harm to children and teenagers who ingest them. Manufactured in China, the 22,000 sets sold in the United States after August 2010 contain from 125 to more than 1,000 rare earth magnets. The company will provide full refunds to those returning full sets and a prorated refund for those returning less than a full set; all sets will be destroyed. The settlement of CPSC's administrative complaint against the company also requires that it cease making, importing, distributing, and selling the products. The company's agreement with CPSC states that signing it "does not constitute an admission . . . of the existence of a defect in the Subject Products, a substantial product hazard or reportable information pursuant to Section 15(b) of the CPSA, 15 U.S.C. § 2064(b)." *See CPSC News Release*, August 4, 2014.

NHTSA Opens Preliminary Evaluation over Three-Wheeled Vehicle Fires

The U.S. National Highway Traffic Safety Administration's (NHTSA's) Office of Defects Investigation has opened a preliminary evaluation to gather additional information about reports of two fires involving three-wheeled motorcycles made by Bombardier Recreational Products, Inc. According to the agency, within the past two years, the company "has conducted three safety recalls to address defects that could result in a fire on the subject vehicles." The two July 2014 fires, however, are apparently unrelated "to the issues covered by the previously released safety recalls." The first fire involved "a MY 2011 Spyder RT used as a traffic enforcement vehicle by the Morgantown, WV police department"; the second involved "a MY 2013 Spyder RT SE5" and "occurred in the Mojave desert region of California." NHTSA apparently became aware of this incident through a posting on the Spyderlovers.com Website. *See NHTSA Investigations*, August 4, 2014.

Appellate Procedure Advisory Committee Schedules Meeting

The Judicial Conference of the U.S. Advisory Committee on Rules of Appellate Procedure will [meet](#) October 20, 2014, in Washington, D.C. While the meeting will be open for public observation, no participation will be permitted. According to the most recent report of the Judicial Conference Committee on Rules of Practice and Procedure, the appellate rules advisory committee has been considering possible amendments to Rule 4's treatment of the deadlines for filing notices of appeal.

According to the committee, "a circuit split has developed as to whether a motion filed within a purported extension of a non-extendable deadline under Civil Rules 50, 52, or 59 counts as 'timely' filed under Appellate Rule 4(a)(4)." The committee has reached consensus that the meaning of "timely" should be clarified and is currently weighing whether to implement the majority or minority approach. The committee

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is also “working on projects concerning requirements for filings in the courts of appeals,” including amicus filings in connection with petitions for panel rehearing and/or rehearing en banc and briefing length limits. *See Federal Register*, July 30, 2014.

LEGAL LITERATURE REVIEW

Roger Michalski & Abby Wood, “*Twombly* and *Iqbal* at the State Level,” *UCS Law Legal Studies Paper*, July 31, 2014

Brooklyn Law School Professor Roger Michalski and University of Southern California Assistant Professor of Law Abby Wood explore state-court data to determine whether those states that have adopted the plausibility-pleading standard have experienced any changes in the ways plaintiffs or defendants handle their civil complaints. Because state litigants “are typically more sensitive to the cost of litigation . . . [and] more susceptible to even small changes in the gate-keeping capacity of pleading,” and because state judges “labor under higher caseload pressures than their federal counterparts” and could be expected to use the standard to control their dockets, the authors anticipated seeing empirical effects of *Twombly* and *Iqbal* at the state level that have not been reliably demonstrated by researchers at the federal level. To their surprise, they found “no decrease in filings, no evidence that plaintiffs were changing their strategies conditional on filing complaints, no increase in motions to dismiss, and no increase in the grant rate on motions to dismiss.”

Linda Mullenix, “*Designing Compensatory Funds: In Search of First Principles*,” *Stanford Journal of Complex Litigation* (forthcoming 2015)

Concerned that victim-compensation funds may not accomplish justice for victims of mass disaster events, particularly where a responsible party is identifiable, University of Texas School of Law Professor Linda Mullenix suggests that “not all situations of mass harm should legitimate the creation and implementation of a compensation fund.” She examines the proliferating use of such funds since the World Trade Center Victims’ Compensation Fund of 2001 was established, proposals for designing future funds—drawing on existing models—questions about the goals of these funds, “and whether and to what extent disaster compensation funds comport with theories of justice.” Most have been intended to “provide an alternative to the tort compensation system,” operating outside the judicial system’s purview while relying “on tort notions of corrective justice that mimic the tort system.” According to Mullenix, a fund created to address mass harms caused by an identifiable, responsible party—a traditional tort situation—where a single, special master’s sense of corrective justice and individual calculations of specific awards are divorced from the tort system, constitutes an illegitimate circumvention of the adjudicative tort system and should not be permitted without judicial oversight.

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In contrast, in the case of “communitarian disasters,” where blameworthiness is difficult if not impossible to locate, Mullenix recognizes the value of a compensation fund because such disasters “ought to call forth communitarian responses, which justify either governmental subsidization of a fund or charitable resources voluntarily given. The creation of compensation funds in such circumstances is legitimate precisely because it is not, essentially, an alternative to the tort system.”

LAW BLOG ROUNDUP

Clues to Tort-Litigation Pressure?

“For a sense of where tort pressure is being felt, list of litigation groups at AAJ (including newly formed groups) often provides clues.” Cato Institute Senior Fellow Walter Olson, providing a link to the American Association for Justice’s (AAJ’s) litigation group list, which, in addition to a number of pharmaceuticals and medical devices, includes products such as bicycles, motorcycles, electric blankets, lawn mowers, energy drinks, and tasers. AAJ is a plaintiffs’ counsel organization.

Overlawyered.com, August 11, 2014.

THE FINAL WORD

Kentucky Court Finds Chesley Jointly Liable for \$42 Million Judgment in Fen-Phen Litigation

A Kentucky court has ruled that Stanley Chesley is jointly and severally liable for breach of fiduciary duty in the representation of “fen-phen” diet drug plaintiffs. *Abbott v. Chesley*, No. 05-CI-00436 (Boone Cir. Ct., Ky., entered August 1, 2014). The court agreed with the plaintiffs that summary judgment was appropriate on the basis of issue preclusion or collateral estoppel, relying on the findings made in disciplinary proceedings against Chesley. According to the court, he had a “realistically full and fair opportunity to present his case before the Trial Commissioner,” and thus, Chesley was bound by its findings and legal conclusions, which the state supreme court affirmed. Finding no genuine issues of material fact and that Chesley’s conduct caused the plaintiffs to “receive only a portion of the settlement monies they were entitled to,” the court granted the summary judgment motion as to the breach of fiduciary duty claims and further found Chesley jointly and severally liable with William Gallion, Shirley Cunningham and Melbourne Mills for the existing judgment of \$42 million.

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UPCOMING CONFERENCES AND SEMINARS

[Perrin Conferences](#), San Francisco, California – September 8-10, 2014 – “Asbestos Litigation Conference: A National Overview & Outlook.” Shook, Hardy & Bacon Public Policy Partner [Mark Behrens](#) will take part in a panel discussion on “Asbestos Compensation: The Impact of Bankruptcy on the Tort System.” The firm 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).

