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PRODUCT LIABILITY LITIGATION REPORT



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Strongman and Swan Address Biological Plausibility's Role in Causation Analysis

Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Attorneys

Jon Strongman and Eric Swan have co-authored an article titled "The Abuse of Biological Plausibility as a Factor" appearing in the September 2013 issue of For the Defense. Focusing on the courts' increasing "overreliance" on "biologic plausibility as a factor in general causation analysis," particularly in the context of drug and medical device mass torts, they argue that this reliance is misplaced because "biologic plausibility is virtually worthless in assessing whether an association is causal." While they suggest that it has its place and is "most useful as an exclusionary criterion," the authors urge courts to view "plausible explanations" with great suspicion and consider instead the underlying evidence.

CASE NOTES

SCOTUS Denies Review in Disbarred Asbestos Attorney's Appeal of Fraud Conviction

On the opening day of its new term, the U.S. Supreme Court issued an order denying review of a Fifth Circuit decision affirming the conviction of plaintiffs' lawyer Richard (Dickie) Scruggs for bribing a judge. *Scruggs v. United States*, No. 13-206 (U.S., *cert*. denied October 7, 2013). Scruggs, known for his role in asbestos and tobacco litigation, allegedly sought to influence the judge hearing Scruggs's feesharing dispute by promising to recommend the judge to Scruggs's brother-in-law, then-U.S. Senator Trent Lott, for a seat on the federal bench. The judge apparently provided considerable information and assistance to Scruggs's attorneys, and after a grand jury returned an indictment charging Scruggs with fraud-related charges, he pleaded guilty to one count of aiding and abetting honest-services mail fraud. Thereafter, the U.S. Supreme Court issued a decision narrowing application of the law under which Scruggs was charged and convicted. Scruggs then filed a motion to vacate his sentence. Because Scruggs showed neither his actual innocence nor that "there was cause or prejudice for failing to raise a constitutional-vagueness



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challenge to [the law], ... he procedurally defaulted the claim, and the district court correctly denied his [28 U.S.C.] section 2255 motion," the Fifth Circuit said. Details about Scruggs's certiorari petition appear in the August 22, 2013, <u>Issue</u> of this Report.

First Circuit Dismisses Unsuccessful MedMal Plaintiffs' Suit Against Medical Journal, Authors

The First Circuit Court of Appeals has affirmed a lower court's dismissal of allegations that a purportedly false medical journal article, introduced by the defense in two unsuccessful medical malpractice lawsuits, caused the juries to find against the plaintiffs. A.G. v. Elsevier, Inc., No. 12-1559 (1st Cir., decided October 16, 2013). The minor plaintiffs were allegedly born with permanent nerve damage after their obstetricians applied traction during their delivery when their shoulders became stuck after their heads were delivered, a circumstance referred to as shoulder dystocia. The juries in both cases rendered verdicts in favor of the defendants. The plaintiffs then sued the journal article's authors, the journal and its publisher, claiming that the case report was false because it described a similar injury occurring in the absence of traction or shoulder dystocia, when the delivery actually involved both, and that it had "tipped the balance in their state-court malpractice trials."

According to the court, while the plaintiffs likely stated a cause of action for fraud by providing sufficient factual detail, the complaint's "bald [causation] assertion that '[b]ut for' the Case Report the plaintiffs 'would have been successful' at the malpractice trials is exactly the type of conclusory statement that need not be credited at the Rule 12(b)(6) stage" under the plausibility pleading standard established in Ashcroft v. Igbal, 556 U.S. 662 (2009), and Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007). The court also rejected the plaintiffs' argument that the standard applies "only to allegations of wrongful conduct and not to allegations of causation." In this regard, the court observed, "it is neither necessary nor desirable to balkanize the plausibility standard element by element."

Federal Court Rejects Medical Monitoring in Spray-Foam Insulation Class Action

A federal court in Pennsylvania has dismissed, with prejudice, the medical-monitoring claim in a putative class action against the manufacturer and installer of an allegedly toxic spray-foam home-insulation product, finding it insufficiently pleaded in the first amended complaint. Slemmer v. McGlaughlin Spray Foam Insulation, Inc., No. 12-6542 (U.S. Dist. Ct., E.D. Pa., decided October 17, 2013). While Pennsylvania recognizes medical-monitoring claims "as separate and apart from traditional tort claims involving physical injury," it requires plaintiffs to plead and prove seven elements, three of which, the defendants claimed, were not pleaded.



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The court agreed, ruling (i) the plaintiffs' "allegation that the 'serious latent disease' to be monitored is 'lung damage, and throat, eye and nose irritations' does not give defendants 'fair notice of what the ... claim is and the grounds upon which it rests" because lung damage encompasses "a host of different diseases [and] defendants must know which lung diseases are relevant when conducting discovery or retaining experts"; (ii) the plaintiffs' "proposed monitoring regime of 'diagnostic tests and pharmaceutical interventions' fails to identify specific monitoring procedures as required" and "fails to aver that a monitoring program procedure exists that makes early detection of a specific disease possible"; and (iii) the plaintiffs' allegation "that '[m]onitoring procedures exist that make the early detection of any latent disease possible that are different from those normally recommended in the absence of the exposure' is insufficient because it is a 'formulaic recitation of the element[]."

Mississippi Supreme Court Sanctions Judge for Refusing to Step Aside in **Asbestos Suit**

The Mississippi Supreme Court has imposed a \$500 fine, in addition to a public reprimand and \$200 in costs, on a judge who failed to timely reveal in an asbestos lawsuit tried in his courtroom that family members had been involved in asbestos

After trial, the judge then failed to rule on the motion to recuse filed by one of the defendants, which appealed to the state high court and secured a ruling that "a reasonable person, knowing all the circumstances, would have doubts regarding Judge Bowen's impartiality in the case."

litigation against several of the defendants and that his father had submitted an asbestos-related claim to the bankruptcy trustee for one of the defendant's suppliers. Miss. Comm'n on Jud. Performance v. Bowen, No. 2013-JP-00776-SCT (Miss., decided October 3, 2013). The judge also refused to reveal his father's name when asked. After trial, the judge then failed to rule on the

motion to recuse filed by one of the defendants, which appealed to the state high court and secured a ruling that "a reasonable person, knowing all the circumstances, would have doubts regarding Judge Bowen's impartiality in the case."

Additional information about the court's disqualification of the judge appears in the October 13, 2011, **Issue** of this *Report*. The jury verdict exonerating the defendants of liability on retrial is summarized in the May 10, 2012, <u>Issue</u> of this *Report*.

Finding the judge's action intentional, noting that the parties were forced to incur the expense of a second trial after the substituted judge hearing the case vacated the jury verdict and reversed all of Judge Bowen's rulings and orders, and reporting that media outlets made the public aware of the matter, the supreme court added a fine to the judicial commission's recommended sanction. It also stated that the judge's "actions compromised the integrity and independence of the judiciary and his duties as a judicial officer."



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ALL THINGS LEGISLATIVE AND REGULATORY

Buckyballs® Co. CEO Launches "United We Ball" Campaign to Fight CPSC Lawsuit

Craig Zucker, founder of the now-defunct company that made Buckyballs® high-power magnetic desk toys and the subject of a lawsuit in which the Consumer Product Safety Commission (CPSC) reportedly aims to hold him personally liable for the costs of a product recall estimated at \$57 million, has started a new company that sells larger magnetic balls—called Liberty Balls®—the sales of which will evidently be used to support his legal battle.

In July 2012, after selling millions of Buckyballs® and related products while reportedly

According to Zucker, CPSC pressured retailers into removing Buckyballs® from their shelves without providing the company a chance to defend itself, and, lacking distributors for its products and unable to simultaneously run the company and fight the government, the company dissolved in December 2012.

working with CPSC to ensure that the products met all safety standards, Zucker's company, Maxfield & Oberton Holdings, LLC, was sued by CPSC to force a full product recall. According to Zucker, CPSC pressured retailers into removing Buckyballs® from their shelves without providing the company a chance to defend itself, and, lacking distributors for its products and unable to simultaneously run the company and fight the govern-

ment, the company dissolved in December 2012. Zucker was later individually named in the lawsuit.

With a campaign titled "United We Ball," Zucker's new company, Assemble LLC, seeks to prevent "more overreaching bureaucratic lawsuits against job-creating entrepreneurs who speak out against selective justice and to fight to preserve principles of limited liability for responsible company officers."

Zucker, who claims that "CPSC sued me personally as an officer of a small business because the company disagreed with the agency and addressed their double standard when it came to Buckyballs," argues that CPSC is "trying to have a court ignore and rewrite the cherished American principle of 'limited liability,' which protects responsible, law-abiding company officers like myself from being unjustly sued." Noting that the products have never been proven to be defective and versions of them are still on the market, Zucker said that if CPSC succeeds in forcing an individual to pay for a company's product recall, government agencies, in the future, could pursue any entrepreneur or officer of any company and hold him or her personally responsible for the company's actions, even if no laws or regulations were violated. Additional details about the Buckyballs® case appear in the June 13, 2013, **Issue** of this *Report*. See PR Newswire, and Reason.com, October 9, 2013.

In a related development, a CPSC hearing on a proposed magnet safety standard was held on October 22. Speakers included representatives of the Consumer Federation of America and Consumers Union, the founder of Nano Magnetics Ltd., pediatricians, and pediatrics professors.



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CSPC Approves Standard for Bassinets and Cradles

The Consumer Product Safety Commission (CSPC) has approved a new mandatory safety standard for bassinets and infant cradles. The new standard incorporates provisions in the voluntary standard with five modifications: (i) clarification of the standard's scope; (ii) a change to the pass/fail criterion for the mattress flatness test; (iii) exemption from the mattress flatness requirement for bassinets that are less than 15 inches across; (iv) the addition of a removable bassinet bed stability requirement; and (v) a change to the stability test procedure. The new standards, which are based on a review of 426 bassinet and cradle incidents, including 132 fatalities, during a six-year period, will take effect six months after publication in the Federal Register. Manufacturers will be allowed an additional 12 months to comply with the provision for removable bassinet beds. See Consumer Product Safety Commission News Release, September 30, 2013.

Principles for the Adoption of Safer Alternative Chemicals in Consumer **Products Endorsed**

Dozens of business, university, government, and environmental group representatives have endorsed the "Common Principles for Alternatives Assessment," a document that establishes a framework for manufacturers and retailers to phase out hazardous

Those signing the principles include a Staples, Inc. scientist, the president and CEO of the South Carolina Small Business Chamber of Commerce, a Recreational Equipment, Inc. manager, and a Marriott International, Inc. procurement professional.

materials in their products and phase in safer substitutes. In development since late 2012 and based on the foundational work of the Lowell Center for Sustainable Production, Massachusetts Toxics Use Reduction Institute, Environmental Defense Fund, and BizNGO Working Group, the principles urge product reformulation, exposure limits, transparency and disclosure, and

action, among other matters. Those signing the principles include a Staples, Inc. scientist, the president and CEO of the South Carolina Small Business Chamber of Commerce, a Recreational Equipment, Inc. manager, and a Marriott International, Inc. procurement professional.

In a related development, Target Corp. has reportedly rolled out its "Sustainable Product Standard" program, which assigns points to products on the basis of a product's ingredients, transparency and environmental impact. Specifically, the program includes an assessment of the toxicity of the ingredients, whether the complete ingredient list is available, if animal testing was used during development and production, product packaging, and potential effects on the "aquatic environment." See Bloomberg BNA Product Safety & Liability Reporter, October 15, 2013.

California Governor Approves Prop. 65 Relief for Some Small Businesses

California Gov. Jerry Brown (D) has signed into law a bill (A.B. 227) that imposes a number of restrictions on private parties seeking to enforce the Safe Drinking Water



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and Toxic Enforcement Act of 1986 (Prop. 65) and provides relief for some small businesses that have been litigation targets since its enactment. Prop. 65 prohibits product manufacturers from knowingly and intentionally exposing residents to a chemical known to the state to cause cancer or reproductive toxicity without first providing a warning. It allows the attorney general, district attorneys or private parties to enforce it and provides for civil penalties of up to \$2,500 per day per violation to be imposed.

Effective immediately, the new law requires a person bringing a matter in the public interest under Prop. 65 to prepare a certificate of merit stating that the person or her attorney "has consulted with one or more persons with relevant and appropriate

the warning required complies with the law and that the attorney's fee and penalty are reasonable.

experience or expertise who has reviewed facts, studies, To approve a Prop. 65 settlement, a court must find that or other data regarding the exposure to the listed chemical" and, on the basis of that information, the person executing the certificate "believes there is a reasonable and meritorious case for the private action."

> If a court concludes that "there was no actual or threatened exposure to a listed chemical," it is permitted to review the information in the certificate of merit and deem the action "frivolous" if it "finds that there was no credible factual basis for the certifier's belief that an exposure to a listed chemical had occurred or was threatened."To approve a Prop. 65 settlement, a court must find that the warning required complies with the law and that the attorney's fee and penalty are reasonable.

The bill also gives a purported violator an opportunity to correct an alleged transgression and, further, forbids the filing of a Prop. 65 action or any recovery if it has done so and if the violation involves exposure to (i) alcoholic beverages consumed on the alleged violator's premises; (ii) a listed chemical "in a food or beverage prepared and sold on the alleged violator's premises" to the extent "the chemical was not intentionally added" or formed by cooking "necessary to render the food or beverage palatable or to avoid microbiological contamination"; (iii) "environmental tobacco smoke caused by entry of persons (other than employees) on premises owned or operated by the alleged violator where smoking is permitted at any location on the premises"; or (iv) listed chemicals in engine exhaust, "to the extent the exposure occurs inside a facility owned or operated by the alleged violator and primarily intended for parking noncommercial vehicles."

LEGAL LITERATURE REVIEW

A. Benjamin Spencer, "Pleading and Access to Civil Justice: A Response to Twigbal Apologists," UCLA Law Review (2013)

Washington & Lee University School of Law Professor A. Benjamin Spencer asserts that those who support the plausibility pleading standard espoused by the U.S. Supreme Court in Bell Atlantic Corp. v. Twombly and Ashcroft v. Iqbal, do so on specious grounds and have imperiled the access to justice promised by changes



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in the federal rules from fact pleading to notice pleading. Among other matters, Spencer contends that those, including the Court, claiming excessive discovery costs to defend stricter pleading standards have been proven wrong by Federal Judicial Center data showing that "in almost 40% of federal cases, discovery is not used at all, and in an additional substantial percentage of cases, only about three hours of discovery occurs." The author concludes that post-Iqbal pleading is little different from 19th century fact-based code pleading, which required "hopeless distinctions among allegations of ultimate fact, legal conclusions, and evidentiary facts." He states that in Igbal "Justice Kennedy saw conclusions (the allegation of policy design and approval) where Justice Souter saw facts"; and in Twombly "Justice Souter saw conclusions (the allegation of an agreement) where Justice Stevens saw facts. Who is right? What will the judge in your next case see?"

Catherine Sharkey, "The Future of Classwide Punitive Damages," Univ. of Michigan Journal of Law Reform (2013)

New York University School of Law Professor Catherine Sharkey suggests that the punitive damages class action is not entirely foreclosed by the U.S. Supreme Court's ruling in Philip Morris USA v. Williams, and she outlines reform possibilities that depend on "whether courts conceptualize punitive damages as societal or individualistic." While Williams does not allow "certification of Rule 23(b)(1)(B) limited fund punitive damages classes based upon a societal retributive theory of punitive damages," it does not, in Sharkey's view, "meaningfully obstruct certification of punitive damages classes—either equitable relief class actions under Rule 23(b)(2) or money damages class actions under Rule 23(b)(3)—based on a societal, deterrent conceptualization of punitive damages." She argues that state legislatures could adopt constitutionally sound measures imposing "a statutory multiplier for certain torts" based on underenforcement and under-deterrence rationales. She also argues that federal courts could, under the Rules Enabling Act, "consider the underlying societal rationale for punitive damages in the course of their certification decisions."

Alexander Reinert, "Screening Out Innovation: The Merits of Meritless <u>Litigation," Indiana Law Journal</u> (forthcoming 2013)

Benjamin N. Cardozo School of Law Professor Alexander Reinert posits that while frivolous litigation is rightly dismissed "as early in a case's trajectory as possible,"

He argues that litigant failure should not be overlooked because it "can mark the boundaries of established law, prompt legal change, or provoke a broader discussion of legal norms."

meritless litigation actually has a value in, for example, bringing to light "facts that may lead to systematic reform (even where no legal cause of action lies)," and thus has value and should be distinguished from frivolous lawsuits. He argues that litigant failure should

not be overlooked because it "can mark the boundaries of established law, prompt legal change, or provoke a broader discussion of legal norms." Reinert calls for courts and legislatures to "take greater care in translating assumptions about the relative



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value of frivolous and meritless litigation into doctrine and statutes." Among other matters, he suggests that the courts provide "more specificity in judgments at the motion to dismiss stage" to "provide more clarity and guidance in the law as we move forward."

LAW BLOG ROUNDUP

Questioning Film's Veracity

"All future discussion of 'Hot Coffee'—and certainly any cable/broadcast airings or public screenings whose sponsors care about accuracy and fairness—will need to warn audiences that the Jones case can now be seen in retrospect as almost unrecognizably different from the picture it presented in that trial-lawyer-produced 'documentary.' If this is what becomes of one of Saladoff's central cases, how reliable ought we to consider the rest of her film?" Overlawyered.com Editor Walter Olson, blogging about a recent article by journalist Stephanie Mencimer questioning the story of Jamie Lee Jones, who tried to hold her employer liable for her alleged brutal rape in Iraq. Jones's story was among those highlighted in the film "Hot Coffee," produced by Susan Saladoff, who also re-examined the lawsuit brought against McDonald's Co. by a woman claiming serious injury from spilling hot coffee from a drive-through in her lap.

Overlawyered.com, October 22, 2013.

THE FINAL WORD

Senate Commerce Report Outlines Shutdown's Impact on Government Agencies

Senate Commerce Committee Chair Jay Rockefeller (D-WV) has released a report detailing the impact of the government shutdown on a host of agencies under its purview, including the Consumer Product Safety Commission (CPSC), Federal Trade Commission (FTC) and National Highway Traffic Safety Administration (NHTSA). The report was issued to provide a "snapshot" of the impact of the shutdown in advance of an October 11, 2013, hearing.

With regard to CPSC, the report noted that approximately 95 percent of agency employees who work on hazard identification and reduction, compliance and field operations, and import surveillance, as well as in the general counsel's office were furloughed. As a result, all product safety investigations, civil penalty negotiations, and enforcement proceedings or recalls that did not meet the threshold of involving a "substantial and immediate threat to the safety of human life" stopped.



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NHTSA, which is responsible for ensuring the safety of vehicles on the roads and for providing consumer information about the safety of vehicles on the market, furloughed 333 of the 337 employees whose work relates to vehicle safety. The agency was unable to send Special Crash Investigations teams to any crashes during the shutdown and could not review any safety data submitted during the shutdown, including regular reports from vehicle manufacturers, consumer complaints and reports from manufacturers regarding potential defects. According to the report, 925 of 1,178 FTC employees in Washington, D.C., and seven regional offices were furloughed, shutting down all consumer protection activity except for ongoing cases for which there were pending court dates that could not be postponed.

UPCOMING CONFERENCES AND SEMINARS

Shook, Hardy & Bacon Data Security & Privacy Practice Partners Amor Esteban and Al Saikali will participate in The Sedona Conference® on Cyber Liability slated for October 24-25, 2013, in Del Mar, California. Co-chaired by Esteban, who also leads The Sedona Conference® Working Group 6 on Cross-Border Discovery and Data Protection, the conference will address, among other things, (i) "the current state of the law regarding data security and privacy," (ii) "responding to data breach incidents," (iii) "regulatory responses to data breach incidents," and (iv) "protecting valuable intellectual property in a global cyber environment." Saikali will serve on two panels discussing civil data breach litigation and data security in the health care, pharmaceutical and biotechnology industries.

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