Shook, Hardy & Bacon L.L.P.

MARCH 13, 2014

PRODUCT LIABILITY LITIGATION REPORT

CONTENTS

CASE NOTES

Federal Court Denies Certification Motion in Moldy Infant Sleeper Suit

A federal court in California has refused to certify a nationwide class in litigation alleging that Fisher-Price's Rock 'N Play Sleeper® is defective because it has a "dangerous propensity" to grow mold. *Butler v. Mattel, Inc.*, No. 13-0306 (U.S. Dist. Ct., C.D. Cal., order entered February 24, 2014). According to the court, the plaintiffs' request "to have the case handled on a class basis fails because they fail to establish that any actual defect was common to the entire class. There was ample evidence in the record that the vast majority of the proposed class did not experience mold growth on the Sleeper to a degree that they saw fit to complain to Defendants or to the Consumer Product Safety Commission (CPSC)." In a footnote, the court observes that the companies claimed that they had received 600 reports of mold by the end of the class period on total sales of more than 800,000 infant sleepers. While the plaintiffs did not provide the court with evidence that the sleeper grows mold with normal use, the company's effort to grow mold on the sleeper involved "extreme levels and duration of dampness," the court said. Because the issue of standing "is not common to all class members and must be addressed on an individual basis," the court found that common questions did not predominate.

Florida Supreme Court Addresses Relation Back of Pleading Amendment in HVAC Suit

The Supreme Court of Florida has determined that "an amended complaint filed after the statute of limitations has expired, naming a party who had previously been made a third-party defendant as a party defendant, relates back under rule 1.190(c) to the filing of the third-party complaint [where] the third-party complaint [was] filed prior to the expiration of the statute of limitations and the plaintiff's claims in the amended complaint … arise from the same 'conduct, transaction, or occurrence' set forth in the third-party complaint." *Caduceus Props., LLC v. Graney, P.E.,* No. SC12-1474 (Fla., decided February 27, 2014). So ruling, the court resolved an appellate court split on the issue. The matter arose in the context of an alleged malfunctioning heating, ventilation and air-conditioning (HVAC) system installed in an ambulatory surgical center.

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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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Florida Rule of Civil Procedure 1.190(c) provides that an amendment relates back to the date of the original pleading "[w]hen the claim or defense asserted in the amended pleading arose out of the conduct, transaction, or occurrence set forth or attempted to be set forth in the original pleading." Referring to the state's judicial policy of "freely permitting amendments to the pleadings so that cases may be resolved on the merits, so long as the amendments do not prejudice or disadvantage the opposing party," the court found that allowing amendment in the circumstances presented by this case would be consistent with that policy and is consistent with Florida case law establishing that the rule "is to be liberally construed and applied."

FDA Sued for Failure to Prohibit Mercury Dental Fillings

A number of non-profit organizations and individuals have filed a declaratory action against the U.S. Food and Drug Administration (FDA), claiming that it has failed to act on their petition for rulemaking to "formally ban the use of dental amalgam as a dental restorative material." *Int'l Acad. of Oral Med. & Toxicology, Inc. v. FDA*, No. 14-0356 (U.S. Dist. Ct., D.D.C., filed March 5, 2014). According to the complaint, more than four years have passed since the plaintiffs asked the agency to reconsider its action classifying dental fillings with mercury as Class II medical devices, "essentially finding that mercury fillings are safe." Alleging that these fillings are not safe or should be placed in Class III "so that the amalgam manufacturers are required to prove that they are safe," the plaintiffs point to a number of other mercury-containing products that are no longer available, due to safety concerns, on the market. The plaintiffs seek an order declaring that FDA's failure to "promptly" take meaningful action on their petitions for reconsideration violates the Administrative Procedure Act and an order requiring an FDA response "as soon as reasonably practicable."

DOJ Seeks Injunction Against Importers of Toys with Lead, Phthalates, Small Parts

The U.S. Department of Justice (DOJ) recently accused four California companies and six individuals of importing into the United States "illegal children's products containing, among other things, lead, phthalates and small parts inappropriate for children under age three." *United States v. Toys Distrib. Inc.*, No. 14-1364 (U.S. Dist. Ct., C.D. Cal., filed February 24, 2014). Filed at the request of the Consumer Product Safety Commission, the action follows an investigation of motorized and "pull-back" toy cars, toy musical instruments, dolls, and other toys that allegedly violate the Consumer Product Safety Act and Federal Hazardous Substances Act. Because the defendants' operations were allegedly associated with each other and "the companies share various personal or professional ties," DOJ claims that joining the conduct in a single lawsuit is appropriate.

Three of the companies and two individuals have apparently agreed to settle the litigation under a consent decree of permanent injunction that will enjoin them from committing statutory violations. According to DOJ Civil Division Assistant Attorney General Stuart Delery, "Companies cannot be allowed to import hazardous toys into the United States. Parents have a right to feel confident that the toys their children play with are safe." *See DOJ News Release*, February 24, 2014.

Putative Class Challenges Effectiveness Claims for Ear Cleaning Device

New Jersey and Pennsylvania residents have filed a putative nationwide consumer-fraud class action against a company that, despite a warning from the U.S. Food and Drug Administration (FDA), continues to advertise for sale through a variety of media its WAXVAC® Ear Cleaner as "the safe way to clear your ears" and a product that "gently draws dirt particles and moisture out quickly and safely." *Weinstein v. Lenfest Media Group, LLC*, No. 14-1251 (U.S. Dist. Ct., E.D. Pa., filed February 28, 2014). According to the complaint, "the product does not remove dirt particles and moisture as promised."

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The plaintiffs quote FDA's July 2013 warning letter, which characterized the product as adulterated because the company failed to secure premarket approval for its device and called for the company to cease distributing the product for the uses advertised, and note that the disputed claims continue to appear in the company's "marketing campaign today." Alleging unjust enrichment as to the New Jersey and Pennsylvania classes, violation of consumer protection laws of all 50 states and U.S. territories, violation of the Magnuson-Moss Warranty Act, breach of express warranty, implied warranty of merchantability and duty of good faith and fair dealing, the plaintiffs seek a declaration that the product was "negligently designed and/or manufactured," compensatory damages, equitable relief, restitution, interest, attorney's fees, and costs.

ALL THINGS LEGISLATIVE AND REGULATORY

Final Rule Addresses Carriage and Stroller Safety

The U.S. Consumer Product Safety Commission (CPSC) has **issued** a final rule approving a federal mandatory standard intended to improve the safety of infant and child carriages and strollers. The rule incorporates a voluntary ASTM International standard with a change to address the risk that children's heads could become trapped in adjustable grab bars. Observing that four stroller-related fatalities and 359 injuries occurred between 2008 and 2012, mostly due to wheel, parking brake and lock-mechanism problems, CPSC asserts that the standard aims to "prevent hinge-related issues that have caused finger amputations and other injuries" and addresses

broken and detached wheels, parking brake failures, product stability, and other safety issues. The revision takes effect September 10, 2015, and manufacturers and sellers will have 18 months to comply. *See Federal Register*, March 10, 2014.

Comments Sought on Crib Information Collection Time Burdens

The U.S. Consumer Product Safety Commission (CPSC) **seeks** comments on the estimated time burdens on its request for extension of approval of an information collection from the manufacturers of full-size and non-full-size baby cribs to create and update safety labels.

Originally published in the December 24, 2013, *Federal Register*, CPSC reportedly received one comment that was "outside the scope of the proposed renewal request." The agency estimates an annual recordkeeping burden of 954 hours associated with marking, labeling and creating instructional literature. Comments will be accepted until April 3, 2014. *See Federal Register*, March 4, 2014.

CPSC Schedules Workshop to Reduce Third-Party Testing Burdens for Children's Products

The U.S. Consumer Product Safety Commission will **conduct** an April 3, 2014, information-gathering workshop in Rockville, Maryland, aimed at developing ways to reduce third-party testing burdens for children's products. The workshop will focus on identifying materials that do not need to be tested to determine compliance with phthalate limits or with content and solubility requirements for the eight toxic substances listed in CPSC's toy standard. The commission will also discuss expanding the list of materials that do not contain enough lead to require testing. Individuals wishing to participate in the workshop must register by March 13. Attendees must register by March 27. Comments on workshop topics will be accepted until April 27. *See Federal Register*, February 27, 2014.

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CPSC Information Disclosure Rulemaking Published in *Federal Register*

The U.S. Consumer Product Safety Commission (CPSC) has **published** its notice of proposed rulemaking to amend a regulation implementing Section 6(b) of the Consumer Product Safety Act, governing the agency's disclosure of product information to the public. Additional information about the proposal appears in the **February 20, 2014**, issue of this *Report*. Comments on the proposal are requested by April 28. *See Federal Register*, February 26, 2014.

CPSC Requests Comments on Multi-Purpose Lighters

The U.S. Consumer Product Safety Commission (CPSC) has **requested** comments on the time and expense burdens estimated for its proposed request for extension of approval of an information collection relating to the safety standard for multi-purpose lighters.

Issued in 1999, the standard (16 C.F.R. part 1212) requires multi-purpose lighter manufacturers and importers to issue certificates of compliance based on "a reasonable testing program." The standard also requires that manufacturers and importers maintain certain records. CPSC specifically seeks comments on whether the estimates are accurate, the information collected could be improved and whether the use of information technology could minimize the estimated burdens. Comments are requested by May 5, 2014. *See Federal Register*, March 4, 2014.

NHTSA Makes Final Technical Specification for VIN Interface Available

The U.S. National Highway Traffic Safety Administration (NHTSA) has **issued** a notice advising that its technical specifications, which vehicle manufacturers need to support the vehicle identification number (VIN)-based safety recall look-up tool housed on the agency's Web site—www.safercar.gov, are now available. The technical specifications are intended to facilitate the secure electronic transfer of manufacturer recall data to NHTSA when a consumer submits VIN information to the agency's Web site to learn vehicle recall information. The requirement applies to companies that manufacture 25,000 light vehicles annually or 5,000 motorcycles annually. *See Federal Register*, March 10, 2014.

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NHTSA Amends Child-Restraint Systems Rule

The U.S. National Highway Traffic Safety Administration (NHTSA) has **issued** a final rule denying most aspects of a petition seeking reconsideration of its February 27, 2012, rule regarding child-restraint systems and amending weight-limit labeling for Lower Anchors and Tethers for Children (LATCH)-installed car seats to include both the weight of the child and the car seat itself. In response to the petition's claim that the labeling requirement from the 2012 rule was "unclear and could be misunderstood," NHTSA has revised the label to read "Do not use the lower anchors of the child restraint anchorage system (LATCH system) to attach this child restraint when restraining a child weighing more than * [*insert a recommended weight value in English and metric units such that the sum of the recommended weight value and the weight of the child restraint system does not exceed 65 pounds (29.5 kg)] with the internal harnesses of the child restraint." The amendments took effect February 27, 2014, and manufacturers must comply by February 27, 2015. *See Federal Register*, February 25, 2014.

CRS Report Focuses on Harmonizing U.S. and EU Motor Vehicle Standards

The Congressional Research Service (CRS) has issued a report titled "U.S. and EU Motor Vehicle Standards: Issues for Transatlantic Trade Negotiations," that explores differences in automobile safety regulatory regimes that could be resolved through the comprehensive Transatlantic Trade and Investment Partnership (TTIP) negotiations between the United States and European Union (EU). The United States adopts safety standards that auto makers self-certify as to their compliance, but in the EU, vehicles must secure "type approval" from a government before the manufacturer may sell a new model. To the extent that a TTIP agreement removes unnecessary differences in regulations and allows manufacturers to sell vehicles in either market if they meet standards from either jurisdiction, CRS maintains that pathways to convergence could be achieved.

Civil Procedure Advisory Committee to Meet

The U.S. Judicial Conference has **slated** an open meeting of the Advisory Committee on Rules of Civil Procedure for April 10-11, 2014, in Portland, Oregon. While the meeting is open to public observation, no participation has been scheduled. *See Federal Register*, March 10, 2014.

OEHHA Proposes Reforms to Prop. 65 Warnings

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has **scheduled** an April 14, 2014, public workshop to discuss "a possible regulatory action to change the existing regulation governing Proposition 65 warnings." The Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) requires manufacturers to warn consumers if their products contain any substances known to the state to cause cancer or reproductive toxicity. Failure to provide such warnings exposes manufacturers to enforcement actions filed by private entities or state prosecuting authorities and the possibility of significant fines.

While the draft proposed changes hyperlinked to the meeting announcement could change before OEHHA takes any final action, they were developed on the basis of public input provided in 2013, after the agency conducted a pre-regulatory workshop, and respond to the governor's proposal to reform Proposition 65 to, among other things, "require more useful information to the public on what they are being exposed to and how they can protect themselves."

As to the proposed warnings changes, OEHHA is considering three to five required elements: (i) use of the word "WARNING," (ii) use of the word "expose," (iii) inclusion of the international pictogram for toxic hazards ("only for consumer products other than foods, occupational and environmental warnings"), (iv) disclosure of the names of up to 12 commonly known chemicals that require warnings—such as lead and

mercury—in the warning text, and (v) a link to a new agency Web site with more information about the warning, "including additional chemicals, routes of exposure, and if applicable, any actions that individuals could take to reduce or avoid exposure."

The proposal would also include provisions giving small retailers the opportunity "to cure certain minor warning violations within 14 days and avoid any private enforcement whatsoever," tailoring "language for specific warning contexts (e.g. alcohol, drugs, medical devices, parking garages, hotels, apartments, and theme parks)," and recognizing "warnings covered by existing court-approved settlements." According to an OEHHA timeline, the final changes could be adopted by early summer 2015. Written comments on the draft pre-regulatory warning regulation are requested by May 14. *See OEHHA News Release*, March 7, 2014.

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LEGAL LITERATURE REVIEW

James Henderson & Aaron Twerski, "Optional Safety Devices: Delegating Product Design Responsibility to the Market," *Arizona State Law Journal,* 2014

Cornell Law School Professor James Henderson and Brooklyn Law School Professor Aaron Twerski have proposed a restatement of the law that would establish a no-duty standard when consumers seek to hold manufacturers liable for a product-related injury that could have been prevented by an optional safety device that was offered for sale, but not purchased by the consumer. It would apply only to claims for defective design and would require a reasonable expectation that the purchaser was (i) knowledgeable about the product and its uses, including "both increased costs associated with inclusion of the safety device and increased benefits in the form of accident costs avoided by such inclusion," (ii) "capable of reaching rational conclusions regarding whether or not to include the safety device," and (iii) "motivated, in light of expected circumstances of use, to consider both the costs and the benefits associated with inclusion of the safety device." The authors contend that this rule would honor the desire of product users and consumers "to tailor products to their own personal needs and preferences," while encouraging sellers to offer optional safety features without running the risk of facing a "built-in" plaintiff's reasonable alternative design theory in litigation.

Jill Wieber Lens, "Warning: A Post-Sale Duty to Warn Targets Small Manufacturers," February 2014

Baylor University School of Law Associate Professor Jill Weiber Lens contends that a factually dependent post-sale duty to warn—obligating manufacturers to warn only if the danger to be warned of justifies the costs of the warning—unfairly burdens

small manufacturers whose costs of issuing a warning will always be smaller, and would therefore be deemed reasonable, than those for a large manufacturer. Noting that more than half of the states and the *Restatement (Third) of Torts: Products Liability* have adopted a post-sale duty to warn, the author calls for the courts not to adopt a factually dependent post-sale duty to warn, arguing that it is inconsistent with underlying product liability theories that "support a broad post-sale duty to warn obligating all manufacturers, not just some, and especially not just the small ones."

Mark Geistfeld, "Tort Law in the Age of Statutes," *Iowa Law Review* (forthcoming 2014)

New York University School of Law Professor Mark Geistfeld explores the relationship between tort law and the modern regulatory state and finds these sources of law complementary when viewed through the lens of judicial deference. He discusses how the doctrines of implied preemption, negligence per se and the regulatory compliance defense each relate to one another and finds that "[i]n the age of statutes, deference provides the primary means by which courts integrate health and safety legislation into the common law of torts." The article concludes, "By deferring to legislative safety decisions, the common-law of torts eliminates any deep conflict between federal safety regulations and state tort law, while ensuring that the state tort system adequately accounts for the specialized expertise of regulatory agencies."

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LAW BLOG ROUNDUP

Impediments to Justice?

"The report finds that in a significant and growing number of cases, *Nicastro* has prevented plaintiffs from turning to their own states' courts for redress of in-state injuries that resulted from foreign or out-of-state manufacturers' release of their products into the stream of commerce." Public Citizen Group's Scott Nelson, blogging about a new **report** that analyzes the impact of *J. McIntyre Machinery Co. v. Nicastro*, 131 S. Ct. 2780 (2011), which "significantly limited the ability of a U.S. court to assert jurisdiction over a manufacturer that did not specifically target the marketing of its products at the state where the court is located, even though the product was sold in and caused injury in that state."

CL&P Blog, March 11, 2014.

A New Hook to Curtail "Unduly" Plaintiff-Friendly Liability Standards

"Combining an expertly honed litigation strategy with the ascendant law-and-economics conception of tort law as regulatory (which had never been a significant part of how judges or legislators understood torts), the tort reform movement convinced the [U.S. Supreme] Court to use preemption doctrine as a tort reform tool. As torts professors, we can see *Geier* [preemption] and its progeny as of a piece with *Daubert* [admissibility of expert testimony] and *BMW v. Gore* [punitive damages] and their progeny. Just as the Federal Rules of Evidence provided the means through which the Court could address 'junk science,' and the Due Process Clause of the Constitution anchored the Court's critique of punitive damages run 'amok,' the Supremacy Clause is now the hook for softening what the Justices perceive to be unduly plaintiff-friendly liability standards." Fordham University Law Professor Benjamin Zipursky, critiquing a recent law review article on preemption. He suggests that it was written "without the benefit of a big picture of what has happened in products liability preemption litigation over the past two decades or so."

Jotwell: Torts, March 11, 2014.

THE FINAL WORD

ATRA President Pens *WSJ* Op-Ed on Fighting Fraudulent Lawsuits

Reporting on recent courthouse developments exposing fraudulent lawsuits, American Tort Reform Association (ATRA) President Tiger Joyce calls on companies with the means to bring similar actions under the Racketeer Influenced and Corrupt Organizations Act (RICO) to do so in the absence of action by other bodies with litigation-fraud oversight. He states, "In a more perfect world, self-policing bar associations, state attorneys general and the Department of Justice would show greater interest in investigating and prosecuting litigation fraud. But with few laudable exceptions, these authorities have shown little interest in attacking the problem." Citing data indicating that 25 percent to 50 percent of personal-injury lawsuits "may include elements of perjury or fraud," Joyce is concerned that "too many plaintiffs' lawyers have come to believe there is minimal risk in bringing fraudulent lawsuits." He suggests that RICO "could become a powerful tool in the hands of companies that are tired of lawsuit shakedowns."

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UPCOMING CONFERENCES AND SEMINARS

ABA, Phoenix, Arizona – April 2-4, 2014 – "2014 Emerging Issues in Motor Vehicle Product Liability Litigation." Shook, Hardy & Bacon Tort Associate Amir Nassihi serves as event coordinator for this 24th annual continuing legal education program and will participate in a panel discussion with Global Product Liability Partner Holly Smith to present "Hot Topics in Class Action Litigation. Firm Tort Partner H. Grant Law, who co-chairs the American Bar Association's (ABA's) Tort Trial & Insurance Practice Section Products Liability Committee, will provide a welcome and introduction to the program. Shook, Hardy & Bacon Tort Partner Robert Adams will present "Effective Trial Communication: A Master Class," and Global Product Liability Partner Frank Kelly will join a panel to discuss "Effectively Packaging and Presenting Complex Accident Reconstruction Concepts." SHB Global Product Liability Partner Janet Hickson will participate in a panel discussion titled, "Managing the Corporate Counsel Relationship: The Inside View on Diversity, Retention and Client Expectations."

DRI, Phoenix, Arizona – April 9-11, 2014 – "Product Liability: Plan and Prepare." Shook, Hardy & Bacon Business Litigation Attorney April Byrd will join a distinguished faculty during this continuing legal education conference. Byrd will discuss "Post *Comcast*: Are Federal Courts Considering Individual Damages When Certifying Class Actions?" as part of a specialized litigation-group mass-torts and class-actions workshop.

ACI, Chicago, Illinois – June 4-5, 2014 – "7th Annual Summit on Defending & Managing Automotive Product Liability Litigation." Shook, Hardy & Bacon Tort Partner H. Grant Law will participate in a panel discussion during this continuing legal education summit, which features presentations by judges as well as corporate and agency in-house counsel. His topic is "The Current Battleground for Automotive Class Action Litigation: Class Certification and Managing Experts, Attacks on Pleadings in Class Claims, Choice of Law, Arbitration and More." ■

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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).