Shook, Hardy & Bacon L.L.P.

NOVEMBER 11, 2010

PRODUCT LIABILITY LITIGATION REPORT

CONTENTS

SEVENTH CIRCUIT STOPS REPETITIVE CLASS ACTIONS OVER SEARS STEEL DRUM DRYERS

The Seventh Circuit Court of Appeals has granted a Sears, Roebuck & Co. request to enjoin the filing of class actions involving its dryers with stainless steel drums and raising the same consumer fraud claims alleged in a putative class action that the Seventh Circuit refused to certify because individual issues predominated over common ones. ***Thorogood v. Sears, Roebuck & Co.*, No. 10-2407 (7th Cir., decided November 2, 2010)**.

Further details about the court's previous ruling on class certification appear in the **November 13, 2008, issue** of this *Report*.

The company sought relief under the All Writs Act after "a virtually identical class action" (*Murray*) was filed in a California federal court by the same attorney who had represented the plaintiff in *Thorogood*. The district court (sitting in Illinois), which had entered the order decertifying the *Thorogood* class, refused to enjoin the California action, saying that Sears could "obtain adequate relief against being harassed by repetitive litigation by pleading collateral estoppel" in subsequent litigation. The Seventh Circuit disagreed, noting that while such relief would ordinarily protect against harassment by repetitive litigation, "this case is unusual both because it involves class action litigation and because of the specific tactics employed by class counsel, which include, as we'll see, something close to settlement extortion."

The California court refused to accept Sears' collateral estoppel defense because plaintiffs' counsel altered the pleadings "with just enough differences to confuse the district judge," according to the appeals court. The California court also allowed discovery to proceed against Sears. Because this ruling was unappealable, the Seventh Circuit ruled that the All Writs Act was the company's "only means, other than submitting to lawyer Boling's demands, of avoiding being drowned in the discovery bog." The court emphasized, "There is nothing new in [the California] complaint that would allow an escape from the bar of collateral estoppel. The critical issue was and is what consumers would understand by representations that the Kenmore dryer has a stainless steel drum.… These questions can't be answered on a class-wide basis, and so there would be no economies from allowing the suit to proceed as a class action."

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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The court remanded the case for the district court to fashion an appropriate injunctive order, but indicated that it could not preclude individual lawsuits, could not involve lawsuits filed against other defendants and could not "forbid class action suits challenging representations materially different from those in Thorogood's and Murray's cases, or representation concerning a dryer that contains a different amount of stainless steel." The court also indicated that the order could preclude copycat litigation brought in state courts, but must be subject to whatever the U.S. Supreme Court decides in pending appeals asking whether "a district court that previously denied class certification nonetheless has personal jurisdiction over the absent putative class members such that it may enjoin them from seeking class certification in state court."

THIRD CIRCUIT ADOPTS SUBSTANTIAL COMPLIANCE TEST FOR CONTEMPT OF DIET SUPPLEMENT AD ORDER

The Third Circuit Court of Appeals has reversed and remanded a district court determination that a dietary supplement maker did not violate a consent order with the Federal Trade Commission (FTC). ***FTC v. Lane Labs-USA, Inc.*, No. 09-3909 (3d Cir., decided October 26, 2010)**. While the appeals court found that the lower court correctly decided some of the contempt charges in favor of the supplement maker, it found other rulings erroneous or insufficiently addressed.

Significantly, the Third Circuit adopted a substantial compliance defense that the lower court will have to apply on remand. Under that defense, a party must show that it (i) "has taken all reasonable steps to comply with the valid court order," and (ii) "has violated the order in a manner that is merely 'technical' or 'inadvertent.'" The district court set forth the correct standard but did not address the second part of the substantial compliance inquiry in its analysis.

The case involved an agreement, formalized by court order, reached by the supplement maker with FTC in 2000 involving advertisements for some of its products. The agreement required the manufacturer to refrain from making any product representations unless supported by "competent and reliable scientific evidence," which term was further defined. The agreement also forbade express or implied misrepresentations about any test, study or research in connection with product promotions. Thereafter, the company began promoting calcium and male-fertility supplements for several years, submitting research that purportedly substantiated its claims to FTC, which ultimately decided that the company was in contempt of the earlier court order.

According to the Third Circuit, the company's claims that the calcium supplement was the "only" supplement that "can increase bone density," and is "superior to prescription osteoporosis drugs," are unsupported by scientific evidence. The court agreed with the district court, however, that the company could properly claim that the product has been shown to "increase bone density in the hip." Because the

district court did not "exhaustively" address claims that the product was three to four times more absorbable than other calcium supplements, the appeals court remanded this issue for further development.

The appeals court also determined that the company could claim that its male-fertility supplement can cause sperm count to "skyrocket" in as little as one month, because FTC failed to pursue questioning about a witness's assertion that some positive changes occur within the first month the product is consumed, even though increased sperm count takes at least three months to detect.

U.S. SUPREME COURT CONSIDERS PREEMPTION IN AUTO-DEFECT CASE, CLASS-ACTION EXEMPTIONS IN CELL PHONE CONTRACTS

The U.S. Supreme Court has heard oral argument this term in two cases with a potential impact on product liability law: *Williamson v. Mazda Motor of Am., Inc.*, No. 08-1314 (U.S., argued November 3, 2010), and *AT&T Mobility LLC. v. Concepcion*, No. 09-893 (U.S., argued November 9, 2010). *Williamson* asks the Court whether the husband of a woman who died in an auto accident while wearing a lap-only seat belt can bring state-law-based claims against the car maker despite applicable federal rules that gave manufacturers the option of installing lap-only seat belts or shoulder/lap restraints in the rear middle seats of passenger vehicles. California courts determined that the federal law preempted the plaintiff's state-law claims and dismissed the suit. Counsel for the plaintiff reportedly argued that the federal rule created a minimum standard under a statute with a savings clause that preserved common-law remedies. Mazda contended that the federal regulatory scheme, designed to promote child safety and flexibility, would be frustrated by allowing state-tort lawsuits.

Numerous commentators and legal scholars, meanwhile, wonder whether *Concepcion* "could end class-action litigation in America as we know it." In that case, AT&T was sued for deceptive practices because it advertised discounted cell phones but charged sales tax on the full retail price. The plaintiffs sued on behalf of a class of consumers for alleged overpayments, but AT&T pointed to its customer contract, which required all claims to be submitted to arbitration and did not allow them to be pursued on a class-wide basis. Lower federal courts struck down the contract, ruling that it was imposed on consumers and violated public policy. The company argues that the Federal Arbitration Act preempts states "from conditioning the enforcement of an arbitration agreement on the availability of particular procedures—here, class-wide arbitration—when those procedures are not necessary to ensure that the parties to the arbitration agreement are able to vindicate their claims."

Numerous friend-of-the-court briefs have been filed in the case, and some commentators suggest that if the Court agrees with AT&T, "the consequences could be staggering." According to Vanderbilt Law School Associate Professor Brian Fitzpatrick,

"virtually all class actions today occur between parties who are in transactional relationships with one another: shareholders and corporations, consumers and merchants, employees and employers.… Once given the green light, it is hard to imagine any company would not want its shareholders, consumers and employees to agree to" arbitration agreements with class-action waivers. Fitzpatrick calls such an outcome "a terrible mistake," arguing that the class-action device was created to help those with injuries too small to vindicate on an individual basis. By banding together, they can stop companies from cheating "people out of small amounts with impunity."

Corporate interests find that class actions are not good for business, and an AT&T spokesperson reportedly noted that its arbitration agreement was consumer-friendly and offered significant benefits because it avoids "the burdensome costs of lawyer-driven class actions." *See The National Law Journal*, November 3, 2010; *The Los Angeles Times*, November 5, 2010; *The San Francisco Chronicle*, November 7, 2010.

U.S. SUPREME COURT DISBARS FORMER FEN-PHEN MASS TORTS ATTORNEY

The U.S. Supreme Court has disbarred a mass torts attorney from practicing law in the high court for his alleged role in swindling a pharmaceutical company out of millions of dollars in fraudulent claims over the diet drug Fen-Phen. Robert Arledge of Vicksburg, Mississippi, was suspended from practicing law before the Court in July 2010 and in Mississippi in 2008. The state disbarred him in 2009 after he exhausted an appeals process.

Arledge was convicted of conspiracy and fraud in federal court in 2007 and sentenced to more than six years in prison. He allegedly recruited plaintiffs who falsely claimed that they had taken the drugs and were awarded settlements.

The swindle, which involved numerous attorneys who entered fee-splitting and referral-fee arrangements to recruit clients to Fen-Phen settlements, reportedly netted more than $6 million from the drug's manufacturer.

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ALL THINGS LEGISLATIVE AND REGULATORY

CPSC Announces Teleconference on Potential Hazards of Phthalates, Phthalate Substitutes

The Consumer Product Safety Commission (CPSC) has announced a Chronic Hazard Advisory Panel (CHAP) **teleconference** regarding the effects of phthalates and

phthalate substitutes on children's health. The November 15, 2010, teleconference, to be followed by meetings on December 2 and 3, will include discussion of possible risk assessment approaches.

CPSC appointed this CHAP under the Consumer Product Safety Improvement Act of 2008 to study the effects on children's health of all phthalates and phthalate alternatives used in children's toys and child care articles. The law "permanently prohibits" sales of such products containing "more than 0.1 percent of each of three specified phthalates: Di- (2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), and benzyl butyl phthalate (BBP)." The law also prohibits, on an interim basis, the sale of any "children's toy that can be placed in a child's mouth" or "child care article" containing "more than 0.1 percent of each of three additional phthalates: diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-*n*-octyl phthalate (DnOP)."

CHAP is required to, among other matters, (i) "examine all of the potential health effects (including endocrine disrupting effects) of the full range of phthalates"; (ii) "examine the likely levels of children's, pregnant women's, and others' exposure to phthalates, based on a reasonable estimation of normal and foreseeable use and abuse of such products"; (iii) "review all relevant data, including the most recent, best-available, peer-reviewed, scientific studies"; and (iv) "consider the level at which there is a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals and their offspring, considering the best available science, and using sufficient safety factors to account for uncertainties regarding exposure and other potentially susceptible individuals." *See Federal Register,* November 3, 2010.

Article Claims FDA "Provides Scant Oversight" in Medical Device Monitoring

According to a recent article on the effectiveness of post-market surveillance, medical device manufacturers "often fail to properly conduct safety studies" and the Food and Drug Administration (FDA) "provides scant oversight" in post-approval monitoring of these devices. Jeanne Lenzer and Shannon Brownlee, "Why the FDA can't protect the public," *British Medical Journal,* November 6, 2010. Lenzer is a medical investigative journalist, and Brownlee is an instructor at the Dartmouth Institute for Health Policy and Clinical Practice.

"Most devices and drugs on the market are supported by studies that are underpowered to detect rare but potentially life threatening events that can kill tens of thousands of people if the drug or device is widely used," the authors write. "The impracticality of conducting large scale clinical trials before approval for every drug and device places a burden on post-approval surveillance."

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The authors also note that "FDA's ability to detect potentially unsafe devices is further hampered by the fact that many post-approval studies required as a condition of the device's approval are not conducted or conducted so poorly as to be meaningless."

FDA's Manufacturer and User Facility Device Experience (MAUDE) database is its most "comprehensive source of information about the safety and effectiveness" of medical devices, the authors claim. But they cite several problems associated with this "imperfect tool," especially "the fact that manufacturers—not the FDA or any other independent body—can decide whether the device is connected with a negative outcome." Other alleged problems with MAUDE include (i) "the voluntary nature of the reports," (ii) "fear of litigation by surgeons and others in a position to report the event," and (iii) "failure by patients and healthcare providers to connect new medical problems with a device."

In response to the report, an FDA spokesperson reportedly said that the agency considers "very seriously" post-approval device monitoring, that FDA has "a variety of initiatives underway to bolster postmarket surveillance" and that the agency is reworking its 510(k) premarket approval process for lower-risk medical devices. *See Product Liability Law 360,* November 5, 2010.

FTC Issues Technical Corrections to Appliance Labeling Rule

The Federal Trade Commission (FTC) has issued **technical corrections** to its Appliance Labeling Rule (16 C.F.R. Part 305) effective July 19, 2011. The changes include catalog requirements for ceiling fans that were inadvertently left out of the Code of Federal Regulations and corrected text on labels for instantaneous water heaters.

FTC's amendments state that "any manufacturer, distributor, retailer, or private labeler who advertises a covered product that is a ceiling fan in a catalog, from which it may be purchased, shall disclose clearly and conspicuously in such catalog, on each page that lists the covered product, all information concerning the product required by § 305.13(a)(1)." FTC has also corrected instantaneous water heater labels by changing the phrase "First Hour Rating" to "Capacity (maximum flow rate); gallons per minute (gpm)." S*ee Federal Register,* November 3, 2010.

LEGAL LITERATURE REVIEW

Holly Pauling Smith and Madeleine McDonough, "A New Frontier: Health-Claims Class Actions," *The International Comparative Legal Guide to: Class & Group Actions 2011"*

Shook, Hardy & Bacon Global Product Liability Partner **Holly Pauling Smith** and Pharmaceutical and Medical Device Litigation Partner **Madeleine McDonough** have co-authored this chapter on the consumer-fraud class actions to which plaintiffs' lawyers have resorted given their inability to persuade courts to certify personal-injury mass torts. The chapter, which focuses on recent cases involving health-related claims or omissions for food and beverage products, appears in an international reference on class and group actions. Smith and McDonough have also contributed a **chapter** discussing how the class-action procedure functions in the United States.

Notre Dame Law Review, Symposium to Address U.S. Supreme Court's *Shady Grove* Ruling on the Interplay of Federalism and Class-Action Litigation

- **Joseph Bauer, "Shedding Light on *Shady Grove*: Further Reflections on the *Erie* Doctrine from a Conflicts Perspective" (forthcoming)**

Notre Dame Law School Professor Joseph Bauer suggests in this article that the U.S. Supreme Court could have avoided trying to resolve an apparent "clash" between state and federal law by undertaking a "horizontal choice of law analysis" by which increased deference is given to the interests of other jurisdictions in the application of their law to a disputed issue. In *Shady Grove Orthopedic Associates v. Allstate Insurance Co.*, a Court plurality determined that a state law barring certain claims from eligibility for class certification is procedural and will not be applied in a federal court with diversity jurisdiction over the claims, thus allowing federal procedural rules to displace state limitations on class actions. Bauer contends that dissenting Justice Ruth Bader Ginsburg took the correct approach, avoiding an unnecessary conflict, "in part by giving the law of one or the other jurisdiction a more limited reading."

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- **Adam Steinman, "Our Class Action Federalism: *Erie* and the Rules Enabling Act after *Shady Grove*" (forthcoming)**

Seton Hall University School of Law Professor Adam Steinman focuses his analysis on the questions *Shady Grove* failed to answer about the role of state class-action law in federal courts. Among other matters, Steinman considers whether state law affects federal-court practice after a class is certified under Federal Rule of Civil Procedure 23, particularly with respect to available remedies and the extent to which the limitations period will be tolled for the entire class. Steinman also addresses other unresolved issues such as the preclusive effect of the ultimate judgment.

Discussing the unusual Court alignments in the opinion, Steinman suggests that "the litigants were not in their typical positions vis-à-vis the larger federalism question" that would ordinarily have made each justice's position more predictable. According to Steinman, "*Shady Grove* confronted the *Erie*/class action issue in a case where state law is *more hostile* to class actions than federal law." He speculates that "the 'conservative' Justices in the *Shady Grove* majority may have been thinking ahead to the situation where a plaintiff seeks to transplant a *more lenient* state-court approach into federal court[, while t]he 'liberal' Justices in the *Shady Grove* dissent may have been contemplating that scenario as well, just with a different set of policy preferences."

- **Catherine Struve, "Institutional Practice, Procedural Uniformity, and As-Applied Challenges under the Rules Enabling Act" (forthcoming)**

University of Pennsylvania Law School Professor Catherine Struve addresses the *Shady Grove* debate between the plurality and Justice John Paul Stevens over "the availability of as-applied challenges to the validity of rules promulgated under the Rules Enabling Act." According to Struve, Justice Stevens's approach struck a

reasonable balance, that is, state-specific as-applied invalidation of a federal rule is permissible, but should be rare. While she acknowledges that this approach "can impair the nationally uniform application of the federal rules," such costs "could be controlled by requiring a strong showing before finding a rule invalid as applied." Struve concludes, "In the same way that the federal system imposes a certain amount of disuniformity on state courts in order to vindicate federal rights, it may be reasonable to accommodate some disuniformity in federal practice in order to ensure that the federal rules, as applied, do not impinge on substantive rights (whether those rights are created by federal or state law)."

LAW BLOG ROUNDUP

Iowa Voters Oust Justices Who Reached Unpopular Decision: An Inspiration?

"Look, each of these justices knew they were coming up for a retention election last year, when they issued the *Varnum* opinion. Nevertheless, they ruled the way they did. That story is inspiring for other judges." *WSJ* law blogger Ashby Jones, quoting a University of Iowa law professor in a post about interpreting the November 2, 2010, election results in that state. Three sitting state supreme court justices lost their retention elections after groups opposed to the court's decision legalizing same-sex marriage invested hundreds of thousands of dollars to convince voters to remove them from the bench.

WSJ Law Blog, November 3, 2010.

Iowa Voters Oust Justices Who Reached Unpopular Decision: A Chilling Effect?

"Clearly the election supplies the remaining Justices—and whatever Justices are appointed to replace the ousted Justices—a prudential ground for seeking to overrule *Varnum*. Doing so will help them keep their jobs." Cornell Law School Professor Michael Dorf, blogging about the election's potential impact on the decision that voters repudiated. Dorf suggests that at least one principled ground could support overruling the decision, but cautions "a simple calculation that a certain decision will be popular or unpopular is not generally thought consistent with the rule of law."

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Dorf on Law, November 4, 2010.

Class Actions on the Path to Extinction?

"Of all the issues raised by that film ["Michael Clayton"], I'm sure that the last thing anyone—including George Clooney, one of Hollywood's most politically aware actors—would imagine is that class actions themselves may be on the path to

extinction in America." A Center for Justice and Democracy consumer advocate, discussing a case on the U.S. Supreme Court's November 9, 2010, argument docket, that asks whether companies can bar class actions in the contracts they issue to consumers who purchase their goods or services.

ThePopTort, November 5, 2010.

THE FINAL WORD

Washington Legal Foundation Calls on FDA Not to Increase Criminal Prosecutions of Corporate Executives for Off-Label Drug Promotions

A recent Washington Legal Foundation **letter** to the Food and Drug Administration's (FDA's) Office of Chief Counsel expresses concern over remarks by Deputy Chief for Litigation Eric Blumberg that suggest monetary settlements in off-label promotions disputes with drug makers might not be as effective as criminal prosecutions of corporate officers.

The foundation, which describes itself as a public interest law and policy center that defends free enterprise, individual rights and a limited and accountable government, called Blumberg's remarks "irresponsible." It contends, "increased criminal prosecution of company executives for promotional activities has the potential to adversely affect the nation's healthcare delivery system by labeling responsible corporate officials as criminals—even if they never participated in, encouraged, or had knowledge of the alleged violations." The letter argues that it would be a mistake to broadly apply the responsible corporate officer doctrine to convict innocent corporate executives and managers, noting that FDA has a history of charging company officials with violations of the Federal Food, Drug, and Cosmetic Act only where personal wrongdoing or actual knowledge of wrongdoing was involved.

UPCOMING CONFERENCES AND SEMINARS

SHB, London, England – December 8, 2010 – "Product Recall, The Inside Track: Practical guidance on product recall law and related risk management." Shook, Hardy & Bacon is presenting this seminar which "brings together a range of experts from government, retail, manufacturing, corporate communications and the legal profession" to address issues such as the current product recall regulatory framework, key product recall risks and risk management procedures, and brand an reputation implications. Shook, Hardy & Bacon Tort Partner **Mark Tyler** will discuss "The legal environment for product recalls in the EU," and Shook, Hardy & Bacon Tort Associate **Alison Newstead** will discuss "Risk management concerns: FOI requests, Product liability claims, Directors liabilities and corporate manslaughter."

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GMA, Scottsdale, Arizona – February 22-24, 2011 – "2011 Food Claims & Litigation Conference: Emerging Issues in Food-Related Litigation." Shook, Hardy & Bacon Agribusiness & Food Safety Partner Paul LaScala will participate in a panel addressing "Standards and Expectations of Corporate Social Responsibility: The Retailer's Perspective." Business Litigation Partner Jim Eiszner and Global Product Liability Partner Kevin Underhill will share a podium to discuss "Labels Certainly Serve Some Purpose—But What Legal Effect Do They Have?" Shook, Hardy & Bacon 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 93 percent of our more than 500 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).