Shook, Hardy & Bacon L.L.P.

OCTOBER 25, 2012

PRODUCT LIABILITY LITIGATION REPORT

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ITALY'S SUPREME COURT LINKS MOBILE PHONES TO BRAIN TUMORS IN LANDMARK RULING

Italy's Supreme Court of Cassation has reportedly affirmed a lower court ruling allowing businessman Innocente Marcolini to recover compensation for developing a brain tumor after using a mobile phone for up to six hours each day for 12 years. Apparently recognizing a causal link between the exposure and the neurinoma Marcolini developed near his cranial nerve, the court distinguished his exposure from the "normal, non-professional use of a mobile telephone." The court reportedly found that the supporting testimony provided by oncologist and professor of environmental mutagenesis Angelo Gino Levis and neurosurgeon Giuseppe Grasso was reliable. So ruling, the court rejected an appeal filed by the worker's compensation authority.

According to a news source, the witnesses testified that mobile and cordless phones emit electromagnetic radiation, which allegedly damages cells and increases the risk of tumors. The evidence was reportedly based on research conducted in 2005-2009 by a cancer specialist at the University Hospital in Orebro, Sweden. Professor Levis was quoted as saying, "The court decision is extremely important. It finally officially recognizes the link. It'll open not a road but a motorway to legal actions by victims. We're considering a class action." Critics contend that most of the research to date has found insufficient evidence of a link between mobile phone use and diseases such as cancer. They believe the ruling will have limited impact. *See Mail Online*, *Reuters, Telegraph*, and *dnaindia.com,* October 19, 2012.

NO SCOTUS REVIEW FOR EAR CANDLERS' CHALLENGE TO FDA WARNING LETTERS

The U.S. Supreme Court has denied the petition for review filed by the Holistic Candlers and Consumers Association and others claiming that the D.C. Circuit Court of Appeals erred when it determined that Food and Drug Administration (FDA) warning letters are not subject to judicial review. ***Holistic Candlers & Consumers Ass'n*, No. 11-1454 (U.S., cert. denied October 15, 2012)**. Additional information about the case appears in the September 27, 2012, **issue** of this *Report.* FDA warned the petitioners that they violated the Food, Drug, and Cosmetic Act by marketing their ear candle products, deemed medical devices, without obtaining FDA approval.

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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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WHEN DOES A SHIRT BECOMES A SERVICE IN A PERSONAL INJURY LAWSUIT?

A federal court in Indiana has determined that a reasonable jury could find that the relationship between an injured plaintiff and the company that supplied the shirt he was wearing while employed as a welder/plasma torch operator "was predominantly for the sale of a service"; thus the court allowed the plaintiff's negligence claim to proceed while granting the defendant's motion for summary judgment on claims of product defect. *Hathaway v. Cintas Corporate Servs., Inc.*, No. 1:10 CV 195 (U.S. Dist. Ct., N.D. Ind., Fort Wayne Div., decided October 11, 2012).

The shirt, made of 100-percent cotton and untreated with any flame-retardant chemical, caught fire when a spark from the plaintiff's plasma cutter contacted the shirt. He allegedly sustained serious burns to a substantial part of his body.

The court found that the plaintiff's breach-of-warranty and product-liability claims merged into his claims under the Indiana Products Liability Act (IPLA). Because he failed to support those claims and some of his liability theories with sufficient evidence, the court granted the defendants' motion for summary judgment as to these counts. As for the plaintiff's negligence claim, the court determined that when, as here, a company provides clothes, including repair and laundering services, a jury could find that it is providing a service, and thus the negligence claim would not be merged into the IPLA. Under Indiana law, "The IPLA does not apply to transactions that involve wholly or predominantly the sale of a service rather than a product."

PARTIES SEEK DISMISSAL IN CASE QUESTIONING FDA AUTHORITY TO REGULATE ANIMAL-DRUG COMPOUNDING

A Florida pharmacist, whom the Food and Drug Administration (FDA) sought to enjoin from filling veterinarians' prescriptions for non-food producing animals by compounding from bulk substances without FDA approval, has joined with the U.S. government in seeking the dismissal of its appeal from a district court decision finding that FDA had no authority to do so. *United States v. Franck's Lab, Inc.*, No. 11-15350-BB (11th Cir., motion to vacate and dismiss as moot filed October 16, 2012). According to the parties, the matter is moot because the pharmacist has sold his business and signed a 7-year, non-competition agreement. They also ask the court to vacate the lower court's ruling with instructions to dismiss the complaint. According to the district court, pharmacists are state-regulated, and FDA had premised its authority on guidance documents explaining the factors it will consider when deciding whether to regulate drug compounders. Oral argument had been scheduled for November 1, 2012, but will presumably be cancelled, assuming the Eleventh Circuit grants the motion.

FEDERAL COURT DISMISSES SUIT CHALLENGING DIETARY SUPPLEMENT LABELING CLAIMS

A federal court in California has dismissed with prejudice a claim alleging mislabeling of a dietary supplement product under the Magnuson-Moss Warranty Act and has dismissed the remaining claims without prejudice for failure to satisfy the amount-in-controversy requirement under 28 U.S.C. § 1332(a) and (d). *Bates v. Gen. Nutrition Ctrs.* No. 2:12-cv-1336-ODW(AJWx) (U.S. Dist. Ct., C.D. Cal., decided October 12, 2012). The plaintiff sought to represent a class of those purchasing the defendants' C-4 Extreme® dietary supplement, advertised as containing DMAA (1,3-dimethyl-amylamine), a geranium component.

Because the Magnuson-Moss Warranty Act does not apply to "any written warranty the making or content of which is otherwise governed by Federal law," and because the product is governed by the Food, Drug, and Cosmetic Act, the court determined that the plaintiff failed to state a breach-of-warranty claim under federal law. The court also determined that "Defendants sold C-4 Extreme in 30-dose bottles for $29.99. The Complaint fails to state—rightly so—that Plaintiff (or class members) have individually suffered damages in excess of $75,000; the Court sees no reason how they could. Based on the sale price of C-4 Extreme and Plaintiff's allegations, the Court finds that no class member's (including the Plaintiff) claim—not just under a preponderance, but with a legal certainty—could possibly exceed $75,000. Accordingly, as a regular class-action suit, there is no diversity jurisdiction here under § 1332(a)."

Because the Magnuson-Moss Warranty Act does not apply to "any written warranty the making or content of which is otherwise governed by Federal law," and because the product is governed by the Food, Drug, and Cosmetic Act, the court determined that the plaintiff failed to state a breach-of-warranty claim under federal law.

Noting that the plaintiff also alleged that the case was a mass action under section 1332(d) of the Class Action Fairness Act (CAFA) "because it involves more than 100 plaintiffs and over $5 million in aggregated damages," the court ruled that under Ninth Circuit law, at least one individual plaintiff must still meet the $75,000 amount-in-controversy requirement in a CAFA mass action. In this regard, the court stated that it was "unaware of any binding authority that applies the $75,000 amount-in-controversy requirement to plaintiffs in a mass action originating in federal court, as opposed to on removal. … But this Court finds it illogical that the amount-in-controversy requirement for removal would be different (and more strict) than for a case originating in federal court."

ALL THINGS LEGISLATIVE AND REGULATORY

CRS Finds FDA Authority to Regulate Drug Compounding Non-Uniform

In the wake of a meningitis outbreak purportedly linked to a contaminated compounded steroid injection, the Congressional Research Service (CRS) has updated its look at the Food and Drug Administration's (FDA's) authority to regulate

drug compounding. In its October 17, 2012, report, CRS examines FDA guidance documents on the issue, a 1997 amendment to the Federal Food, Drug, and Cosmetic Act (FFDCA) and conflicting decisions from the Fifth and Ninth Circuits to determine the extent of that authority in an era when pharmacies are no longer compounding drugs to create medication for an individual patient, but are instead producing drugs on a much larger scale.

FDA's compliance guides of 1992 and 2002 outline the factors the agency will consider in exercising enforcement discretion as to pharmacy compounding. CRS notes that such guidance does not establish legally enforceable rights or responsibilities and does not legally bind the public or FDA. Congress addressed FDA's role in the regulation of drug compounding as part of the FDA Modernization Act of 1997, generally exempting compounded drugs from FFDCA requirements on drug adulteration, misbranding, and new drug approval, if certain conditions are satisfied. "The compounded drug must comply with standards of an applicable U.S. Pharmacopoeia, or made from FDA-approved drug ingredients, meet certain manufacturing criteria, and the drug compounded must not be one that appears on a list of drugs or drug products that have been withdrawn or removed from the market because the product, or components of the product have been found to be unsafe or not effective." The pharmacy also may not compound regularly or in inordinate amounts "any drug products that are essentially copies of a commercially available drug."

The law included provisions on advertising, stating that drugs may be compounded and subject to the exemptions if they are based on a valid prescription that was not solicited and if the pharmacy, licensed pharmacists, or licensed physician does not advertise or promote the compounding of any particular drug. The advertising provisions and whether they are severable from the remainder of the statute were at issue before the Fifth and Ninth Circuits, and were found unconstitutional by the U.S. Supreme Court, which did not address the severability issue.

According to author Jennifer Staman, "the cases have created an interesting scenario of non-uniform enforcement throughout the U.S. In the Fifth Circuit, compounded drugs are specifically exempted from new-drug, adulteration, and misbranding requirements of the FFDCA if certain criteria are met; while in the Ninth Circuit (and, according to the FDA, the rest of the United States), compounded drugs are subject to these requirements, but the FDA may exercise discretion in taking action against an entity that violates these provisions."

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PeaPod™ Travel Beds Draw Regulator Scrutiny

The Consumer Product Safety Commission (CPSC) has reportedly confirmed an ongoing investigation into a popular infant travel bed after Health Canada urged consumers to stop using the product. According to media sources, a CPSC spokesperson indicated that the agency is still reviewing a March 16, 2012, **report** that KidCo, Inc.'s PeaPod™ Travel Beds allegedly contributed to a suffocation-related fatality.

CPSC's statement apparently followed Health Canada's decision to issue a **consumer advisory** about the infant beds in the wake of two incident reports filed by parents concerned about suffocation hazards. "Health Canada is currently in discussions with the company about how it will address the safety concerns related to the use of this product," states the advisory. "In the meantime, the department is warning consumers to immediately stop using the product for infants under 1 year of age." *See Bloomberg BNA Product Safety & Liability Reporter,* October 22, 2012.

Meanwhile, the consumer group Kids in Danger (KID) has pointed to regulatory loopholes in CPSC's process for testing and approving children's products. "The bigger problem is that when parents go to buy a travel sleep product or any children's product, they have no way to tell which are tested to strong mandatory—or even weak industry—standards and which, like the Peapod, fall outside the scope of standards and so are sold with insufficient testing," states KID on its Website. "The Peapod doesn't meet the definition of a play yard, portable crib or crib, so is not covered by those standards."

CPSC Proposes Bassinet and Cradle Standard

The Consumer Product Safety Commission (CPSC) has **proposed** a safety standard for bassinets and cradles in response to the Consumer Product Safety Improvement Act of 2008, which requires the agency "to promulgate consumer product safety standards for durable infant or toddler products." Opening a second round of comments, CPSC's latest supplemental notice of proposed rulemaking (NPR) for bassinet and cradle products and accessories takes into account an earlier consultation with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, and members of the public.

Based on voluntary standards developed by ASTM International, the draft safety rules seek to revise "the scope and definition of a bassinet/cradle and bassinet/cradle accessory" to include cradle swings as well as "products that can be supported by a stationary frame/[stand], such as carriage attachments to strollers and Moses baskets, only when they are used with a stationary or rocking stand." The Commission has also proposed expanding the standard beyond products "*only* used to provide sleeping accommodations" to cover products "*primarily*" used to provide sleeping accommodations. "This would ensure, for example, that a bassinet sold with a toy mobile that is meant to entertain

The Commission has also proposed expanding the standard beyond products "only used to provide sleeping accommodations"

an infant who is lying in the bassinet would still fall within the scope of the rule," concludes CPSC, which will accept comments on the NPR until January 2, 2013. *See Federal Register,* October 18, 2012.

CDC Report Highlights Detergent-Pod Hazards

The Centers for Disease Control and Prevention (CDC) has published a **study** in the October 19, 2012, edition of *Morbidity and Mortality Weekly Report* focusing on the alleged health risks of laundry detergent pods. According to CDC, which gathered data between May 17 and June 17, 2012, "poison centers reported 1,008 laundry detergent exposures to the National Poison Data System (NPDS), of which 485 (48%) exposures involved laundry detergent pods." But compared with non-pod exposures, the exposures involving detergent pods were more often unintentional and more likely to entail ingestion, a fact highlighted by CDC in its advice to caregivers and healthcare providers.

"Among children aged ≤5 years, a significantly greater proportion of those exposed to laundry detergent from pods had gastrointestinal and respiratory adverse health effects and mental status changes compared with those with non-pod laundry detergent exposures," states CDC's summary of the data. "Parents and caregivers should keep laundry detergent pods, as well as other household cleaning products, out of reach and out of sight of children. Health-care providers should be aware that exposure to laundry detergent from pods might be associated with adverse health effects more often than exposure to non-pod laundry detergents."

Meanwhile, the Consumers Union (CU) has reportedly joined U.S. Senator Charles Schumer (D-N.Y.) in calling on the Consumer Product Safety Commission (CPSC) to further regulate laundry detergent pods in light of these statistics. More information about the senator's initiative appears in the September 13, 2012, **issue** of this *Report.* After Schumer wrote a letter about the issue to CPSC Chair Inez Tenenbaum, the consumer group released its own missive urging detergent-pod manufacturers and CPSC to "step up efforts" to prevent accidental exposures. "The small size of these packets makes them accessible to children, and the colors and textures of certain products could be attracting children in ways that conventional detergents do not," CU said of the pods. "We urge [CPSC] to investigate this matter quickly and consider regulations to require adequate child-safe packaging, as well as prominent warning labels, for single-use detergent packs."

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FDA Issues Warning to Avon, Some Beauty-Product Claims Render Them New Drugs

The Food and Drug Administration (FDA) recently issued a **warning letter** to the chair and CEO of Avon Products, Inc., advising the company that marketing claims for several of its Anew® beauty products, including a wrinkle corrector, night cream, serum, and face-lifting cream, violate the Food, Drug, and Cosmetic Act. According

to FDA, "The claims on your web site indicate that these products are intended to affect the structure or any function of the human body, rendering them drugs under the Act."

Avon apparently claims that the products "boost shock-absorbing proteins" in the skin, "activate a key repair molecule," "fortify damaged tissue with new collagen," "help tighten the connections between skin's layers," and "help boost production of collagen and elastin." FDA contends, "[y]our products are not generally recognized among qualified experts as safe and effective for the above referenced uses and, therefore, the products are new drugs as defined in section 201(p) of the Act," and may not be marketed without FDA approval. FDA requests action to correct these alleged violations and notification within 15 days of steps taken to correct them. "Failure to do so may result in enforcement action without further notice. The Act authorizes injunctions against manufacturers and distributors of illegal products and seizure of such products."

Draft Guidance Available for Medical Device Makers to Provide Electronic Submissions

The Food and Drug Administration (FDA) has made available for public comment draft **guidance** titled "eCopy Program for Medical Device Submissions." Comments are requested by November 16, 2012.

According to FDA, "The draft guidance describes how FDA plans to implement the eCopy Program under the Federal Food, Drug, and Cosmetic Act." Submitting an electronic copy of a medical device submission is currently voluntary; once the guidance is finalized, however, eCopy submission of certain device submissions will be required. An eCopy does not change "the type or amount of data the applicant includes in a submission to support clearance or approval. An eCopy is defined as an exact duplicate of the paper submission, created and submitted on a compact disc, digital video disc, or in another electronic media format that FDA has agreed to accept, accompanied by a copy of the signed cover letter and the complete original paper submission." *See Federal Register*, October 17, 2012.

According to FDA, "The draft guidance describes how FDA plans to implement the eCopy Program under the Federal Food, Drug, and Cosmetic Act."

Maker of Inflatable Baby Boat Agrees to CPSC Settlement

The Consumer Product Safety Commission (CPSC) has provisionally accepted a settlement with Aqua-Leisure Industries, Inc. requiring the company to pay $650,000 for allegedly failing to promptly notify the Commission after learning that the leg straps in the seats of its inflatable baby boats "can tear with normal use, causing children to unexpectedly fall into or under the water, posing a risk of drowning." The company agreed to the settlement without admitting liability, and CPSC requests that those opposed to it or otherwise wishing to comment file a written request no later than November 1, 2012.

The company recalled an inflatable baby boat product in 2001 due to sudden tearing of the seat crotch, and the company continued to sell versions of the product thereafter, distributing some 4 million inflatable baby boats between 2002 and 2009. According to CPSC, the company learned of 17 incidents of seat ripping between July 2003 and July 2006 and was informed that the leg straps were not being produced according to its specifications. "Aqua Leisure waited until March 12, 2009, to report to the CPSC, just hours before the publication of a news story by a Boston news team about problems with the Subject Products and Aqua Leisure's handling of complaints and potential failure to report to the Commission." The company thereafter recalled the products, disclosing "31 reports of inflatable baby boat seats tearing, causing children to fall into or under the water."

Still, according to the company, few of its products failed and no substantiated injuries were reported in association with its use. The company also contends that the boats are sold with warnings, including warnings that parents not use the product without supervising their children. "For these reasons, Aqua Leisure did not believe the leg straps tears were reportable events." *See Federal Register*, October 17, 2012.

ATV Safety Summit Concludes with Calls for Improved Crash and Injury Data

According to a news source, a recent all-terrain vehicle (ATV) safety summit hosted by the Consumer Product Safety Commission (CPSC) raised a pressing need for more detailed crash and injury data. While most participants generally agreed that ATV-related deaths and injuries must be reduced, stakeholders and others disagreed about how to accomplish that goal. CPSC Chair Inez Tenenbaum reported that some 780 people have died in ATV accidents in the United States since 2009, and 130,000 riders were treated in hospital emergency rooms. Surveillance data apparently do not provide information that would identify how crashes occur or even what ATVs are involved in accidents. Some researchers called for onboard cameras or event data recorders, a suggestion rejected by other summit attendees as too costly.

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CPSC has just concluded an official comment period on an outdated 2006 notice of proposed rulemaking on ATV safety. And the Consumer Product Safety Improvement Act of 2008 required the agency to adopt the industry's 2010 ANSI/SVIA voluntary standard as a mandatory standard. This occurred in February 2012. The summit gave stakeholders an opportunity to discuss outstanding ATV safety issues, including discrepancies between the 2006 proposal and the 2010 standard. With the inevitability of human error acknowledged, some called for more research into cognitive behavior. *See Bloomberg BNA Product Safety & Liability Reporter*, October 15, 2012.

LEGAL LITERATURE REVIEW

Stacey Lee, "*PLIVA v. Mensing:* Generic Consumers' Unfortunate Hand," *Yale Journal of Health Policy, Law, and Ethics*, 2012

Johns Hopkins Carey Business School Assistant Professor Stacey Lee explains how the U.S. Supreme Court's *PLIVA v. Mensing* decision, insulating generic drug makers from state law-based failure-to-warn claims, has called into question the safety of generic drugs. The article details the regulatory frameworks applicable to generic and brand-name drugs and proposes changes that Lee contends would restore integrity to generic drug warning labels. Lee's proposal would "provide all manufacturers with increased access to data pertaining to the safety of their drugs. It also offers a structure for open communication among generic manufacturers, their branded counterparts, and the FDA. Finally, the framework grants generic manufacturers unambiguous access to label-changing mechanisms that are available to brand-name manufacturers."

LAW BLOG ROUNDUP

New Opinion Created in the Ninth Circuit

"'Chief Judge KOZINSKI, disagreeing with everyone': Just when you thought that every possible type of appellate opinion had already been created, Ninth Circuit Chief Judge Alex Kozinski goes and invents one more." Inveterate blogger Howard Bashman, writing about the apparently dissenting opinion penned by Ninth Circuit Court of Appeals Judge Alex Kozinski in an immigration case that splintered the court. Kozinski's opinion is titled as indicated above, instead of the usual "concurring," "dissenting," "concurring but writing separately," or "concurring in part, dissenting in part" options generally used by the courts.

How Appealing, October 19, 2012.

Resistance to Government Overkill?

"A small company goes right on defying the Consumer Product Safety Commission." Cato Institute Senior Fellow Walter Olson, blogging about efforts undertaken by the maker of a magnetic toy that the Commission is seeking to ban. Among other matters Maxfield & Oberton has apparently created a series of posters showing various products, including coconuts, hot dogs, stairs, and beds that should also be banned "based on the CPSC's logic." The Buckyballs® company recently gave "7 members of Congress a BIG Bucky hi-five for their letter in support of our fight with the CPSC." Details about the Commission's notice of proposed rulemaking that would prohibit desk toys containing small, high-powered magnets appear in the September 13, 2012, **issue** of this *Report*.

Overlawyered.com, October 17, 2012.

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THE FINAL WORD

Sunscreen Recalled for Propensity to Catch Fire on Skin Before Drying

The company that makes Banana Boat UltraMist Sport SPF 30 and 50 sunscreen products has reportedly recalled them after learning they can ignite on a user's skin before they dry. According to Energizer Holdings, Inc., five incidents of burns associated with the products' use have been reported in the United States and Canada; the company attributes the problem to a larger than normal spray valve opening that dispenses more than other "continuous sun care spray" products. In a statement, the company said, "As a result, the product is taking longer to dry on the skin than is typical with other continuous sprays. If a consumer comes into contact with a flame or spark prior to complete drying of the product on the skin, there is a potential for the product to ignite." *See Law360*, October 19, 2012.

UPCOMING CONFERENCES AND SEMINARS

ABA Section of Litigation, Natick, Massachusetts – November 16, 2012 – "Current Issues in Pharmaceutical and Medical Device Litigation." Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Practice Partner Hildy Sastre will join a distinguished faculty to participate in a panel discussion on "Hot Topics and Recent Developments in Medical Device Regulation and Enforcement." ■

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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 470 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).