Shook, Hardy & Bacon L.L.P.

MAY 13, 2010

PRODUCT LIABILITY LITIGATION REPORT

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CLAIMS ALLEGING HARM FROM FROZEN DINNER COOKING DIRECTIONS DISMISSED

A federal court in California has dismissed a lawsuit against a company that produces frozen pot pies finding that the plaintiffs lacked any injury due to alleged improper cooking instructions and thus lacked standing to bring the suit. *Meaunrit v. The Pinnacle Foods Group, LLC*, No. C09-04555 (U.S. Dist. Ct., N.D. Cal., decided May 5, 2010). The court also determined that a number of the plaintiffs' claims were preempted by federal law. The plaintiffs were given 14 days to amend their complaint to address the deficiencies the court identified, and the court outlined a briefing schedule for a subsequent motion to dismiss, if filed.

Citing unnamed reports, the plaintiffs alleged that they had to throw out defendant's products because if they were to follow the cooking instructions on the product labels, "the pot pies may not 'reach the "kill step" temperature necessary to destroy dangerous bacteria.'" They also alleged that "the non-contamination of the pot pies is uncertain because 'it is difficult to determine if they have been thoroughly cooked." Seeking to certify a class of consumers, the plaintiffs alleged violations of California's Unfair Competition Law and Consumer Legal Remedies Act, breach of express and implied warranties, violation of the Magnuson-Moss Warranty Act, unjust enrichment, strict liability and negligence, and declaratory relief. They did not claim that they or anyone else had been harmed by eating pot pies prepared according to the package directions.

Because the plaintiffs did not allege that they had been injured by contaminated pot pies, the court ruled that they had alleged a "speculative, hypothetical injury" that was insufficient to support standing. According to the court, by simply asserting the potential for contamination and by choosing to discard the product, the plaintiffs failed to make "factual allegations to suggest this action was reasonably attributable to Defendant. They cannot create an injury by taking unilateral action unhinged from Defendant's conduct."

To guide the plaintiffs in crafting an amended complaint, the court also addressed each of the plaintiffs' causes of action to describe how they were either preempted by federal law, insufficiently pleaded or relied on predicate claims that were preempted.

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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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TENTH CIRCUIT UNDERSCORES SIGNIFICANCE OF PROCEDURAL RULES IN PRESCRIPTION DRUG LITIGATION

A divided Tenth Circuit Court of Appeals panel has dismissed an appeal from a trial court's grant of a prescription drug maker's motion for summary judgment, ruling that because the appeal was not timely filed, the court lacked jurisdiction to consider it. ***Vanderwerf v. SmithKline Beecham Corp.*, No. 08-3218 (10th Cir., decided April 27, 2010)**. The plaintiffs alleged that one of the defendant's products had caused their decedent's suicide. They relied on the testimony of a single expert witness to establish general and specific causation, but the trial court ruled that the testimony would not be admissible because it was unreliable. Without any other evidence to support causation, the claims were dismissed.

Eight days after the court dismissed their claims, the plaintiffs filed a motion to reconsider. The court did not act on the motion for about seven months, so the plaintiffs filed a notice of withdrawal of the motion and also filed a notice of appeal.

According to the appeals court majority, federal procedural rules allow the tolling of the time in which an appeal must be filed if a party "timely files" a motion "to alter or amend the judgment." Thereafter, the time to file an appeal "runs for all parties from the entry of the order disposing of" any motion to alter or amend the judgment. Because the lower court never entered an order disposing of the motion to reconsider, due to the plaintiffs' withdrawal of the motion, the appeals court determined that the record was left "as if they had never filed their motion in the first place." Thus, a motion to appeal should have been, but was not, filed within 30 days of the entry of summary judgment. The court acknowledged the "severity" of its holding, but concluded, "Because timely notice of an appeal is mandatory and jurisdictional, we lack jurisdiction to consider this appeal."

The court indicated several steps that the plaintiffs could have taken to preserve their right of appeal, including (i) filing a motion to request a ruling, (ii) seeking a writ of mandamus from the appeals court, (iii) filing a motion for an extension of time to file an appeal, "provided that they might show good cause or excusable neglect underlying the untimely notice," (iv) filing a premature notice of appeal, or (v) moving to withdraw the motion, hoping that the district court would rule on it and thus trigger the 30-day filing period for a timely appeal.

The dissenting judge said that any delay in the case was caused by the court and not the plaintiffs. The judge also opined that "the timely filing of the motion [to reconsider] triggers the tolling" and, "[b]ecause the district court did not rule on the motion [to reconsider], the thirty-day filing deadline has not begun to run." This judge further indicated that the alternative actions recommended by the majority, to the extent that they called for district court action, would have reasonably been rejected by plaintiffs who were already subject to that court's inaction and delay.

FEDERAL COURT FINDS CLAIM FOR COMPENSATION FROM VACCINE INJURY FUND TIMELY

The Federal Circuit Court of Appeals has determined that a physician vaccinated for Hepatitis B timely filed a claim under the Vaccine Injury Compensation Program because the purported link between the vaccine and the multiple sclerosis (MS) symptoms she experienced in 1997 was not known until 2004, and she filed her claim less than 36 months thereafter. ***Cloer v. Sec'y of Health & Human Servs.*, No. 2009-5052 (Fed. Cir., decided May 6, 2010)**.

According to the court, the National Childhood Vaccine Injury Act requires that a petition for compensation be filed within 36 months of "the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of [a vaccine-related] injury." The court agreed with the physician that the medical community at large needs to recognize a link between the injury and the vaccine for the statute of limitations to begin running. Because the first time anyone in the medical community could have objectively recognized a link between MS and a vaccine was September 2004, when an article on the subject was published, the physician's September 2005 petition was timely. The court noted that the government continues to deny a causal association and the Vaccine Injury Table does not list MS as a vaccine-related injury.

The court agreed with the physician that the medical community at large needs to recognize a link between the injury and the vaccine for the statute of limitations to begin running.

A dissenting judge contended that the majority had created a new statute of limitations for non-Table petitioners under the Vaccine Act and, so doing, misread the law.

CALIFORNIA JURY AWARDS MILLIONS FOR SECONDHAND EXPOSURE TO ASBESTOS

A California state jury has reportedly awarded compensatory and punitive damages in excess of $200 million to Bobby and Rhoda Evans for the mesothelioma that Rhoda allegedly contracted from washing her husband's work clothes; he was allegedly exposed to asbestos on the job for some 24 years. *Evans v. A.W. Chesterton Co.*, No. BC 418867 (Cal. Super. Ct., Los Angeles County, Central Dist., verdict reached April 28, 2010). Bobby apparently worked for the Los Angeles Department of Water and Power, and testified that he routinely cut pipe containing asbestos with an abrasive power saw. A spokesperson for the company that purportedly manufactured the pipe indicated that it would "fully and vigorously" contest the verdict, characterizing the award as "grossly excessive." *See Product Liability Law 360*, April 30, 2010.

MDL COURT ORDERS DAMAGES AND FEES FOR DEFECTIVE DRYWALL REMEDIATION

The Louisiana federal court overseeing the multidistrict litigation (MDL) involving defective drywall imported from China has entered an order awarding more than $160,000 in damages in the case of one claimant following a non-jury trial conducted in March 2010. *In re: Chinese-Manufactured Drywall Prods. Liab. Litig. (Hernandez v. Knauf Gips KG, No. 09-6050)*, MDL No. 2047 (U.S. Dist. Ct., E.D. La., decided April 27, 2010). Because the parties agreed that the drywall was defective and that remediation was required, the opinion focuses on the nature and scope of the remediation given a dispute over this aspect of the case. A comprehensive discussion of the damage caused by the drywall is included; that damage apparently ranges from metal corrosion in plumbing and electrical systems, as well as the metals used in appliances and consumer electronics, to flooring, clothing and carpeting ruined with lingering odors. The court also included in the damages calculation alternative living expenses, the costs of a thorough cleaning and certification by an environmental consultant. Attorney's fees will be decided at a later date.

PARTS OF DEFENSE EXPERT WITNESS TESTIMONY EXCLUDED IN CHILDREN'S TYLENOL® LITIGATION

A federal court in California has decided to exclude parts of the expert testimony proffered by a major retailer defending claims that Children's Tylenol® Plus Multi-symptom Cold product caused the death of a 4-month-old child. *Vu v. McNeil-PPC,Inc.*, No. 2:09-cv-01656 (U.S. Dist. Ct., C.D. Cal., decided May 7, 2010). According to the court, Costco designated several of its experts as rebuttal witnesses, but their reports included topics falling outside the expected testimony of plaintiff's expert, such as possible alternative causes for the child's death and whether it is sound medical practice to expect a retailer to provide drug warnings or opinions different from those provided by FDA-approved labeling or a physician's advice. The court limited this testimony to strictly rebuttal evidence. Because Costco also failed to timely disclose several of its expert witnesses, the court struck them as witnesses and precluded the use of their testimony at trial.

PLAINTIFFS' LAWYERS JOCKEY FOR POWER POSITIONS IN MULTIDISTRICT TOYOTA LITIGATION

Plaintiffs' lawyers have reportedly been jockeying in full force for lead positions in multidistrict litigation over alleged sudden unintended acceleration problems with Toyota Motor Co. vehicles. More than 100 lawyers have filed more than 75 federal civil suits, which mostly seek damages for a drop in the resale value of the Japanese manufacturer's vehicles. According to a news source, as much as $500 million in lawyers' fees is at stake, but few will share it.

The case has been consolidated in the Santa Ana, California, courtroom of U.S. District Judge James Selna, who will pick top plaintiffs' lawyers from a slate of applications presented by three interim lead attorneys. The judge has asked the applicants to show that they can work cooperatively and have experience handling complex cases. Some of the applications have apparently been extensive: one totals 114 pages and another attached 13 exhibits. *See The Wall Street Journal*, May 4, 2010.

PRESIDENT NAMES CHOICE FOR U.S. SUPREME COURT SEAT TO BE VACATED BY JUSTICE STEVENS

President Barack Obama (D) has **announced** his nomination of Solicitor General Elena Kagan to replace U.S. Supreme Court Justice John Paul Stevens, who will retire at the end of the Court's current term.

Kagan, at age 50, would be the youngest member of the Court, if confirmed by the Senate, and lacks the judicial experience that has been a hallmark of nearly all sitting justices in recent memory. The Republican-controlled Senate refused to conduct a hearing on her nomination to a seat on the federal appeals court bench in 1999. She has served as Harvard Law School's dean and has distinguished herself in argument before the Court on behalf of the U.S. government.

While Kagan lacks what Senators refer to as a "paper trail" of judicial opinions to indicate how she would rule on particular cases and issues, she did serve as a law clerk for Justice Thurgood Marshall, a jurist she admires for promoting justice and understanding that the law affects the lives of ordinary people. She also took action at Harvard to challenge the military's "Don't Ask, Don't Tell" policy which she said deprives "gay men and lesbians of the opportunity to serve their country." A question that many commentators are asking about Kagan is whether she will follow the recent U.S. Supreme Court trend of favoring corporate interests. The president praised her for defending the "rights of shareholders and ordinary citizens against unscrupulous corporations." He is hoping that she will be confirmed before the Court's fall term begins in October. *See Politico.com*, May 5, 2010; *The White House, Office of the Press Secretary, Slate.com* and *The New York Times,* May 10, 2010.

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ALL THINGS LEGISLATIVE AND REGULATORY

Senators Propose Extensive Auto Safety Bill

U.S. Senators Jay Rockefeller (D-W. Va.) and Mark Pryor (D-Ariz.) have introduced automobile safety **legislation** that would impose strict new controls on automakers and boost the oversight authority of the National Highway Traffic Safety Administration (NHTSA).

The Motor Vehicle Safety Act of 2010 (S. 3302) would strengthen auto safety requirements, set new standards for stopping distance, increase fines against offending automakers, and make it easier for consumers to learn about vehicle defects.

The legislation comes after more than nine million Toyota vehicles have reportedly been recalled worldwide since last fall, including two major recalls for problems with sticking accelerator pedals. "Recent Toyota recalls showed an urgent need to update safety standards to reflect modern vehicle technology and give auto safety regulators the stronger tools and resources they need to protect the public," Rockefeller said in a press statement. "We can do better by the American people—and we will with this bill."

Under the bill, NHTSA's funding would double from $140 million to $280 million by 2013, with the extra funds targeted for hiring additional safety experts and updating crash-testing facilities and databases. The bill would increase civil penalties for automakers from $5,000 to $25,000 per vehicle, and would remove the current $16.4 million cap on fines for companies that intentionally withhold safety information from NHTSA.

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The measure would also force automakers to implement standardized brake override systems, keyless ignitions and vehicle electronic systems, and install crash data recorders like the "black boxes" used in airplanes. It would also bar NHTSA's vehicle safety employees from holding certain positions in the auto industry for three years after leaving the agency. The House Committee on Energy and Commerce discussed its own auto safety **draft bill** on May 6, 2010. *See The New York Times,* May 4, 2010.

CPSC Investigates Reports of Problems Involving New Pampers Diapers

The Consumer Product Safety Commission (CPSC) has reportedly launched an investigation into Pampers diapers with Dry Max® following complaints from parents who claim the new, thinner diapers are causing their babies' and toddlers' persistent rashes and blisters resembling chemical burns. In March 2010, Procter & Gamble updated its Swaddlers® and Cruisers® diapers with a technology that replaces the paper pulp previously used with an "absorbent gelling material."

The company has stated that the claims are "completely false" and that it has received fewer than two complaints about diaper rash for every one million Pampers sold. "These rumors are being perpetuated by a small number of parents, some of whom are unhappy that we replaced our older Cruisers and Swaddlers products, while others support competitive products and the use of cloth diapers," a Pampers official was quoted as saying. Meanwhile, CPSC has encouraged parents and caregivers to report any problems to the agency. *See The Associated Press*, May 7, 2010.

FDA Orders Recall and Destruction of Infusion Pumps

The Food and Drug Administration (FDA) has **ordered** a medical device manufacturer to recall and destroy some 200,000 infusion pumps currently in use in hospitals and health care clinics to accurately deliver fluids, such as nutrients and medications, into a patient's body. According to the May 3, 2010, notice, the agency has been working with the manufacturer since 1999 "to correct numerous device flaws," which have included battery swelling, inadvertent power off and service data errors. The agency has received more than 56,000 adverse event reports associated with the device and claims these events "have included serious injuries and more than 500 deaths."

The company apparently most recently submitted to the FDA a correction schedule that "did not plan to begin the latest round of corrections to the adulterated and misbranded pumps until May 2012." In addition to the recall and destruction, FDA has ordered the company to reimburse customers and assist them in finding a replacement device. FDA will hold a public workshop in May 2010 on infusion pump design, noting that the problems this manufacturer has experienced are not unique. *See FDA News Release*, May 3, 2010.

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U.S. Supreme Court Submits Procedural Rules Changes to Congress

Among the federal rules **changes** most recently submitted to Congress by the U.S. Supreme Court are those affecting disclosure of expert testimony (Rule 26) and motions for summary judgment (Rule 56). In the absence of congressional action, the changes will become effective December 1, 2010. According to the Advisory Committee on Civil Rules, the Rule 26 amendments are intended to "address the problems created by extensive changes to Rule 26 in 1993, which were interpreted to allow discovery of all communications between counsel and expert witnesses and all draft expert reports and to require reports from all witnesses offering expert testimony." The new rule would apply work-product protection to the discovery of draft reports by testifying expert witnesses, and, with some exceptions, communications between those witnesses and counsel.

The summary-judgment rule amendments were apparently designed "to improve the procedures for presenting and deciding summary-judgment motions, to make the procedures more consistent across the districts, and to close the gap that has developed between the rule text and actual practice." Among the changes is the

restoration of the word "shall" to the requirement that a court render a judgment if the record shows that "there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." A stylistic change in 2007 changed the requirement to "should," which the committee believed had changed a "term of art" that could inadvertently risk a change to substantive meaning. *See Committee Notes*, September 2009.

Legal Literature Review

Victor Schwartz, Cary Silverman & Christopher Appel, "Respirators to the Rescue: Why Tort Law Should Encourage, Not Deter, the Manufacture of Products That Make Us Safer," *American Journal of Trial Advocacy* (2010)

Shook, Hardy & Bacon Public Policy attorneys **Victor Schwartz**, **Cary Silverman** and **Christopher Appel** explore the policy and legal issues concerning regulated products that are subject to products liability litigation. Focusing on respirators used in occupational settings to protect workers from inhaling a variety of substances, the authors show how regulators take numerous factors, such as comfort and effective communication, into account when imposing design and labeling requirements on their manufacture. They contend that such "comprehensive regulation … should give courts pause and sound guidance in determining whether [design defect and labeling] claims are sustainable under common law principles of regulatory compliance and federal preemption, particularly in light of tort law's encouragement of rescue and safety and sound public policy."

LAW BLOG ROUNDUP

Let the Battles over a U.S. Supreme Court Nomination Begin

"The 'Kagan must be stopped!' fulminations have largely come from the left. This is in part because the right is largely resigned to their impotence in the Senate." Manhattan Institute Center for Legal Policy's adjunct fellow Ted Frank, blogging about reaction to the nomination of Elena Kagan to a seat on the U.S. Supreme Court.

PointofLaw.com, May 11, 2010.

U.S. Supreme Court Battles – Part II

"Democrats praise Kagan as highly qualified and say she would bring diversity to the high court. Republicans question her lack of judicial experience and criticize her policies toward military recruiters at Harvard Law School." Justice Department Reporter Mike Scarcella, linking to several media sources covering the nomination of Elena Kagan to the U.S. Supreme Court.

The BLT: The Blog of Legal Times, May 11, 2010.

So Much More to Learn

"Undoubtedly, over the next handful of weeks, as people pore over her papers and closely read her remarks, we're going to learn more about Elena Kagan." Lead writer Ashby Jones, introducing the text of a speech U.S. Supreme Court-nominee Elena Kagan delivered to West Point cadets in 2007.

WSJ Law Blog, May 11, 2010.

THE FINAL WORD

Cancer Panel Report Says Environmental Chemicals Causing "Grievous Harm"

Described by the media as "landmark" and "extraordinary," the President's Cancer Panel newly issued **2008-2009 Annual Report** claims that the National Cancer Program has not adequately addressed the "true burden of environmentally induced cancer." According to the panel's transmittal letter, some 80,000 chemicals are on the market in the United States, and Americans are exposed daily to many of them, even before birth. Particularly noted were exposures to chemicals such as bisphenol A (BPA), formaldehyde and benzene. The report examines the impact of environmental exposures on cancer risk, identifies the barriers to understanding and reducing the exposures and makes recommendations to overcome these barriers.

According to a news source, the American Cancer Society (ACS) and industry interests have expressed concerns about the report, claiming that it lacks balance and "under-emphasizes prevention efforts." The ACS suggested that the panel, by concluding that the true burden of environmentally caused cancer has been grossly underestimated, "does not represent scientific consensus." An ACS spokesperson claimed that the panel's view "reflects one side of a scientific debate that has continued for almost 30 years" and also stated, "it would be unfortunate if the effect of this report were to trivialize the importance of other modifiable risk factors that, at present, offer the greatest opportunity in preventing cancer."

While ACS supports "minimizing or eliminating exposure to known or probable carcinogens," the organization **focuses** its prevention activities on "modifiable risk factors," identified as "tobacco use, poor nutrition, physical inactivity and obesity, alcohol consumption, excessive sun exposure, certain chronic infections, and exposures to other known carcinogens in various settings."

Noting that 41 percent of Americans will be diagnosed with cancer and 21 percent will die from the disease, the panel of Bush administration appointees maintains that inadequate attention and funding have been provided to the environmental causes of cancer. The panel also criticizes the scientific tools used to assess cancer risk from environmental exposure and the reactionary rather than precautionary approach that regulators take to environmental hazards. "[I]nstead of requiring

industry or other proponents of specific chemicals, devices, or activities to prove their safety, the public bears the burden of proving that a given environmental exposure is harmful. Only a few hundred of the more than 80,000 chemicals in use in the United States have been tested for safety."

Among the sources and types of environmental contaminants cited in the report are (i) industrial and manufacturing sources, (ii) agricultural sources, including insecticides, herbicides and fungicides, (iii) conveniences of modern life (dry cleaning, mobile source air emissions—cars, trucks, airplanes—water disinfection by-products, household pest control, tanning devices), (iv) medical sources, such as medical radiation and scans, and pharmaceuticals in water supplies, (v) military sources, and (vi) natural sources.

Concluding that the nation must learn more about the full extent of environmental influences on cancer, the panel calls for a comprehensive policy agenda, special protections for children, more and better research, stronger regulation, full disclosure of risks to specific populations ("agricultural and chemical workers and their families, radiation-exposed groups such as uranium mine workers, nuclear industry workers, nuclear test site workers and 'downwinders,' residents of cancer 'hot spots' or other contaminated areas"), and development of safer alternatives to currently used chemicals.

Among the panel's specific recommendations are the adoption of the "precautionary approach" to environmental chemical risks, better regulatory coordination "free of political or industry influence," increased research funding, improved protections for occupational exposures, the incorporation of information about environmental exposures in standard medical histories, and the adoption of "green chemistry" initiatives and research. According to a news source, previous panel reports have focused on treatment and the contribution of diet and smoking to cancer incidence. Nicholas Kristof, writing for *The New York Times*, said, "It's striking that this report emerges not from the fringe but from the mission control of mainstream scientific and medical thinking." He also said, "Industry may howl," because the report calls for "much more rigorous regulation of chemicals." *See Environmental Health News* and *The New York Times*, May 6, 2010; *Inside EPA*, May 7, 2010.

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UPCOMING CONFERENCES AND SEMINARS

DRI, San Francisco, California – May 20-21, 2010 – "26th Annual Drug and Medical Device Seminar." Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partner Mark Hegarty will serve on a panel discussing "Potential Civil and Criminal Liability Arising from Clinical Trials." The firm is a co-sponsor of this continuing education seminar.

ABA, Washington, D.C. – May 27, 2010 – "The Fourth Annual National Institute on E-Discovery: Practical Solutions for Dealing with Electronically Stored Information (ESI)." Shook, Hardy & Bacon Tort Partner John Barkett is serving as moderator for two panels during this American Bar Association (ABA) continuing legal education program, which features some of the federal judges, practitioners, in-house counsel, and scholars most knowledgeable about e-discovery issues today.

American Conference Institute, New York City – July 21-22, 2010 – "Products Liability Boot Camp for the Life Sciences Industry." Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partner Marie Woodbury will join a distinguished faculty of top defense lawyers for life sciences companies to share their expertise on the liability risks facing this industry. Woodbury will analyze clinical-trials processes from a products liability perspective, discussing potential litigation issues related to the scope of the trial, transparency and non-disclosure of results, and discovery involving investigators and subjects. ■

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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).