Shook, Hardy & Bacon L.L.P.

MARCH 22, 2012

PRODUCT LIABILITY LITIGATION REPORT

CONTENTS

D.C. CIRCUIT DIRECTS MERCURY-FREE VACCINE GROUP TO OTHER GOVERNMENT BRANCHES

The D.C. Circuit Court of Appeals has dismissed a lawsuit filed against the Food and Drug Administration (FDA) by a non-profit organization and some of its members seeking to suspend FDA approval for vaccines containing thimerosal, a mercury-based preservative. ***Coal. for Mercury-Free Drugs v. Sebelius*, No. 11-5035 (D.C. Cir., decided March 13, 2012)**. So ruling, the court affirmed the district court's determination that the plaintiffs lacked standing to bring the action.

The plaintiffs had unsuccessfully petitioned FDA in 2007 to prohibit the use of thimerosal-preserved vaccines for children and pregnant women and then filed this suit complaining that FDA had violated its statutory duty to ensure vaccine safety. They alleged (i) past injuries, i.e., miscarriages, autism and other neurological harms to children; (ii) reputational injuries to members who are medical professionals; and (iii) difficulty in obtaining thimerosal-free vaccines. The court determined that none of these concerns constituted the future, redressable injuries required to establish standing.

According to the court, "plaintiffs are not required to receive thimerosal-preserved vaccines; they can readily obtain thimerosal-*free* vaccines. They do not have standing to challenge FDA's decision to allow *other people* to receive thimerosal-preserved vaccines. Plaintiffs may, of course, advocate that the Legislative and Executive Branches ban all thimerosal-preserved vaccines. But because plaintiffs are suffering no cognizable injury as a result of FDA's decision to allow thimerosal-preserved vaccines, their lawsuit is not a proper subject for the Judiciary."

NINTH CIRCUIT RULES *PARENS PATRIAE* SUIT NOT REMOVABLE AS MASS ACTION UNDER CAFA

Joining a circuit split, the Ninth Circuit Court of Appeals has determined that a state *parens patriae* action is not removable to federal court as a mass action under the Class Action Fairness Act (CAFA). ***Nevada v. Bank of Am. Corp.*, No. 12-15005 (9th Cir., decided March 2, 2012)**. The issue arose in a case brought by Nevada through its attorney general alleging that the defendants misled the state's consumers about the terms and operation of their home mortgage modification and foreclosure processes. The defendants moved the action to federal court under CAFA's "class

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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action" or "mass action" provisions. The federal district court refused the state's motion to remand on the ground that the matter was a class action, and the state appealed.

Because the Ninth Circuit determined that a *parens patriae* action is not a class action removable under CAFA in another case after the district court issued its contrary ruling, the appeals court rejected this basis for removal at the outset. Noting that it had "not yet had occasion to decide whether a state's *parens patriae* action is removable as a mass action," the Ninth Circuit explored Fifth and Seventh circuit cases reaching "conflicting results" on the question. According to the court, "the characterization of this case as a 'mass action' thus turns on whether the State of Nevada or the hundred-plus consumers on whose behalf it seeks restitution are the real party(ies) in interest," because this determination affects CAFA's numerosity and minimal diversity requirements.

Examining the "essential nature and effect of the proceeding as it appears from the entire record," the court concluded that the state was the real party in interest. Nevada brought the suit under specific statutory authority to address issues raised by a mortgage crisis that had devastated the state. While the attorney general "tacked on a claim for restitution," its "sovereign interest in protecting its citizens and economy from deceptive mortgage practices" was not thereby diminished, given that any award would first be paid to the state and then distributed to individual consumers. Other relief requested strengthened the court's finding that the state had a distinct interest in the litigation; the state sought (i) the enforcement of a consent judgment, (ii) civil penalties not available to individual consumers, (iii) injunctive relief, and (iv) recoupment of the costs of investigating the defendants' practices.

FEDERAL COURT ANALYZES 1ST AMENDMENT IMPLICATIONS OF FDA QUALIFIED HEALTH CLAIMS PROCESS

A federal court in Connecticut recently determined that part of a disclaimer required by the Food and Drug Administration (FDA) as a modification to qualified health claims made for a green tea product impermissibly burdened more speech than necessary under the First Amendment. *Fleminger, Inc. v. HHS*, No. 10-855 (U.S. Dist. Ct., D. Conn., decided February 23, 2012). So ruling, the court granted in part and denied in part both parties' motions for summary judgment.

The company had sought authorization from FDA to claim that "Daily consumption of 40 ounces of typical green tea containing 710 µg/ml of natural (-) –epigallocat-echin gallate (EGCG) may reduce the risk of certain forms of cancer. There is scientific evidence supporting this health claim although the evidence is not conclusive." FDA determined that the scientific evidence did not adequately support this claim and proposed qualified health claims that specifically referred to the weakness of the

applicable studies and also stated "FDA concludes that it is highly unlikely that green tea reduces the risk of breast cancer" and "FDA concludes that it is highly unlikely that green tea reduces the risk of prostate cancer." The company sought reconsideration, and its petition was denied. The company then marketed its product for several years with the following representation: "Green tea may reduce the risk of cancer of the breast and prostate. The FDA has concluded that there is credible evidence supporting this claim although the evidence is limited."

FDA warned the company that these representations violated the Food, Drug, and Cosmetic Act and said it would approve the following statement: "Green tea may reduce the risk of breast or prostate cancer. FDA does not agree that green tea may reduce the risk because there is very little scientific evidence for the claim." Exploring the statutory and constitutional dimensions of the agency's health-claims enforcement authority, the court determined that the "very little scientific evidence" part of the disclaimer "strikes a reasonable fit between the government's ends and the means chosen to accomplish those ends." The court disagreed with FDA, however, that the statement "FDA does not agree that green tea may reduce that risk" was appropriate under the First Amendment, because it "effectively negates the substance-disease relationship claim altogether." The court remanded the matter to FDA "for the purpose of drafting appropriate disclaimers consistent with this Memorandum Opinion."

The court disagreed with FDA, however, that the statement "FDA does not agree that green tea may reduce that risk" was appropriate under the First Amendment, because it "effectively negates the substance-disease relationship claim altogether."

BULLDOZER ROLLOVER VERDICT UPHELD, JURY PROPERLY INSTRUCTED ABOUT SAFETY CODE PROVISION

The Eighth Circuit Court of Appeals has affirmed a jury verdict and directed verdict in favor of the company that manufactured a bulldozer which allegedly caused a plaintiff's injuries when it rolled over on a steep bank. ***Linden v. CNH Am., LLC*, No. 11-1984 (8th Cir., decided March 14, 2012)**. The plaintiff had alleged that its seat belt was defective in design, manufacture and warnings.

Among other matters, the plaintiff argued on appeal that the trial court erred by instructing the jury about the relevance of an industry safety code, i.e., "You have received evidence of SAE J386. Conformity with the provisions of a safety code is evidence that Defendant CNH was not negligent and non-conformity is evidence that Defendant CNH was negligent. Such evidence is relevant and you should consider it, but it is not conclusive proof." The plaintiff contended that the instruction was erroneous because evidence was lacking that SAE J386 was a safety code. According to the court, Iowa law directs that either a "safety code" or "custom" may be considered by a factfinder when assessing a manufacturer's negligence. Thus, "[e]ven if SAE J386 is more properly termed a 'custom' instead of 'safety code,' the instruction still fairly and adequately characterizes Iowa products liability law."

The court also rejected the plaintiff's claim that SAE J386 could not set a standard for seat belts made more than 10 years earlier and stated, "the instruction does not invite the jury to view evidence relating to the J386 standard through the limited lens offered by Linden. Instead, the instruction correctly informs the jury that it may take into consideration CNH's compliance with an industry standard in determining whether CNH acted negligently."

NO CLASS CERTIFICATION FOR DEFECTIVE PRINTER LAWSUIT AND NO ADVISORY OPINION

A federal court in California has denied a plaintiff's motion to certify a nationwide class of purchasers of a purportedly defective printer and further declined to issue an advisory opinion that would rule on class-certification elements not addressed by controlling Ninth Circuit authority "in order to guide the parties and create a record for any eventual appeal." *Kowalsky v. Hewlett-Packard Co.*, No. 10-02176 (U.S. Dist. Ct., N.D. Cal., San Jose Div., decided March 14, 2012).

The Ninth Circuit had reversed certification of a nationwide class in which other plaintiffs also asserted claims under California's Unfair Competition Law and Consumers Legal Remedies Act, finding that "each class member's consumer protection claim should be governed by the consumer protection laws of the jurisdiction in which the transaction took place, [and] variances in state law overwhelm common issues and preclude predominance for a single nationwide class." *Mazza v. Am. Honda Motor Co., Inc.*, 666 F.3d 581 (9th Cir., Jan. 12, 2012). According to the California district court, *Mazza* was binding, but the court denied the motion without prejudice to give the plaintiff the opportunity to file an amended complaint to comply with the Ninth Circuit's ruling.

The court refused to reach any other class certification issues because "any discussion of the other class certification requirements or the suitability of Plaintiff and his counsel as Class Representative and Class Counsel would not be necessary for the determination of Plaintiff's Motion for Class Certification."

ALABAMA SUPREME COURT REVERSES PART OF VERDICT AGAINST OFF-ROAD VEHICLE PLAINTIFFS

The Alabama Supreme Court has determined that a trial court erred by entering a judgment as a matter of law at the close of evidence on a couple's wantonness claim against the company that manufactured an off-road vehicle in which the wife sustained injuries during a rollover accident. ***McMahon v. Yamaha Motor Corp., U.S.A.*, No. 1100679 (Ala., decided March 2, 2012)**. Because the court found that the plaintiffs "produced substantial evidence to support their wantonness claim" and thus that it should have been submitted to the jury, the court reversed the verdict and remanded for further proceedings.

The court rejected the plaintiffs' argument that the trial court also erred in entering a judgment on their negligence claim, finding any error harmless because "the jury's verdict on their AEMLD [Alabama Extended Manufacturer's Liability Doctrine] claim establishes that their negligence claim would have been unsuccessful as well." Under Alabama law, proving negligence in products liability cases apparently placed an "almost impossible burden" on some plaintiffs, so the court adopted AEMLD in 1976 to lighten that burden.

According to the court, "a plaintiff pursuing a products-liability claim against a manufacturer under either theory can succeed only if the plaintiff establishes that the product at issue is sufficiently unsafe so as to render it defective. In an AEMLD case, this is done by proving that a safer, practical, alternative design was available to the manufacturer at the time it manufactured the allegedly defective product. Once established, that is sufficient to succeed on the AEMLD claim. In a negligence case, the plaintiff must establish not only that the product at issue is defective, but also that the manufacturer failed to exercise due care in the product's manufacture, design, or sale."

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The jury's verdict on the AEMLD claim demonstrated either that the plaintiffs failed to establish that the off-road vehicle was an unsafe product or that the defendants successfully established that the accident was the result of the wife's contributory negligence. "Either conclusion would have required a verdict in favor of the Yamaha defendants on the McMahons' negligence claim as well if that claim had been submitted to the jury," the court said. A concurring and dissenting justice would have added to the analysis that this verdict also "could have been the result of a finding of an assumption of the risk on Jacklyn's part."

TENNESSEE HIGH COURT AGREES TO REVIEW PREEMPTION ISSUE IN SHUTTLE BUS ACCIDENT CASE

According to a news source, the Tennessee Supreme Court has agreed to hear a personal injury case involving whether federal safety standards on window glazing and seat belts in large buses preempt state-law claims that the manufacturer of a shuttle bus involved in an accident should have installed seat belts and used a different type of glass. *Lake v. The Memphis Landsmen LLC*, No. W2011-00660-SC-R11-CV (Tenn., order granting appeal entered March 6, 2012). The breadth of the U.S. Supreme Court's preemption ruling in *Williamson v. Mazda Motor of Am. Inc.*, 131 S. Ct. 1131 (2011), is apparently at issue. In *Williamson*, the Court determined that a federal motor vehicle safety standard, which gave manufacturers a choice of seat belts to install for rear-seat passengers, did not impliedly preempt a claim based on a minivan manufacturer's use of a lap-only seat belt in a rear seat. Additional

information about *Williamson* appears in the March 3, 2011, **issue** of this *Report*. *See Bloomberg BNA Product Safety & Liability Reporter*, March 13, 2012.

ALL THINGS LEGISLATIVE AND REGULATORY

CPSC Publishes Data on One-Year Anniversary of Product Incident Report Database

Marking the first anniversary of its launch of a consumer products safety information Website, the Consumer Product Safety Commission (CPSC) has **indicated** that 6,600 consumers reported product-related incidents in the first year and has released other statistics about the types of products that generated the most reports. Apparently, kitchen products, such as ranges or ovens, dishwashers, refrigerators, microwaves, and electric coffee makers, were responsible for 36 percent of the consumer product-incident reports. CPSC also noted that the agency is working with software developers to create mobile apps, devise scanners and build search tools that will integrate SaferProducts.gov reports with online product reviews.

While consumer safety advocates continue to support the database, which was designed to serve as an early-warning system for potentially dangerous products, industry interests, concerned about accuracy and their reputations, continue to criticize certain parts of the reporting system. They reportedly contend that the posting procedures are inadequate to ensure that material inaccuracies are not published.

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A case filed by an anonymous company seeking to stop CPSC from posting an incident report about one of its products remains pending under seal in a federal court in Maryland. *See Bloomberg BNA Product Safety & Liability Reporter*, March 12, 2012.

Warning Issued About Discount Resale of Recalled Products

The Consumer Product Safety Commission (CPSC) recently issued a **consumer warning** about recalled products sold by discount retailers, dollar stores, liquidation companies, flea markets, and thrift stores. While the recalling companies fully complied with the terms of the original recall, the items "were improperly disposed of by offering them for sale" by discounters. The products include baby slings, toys, a vacuum cleaner, and infant teethers. Most of the products were recalled in 2010 and originally sold by a Midwestern retailer that also complied with the recall.

FDA Issues Draft Guidance on Direct-to-Consumer TV Ads for Prescription Drugs

The Food and Drug Administration (FDA) has issued **draft guidance** for industry titled "Direct-to-Consumer Television Advertisements—FDAAA DTC Television Ad Pre-Dissemination Review Program." Comments are requested by May 14, 2012, to ensure consideration before the final draft is prepared. The guidance "is intended

to assist sponsors of human prescription drug products, including biological drug products, who are subject to the pre-dissemination review of television advertisements (TV ads) provision of the Federal Food, Drug, and Cosmetic Act." The guidance addresses "which TV ads FDA intends to made subject to this provision, explains how FDA will notify sponsors that an ad is subject to review under this provision, and describes the general and center-specific procedures sponsors should follow to submit their TV ads to FDA for pre-dissemination review."

Report Claims High Levels of Toxic Chemicals Found in Inexpensive Jewelry

The Ecology Center, a Michigan-based environmental group, has released a **study** asserting that more than half of the low-cost children's and adult jewelry it recently tested presented a "high" level of concern because the products contained at least one hazardous chemical. Using an X-ray fluorescence analyzer, researchers tested 99 pieces of jewelry from 14 retailers in six states—Massachusetts, Michigan, Minnesota, New York, Ohio, and Vermont. They looked for chemicals including lead, cadmium, arsenic, mercury, bromine, and chlorine (PVC), which "have been linked in animal and some human studies to acute allergies and to long-term health impacts such as birth defects, impaired learning, liver toxicity, and cancer," according to the group's Website, HealthyStuff.org.

Researchers found that overall (i) 59 percent (58 products) rated as a high level of concern because they contained one or more hazardous chemicals or metals at high levels; (ii) 27 percent (27 products) contained more than 300 parts per million (ppm) lead, exceeding the Consumer Product Safety Commission's limit of lead in children's products; (iii) 10 percent (10 products) contained more than 100 ppm cadmium in one or more component; (iv) 13 percent (12 products) contained greater than 100 ppm arsenic; (v) 5 percent (5 products) contained more than 100 ppm mercury; (vi) 7 percent (7 products) contain brominated flame retardants with greater than 1,000 ppm bromine; and (vii) 12 percent (11 products) contained PVC greater than 25,000 ppm chlorine.

"There is no excuse for jewelry, especially children's jewelry, to be made with some of the most well studied and dangerous substances on the planet," said Ecology Center Research Director Jeff Gearhart.

"There is no excuse for jewelry, especially children's jewelry, to be made with some of the most well studied and dangerous substances on the planet," said Ecology Center Research Director Jeff Gearhart. Urging manufacturers to immediately start replacing these chemicals with non-toxic substances, the group is calling for lawmakers to overhaul the Toxics Substances Control Act, the federal law that regulates chemicals in commerce, by supporting the Safe Chemicals Act (S. 847) introduced in 2011. *See HealthyStuff.org Press Release,* March 13, 2012.

Minnesota Governor Signs Tort Reform Bill

Minnesota Governor Mark Dayton (DFL) has signed legislation (**S.F. No. 1183**) that limits the tort liability of the state and its employees for "any number of claims arising out of a single occurrence, if the claim involves a nonprofit organization

engaged in or administering outdoor recreational activities funded in whole or in part by the state or operating under the authorization of a permit issued by an agency or department of the state."

Approved by the legislature with near-unanimous support, the bill restores tort liability limits in those cases to pre-2008 levels. The new law caps Minnesota's liability at $1 million and limits municipalities' liability for punitive damages to $1 million under similar circumstances. Dayton previously vetoed a number of tort-reform measures; further details appear in the February 23, 2012, **issue** of this *Report*. *See Star Tribune*, March 15, 2012.

Civil Case Filings in Federal District Courts Increased Again in 2011

The Administrative Office of the U.S. Courts has released a **caseload statistics report** showing that federal district court cases increased in fiscal year 2011 in probation and pretrial sectors, while appellate and bankruptcy courts saw slightly decreased caseloads.

Titled "2011 Judicial Business of the United States Courts," the 409-page report indicates that civil appeals "held relatively steady, falling by 207 to 30,733," while civil case filings "grew 2 percent for the second consecutive year, up 6,357 cases to 289,252."

According to the report, filings in regional courts of appeals fell 1.5 percent to 55,126, and original proceedings in civil appeals also decreased. Noting that the "median time from filing of a notice of appeal or docket date to final disposition fell from 11.5 months to 11 months," the report said that since 2007, appeals court filings have declined 6 percent—down 3,284 appeals.

In addition, the data show that civil case terminations declined 2 percent to 303,158. "The Eastern District of Pennsylvania terminated 59,375 cases, most of them multi-district litigation (MDL) personal injury/product liability cases involving asbestos," the report states. It noted that the "median time from filing to disposition for civil cases was 7.3 months, down from 7.6 months in 2010." *See Administrative Office of the U.S. Courts Press Release,* March 13, 2012.

LEGAL LITERATURE REVIEW

Michael Sant'Ambrogio & Adam Zimmerman, "The Agency Class Action," *Columbia Law Review* (forthcoming 2012)

Assistant Law Professors Michael Sant' Ambrogio and Adam Zimmerman suggest in this paper that federal agencies adopt the same types of aggregate or class action procedures available to the courts to address problems inherent in administrative decisionmaking, including wasting resources on repetitive cases, reaching inconsistent decisions for the same kinds of claims and denying individuals access

to affordable representation. Noting that some types of claims, such as false advertising and defective drugs, are already brought by agencies on behalf of large groups of allegedly injured individuals who may receive a monetary award, the authors observe that "restitution cases fail to include aggregation procedures to ensure that victims participate in their own redress, to police conflicts of interest, or to compensate parties efficiently and consistently with their own injuries." Contending that current administrative law tools cannot adequately meet increasing demands on agencies' adjudicatory processes, the article recommends the adoption of "rules from private class action litigation to better resolve disputes within a public agency."

LAW BLOG ROUNDUP

Republican House Members Focus on Tort Reform in "Obamacare" Repeal Bill

"You can never be too rich or too thin, and apparently you can never get enough 'tort reform,' either." St. Thomas University School of Law Associate Professor Patricia Hatamyar Moore, blogging about the addition of tort reforms, such as a cap on noneconomic damages, a shorter limitations period, elimination of joint and several liability, reduced contingency fees, and limitations on punitive damages, to a House bill that previously had bipartisan support and would have repealed a portion of the health care reforms enacted in 2009. Despite the loss of Democrats' support, the proposal is expected to pass the House.

Civil Procedure & Federal Courts Blog, March 16, 2012.

The Costs of Privately Produced Technical Public Safety Standards

"Did you know that vital parts of the US law are secret, and you're only allowed to read them if you pay a standards body thousands of dollars for the right to find out what the law of the land is?" Public domain advocate and author Carl Malamud, writing a guest post to discuss the voluntary consensus standards that "govern and protect a wide range of activity, from how bicycle helmets are constructed to how to test for lead in water to the safety characteristics of hearing aids and protective footwear." Malamud's foundation, Public.Resource.Org has apparently purchased copies of 73 standards at a cost of nearly $7,500, and it intends to duplicate them "because citizens have the right to read and speak the laws that we are required to obey and which are critical to the public safety."

"Did you know that vital parts of the US law are secret, and you're only allowed to read them if you pay a standards body thousands of dollars for the right to find out what the law of the land is?"

Boing Boing, March 19, 2012.

More on the Costs of Privately Produced Technical Public Safety Standards

"Do the organizations that set these technical standards usually know when they create them that they are likely to be incorporated by reference into law?"

Brooklyn Law School Professor Adam Kolber, responding to Carl Malamud's guest post (above). A comment posted by Emily Bremer responded affirmatively and indicated that the Administrative Conference of the United States, where she serves as attorney advisor, recently adopted a recommendation that agencies work with standards development bodies to use "technological tools, such as read-only access, to improve the public availability of standards without destroying the value of the copyright."

PrawfsBlawg, March 20, 2012.

THE FINAL WORD

Tort Reform and Illinois Asbestos Litigation Spur Debate

Shook, Hardy & Bacon Public Policy Partner **Mark Behrens** was quoted in a recent article in response to the claims of plaintiffs' counsel that defendants are trying to manipulate the system in Madison County, Illinois, asbestos cases. While defense interests claim that current rules deprive them of the right to show comparative fault before trial, plaintiffs' lawyers contend that defendants use information about prior awards to asbestos claimants in a way to limit their own liability. According to Behrens, it is plaintiffs' attorneys who "are gaming the system. He observed that they delay the filing of claim forms with bankruptcy trusts until after a civil suit goes to the jury. "The (bankruptcy trust) claim form is one tool to get evidence as to what products the plaintiffs have been exposed. But the plaintiff's counsel does not want to share this information with the jury, Behrens said." *See LegalNewsline.com*, March 16, 2012.

UPCOMING CONFERENCES AND SEMINARS

ABA, Phoenix, Arizona – March 28-30, 2012 -- "2012 Emerging Issues in Motor Vehicle Products Liability Litigation." Shook, Hardy & Bacon Tort Partners **Robert Adams** and **H. Grant Law** join a distinguished faculty discussing an array of topics relating to motor vehicle litigation and products liability law during this 22nd annual national CLE program. Adams will present on "Communicating with the Modern Juror at Trial," and Law will serve as co-moderator of a panel addressing the topic, "An Automobile Is Only as Good as the Sum of Its Parts: The Component Parts Panel."

Shook, Hardy & Bacon Tort Associate **Amir Nassihi**, who is serving as conference co-chair, will join several panels to discuss "The Rise and Fall of the Consumer Expectations Test" and "The Blockbuster Developments in Class Action Litigation." He will also participate as co-moderator of a panel discussion addressing "Managing and Developing the Corporate Counsel Relationship: The Inside View on Diversity, Retention and Client Expectations." Shook, Hardy & Bacon is a conference co-sponsor.

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PRODUCT LIABILITY LITIGATION REPORT

MARCH 22, 2012

ABA Section of Litigation, Washington, D.C. – April 18-20, 2012 – "Annual CLE Conference. Shook, Hardy & Bacon Tort Partner **John Barkett** is serving as chair of this year's American Bar Association (ABA) event, scheduled for April 18-20, 2012, in Washington, D.C. With 200 distinguished speakers participating in 45 CLE programs and seven networking sessions, this conference promises to be a "premier event for litigators." Shook, Hardy & Bacon is a conference co-sponsor.

ABA, Beijing, China – April 19, 2012 – "Doing Business in the United States: What You Need to Know About Investing, Product Liability and Dispute Resolution." As a Premiere Sponsor for this program, presented in conjunction with the China Council for the Promotion of International Trade and the American Chamber of Commerce, Beijing, Shook, Hardy & Bacon will also moderate and present during the event. Employment Litigation Partner **William Martucci** will serve on a panel discussing "Operations in the United States and Compliance with United States Employment and Labor Laws." Global Product Liability Partner **H. Grant Law** will serve as the moderator of a program session focusing on "Minimizing Exposure for Product Liability." Pharmaceutical & Medical Device Litigation Chair **Madeleine McDonough** will introduce U.S. agency officials with the Consumer Product Safety Commission (CPSC) and Food and Drug Administration (FDA) and provide an overview of "The United States Regulatory Landscape: Focusing on the CPSC and the FDA."

FDLI, Washington, D.C. – April 24-25, 2012 – "55th Annual Conference." Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partner **Michelle Mangrum** will be serving as a breakout session moderator. This session, the "FDA Center Directors Roundtable," features representatives from each of the Food and Drug Administration's (FDA's) six product centers discussing "the three most important developments from the last year and their three most important goals in 2012." Mangrum's panel will focus on Center for Drug Evaluation and Research (CDER) issues and include CDER Director Janet Woodcock and a Novartis Pharmaceuticals Corp. representative.

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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).