Shook, Hardy & Bacon L.L.P.

Product Liability Litigation Report

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MIXED DECISIONS REACHED ON PUNITIVE DAMAGES IN CIGARETTE LAWSUITS

The Oregon Supreme Court has upheld a $79.5 million punitive damages award against Philip Morris, finding that it could be justified on grounds other than those that caused the U.S. Supreme Court to twice overturn it. ***Williams v. Philip Morris, Inc.*, SC S051805 (Ore., decided January 31, 2008)**. The Oregon court focused its analysis on a jury instruction about punitive damages that Philip Morris asked the court to use. The court reasoned that where, as here, the trial court refuses to give a jury instruction proffered by a party, the reviewing court looks to see whether the proffered instruction is "correct respecting the rule of law stated in the instruction.… It is not enough, for example, to offer a proposed instruction that is correct in part and erroneous in part, leaving the trial court to solve the problem for itself."

According to the Oregon Supreme Court, the trial court did not err in refusing to give the multi-page punitive damages instruction proffered because it included both correct and incorrect statements of the law. The correct statements involved the issue before the U.S. Supreme Court, i.e., that juries may not use a punitive damages verdict to punish a defendant for harm allegedly caused to parties not before the court. *Philip Morris USA v. Williams*, 127 S.Ct. 1057 (2007). The punitive damages award the Oregon court upheld is nearly 100 times the compensatory award; the U.S. Supreme Court did not consider whether it was "grossly excessive" under the U.S. Constitution's Due Process Clause.

An appeals court in California, on the other hand, has reversed a punitive damages award in a smoking and health case, because the trial court erred when it refused Philip Morris's proposed jury instruction which stated "You are not to impose punishment for harms suffered by persons other than the plaintiff before you." *Bullock v. Philip Morris USA, Inc.*, Nos. B164398 & B169083 (Cal. Ct. App., 2d App. Dist., Div. 3, decided January 30, 2008). The jury in this case had awarded the plaintiff $28 billion in punitive damages, but that was later reduced to $28 million when the court conditioned its grant of a new trial motion on the plaintiff's agreement to reduce the award. The court discussed the U.S. Supreme Court's decision in *Philip Morris USA v. Williams*, 127 S.Ct. 1057 (2007), and found that it made the proposed instruction a correct statement of the law. Because the court could not "determine how the instructional error that

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we have found affected the amount of the punitive damages award," the court decided to remand the case for a new trial limited to the amount of punitive damages to be awarded.

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PLAINTIFFS' LAWYERS FILE MOTION TO INCLUDE 300 FLORIDIANS IN VIOXX® SETTLEMENT

Plaintiffs' lawyers have reportedly filed a motion in federal court to include 300 Floridians in a $4.59 billion Vioxx® settlement, despite failing to file suit before both sides reached an agreement on November 9, 2007. The Florida lawyers allege that they submitted a list of clients who had not yet filed suit to the plaintiffs' steering committee, which negotiated the settlement with drug-maker Merck & Co., but were not informed of a pending deal. As a result, hundreds of people were left out of the agreement, notwithstanding Florida's four-year statute of limitations which gives plaintiffs until September 30, 2008, to file claims. "They didn't want people running out and getting new cases. I agree with that," said Jacksonville, Florida, lawyer Norwood Wilner in response to Merck's opposition to redrafting the agreement. "But what they obviously overlooked was a few states have four-year statutes, Florida included."

The plaintiffs' steering committee, however, has apparently backed the settlement terms, countering that the committee agreed only to share information with lawyers, not to represent or take on new clients. Moreover, if the motion is successful, it could affect cases in other states, including North Dakota, Minnesota and Wyoming, with longer statutes of limitations that had not expired when the deal was finalized.. "They want to play it out, not file suits, not spend money. When cases get resolved, they want to jump on the bandwagon," said Russ Herman, the spokesperson for the plaintiffs' steering committee. *See Associated Press,* January 29, 2008.

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ALABAMA CHANGES TIME-TO-FILE RULE IN TOXIC EXPOSURE CASES

The Alabama Supreme Court has agreed to allow wrongful death claims to proceed in a toxic exposure case that would have been time-barred had the court not decided to overturn prior case law. ***Griffin v. Unocal Corp.*, No. 1061214 (Ala., decided January 25, 2008)**. The suit was filed by the wife of a man who had occupational exposure to benzene, benzene derivatives, rubber solvents, formaldehyde, and other chemicals from 1973 to 1993. He was diagnosed in 2003 with acute myelogenous leukemia and died five months later. The wrongful death lawsuit was brought against the chemical manufacturers less than two years after his death.

The trial court dismissed the complaint, because Alabama law required those injured from toxic exposures to file their claims within two years of the date of last exposure. If injury or disease did not manifest in that time, plaintiffs were essentially denied any remedy for injury occurring thereafter, a dilemma the justices recognized in other cases. The court adopted as its rationale a

dissenting opinion from another case that proposed a new accrual rule in toxic exposure cases and would have allowed lawsuits occurring beyond the two-year "last exposure" window. The court stated that "the date of last exposure rule" is no longer the law in Alabama. So ruling, the court decided to apply its decision to the present case, but otherwise limited its application to future claims. Three dissenting justices accused the majority of improperly exercising legislative powers.

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TOY MANUFACTURER AGREES TO SETTLE LEAD CLASS ACTION FOR $30 MILLION

An Illinois state court has reportedly given preliminary approval to a class-action settlement in a case involving recalled toys that allegedly contained lead paint. Hundreds of thousands of consumers who purchased the Thomas & Friends railway toys made by RCRC will apparently be either reimbursed or offered a replacement and a bonus toy. The company also reportedly agreed to institute product safety improvements. According to a company spokesperson, such improvements have already been implemented and include more frequent testing of materials, more stringent standards for manufacturers and paint suppliers and random inspections and audits. Final approval of the settlement is expected in May 2008. *See USA Today*, January 22, 2008.

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LEAD POISONING FROM DINNERWARE ALLEGED IN NEW COMPLAINT

Alleging that their minor sons have been poisoned by lead leaching from dinnerware made by Martha Stewart Living Omnimedia, Inc., plaintiffs Raymond and Sandra Jo Dombroski filed a products liability complaint against the manufacturer and its retailers in a Pennsylvania federal court. *Dombroski v. Martha Stewart Living Omnimedia, Inc*, No. n/a (U.S. Dist. Ct., W.D. Pa., filed January 15, 2008). According to the complaint, the plaintiffs used the dinnerware from June 2001 until December 2006, and, while both sons were allegedly poisoned due to unsafe levels of lead, one has mental, emotional and cognitive impairment, as well as learning disabilities, social and other behavioral impairments, and pica. The plaintiffs allege negligence, strict liability for design defect and failure to warn, and breach of warranty. They seek compensatory and punitive damages, attorney's fees, costs, and interest.

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ALL THINGS LEGISLATIVE AND REGULATORY

EPA Launches Nanoscale Materials Stewardship Program

The Environmental Protection Agency (EPA) has implemented a program that invites those who manufacture or use nanoscale materials in their products to submit data including "information on material characterization,

hazard, use, potential exposures, and risk management practices." The agency's "Nanoscale Materials Stewardship Program" will have two phases. The first will run for six months, or until July 28, 2008, and the second, which will be developed based on information submitted during the first phase, will allow more in-depth data development and analysis. EPA expects to eventually develop a plan of action that could include (i) "Characterizing the physical/chemical properties of the material"; (ii) "Testing for health and environmental hazards"; and (iii) "Monitoring or estimating exposures and releases." According to the notice, EPA will use the data collected to better understand "the nature of nanoscale materials that are produced; the quantities in which they are produced; how they are or will be used; any hazards, exposures, or releases associated with those materials; and how these hazards are being addressed." *See Federal Register*, January 28, 2008.

Critics call the initiative too little too late and note that a similar program in the United Kingdom attracted few participants. A scientist with "green think tank Environmental Defense" was quoted as saying "EPA is simply 'kicking the can down the road' by shunning approaches that could have delivered needed information faster, and by opting instead to pursue an open-ended approach with no end in sight." *See Product Liability Law 360*, January 31, 2008.

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Public Citizen Blames CPSC and Manufacturers for Recall Delays

The consumer interest group Public Citizen has issued a **report** titled "Hazardous Waits: CPSC Lets Crucial Time Pass Before Warning Public About Dangerous Products," which claims that after learning of a product defect, the Consumer Product Safety Commission (CPSC) on average allows nearly seven months to elapse before issuing a recall. The study examined 46 settlement cases published in the *Federal Register* since 2002, finding that companies fined for tardy reporting also took an average of 2.7 years to notify regulators of dangerous product flaws. Public Citizen specifically faults some manufacturers for withholding "key details," including consumer product complaints, efforts to resolve design flaws and fatality reports. In addition, the study blames CPSC's apparent inaction on "the manufacturers' ability to sue the agency to block public disclosure of information about hazards."

The report recommends that lawmakers crafting reauthorization legislation should (i) "provide the CPSC with the freedom to inform the public about risks promptly"; (ii) grant authority to levy higher fines and seek criminal penalties"; (iii) "provide the CPSC with a significantly larger budget and staff"; and (iv) "give state attorneys general broader enforcement powers." "There's no excuse for manufacturers waiting nearly three years before telling the CPSC about a defective product that can kill people – or for the CPSC to take another seven months to negotiate a recall and warn the public," said Public Citizen President Joan Claybrook. "Manufacturers now have the power to hamstring the agency. Given these inordinate delays, the law must be changed to allow the agency to inform consumers and give it enough money, authority and enforcement muscle." *See Public Citizen Press Release,* January 31, 2008.

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In a related development, CPSC Acting Chair Nancy Nord has announced several initiatives aimed at improving product safety. Speaking at the National Press Club in Washington, Nord reportedly noted that because many of the

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15,000 products regulated by the agency are made overseas, CPSC plans to focus resources on retailers, in addition to manufacturers, if Congress passes pending product-safety legislation. The proposed strategy would require retailers to ensure that products for sale have been tested and certified for safety, since U.S.-based merchants have "the ultimate responsibility to make sure that their products are safe and if they do not, [CPSC] will take enforcement activity at the product sellers," according to Nord. CPSC also intends to extend inspections of imported goods using funds recently appropriated by Congress. Some critics, however, have voiced concern that focusing on retail establishments could take the onus off manufacturer reporting. "The primary responsibility has to fall on the manufacturer," a spokesperson for the National Retail Federation was quoted as saying. "Our view is that the most effective point to enforce and determine safety is at the point of manufacture. It is too late at the point of sale." *See The Washington Post,* January 7, 2008; *The Wall Street Journal,* January 8, 2008.

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Meanwhile, the White House is apparently considering a scientist to fill the CPSC lead position, which Nord has held since former chair Harold Stratton stepped down in July 2006. After the previous nominee, Michael Baroody, failed to win Senate approval, Bush administration officials have purportedly turned to Gail Charnley, an industry consultant who holds a doctorate in toxicology from the Massachusetts Institute of Technology. Charnley has also served on several National Academy of Sciences committees and as director of its toxicology program in the mid-1990s. Other potential candidates include Jacqueline Glassman, a former deputy administrator at the National Highway Traffic Safety Administration; and John Kupsch, the former technical director of *Good Housekeeping* magazine's product-testing arm. Democrats have called for Nord's resignation based on her alleged industry ties, including free trips worth thousands of dollars, as well as her initial opposition to provisions in a 2007 Senate bill that would have increased the agency's recall authority and raised the current $1.8 million penalty to $100 million for manufacturers who fail to report hazards. *See The Washington Post,* January 26, 2008.

Lawmakers Challenge FDA Proposed Rule on Drug Labeling

A group of lawmakers led by U.S. Representative Henry Waxman (D-Calif.) and U.S. Senator Edward Kennedy (D-Mass.) have sent a letter to the Food and Drug Administration (FDA) asking that the agency reconsider a proposed drug labeling rule. The rule would amend current regulations permitting companies to update their drug and medical device labels to add or strengthen contraindication, warning, precaution, or adverse reaction information without waiting for agency approval. Looking to codify "the agency's long-standing view" on these types of labeling changes, the proposal specifically aims to "clarify that such a supplemental application may be used to add or strengthen a contraindication, warning, precaution, or adverse reaction only if there is sufficient evidence of a causal association." According to the lawmakers' letter, these changes are "apparently designed to bolster the argument by companies defending against lawsuits that the regulations precluded them from adding contraindications, warnings, precautions, and adverse reactions in the absence of FDA approval, whereas under FDA's current regulations, it is clear they would have been free to do so."

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Expressing concern that such a revision would shield pharmaceutical and medical device makers from legal liability, the eight congressional Democrats who authored the letter have also asked FDA to supply data on the number of "changes being effected" (CBE) supplements submitted since 1982 and to describe any cases in which a company's move to strengthen warning language resulted in consumer harm. The legislators have argued that the proposed rule would delay the release of vital information, citing as an example Merck & Co's 14-month struggle with FDA to effect a labeling change for Vioxx®, a drug later recalled over safety concerns. "At a time when the FDA lacks the resources to adequately protect Americans from unsafe drugs and devices, it is astonishing that the Bush administration has opted to dedicate the FDA's strained resources to protecting the drug and device industry from liability for marketing dangerous products," the authors concluded. *See Product Liability Law 360,* January 25, 2008.

GAO Testifies About FDA's Ability to Inspect Medical Device Makers

The Government Accountability Office (GAO) recently provided **testimony** before a House Energy and Commerce subcommittee about the Food and Drug Administration's (FDA) ability to ensure the manufacturing quality of medical devices. According to the GAO, FDA inspectors are unable to meet the agency's biennial inspection requirement for U.S. manufacturing facilities. They apparently inspect high-risk device makers once every three years and medium-risk device makers once every five years. Foreign establishments are visited once every six years for high-risk devices or 27 years for medium-risk devices. Nor have third-party inspection programs taken up the slack.

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"The small number of inspections completed to date by accredited third-party organizations raises questions about the practicality and effectiveness of establishing similar programs that rely on third parties to quickly help FDA fulfill its responsibilities," according to GAO's testimony summary. GAO Director of Health Care Marcia Crosse concluded that "FDA's ability to fulfill its regulatory responsibilities is jeopardized, in part, by information technology and human resources challenges." According to a news source, the Subcommittee on Oversight and Investigations is exploring a broad range of issues relating to FDA's ability to meet its statutory responsibilities. *See The Wall Street Journal*, January 29, 2008.

Meanwhile, FDA Commissioner Andrew von Eschenbach has reportedly indicated that the agency is considering opening offices in U.S. embassies around the world in an effort to better ensure the safety of imported products. The plan would apparently target five regions – Asia, Europe, Central and South America, and the Middle East – and could involve establishing closer ties to foreign government counterparts and instituting inspection and certification programs. *See Health Law 360*, January 28, 2008.

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Deadline Nears for Comments on Changes to Federal Appellate Rule Amendments

Public comments on the latest proposed amendments to the Federal Rules of Appellate Procedure must be submitted by February 15, 2008. One proposed **change** that has generated interest in the legal community concerns

the way filing deadlines are calculated. The current rules apply different methods depending on whether the specific deadline is short or long. Ten-day deadlines, for example, are calculated by omitting intervening holidays and weekends, while longer 30-day deadlines are calculated without omitting any intervening days. The proposed change would require all days to be counted regardless of the period's length, and some of the shorter deadlines would be lengthened. According to at least one commentator, extending the deadline for filing post-judgment motions to 30 days could affect "prematurely filed" notices of appeal by placing them in "suspended animation" until the district courts dispose of the post-judgment motions in a particular case. *See Law.com*, February 4, 2008.

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LEGAL LITERATURE REVIEW

Elizabeth Chamblee Burch, "CAFA's Impact on Litigation as a Public Good," *Cardozo Law Review* (forthcoming 2008)

This article starts with the premise that class-action litigation performs a public service in a number of ways, such as making "information about corporate products and practices publicly available," prompting policy changes with the threat of litigation, engendering a "private cadre of supplement regulators," establishing "rules of conduct that both delineate boundaries for acceptable social behavior and decrease the need for future lawsuits," and shaping "acceptable procedures for processing aggregate claims." Law Professor Elizabeth Chamblee Burch then describes how the Class Action Fairness Act of 2005 (CAFA) has impeded class-action litigation in the United States and thus "significantly" affected "class litigation's regulatory function." According to the author, "the most important effect from a consequentialist standpoint is that CAFA may weaken deterrence and inhibit litigation's use as ex post regulation."

Robert Goldberg, "*Insta-Americans*: The Empowered (and Imperiled) Health Care Consumer in the Age of Internet Medicine, *Center for Medicine in the Public Interest* (January 2008)

A non-profit with an educational mission has published an article that explores how the public is increasingly relying on the Internet to find information about health and medicine. Through case studies, the authors show that "the information prominently displayed in search engine results was not only misleading and confusing, but dangerous for patients." Apparently, "online real estate was dominated by Web sites paid for and sponsored by either class action law firms or legal marketing sites searching for plaintiff referrals. Other sites were sponsored by groups or individuals selling 'alternatives. With few exceptions, the information online was presented in a way that the sites appeared legitimate but had no medical authority whatsoever." The authors studied Google® search results for several drugs, including Crestor® and Avandia® and concluded that any positive safety data about the drugs can not readily be found online. They conclude that patients who could be helped with safe and effective drugs are being exposed to "overwhelmingly biased and misleading information" online. They suggest that patients be aware of the sources of online information and the "possible ulterior motives of site owners."

Through case studies, the authors show that "the information prominently displayed in search engine results was not only misleading and confusing, but dangerous for patients."

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Trevor Morrison, "The State Attorney General and Preemption," ***Preemption Choice: The Theory, Law, and Reality of Federalism's Core Question*** **(William Buzbee ed. forthcoming 2008)**

Cornell Law School Associate Professor Trevor Morrison discusses how the increasing preemption of state laws and regulations by federal agencies has affected the authority of elected state attorneys general to conduct their investigative and enforcement powers under state consumer protection and other laws. This article, which will appear as a chapter in a forthcoming compendium about federalism, or the balance between federal and state authority, suggests that the courts consider this effect as they weigh preemption issues coming before them. According to the author, the state attorney general is "a democratically accountable officer charged with safeguarding the public and, to that end, invested with broad-ranging authority to monitor compliance with state (and sometimes federal) laws and to initiate lawsuits and other enforcement actions when necessary." To the extent that federal law displaces "this institution in order to advance some overarching national regulatory goal, such displacement carries substantial costs." Morrison calls for Congress to take account of the state attorney general when legislating in areas with the potential for preemption and allow the preemption of "core investigative and enforcement work of state attorneys general only by express statutory language." This approach, according to the author, would best preserve significant federalism values.

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LAW BLOG ROUNDUP

The Public Administration of Private Mass Tort Claims?

"The evolved response of the civil justice system to mass torts has been to shift from litigation on the private-law model of tort law to something much more like public administration. Simply put, the endgame of mass tort litigation today is not trial but some form of comprehensive settlement – what lawyers on both sides describe, with only a smidgen of exaggeration, as 'global peace.'" Vanderbilt University Law School Professor Richard Nagareda, blogging about his latest book on mass tort settlements and explaining how legal institutions must change to reflect the shift from individual client representation to "the practical reality of peacemaking in the aggregate."

PointofLaw.com, January 28, 2008.

Mississippi Has Plaintiff's Lawyer to Thank for Reform Legislation

"One offshoot of the Scruggs scandal is a bill making its way through the state legislature that would require the state to go through a public bidding process before contracting with a private law firm." Attorney Robert Ambrogi, discussing legislation approved by Mississippi's Senate that would limit the ability of the state attorney general to hire private counsel to bring civil lawsuits. Richard

Scruggs was one such attorney who made millions suing cigarette manufacturers on the state's behalf; he has since been indicted on charges that he tried to bribe a state judge.

Legal Blog Watch, January 30, 2008.

Just Say No?

"The Court is going to be faced with the need to write a "No, this time we really mean it" reversal, or effectively undo its precedents in the area." Ted Frank, attorney and director, American Enterprise Institute Liability Project, commenting on the Oregon Supreme Court's decision to reinstate a punitive damages verdict that has twice been reversed by the U.S. Supreme Court.

PointofLaw.com, February 1, 2008.

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THE FINAL WORD

Tulane University Professor Conducts Review of Judicial Campaign Contributions

A Tulane University law professor has reportedly conducted a review of the campaign contributions made to elected justices sitting on the Louisiana Supreme Court, concluding that in nearly one-half of the cases sampled from a 14-year period, a litigant or lawyer had donated funds to at least one justice presiding over the matter. Vernon Valentine Palmer, who also directs the European legal studies program at Tulane, found that "[o]n average, justices voted in favor of their contributors 65 percent of the time, and two of the justices did so 80 percent of the time," according to a January 28, 2008, article by Adam Liptak, the "Sidebar" columnist for *The New York Times.* In this piece, Liptak dissects the ethical dilemma posed by judicial campaign contributions, noting the difficulty in determining whether a judge has been influenced by donations or whether contributors have simply supported a judge sympathetic to their legal philosophies and incidentally benefited from the judge's consistent application of these shared principles. To answer this question, Palmer's study establishes a baseline by examining how justices voted in cases where neither party donated campaign funds. As Liptak explains:

> Justice John L. Weimer, for instance, was slightly pro-defendant in cases where neither side had given him contributions, voting for plaintiffs 47 percent of the time. But in cases where he received money from the defense side (or more money from the defense when both sides gave money), he voted for the plaintiffs only 25 percent of the time. In cases where the money from the plaintiffs' side dominated, on the other hand, he voted for the plaintiffs 90 percent of the time. That is quite a swing.

"The Court is going to be faced with the need to write a "No, this time we really mean it" reversal, or effectively undo its precedents in the area."

"…[o]n average, justices voted in favor of their contributors 65 percent of the time, and two of the justices did so 80 percent of the time…"

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In addition, Palmer has alleged that "the greater the size of the contribution, the greater the odds of favorable outcomes." "It is the donation, not the underlying philosophical orientation, that appears to account for the voting outcome," he told Liptak, who also points to a similar study of the Ohio Supreme Court carried out by *The New York Times* in 2006.

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UPCOMING CONFERENCES AND SEMINARS

GMA, The Association of Food, Beverage and Consumer Products Companies, New Orleans, Louisiana – February 19-21, 2008 – "2008 Food Claims & Litigation Conference: Emerging Issues in Food-Related Litigation." Shook, Hardy & Bacon Product Liability Litigation Partner **Laura Clark Fey** and Pharmaceutical & Medical Device Litigation Partner **Paul La Scala** will discuss "Product Liability When There Is No Injury: The Deceptive Trade Practices Class Action. Shook, Hardy & Bacon is co-sponsoring this event.

Food & Drug Law Institute (FDLI) & FDA, Washington, D.C. – March 26-27, 2008 – "FDLI's 51st Annual Conference," Shook, Hardy & Bacon Pharmaceutical & Medical Device Partner **Madeleine McDonough** will serve on a panel discussing "Clinical Trials: Developments in Human Subject Protection." Other confirmed speakers include U.S. Supreme Court Justice Antonin Scalia, and Food & Drug Administration Commissioner Andrew von Eschenbach.

DRI, New Orleans, Louisiana – May 1-2, 2008 – "Drug and Medical Device Seminar," Shook, Hardy & Bacon Pharmaceutical & Medical Device Partner **Scott Saylor** will chair the program, and Pharmaceutical & Medical Device Litigation Partner **Marie Woodbury** will present a session titled "Crossing Borders and Seas – International Regulatory Events and Their Impact on United States-Based Litigations and Trials."

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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 its nearly 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).

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