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Product Liability Litigation Report

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FEDERAL COURT URGES STATE LEGISLATURE TO RECONSIDER STATUTE OF REPOSE IN DRUG CASES

A federal court in Tennessee has dismissed claims filed against a drug manufacturer because the plaintiff's cause of action did not accrue, i.e., injury did not manifest, until after it was extinguished by the state's statute of repose. *Montgomery v. Wyeth*, No. 1:05-CV-323 (U.S. Dist. Ct., E.D. Tenn., S. Div., decided March 19, 2008). Plaintiff alleged that she used defendant's diet drug in 1996 and 1997 and developed primary pulmonary hypertension (PPH) in 2005 as a result of taking the drug. She filed product liability claims later that year. After the case was removed to federal court, consolidated before an MDL court for pre-trial proceedings and returned to the originating federal district court, defendant filed a motion for summary judgment, invoking Tennessee's product-liability statute of repose. Under that law, claims must be brought within one year after the expiration of the anticipated life of the product, if that period is shorter than 10 years from the date on which the product was first purchased, which period also extinguishes product claims. Because the drug's latest expiration date would have been in 2000, Wyeth argued that plaintiff's claim had to be filed no later than 2001.

The court agreed with Wyeth, but noted the unfairness to plaintiff because she could not have filed her claims before injury occurred in 2005 and thus lost her right to sue even before she was allegedly injured. In this regard, the court stated, "this is one of those rare cases where the Court believes it is appropriate to urge the Tennessee legislature to look closely at the law governing this case." According to the court, five other states "have statutes of repose predicated on the life of a product, but unlike Tennessee, all those states allow lawsuits for harm that does not manifest itself until after the repose period. Tennessee's anticipatory life provision thus appears to be harshest of those statutes of repose, and in this case bars Plaintiff from bringing her claim for PPH." (citations omitted) The court rejected plaintiff's argument that the statute of repose should not apply because a class action settlement involving the drug preserved her right to sue for PPH, defendant waived its statute of repose defense, and, due to a conflict between the laws of Tennessee and Georgia, it would be appropriate to apply Georgia law to the case.

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APPEALS COURT OVERTURNS *DAUBERT* RULING ON WARNINGS EXPERT IN AUTO CASE

The Third Circuit Court of Appeals has ruled that a trial court erred in excluding the testimony of plaintiff's proffered expert who was retained to support his claims, including whether the warnings provided to an automobile technician, injured while repairing the rear liftgate glass of a sports utility vehicle, were adequate. ***Pineda v. Ford Motor Co.*, No. 07-1191 (3d Cir., decided March 24, 2008)**. Relying on the expert's *Daubert* hearing testimony that he was not a warnings expert, the trial court granted Ford's motion to exclude his testimony, finding him unqualified and his testimony unreliable. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). Without an expert to support his claims, plaintiff did not respond to defendant's motion for summary judgment, and it was granted.

The appeals court construed the expert qualification requirements of the Federal Rules of Civil Procedure liberally and found that the expert's education and experience with fracture mechanics far outweighed his single statement that he was not a warnings expert. While the expert "did not purport to opine on how the warning should be worded or how it should appear to effectively convey its message to an automobile technician," he knew enough about the engineering issues to testify that a warning was necessary to alert a technician to potential problems and that a proper warning "was a solution to an engineering problem under the safe-guarding hierarchy." The court also found that the expert could rely on a safety recall instruction that Ford issued after the vehicle at issue had been manufactured despite its inadmissibility, because Rule 703 permits an expert to rely on subsequently issued safety instructions or warnings "in forming an opinion that an earlier service manual fails to provide adequate instructions and warnings."

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TRIAL COURT ALLOWS CLAIMS INVOLVING GENERIC DRUGS TO PROCEED AGAINST NAME-BRAND MANUFACTURER

A Pennsylvania trial court has determined that under state law a name-brand drug manufacturer can be held liable for claims involving off-label marketing filed on behalf of purchasers of its generic equivalent. *Clark v. Pfizer, Inc.*, No. 1819 (Philadelphia County Ct. of Common Pleas, Pa., decided March 14, 2008). The named plaintiffs in the putative class action filed negligence, negligent misrepresentation, intentional misrepresentation, and warranty claims against the makers of Neurontin® purporting to represent all those who purchased the drug or its generic equivalent. They seek a refund for those prescriptions written for off-label uses not approved by the Food and Drug Administration (FDA).

Defendants sought summary judgment as to all claims involving purchases of the drug that they did not manufacture, i.e., the generic equivalent. The court granted judgment as to the warranty claims, but denied it as to all

other claims. Its opinion recites defendants' extensive alleged efforts to promote off-label use without FDA approval or scientific support and includes the criminal information to which defendant Warner-Lambert entered a plea agreement in a Massachusetts federal court. According to the court, "At least 200,000 prescriptions were written in Pennsylvania. Defendants earned between $53 [million] and $64 [million] on the drug per quarter in Pennsylvania alone."

The court articulated the question raised by defendants' motion for summary judgment as "whether under Pennsylvania Law, a drug company which negligently or intentionally perpetrates a fraud upon the medical community may be held responsible for sums paid to other drug manufacturers because of their misrepresentations." Because Pennsylvania courts have adopted those sections of the *Restatement (Second) of Torts* that allow a defendant to be held liable for misrepresentation to foreseeable plaintiffs even without any direct relation between the parties and because the medical literature allegedly manipulated by defendants often referred to the drug's generic chemical name, the court determined that "[t]he significant increased sale of generic Gabapentin was a foreseeable result of defendants actions in marketing Neurontin® for 'off-label' use."

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STATE HIGH COURT RULES PUNITIVE DAMAGES NOT INTENDED TO DETER NONPARTIES FROM WRONGDOING

The New Jersey Supreme Court has determined, in the context of a case involving sexual harassment in the workplace, that punitive damages may be awarded only to deter a specific defendant from engaging in similar wrongdoing in the future. ***Tarr v. Bob Ciasulli's Mack Auto Mall, Inc.*, No. A-19-07 (N.J., decided March 27, 2008)**. Apparently, the jury which had awarded the plaintiff $85,000 in punitive damages was instructed that it could enhance a punitive damages award against the defendant "to deter others from wrongdoing similar to defendant's." Construing the state's Punitive Damages Act and its legislative history, the court concluded that "while general deterrence remains inherent in the nature of exemplary damages, the Act does not permit counsel to urge the jury to increase a punitive damage award in order to enhance the general deterrence of others." The case was remanded for a new trial limited to a punitive damages determination.

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COURT ORDERS CABLE NETWORK TO PRODUCE UNAIRED FOOTAGE RELATED TO GROUT SEALER LITIGATION

A federal court in Georgia has ordered Cable News Network (CNN) to produce unaired footage from an interview it conducted with a plaintiff in litigation against the makers of a spray-on grout sealer alleged to have caused personal injury. *Flynn v. Roanoke Cos. Group, Inc.*, No. 1:06-CV-1809, No. MDL 1804 (U.S. Dist. Ct., N.D. Georgia, Atlanta Div., decided March 24, 2008). Plaintiff Walter Friedel testified during a deposition that he had appeared on a segment of CNN's *Anderson Cooper 360º* titled "Consumer Product Safety Commission Falling Down on the Job?" The segment apparently discussed complaints about the grout's safety.

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A defendant subpoenaed CNN, demanding "footage, raw and final, aired or unaired, of any interviews with Walter Friedel or any other witness relating to the Tile Perfect Stand 'n Seal 'Spray-On' Grout Sealer." CNN sought to quash the subpoena claiming it was entitled to a reporter's privilege and that it was protected by a state reporter's shield. While the defendant did not contest the fact that a qualified reporter's privilege applied, it argued that CNN should comply because the footage was relevant and could not be obtained by alternate means, and defendant had a compelling interest in the information. Relevance was claimed on three grounds: (i) the footage would fill gaps in the plaintiff's deposition testimony; (ii) the footage could support a contributory negligence defense because unaired portions showed Friedel demonstrating how he used the product; and (iii) the unaired footage would "yield probative evidence of how the product was actually used."

The court recognized the privilege, but because CNN had made no promises of confidentiality, ruled that the defendant was entitled to make a "lesser showing" of compelling interest than if confidential information were at issue. Finding that the minimal showing had been made under Georgia's shield law, the court granted in part and denied in part CNN's motion to quash. The motion was granted and access was blocked only to the extent that the subpoena covered footage that had nothing to do with Friedel. After the court ruled on CNN's motion, the cable news network made an oral request that the court conduct an *in camera* review of the footage. CNN subsequently filed a motion for reconsideration of its oral request, and the court denied the motion finding that CNN was simply trying to argue relevance, "arguments that it should have made in its Motion to Quash Subpoena."

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COURT DENIES DRUG COMPANY'S REQUEST FOR ACCESS TO MEDICAL JOURNALS' PEER REVIEW COMMENTS

According to a news source, a federal magistrate in Chicago, Illinois, has denied Pfizer Inc.'s request to access documents related to confidential comments made by peer reviewers regarding medical journal articles about its painkilling drugs. The ruling is apparently the subject of an editorial that will be published in the April 23/30, 2008, print edition of the *Journal of the American Medical Association* (*JAMA*). According to the journal's editor, the company's subpoena, issued in connection with litigation over the drugs, may be the first to seek confidential peer-review material from a medical journal. The editorial apparently notes that such material is confidential so that peer reviewers are able to "work in an unrestrained environment…. Producing any of these documents, with or without names, would seriously compromise the process and the trusting relationship among the editors, authors and reviewers." The magistrate has apparently rejected Pfizer's access to *JAMA* documents and material from the *Archives of Internal Medicine*, but has yet to rule on challenges to subpoenas involving the *New England Journal of Medicine. See The Wall Street Journal*, March 25, 2008.

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ALL THINGS LEGISLATIVE AND REGULATORY

Democrats to Introduce House Bill Reversing Supreme Court's Medical Device Preemption Ruling

U.S. Representatives Frank Pallone (D-N.J.) and Henry Waxman (D-Calif.) have reportedly drafted a bill, the "Medical Device Safety Act of 2008," that will, if passed, amend the Food, Drug, and Cosmetic Act by stating "Nothing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State." The legislation, which will apparently be introduced some time in April 2008, is intended to override the U.S. Supreme Court's medical device preemption ruling in *Riegel v. Medtronic, Inc.*, No. 06-179 (U.S., Feb. 20, 2008). The legislators are reportedly concerned that the decision "denies patients any legal recourse if they are a victim of a faulty medical device." *See FDAnews Device Daily Bulletin*, March 25, 2008.

CPSC Issues Final Rule on Flammability of Clothing Textiles; Issues State Law Preemption Statement

The Consumer Product Safety Commission (CPSC) has published a final **rule** that amends its "Standard for Flammability of Clothing Textiles." According to the agency, the changes update and clarify a standard originally issued in 1953. In a preamble to the new rule, effective September 22, 2008, the CPSC purports to preempt state or local standards that are not identical to the federal standard. According to CPSC, clothing-ignition fatalities have decreased from a high of 311 in 1980 to approximately 120 annually in recent years. The rule, which applies to most articles of clothing, establishes three classes of flammability and describes a test apparatus and procedures for testing the flammability of clothing and textiles used for clothing. Its purpose is "to reduce danger of injury and loss of life" and prohibit "the use of any dangerously flammable clothing textiles."

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FTC Counsel Publishes Article About Agency's Role in Nanotechnology Regulation

A senior Federal Trade Commission (FTC) attorney has published an article discussing the possible role the agency could play in regulating advertisements for products containing nanomaterials. According to the article, while such products are subject to "little regulation," the FTC "has placed a high level of scrutiny" on them. Apparently, product manufacturers are expected to make "both reasonable and outlandish" claims about the effectiveness of nanotech products. Because the FTC has the authority to regulate false and deceptive advertising, it can and has issued warning letters to companies making unsubstantiated treatment or cure claims as to "nano" products. *See FDLI Update*, March/April 2008.

Meanwhile, legislators at both state and national levels are apparently considering bills to address the environmental, health and safety aspects of nanotechnology. Congressional Democrats are reportedly drafting measures

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that would boost research funds to better understand whether nanomaterials pose risks to human health or the environment. And in California, legislation will apparently be introduced in 2009 to establish a nanotechnology regulatory program that would address environmental health issues. A meeting of stakeholders will reportedly be held in southern California in April 2008, and lawmakers intend to use the ideas presented as a basis for the legislation. *See Inside EPA* and *Inside Cal/EPA*, March 28, 2008.

Center for Justice & Democracy, "State Attorneys General: The People's Champion," March 2008 White Paper

This **white paper** purports to demonstrate that when state attorneys general (AGs) act on behalf of citizens in areas such as consumer and environmental protection, they have greatly benefited state consumers. The authors contend that business interests "have launched unfair, misleading" attacks on AGs and their lawsuits and have focused their criticism on the use of outside counsel to bring litigation against tobacco companies, lead paint manufacturers and the manufacturers of drugs and medical devices. According to the article, "Contingency fee arrangements [with private outside counsel] make it possible for relatively underfunded, understaffed Attorneys General offices to bring important public interest lawsuits." Arguing that "without state AGs getting involved in these types of large consumer actions, there may be virtually no check on the behavior of some of our most powerful industries," the article provides specific examples of litigation state AGs have pursued in recent years, sometimes with the help of outside counsel.

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THINKING GLOBALLY

Adam Liptak, "American Exception: Foreign Courts Wary of U.S. Punitive Damages," *The New York Times*, March 26, 2008

New York Times national legal affairs correspondent Adam Liptak observes, "Most of the rest of the world views the idea of punitive damages with alarm," and finds the concept so offensive to "notions of justice" that some foreign courts have refused to enforce large punitive awards rendered against foreign defendants in U.S. courtrooms. According to lawyers in other countries, particularly large U.S. punitive awards bring the country "into total and utter contempt around the world." Liptak discusses the common law roots of punitive damages, noting how they changed in the United States over time and have come to represent populist messages to large corporations. Foreign courts tend to view large punitive awards as windfalls to individual plaintiffs that infringe on the government's monopoly on punishment. Nevertheless, such hostility is apparently beginning to change as U.S. states have adopted reforms that either ban or limit punitive damages, and the U.S. Supreme Court has started to impose constitutional constraints. Liptak provides examples of foreign courts agreeing to enforce pared-down awards, particularly in those countries that have expanded their availability and no longer find such punishment offensive.

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LEGAL LITERATURE REVIEW

Christopher Robinette, "Peace: A Public Purpose for Punitive Damages?," 2 *Charleston Law Review* 327 (2008)

Widener University School of Law Professor Christopher Robinette explores the historical underpinnings of punitive damages awards and agrees with a theory put forward by Brooklyn Law Professor Anthony Sebok in a 2007 paper that punitive damages can be viewed as serving a peacekeeping function. Our summary of Sebok's paper appears in the February 15, 2007, issue of this Report. Such damages preserve the peace because they are most commonly awarded when the right to dignity is violated, a circumstance most likely to be met with violence. According to Robinette, however, "three significant changes – the increased reliance on criminal law as a means of social control, the advent of corporations [on which violent feelings are more difficult to focus], and the establishment of a general social norm against violent solutions to serious conflicts – have substantially decreased the necessity of a pacificatory function for punitive damages."

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Lars Noah, "The Little Agency that Could (Act with Indifference to Constitutional and Statutory Strictures," 93 *Cornell Law Review* 2008

Focusing on the Food and Drug Administration (FDA), this article takes the agency to task for acting throughout its history with a calculated disregard for statutory limitations on its authority, the procedures that Congress has imposed on rulemaking and even First Amendment free speech protections in the case of off-label promotions for drugs and medical devices. University of Florida Law Professor Lars Noah explores specific instances where the FDA, with jurisdiction over 25 percent of all consumer products, stretched legal boundaries to compel manufacturers to take action not required under the law. While the courts and Congress have belatedly endorsed "the agency's creativity," Noah contends that "[m]ost of the FDA's decisions, however, escape any such scrutiny, which means that nothing other than humility and self-restraint stand in the way of regulatory overreaching." He concludes, "Even if we applaud the ends that the agency sought to achieve, such a pattern of behavior represents a serious affront to the rule of law."

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David Stras & Ryan Scott, "Navigating the New Politics of Judicial Appointments," 102 *Northwestern U. Law Review* 2008

Noting that six of the nine U.S. Supreme Court justices will be older than 70 by January 2009 and that the next president will likely be called upon to replace one or more of them, this essay discusses the types of judicial selection reforms that scholars have advanced and contends that Senate-focused reforms are unlikely to succeed. The authors, a law professor and a lawyer with the Department of Justice, describe how the selection process has become increasingly politicized since at least 1980. They explain that senators will not "get tough" in their questioning during confirmation proceedings because they must answer to vocal constituencies and interest groups. They also argue that

obstructionist tactics can be easily overcome with powerful presidential tools such as the ability to make recess appointments, take direct appeals about a nominee's qualifications and attributes to the public or make credible legislative veto threats.

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LAW BLOG ROUNDUP

The Value of the Width of a Piece of Adhesive Tape?

"Does it make a difference that most users of tape don't really care much about precise widths, inasmuch as they will not run out of tape any faster if its dimensions run slightly narrower than one inch?" Manhattan Institute Center for Legal Policy senior fellow Walter Olson, commenting on the $700,000 3M Co. agreed to pay to settle a case brought by California prosecutors who alleged that the company's Scotch® and Tartan® adhesive tapes were marketed as "for one inch use" when they actually measure .94 inch.

Overlawyered.com, March 30, 2008.

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Supreme Court Criticism of the Press Scrutinized

"Can the *Times* editorial be blamed for echoing the judgment of Scalia's colleague?" University of Chicago Law Professor Eric Posner, blogging about Justice Antonin Scalia's recent criticism of the press for making it appear that the Court made a policy judgment when it ruled in *Riegel v. Medtronic, Inc.* that federal law preempts state common-law claims against medical device makers. Posner reviews stories appearing in *The New York Times, The Los Angeles Times* and *The Washington Post* and finds that two of them accurately described the Court's ruling as a textual interpretation of a federal statute. Posner contends, nevertheless, that the Court's majority opinion could be construed as advancing a policy argument, an analysis with which Justice Anthony Stevens appears to agree in a separate opinion.

Convictions: *Slate's* Blog on Legal Issues, March 29, 2008.

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THE FINAL WORD

Plaintiffs' Counsel to Meet in Las Vegas and Discuss Next Generation of Mass Tort Lawsuits

Florida-based Mass Torts Made Perfect has scheduled a **conference**, April 10-11, 2008, in Las Vegas at which plaintiff's lawyers will discuss "What's Next? The Best is Yet to Come…" Presentations on a variety of drugs, medical devices and diseases are featured, and attendees will also hear war stories

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from successful lawyers and consider the latest automobile liability issues. Special guest speakers include former Steelers football quarterback and sports broadcaster Terry Bradshaw and political consultant James Carville.

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UPCOMING CONFERENCES AND SEMINARS

American Bar Association, Phoenix, Arizona – April 9-11, 2008 – "2008 Emerging Issues in Motor Vehicle Product Liability Litigation," Shook, Hardy & Bacon Tort Partner **H. Grant Law** will make opening remarks and moderate a panel discussion about issues that manufacturers must address when they evaluate the claims filed against them. Shook, Hardy & Bacon Class Actions and Complex Litigation Partner **Tammy Webb** will discuss "Recent Trends in Automotive Class Actions."

The Sedona Conference, Sedona, Arizona – April 17-18, 2008 – "Tenth Annual Sedona Conference® on Complex Litigation: Health Law and Medical Products Litigation," Shook, Hardy & Bacon Tort Partner **Amor Esteban** will participate in a panel discussion on e-discovery and records management issues. Esteban will join a distinguished faculty that includes current and former members of the judiciary, in-house counsel for medical and health care companies, and the chief of the Litigation I Section of the Antitrust Division, U.S. Department of Justice.

Lorman Education Services, Kansas City, Missouri – June 18, 2008 – "Electronic Discovery and Document Storage," Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partner **Madeleine McDonough** will discuss issues related to corporate e-discovery. Her sessions are titled "Practical Considerations in Defending Corporate E-Discovery Programs" and "Practical Considerations to Reduce the Risk that E-Discovery May Improperly Be Used as Leverage."

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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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