Shook, Hardy & Bacon L.L.P.

Product Liability Litigation Report

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U.S. SUPREME COURT ASKED TO RESOLVE LOWER COURT CONFLICTS OVER FEDERAL PREEMPTION OF STATE LAW CLAIMS INVOLVING MEDICAL DEVICES

In late June 2007, the U.S. Supreme Court agreed to hear an appeal filed by attorneys for Public Citizen Litigation Group and a man allegedly injured by a Medtronic catheter during coronary artery surgery to consider whether federal law governing the approval of medical devices preempts state law claims seeking damages for injuries caused by devices that received premarket approval from the Food and Drug Administration. *Riegel v. Medtronic, Inc.* No. 06-179 (U.S., *cert. granted* June 25, 2007). While the Medical Device Amendments to the Food, Drug and Cosmetic Act contain an express preemption provision, petitioners contend that Congress intended the provision to apply only to the potential for preemption of state and local laws and regulations and not to litigation.

Petitioners also point to decisions in state and federal courts that have split over the issue and to lengthy dissents to those decisions finding preemption. They claim that the lower courts, in cases involving similar preemption provisions, "have not gotten the message that express preemption provisions are to be narrowly construed." Petitioners further argue that preemption leaves consumers injured by approved devices "without any remedy in many parts of the country" and that any notion "that section 360k(a) unambiguously preempts state damages claims 'is "particularly dubious" considering it appears that until relatively recently neither the industry nor the FDA thought such claims were preempted.'" The U.S. Supreme Court has invited the solicitor general to file a brief expressing the federal government's views on the issue.

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FEDERAL COURT SAYS VIOXX® INDEQUATE-WARNING CLAIMS NOT PREEMPTED BY FEDERAL LAW

U.S. District Judge Eldon Fallon has refused to dismiss inadequate-warning claims in two individual Vioxx® cases, finding that they are neither "expressly nor impliedly preempted by the federal regulation of prescription drugs." ***In re: Vioxx Prods. Liab. Litig.*, MDL No. 1657 (U.S. District Court, E.D. La., decided July 3, 2007)**. Merck had sought summary judgment on

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preemption grounds, arguing that "the federal regulatory scheme devised for regulating prescription drugs cannot function properly if juries applying state law are allowed to 'force' drug manufacturers to add information to prescription drug labels beyond language that the FDA has approved." To support its argument, Merck cited the Food and Drug Administration statements about preemption appearing in a preamble to its 2006 labeling regulations.

The court discusses the history of drug regulation in the United States, noting that before 1902, the states had primary regulatory control over food and drug labeling. Because there is no express preemption provision in the Food, Drug and Cosmetics Act, which was adopted in 1938, the court looks to the tenets of "implied conflict preemption" doctrine and finds no reason to apply it in this context. "Indeed," the court states, "prior to the FDA's recent statements in the preamble to the 2006 Final Rule, courts routinely found that state law failure-to-warn claims were not impliedly preempted." The court acknowledges that some courts have deferred to the FDA preamble and "have recognized an implied Congressional intent to preempt certain state-law claims," but notes the majority has not done so.

Judge Fallon chose not to defer to the FDA, finding that its "views on preemption were not promulgated pursuant to its rulemaking authority, nor do they seek to clarify any ambiguity in the FDA regulations. Rather, the FDA added these views at the end of the rulemaking process in a preamble to the 2006 Final rule, that is, 'through the back door.'" The court also notes that the preemption statements actually conflict with statements the agency made in the original notice of proposed rulemaking "out of which the 2006 Final Rule grew." He calls the FDA's current position "both unpersuasive and untenable in this multidistrict litigation" and concludes that "a finding of implied preemption in these cases would abolish state-law remedies and would, in effect, render legally impotent those who sustain injuries from defective prescription drugs. To stake such drastic action based solely on a preamble inserted at the eleventh hour and drafted by an agency without the express or implied authority to abolish such remedies is Draconian and unacceptable."

A contrary state-court ruling involving nearly 1,000 Vioxx® claimants was discussed in the April 26, 2007, issue of this Report.

Meanwhile, according to *The New York Times*, Judge Fallon has indicated he will be scheduling a hearing on Merck's request for permission to immediately appeal his preemption ruling. Plaintiffs' attorneys have apparently subpoenaed several governors to find out how they responded to an FDA request about whether its new label rules would violate states' rights. They claim that the FDA was supposed to get states' opinions before the rule took effect. Those subpoenaed include Governor Haley Barbour (R-Miss.), who once lobbied on behalf of major drug companies, and Governor Mitch Daniels (R-Ind.), a former Eli Lilly and Co. executive. The judge also reportedly observed that Vioxx® cases which will be tried in his court in 2008 may include people who blame the anti-inflammatory medication for their strokes. Merck has won four of the five heart-attack cases tried to date in federal court. *See The New York Times*, July 29, 2007.

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WEST VIRGINIA COURT REJECTS LEARNED INTERMEDIARY DEFENSE

In a split decision, the West Virginia Supreme Court has declined to adopt the learned intermediary doctrine which, in some 22 other states, protects prescription drug manufacturers from the duty to warn consumers abut the risks of their products. ***State ex rel. Johnson & Johnson Corp. v. Karl*, No. 33211 (W.Va., decided June 27, 2007)**. The issue arose in a case involving the prescription drug Propulsid.® According to the complaint, three days after she started taking the drug, which her primary care physician prescribed, Nancy Gellner died. Contending that it fulfilled its duty to warn by providing warnings to her physician, the drug maker sought a motion in limine to exclude evidence or argument by her estate suggesting that it had a duty to provide her with any warnings regarding the drug. When the trial court denied the motion, the company filed a writ of prohibition asking the high court to adopt the learned intermediary doctrine.

The court discusses the primary justifications supporting the doctrine, i.e., "the difficulty manufacturers would encounter in attempting to provide warnings to the ultimate users of prescription drugs"; "patients' reliance on their treating physicians' judgment in selecting appropriate prescription drugs"; "the fact that it is physicians who exercise their professional judgment in selecting appropriate drugs"; "the belief that physicians are in the best position to provide appropriate warnings to their patients"; and "the concern that direct warnings to ultimate users would interfere with doctor/patient relationships." The court finds these justifications meaningless now that drug manufacturers advertise directly to consumers via radio, television, the Internet, billboards, and magazines at a cost of more than $2 billion annually since 2000.

According to the court, "with rare and wonderful exceptions, the 'Norman Rockwell' image of the family doctor no longer exists." "Because managed care has reduced the time allotted per patient, physicians have considerably less time to inform patients of the risks and benefits of a drug," and having spent billions on advertising, "drug manufacturers can hardly be said to 'lack effective means to communicate directly with patients.'" The court suggests that consumers are now active participants in their health care decisions. "It is illogical that requiring manufacturers to provide direct warnings to a consumer will undermine the patient-physician relationship, when, by its very nature, consumer-directed advertising encroaches on that relationship by encouraging consumers to ask for advertised products by name."

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The two dissenting justices contended that the doctrine has not completely outlived its usefulness, particularly with respect to drugs not heavily advertised and in those cases where the prescribing doctor did "in fact assume the role of a 'learned intermediary'" in advising and recommending the use of a particular drug. They would have adopted the doctrine and its exceptions as articulated in the *Restatement (Third) of Torts.*

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MICHIGAN SUPREME COURT FINDS NO DUTY IN INDIRECT ASBESTOS EXPOSURE CASE

Answering a question certified to it by a Texas appeals court, the Michigan Supreme Court has determined that Michigan law does not require a property owner to protect a woman who died after contracting mesothelioma from exposure to asbestos carried into her home on the clothing of a household member who worked on the property as the employee of independent contractors. ***Miller v. Ford Motor Co.*, No. 131517 (Mich., decided July 25, 2007)**. The complaint alleged that the decedent contracted mesothelioma from washing her stepfather's work clothes; he worked for independent contractors who were hired by defendant at its Dearborn, Michigan, plant to reline the interiors of blast furnaces with materials containing asbestos. Finding the defendant negligent, a jury awarded plaintiffs $9.5 million. When defendant appealed, the court of appeals certified the question to Michigan's high court.

The court focused on the relationship between the defendant and the decedent, the foreseeability of the harm, the burden that would be imposed on the defendant, and the nature of the risk presented. Characterizing the relationship as "highly tenuous," the court described it as "defendant hired an independent contractor who hired [the stepfather] who lived in a house with Miller [decedent], who sometimes washed his clothes. Miller had never been on or near defendant's property and had no further relationship with defendant." The court also found that imposing a duty to protect "every person with whom a business's employees and the employees of its independent contractors come into contact, or even with whom their clothes come into contact, would impose an extraordinarily onerous and unworkable burden." While the court acknowledged a causal relationship between asbestos exposure and mesothelioma, it questioned whether anyone knew from 1954 to 1965, when the exposure in this case occurred, that washing asbestos-laden clothing could present a risk of injury.

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The court further supports its conclusion by discussing the policy issues raised by the "asbestos-litigation crisis" burdening the nation's legal system and cites an article about the issue of premises owner liability for secondhand asbestos exposure written by Shook, Hardy & Bacon Public Policy Partner **Mark Behrens** and Tobacco Associate **Frank Cruz-Alvarez.** An *amicus* brief filed in the case underscores the argument against imposing liability when peripheral plaintiffs are involved by focusing on the policy issues and persuasive authority from other jurisdictions. Filed on behalf of insurers and organizations representing Michigan companies frequently involved in asbestos litigation as defendants, the *amicus* brief was prepared by Shook, Hardy & Bacon Business Litigation Associate **Dana Mehrer**, Public Policy Partners **Victor Schwartz** and **Mark Behrens**, and Staff Attorney **Chris Appel.**

Three justices dissented from the majority opinion; one of them found that answering a certified question from another state court was unprecedented and exceeded the court's authority. The other two opined that imposing liability under these circumstances would better protect public health and provide "a tremendous social benefit."

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SECOND CIRCUIT DECIDES TOLLING ISSUE IN SECURITIES LITIGATION

The Second Circuit Court of Appeals has determined that the filing of a class-action complaint tolls the statute of limitations for putative class members who file individual suits, asserting the same claims, before the class-certification issues are decided. ***In re: Worldcom Sec. Litig.*, No. 05-6979 (2d Cir., decided July 26, 2007)**. The district court had dismissed the individual claims, ruling that the tolling doctrine announced in *American Pipe & Construction Co. v. Utah*, 414 U.S. 538 (1974), "is unavailable to class members who, like the Appellants, file individual suits before the class certification decision." In *American Pipe*, the U.S. Supreme Court determined that the filing of a class suit tolled the statute of limitations for class members who sought to intervene after the class-certification motion was denied for failure to demonstrate numerosity. The issue here arose in the context of complex securities litigation and posed a scenario the Second Circuit had not yet faced. Analyzing the rationale underlying *American Pipe* and subsequent related decisions, the court agreed with appellants that their actions were tolled.

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CONSUMER-PROTECTION CLASS-ACTION TREND RECOGNIZED

The National Law Journal recently highlighted the trend among plaintiff's lawyers to forego seeking personal-injury damages from corporate defendants in class-action litigation, opting instead to bring economic injury claims under state consumer-protection laws. The courts have been refusing to certify personal-injury classes, finding the facts and circumstances of each case to be too dissimilar to try together. So plaintiff's lawyers are now seeking reimbursement for people "who claim they would not have purchased a product if they had known it might cause physical harm," believing such claims will be more palatable to the courts and easier to prove, given the "lower bar when it comes to proof." Companies are apparently finding it prudent to settle such claims, concerned that they are likely to obtain class certification. For example, some beverage companies agreed to settle consumer class actions alleging no injuries, but claiming that their products contained dangerous amounts of benzene. Other companies are seeking to dismiss claims without injury in cases involving products ranging from cookware and prescription drugs to headphones. *See The National Law Journal*, July 9, 2007.

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STATES WITH ELECTED JUDGES ASSESS HIGHER AWARDS AGAINST OUT-OF-STATE DEFENDANTS

Opening with a reference to the lawsuit filed by a Washington, D.C. judge against a dry cleaner, seeking $67 million in damages for a lost pair of pants, an economics professor opines on *Forbes.com* that such "bizarre" stories are increasingly common. Alexander Tabarrok suggests that real abuses in the legal system are systematic and stem from politics and poverty. Research he conducted apparently shows that damage awards against out-of-state defendants are higher in states that use partisan elections to select their judges than in states appointing their jurists. "Such awards help judges get re-elected," Tabarrok

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claims. He quotes a retired West Virginia Supreme Court judge as saying, "As long as I am allowed to redistribute wealth from out-of-state companies to injured in-state plaintiffs, I shall continue to do so. Not only is my sleep enhanced when I give someone else's money away, but so is my job security, because the in-state plaintiffs, their families and their friends will re-elect me." Tabarrok also discusses the "Bronx effect," where tort awards increase in counties with poverty rates greater than 35 percent. While he does not say whether venue issues or forum shopping play a role in this phenomenon, he does not find it surprising that judicial elections coincidentally occur in the poorest areas of the country. *See Forbes.com*, July 24, 2007.

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ALL THINGS LEGISLATIVE AND REGULATORY

U.S. Supreme Court Approves Revisions to Rules About *Amicus Curiae* Disclosures

Among the **changes** the U.S. Supreme Court adopted July 17, 2007, to the Rules of the Court is a requirement that those filing *amicus curiae*, or friend of the court, briefs must disclose "whether counsel for a party authored the brief in whole or in part and whether such counsel or a party made a monetary contribution intended to fund the preparation or submission of the brief." Such briefs must also "identify every person other than the amicus curiae, its members, or its counsel, who made such a monetary contribution." The changes will become effective October 1. The Court evidently altered the revision in response to concerns among business interests that its original proposal, which would have required disclosure of whether a party or its counsel was a member of trade association submitting an *amicus* brief, would have had a chilling effect on organizations' ability to attract and retain members and prepare high quality *amicus* briefs. *See BNA U.S. Law Week*, July 24, 2007.

Illinois Senator Introduces CPSA Reauthorization Bill

Senator Richard Durbin (D-Ill.) has introduced a bill (S. 1847) that would provide appropriations to carry forward the mandates of the Consumer Product Safety Act through fiscal year 2012 and increase maximum civil penalties for violations of the Act's provisions from $1.25 million to $20 million. The proposal, which has been referred to the Committee on Commerce, Science, and Transportation, would also alter the Consumer Product Safety Commission's quorum requirements and allow the public disclosure of information about consumer products where such disclosure "is necessary to prevent an unreasonable risk to health and safety" and "such manufacturer or private labeler is not cooperating with the Commission."

Regulatory Policy Officers Now in Place at Federal Agencies

President George W. Bush (R) issued an executive order in January 2007 requiring executive branch departments and agencies to filter their rule-making initiatives through a regulatory policy officer (RPO), who is required to be "one of the agency's presidential appointees." Watchdog groups and public interest organizations, concerned about a further politicization of regulatory

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processes, lobbied to overturn the order, and the House of Representatives recently took steps to bar the administration from spending funds needed to implement it. The order's defenders claim that many RPOs were already presidential appointees and that such individuals should serve in this role to avoid putting civil servants in the position of articulating the administration's position before Congress. Those designated to assume the positions apparently include former Office of Management and Budget employees, individuals who formerly worked in regulated industries and partners at major law firms. *See BNA U.S. Law Week*, July 24, 2007.

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LEGAL LITERATURE REVIEW

Jamie Grodsky, "Genomics and Toxic Torts: Dismantling the Risk-Injury Divide," 59 *Stanford Law Review* 1671 (2007)

George Washington University Law School Associate Professor Jamie Grodsky addresses how changing technologies are likely to affect toxic-tort litigation. The article focuses on the genomic revolution and its subcellular focus, arguing that it could alter the way courts view injury from toxic exposures in a medical-monitoring context. While Grodsky acknowledges that courts have retreated from monitoring and other nontraditional tort claims and that scientists do not yet know which molecular markers will prove most useful in the courtroom, she suggests that if emerging technologies can identify and treat potential injury before it manifests, "medical monitoring would be converted into the equivalent of a compensatory damage remedy – yet with damages greatly reduced from the damages of today."

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Rick Swedloff, "Can't Settle, Can't Sue: How Congress Stole Tort Remedies from Medicare Beneficiaries," July 24, 2007

According to this article, 2003 amendments to the Medicare Secondary Payer Act have made it all but impossible for Medicare beneficiaries to participate in the settlement of individual or mass tort claims. The Health and Human Services secretary is now authorized to collect any money that Medicare spent on a beneficiary's health care needs from a settling tort defendant, regardless of fault; a settling Medicare beneficiary, even if the settlement does not reflect medical payments; or the settlement proceeds, even if they are distributed to a contingency-fee attorney. Author Rick Swedloff, a fellow and lecturer in the law at the Temple University Beasley School of Law, contends that the changes not only affect individual claims, they "may have a profound impact in the area of mass tort litigation" by providing disincentives for beneficiary claims to be settled. "If individual parties to a mass tort cannot settle, plaintiffs' attorneys, who make the litigation decision in mass torts, may determine that it is not lucrative to include Medicare beneficiaries in mass tort litigation or to bring mass tort litigation at all." Among the negative consequences of such a result are that the "the Secretary will not have access to the discovery done by private litigation against the mass tort defendants [and] may have a harder time collecting Medicare's conditional outlays from truly tortious parties." Swedloff suggests that the secretary should be forced to use the clear right of subrogation against tortfeasors to alleviate any settlement disincentives.

LAW BLOG ROUNDUP

A Trio of Nuggets from Blogs.wsj.com/law

"The U.S. justice system is frayed enough without making trial lawyers the deputized vigilantes of public prosecutors." Reporter Peter Lattman quoting a *Wall Street Journal* editorial supporting the president's executive order which bars the federal government from using lawyers on a contingency-fee basis. Lattman notes that the practice, frequently used at the state level, "came under the spotlight after the states' settlements with Big Tobacco in the 1990s. Significant portions of those settlements went to outside plaintiffs' attorneys hired by the states."

July 5, 2007

"Acne! Boils! Unwanted facial hair!"

"Acne! Boils! Unwanted facial hair! Ask any New York subway rider how to rid yourself of these unfortunate maladies and they most certainly will tell you, "Go and see Dr. Z!" Reporter Peter Lattman observing that such ads came to mind when he considered a federal judge's decision striking down, on free speech grounds, portions of New York's recently instituted lawyer advertising rules. Stricken were bans on the use of nicknames such as "heavy hitters," active client testimonials, portrayals of judges and fictitious law firms, and Internet pop-up ads.

July 24, 2007

"We're catching ourselves up on the Dickie Scruggs drama in the South, which has taken an interesting turn." Reporter Amir Efrati blogging about the appointment of special prosecutors to pursue charges against plaintiff's lawyer Richard Scruggs for "willfully" violating an injunction requiring State Farm whistleblowers to return documents purportedly containing evidence of misconduct related to the handling of insurance claims filed after Hurricane Katrina. Scruggs was given the documents and is using them in his litigation against State Farm and other insurance companies for denying Katrina claims. The whistleblowers have been sued for violating employment agreements and stealing trade secrets, and the injunction was issued in relation to that case.

July 27, 2007.

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THE FINAL WORD

Supreme Court Watchers Unanimous, High Court Under Chief Justice John Roberts Limits Judicial Authority and Favors Business Interests

As usual, a plethora of end-of-term articles was published when the U.S. Supreme Court concluded its 2006-2007 term, analyzing in which direction the Court was heading on a number of issues. This year, legal commentators focused on changes brought about by a new chief justice and unanimously concluded that he has shifted the court to the right. *The Wall Street Journal* noted that the biggest change "might not involve who wins on the merits. Rather, it may be who gets through the courthouse door in the first place. In case after

case, the court shifted toward what Chief Justice Roberts has previously referred to as 'judicial self-restraint.'" According to Linda Greenhouse, writing in *The New York Times*, the term could be characterized as "the year they closed the courts," and the year that the Court's "overall approach to business cases left many in the business community gleeful." The *Legal Times* said "business was the big winner." *The Los Angeles Times* noted quite frankly, "Progressives are shell-shocked. They believe the Roberts court has transformed the branch of government singularly devoted to the protection of our rights and liberties into a facilitator of discrimination and a guardian of powerful political and moneyed interests. Much the same holds true at the lower federal court level. Conservative appointees dominate almost all of the federal courts of appeal." *The Christian Science Monitor* said "this was not Armageddon for liberal precedents. At least not yet." The paper did concede that the Court is "a more conservative place under Chief Justice John Roberts and associate Justice Samuel Alito." The latest developments are likely to bode well for product-liability defendants who find themselves before the federal courts in the future.

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UPCOMING CONFERENCES AND SEMINARS

ABA Annual Meeting, Tort Trial & Insurance Practice Section Committees **CLE Program**, San Francisco, California – August 10, 2007 – "Post Sale Duty to Warn, Recall, and Retrofit." Shook, Hardy & Bacon Tort Partner **H. Grant Law** will moderate this program. Speakers include Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partner **Madeleine McDonough** and Product Liability Litigation Of Counsel **Kevin Underhill**.

Charleston School of Law, Charleston, South Carolina – September 7, 2007 – "Punitive Damages, Due Process, and Deterrence: The Debate After Williams." Speakers include Shook, Hardy & Bacon Public Policy Partner **Victor Schwartz** who will address the topic "Looking Forward: Punitive Damages in the Next Two Decades – Guideposts From Precedent, History & Sound Public Policy."

American Conference Institute, New York City, New York – December 12-14, 2007 – "12th Annual Drug and Medical Device Litigation" conference. Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partner **Harvey Kaplan** will serve on a panel that will be discussing "Jury Communication: Changing Perceptions of the Industry/FDA and Putting Adverse Events and the Approval Process in Context."

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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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GLOBAL PRODUCT LIABILITY LAW FIRM OF THE YEAR 2005|2006|2007 WHO'S WHO LEGAL

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