Shook, Hardy & Bacon L.L.P.

Product Liability Litigation Report

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GEORGIA COURT ALLOWS DESIGN DEFECT CLAIMS TO PROCEED AGAINST VACCINE MAKERS

The Georgia Supreme Court has ruled that the 1986 National Childhood Vaccine Injury Compensation Act does not bar the parents of a child allegedly injured by the thimerosal in his childhood vaccines from pursuing strict liability and negligence claims for design defect. *Am. Home Prods. Corp. v. Ferrari*, No. 07G1708 (Ga., decided October 6, 2008). The ruling marks the first time that any U.S. court has recognized that the federal law, which established a national procedure for handling vaccine injury cases, "does not preempt all design defect claims against vaccine manufacturers, but rather provides that such a manufacturer cannot be held liable for defective design if it is determined, on a case-by-case basis, that the particular vaccine was unavoidably unsafe."

The plaintiffs alleged that the vaccine manufacturers could and should have manufactured children's vaccines without thimerosal before their son was vaccinated in 1998 and purportedly sustained neurological damage (autism) as a result. Noting that the federal law was modeled after comment k to § 402A of the *Restatement (Second) of Torts*, which excepts from strict liability the seller of unavoidably unsafe products, the court explained that few courts, applying comment k, have held that all prescription drugs are unavoidably unsafe and thus barred all design defect claims against drug makers. According to the court, under the federal law, if some side effects are avoidable by a feasible alternative design, liability is not completely barred.

The court found support for its interpretation in Congress's failure to adopt an amendment to the Vaccine Act that "would have established 'that a manufacturer's failure to develop [a] safer vaccine was not grounds for liability.'" Reversing the trial court's summary dismissal of the plaintiffs' claims, the unanimous state high court also noted that the courts which have provided blanket immunity for design defect claims "failed to explain how the National Vaccine Program set up by the Vaccine Act will better promote the discovery of safer alternative designs if manufacturers are given a blanket tort immunity for design defects." The court concluded "[i]n the absence of any clear and manifest congressional purpose to [grant this immunity to an entire industry] we must reject such a far-reaching interpretation."

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SPLIT APPEALS PANEL TRANSFERS AUTO DEFECT CASE OUT OF DIVISION WITH NO CONNECTION TO CONTROVERSY

A deeply divided Fifth Circuit Court of Appeals, sitting *en banc*, has issued a writ of mandamus ordering the transfer of an automobile accident case involving design defect claims from a district court division "which has no connection to the parties, the witnesses, or the facts of this case" (Marshall) to one "which has extensive connections to the parties, the witnesses, and the facts of this case" (Dallas). *In re: Volkswagen of Am., Inc.*, No. 07-40058 (5th Cir., decided October 10, 2008). The seven dissenting judges objected to the court's use of mandamus "to effect an interlocutory review of a nonappealable order committed to the district court's discretion." A summary of an earlier ruling issued by a three-judge appeals court panel in this case appears in the November 8, 2007, issue of this Report.

Until the November decision, every court that had considered Volkswagen's motion to transfer venue denied the request. The *en banc* panel's decision followed a petition for rehearing filed by the plaintiffs who challenged the November writ of mandamus which ordered the case transferred. The majority first considered whether mandamus was "an appropriate means to test a district court's ruling on a venue transfer motion," and found it appropriate "when there is a clear abuse of discretion." Because the only factor favoring keeping the case in its original jurisdiction was plaintiffs' choice of venue and because "the district court gave undue weight to the plaintiffs' choice of venue, ignored our precedents, misapplied the law, and misapprehended the relevant facts," the majority found that the district court's ruling constituted a clear abuse of discretion, thus satisfying the mandamus requirements.

According to the dissenting jurists, the case is not about a traffic accident; rather, it raises products liability, design defect issues "that will depend heavily on expert testimony from both the plaintiffs and Volkswagen. No claim is made by Volkswagen that any of its experts is Dallas-based, and whether this case is tried in Marshall or Dallas will make little, if any, difference—Volkswagen will be able to get its experts (from Germany or elsewhere) to trial regardless." The dissenting opinion notes the conflict among the federal circuit courts as to whether a writ of mandamus "may be used as a tool to review a district court's § 1404(a) transfer decision" and quotes the late Judge Henry Friendly who called for the courts to "end this sorry business of invoking a prerogative writ to permit appeals, which Congress withheld from us, from discretionary orders fixing the place of trial."

TOOL MAKER WINS REVERSAL BECAUSE TRIAL COURT EXCLUDED EVIDENCE OF LACK OF PRIOR ACCIDENTS

In an unpublished opinion, the Third Circuit Court of Appeals has set aside a jury verdict against the maker of a rotary hammer that allegedly seized up while the plaintiff was drilling a hole in a concrete ceiling, causing him to fall off a ladder and sustain personal injuries. *Harold v. Black & Decker U.S., Inc.*, No. 07-1674 (3d Cir., decided October 7, 2008). The company offered into evidence two electronic databases—a 13-month record of every phone call to a customer complaint hotline and a 12-year record of every claim of loss filed

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against the company—to show a lack of prior accidents involving the product in question. The trial court ruled the evidence inadmissible, finding it more prejudicial than probative. The appeals court disagreed, ruling that its probative value outweighed its prejudicial effect. According to the court, the company satisfied its burden of establishing admissibility by showing that it "maintained a comprehensive database of claims made and lawsuits brought against itself and its subsidiaries" and that the records related to products "functionally identical" to the rotary hammer at issue. The court remanded the case for a new trial.

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ELEVENTH CIRCUIT FINDS FDA EPHEDRINE ALKALOID RULE SUFFICIENT PROOF OF ADULTERATION

Deciding an issue of first impression, the Eleventh Circuit Court of Appeals has ruled that when the Food and Drug Administration (FDA) has issued a relevant regulation about a substance contained in dietary supplements, the government meets its burden of proof as to their adulteration without having to present some additional evidence that the product subject to forfeiture "presents a significant or unreasonable risk of illness or injury" under recommended or ordinary conditions of use. *Hi-Tech Pharms., Inc. v. Crawford*, No. 07-14309 (11th Cir., decided October 7, 2008).

The issue arose in a case involving the government's seizure in 2006 of dietary supplements containing ephedrine alkaloids. The supplement's manufacturer challenged the trial court's reliance on FDA's final ephedrine alkaloid rule, issued in 2004, to find that its product was adulterated. The statute under which the government proceeded when it seized the supplements provides that (i) the United States bears the burden of proof to show that a dietary supplement is adulterated, and (ii) the "court shall decide any issue under this paragraph on a de novo basis." According to the manufacturer, the latter provision "requires a district court to hear original evidence on the question of adulteration, even where the FDA has conducted an administrative rulemaking process and promulgated a valid rule declaring the product adulterated."

The court disagreed, concluding that "Congress used the term de novo to indicate that the Government had the burden of proof, by preponderance of the evidence, that a dietary supplement 'presents a significant or unreasonable risk of illness or injury' under recommended or ordinary conditions of use. In the absence of a regulation like the Final Rule, the Government would have to carry its burden by submitting evidence of the risks of illness or injury under the recommended or ordinary conditions of use." Where the FDA has promulgated a valid, relevant final rule, "it is sufficient for the Government to present evidence that: (1) the regulation exists and (2) it applies to the product that is the subject of the enforcement action."

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ALL THINGS LEGISLATIVE AND REGULATORY

CPSC Issues Notice of Proposed Rulemaking on Warnings for Toys Posing a Choking Hazard

The Consumer Product Safety Commission (CPSC) has issue a notice of proposed rulemaking about promoting toys labeled for choking hazards under

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the direction of the recently enacted Consumer Product Safety Improvement Act of 2008.

Written comments as to "the advertisement requirements with respect to catalogues and other printed materials must be received by October 20, 2008," while comments about "the requirements with respect to the Internet advertisements must be received by November 20, 2008."

The proposed rule applies to toys or games intended to be used by young children, ages 3 to 6, containing small parts. Such products must be labeled with cautionary statements warning that they are not for children younger than 3 because of choking hazards. The proposed rule would require that "when a product's packaging requires a cautionary statement, advertising for the product that provides a direct means for purchase or order of the product, (including catalogues, other printed materials, and Internet Web sites) must bear the same cautionary statement." The proposed Internet requirements would take effect December 12, 2008, and the requirements relating to printed materials and catalogues would become effective February 10, 2008. *See Federal Register*, October 6, 2008.

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Traffic Safety Agency Publishes Final Pre-emptive Rule on Seat Belt Assembly Anchorages

The National Highway Traffic Safety Administration (NHTSA) has issued a final rule, effective December 8, 2008, that "establishes a calculation procedure for determining the number of designated seating positions at a seat location for trucks and multipurpose passenger vehicles with a gross vehicle weight rating less than 10,000 lbs., passenger cars and buses." The rule "eliminates the existing exclusion of auxiliary seats (i.e., temporary or folding jump seats) from the definition of 'designated seating position,'" and "encourages manufacturers to use a variety of visual cues in the design of the vehicle interior to help improve occupant awareness as to which areas of a vehicle are not intended to be used as seating positions." Petitions for reconsideration of the final rule must be submitted by November 24, 2008.

The rule, to be codified at Title 49, part 571 of the *Code of Federal Regulations*, also includes a statement that would expressly preempt "Any State requirement, including any determination under State tort law premised on there being more designated seating positions in a motor vehicle than the number contemplated in the definition," which requirement "would prevent, hinder or frustrate the accomplishment of the purposes of the Federal Motor Vehicle Safety Standards in part 571 of this Title." *See Federal Register*, October 8, 2008.

LEGAL LITERATURE REVIEW

Elizabeth Chamblee Burch, "Procedural Justice in Nonclass Aggregation," *Wake Forest Law Review* (forthcoming)

Florida State University College of Law Assistant Professor Elizabeth Chamblee Burch discusses differences among plaintiffs who pursue non-class

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aggregate litigation and proposes procedures to protect the interests of those on various points of "a continuum for evaluating group cohesion," that is, "individuals-within-the-collective" and "group-oriented-individuals." According to the author, mass litigation, "occurring through transfer, joinder, and consolidation, has increased now that mass torts are more difficult to certify in the wake of the Class Action Fairness Act." Noting how attorney-client relationships can be attenuated where numerous litigants are involved and why procedural justice can be problematic for individuals involved in non-class aggregate litigation, Chamblee Burch suggests that "[m]ass tort plaintiffs' perspectives and procedural preferences differ based on whether they view themselves as part of a group or a collective." She calls for "an extensive conversation" on the issue and "a nuanced approach to a dilemma that is too often ignored or compounded into traditional due process."

LAW BLOG ROUNDUP

State Justices Behaving Badly?

"Finally, the biggest judicial ethics story of the year is heading to the High Court. Well, maybe." *The Wall Street Journal's* legal writer Dan Slater, discussing the possibility that the U.S. Supreme Court will hear cases from West Virginia involving a corporation with ties to some of the state's supreme court justices, "a string of recusals, refusals to recuse and apparent finger-pointing at the court." The state's chief justice lost his re-election bid in May 2008 after pictures surfaced in the newspapers of him vacationing in Monte Carlo with the company's executive. The American Bar Association has apparently filed a supporting brief urging the U.S. Supreme Court to take one of the cases, concerned that its outcome, which favored the company, undermines public confidence in an independent judiciary.

WSJ Law Blog, October 13, 2008.

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Preemption by Regulation

"The National Highway Traffic Safety Administration (NHTSA) once again has launched a 'pre-emptive' strike against state personal injury suits by inserting a pre-emption provision in a new rule governing seat belt safety." Tort reform opponent Justinian Lane, blogging about NHTSA's new rule about "designated seating position," that "also contains language that would specifically pre-empt state tort claims related to seat belt injuries." According to former NHTSA administrator Joan Claybrook, the agency has written standards with pre-emption language 20 times in the past three years; she opined that "fear of lawsuits is one of the greatest incentives automakers have to build stronger and safer vehicles."

Tort Deform, October 13, 2008.

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THE FINAL WORD

Court Watchers Explore Upcoming Election's Effects on U.S. Supreme Court Composition

As the presidential election nears, legal commentators and court watchers have been considering how the outcome could affect the U.S. Supreme Court. With several of the Court's more liberal justices advancing in age, most agree that a John McCain win would move the Court further to the conservative right, which would likely favor business interests. Senator McCain has pledged to appoint "only judges with demonstrated fealty to conservative doctrine." A Barack Obama win would be unlikely to make any significant change because the more conservative justices range in age from 54 to 72 and will probably remain on the bench for many years to come. Senator Obama voted against confirming chief-justice nominee John Roberts and follows an approach to constitutional issues that allows judicial interpretation to be informed by "context, history and the practical outcomes of a decision."

At least one commentator has pointed out that the future of the U.S. Supreme Court is not alone at stake in November, because the "president also selects judges for the many federal district courts and the 13 federal circuit courts of appeal, the last stop before the Supreme Court. These judges, too, have life tenure and often remain on the bench for decades." While most of the circuit courts of appeal, which often shape federal law in the absence of U.S. Supreme Court review, have a Republican majority, that majority is slim on most. Yet, the electorate, with some exceptions, is generally not focused on the candidates' potential power to appoint judges. Both liberal and conservative organizations have apparently begun producing palm cards for voters to explain how important this election will be to the future of the federal courts. *See Salon.com*, October 6, 2008; *The Wall Street Journal*, October 7, 2008; *Law.com*, October 14, 2008.

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UPCOMING CONFERENCES AND SEMINARS

American Conference Institute, Scottsdale, Arizona – October 28, 2008 -- "Positioning the Class Action Defense for Early Success." Joining a faculty that includes federal and state judges, Shook, Hardy & Bacon National Product Liability Litigation Partner Gary Long will participate in a panel discussion titled "Foregoing Settlement and Taking the Class Action to Trial."

Practicing Law Institute (PLI), Chicago, Illinois – October 29, 2008 – "PLI's Electronic Discovery and Retention Guidance for Corporate Counsel 2008." Shook, Hardy & Bacon Tort Partner Amor Esteban will join a distinguished faculty of presenters addressing "Judicial Insight into How Evidentiary Hearings Are Decided Under the Amended Federal Rules." The panel will focus on how the courts handle claims that electronically stored information is inaccessible. Seminar brochure not yet available.

American Conference Institute, Chicago, Illinois – October 29-30, 2008 – "Defending and Managing Automotive Product Liability Litigation." Shook, Hardy & Bacon Tort Partner H. Grant Law will serve on a panel discussing "Preemption: Examining the Current Viability of the Defense in Auto Product Liability Cases."

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BNA Legal & Business Edge, Washington, D.C. – October 30, 2008 – "The Consumer Product Safety Improvement Act of 2008: A New World of Regulation and Enforcement." Shook, Hardy & Bacon Public Policy Partner Victor Schwartz will participate in panel discussions about new federal standards on lead and phthalates, mandatory third-party testing of children's products, the adoption of new regulatory standards, the states' role in enforcing product safety, and product specific provisions under the new law.

American Bar Association, New York, New York – November 7, 2008 – "12th Annual National Institute on Class Actions." Shook, Hardy & Bacon Tort Partner Laurel Harbour and Pharmaceutical & Medical Device Litigation Partner James Muehlberger will join panels addressing the latest developments in class action law. Harbour will discuss "Class Actions Sans Frontières," while Muehlberger will explore the "Rigorous Analysis" standard that courts apply when evaluating whether to certify a class.

Brooklyn Law School, Brooklyn, New York – November 13-14, 2008 – "The Products Liability *Restatement*: Was It a Success?" Shook, Hardy & Bacon Public Policy Partner Victor Schwartz will present along with a number of other distinguished speakers, including *Restatement* reporters James Henderson and Aaron Twerski.

Insight Conferences, Calgary, Alberta – November 26-28, 2008 – "Electronic Records and Information Management." SHB Tort Partner Amor Esteban will present "Lessons Learned from e-Discovery in the U.S.," focusing on issues that include amendments to the Federal Rules and instances in which data sources are "not reasonably accessible" under Rule 26(b)(2)(B).

American Conference Institute, New York, New York – December 9-11, 2008 – "13th Annual Drug and Medical Device Litigation." Shook, Hardy & Bacon Pharmaceutical & Medical Device Litigation Partner Madeleine McDonough will discuss "Successfully Asserting the Preemption Defense Post-*Riegel* and in Anticipation of *Levine*," and International Litigation and Dispute Resolution Partner Simon Castley, who is managing partner of SHB's London office, will serve on a panel to consider "Coordinating the Proliferation of Mass Tort Litigation Outside the U.S.: International Class Action and Product Liability Litigation Trends."

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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