FOLEY HOAG LLP

Product Liability **Update**

In This Issue:

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Foley Hoag LLP publishes this quarterly Update concerning developments in Product Liability and related law of interest to product manufacturers and sellers.

United States Supreme Court Holds Federal Vaccine Statute Expressly Preempts All State Law Design Defect Claims Against Vaccine Manufacturers Rather Than Only Claims Where Injury Could Not Have Been Avoided By Feasible Alternative Design

In *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068 (Feb. 22, 2011), a child's pediatrician administered doses of the diphtheria-tetanus-pertussis ("DTP") vaccine according to the Center for Disease Control's recommended childhood immunization schedule. Within 24 hours of her vaccination, the child began to experience seizures, suffering over 100 of them within a single month. Her doctors eventually diagnosed her with "residual seizure disorder" and "developmental delay." Thereafter, the child's parents commenced a proceeding seeking compensation for her injuries pursuant to procedures set forth in the National Childhood Vaccine Injury Act of 1986 ("NCVIA").

Under the NCVIA, a person injured by a vaccine may file a petition for compensation from the manufacturer in the United States Court of Federal Claims, naming the Secretary of Health and Human Services as the respondent. Within 240 days, a special master is required to make an informal adjudication of the petition applying a detailed no-fault compensation scheme set forth in the statute. Any objections are subject to review under similar time constraints by the claims court, which then enters final judgment. A claimant may choose either to accept the court's judgment and forego a tort action against the manufacturer or reject the judgment and pursue such an action.

After the special master denied plaintiffs' claim and the claims court confirmed the denial, plaintiffs filed suit in Pennsylvania state court alleging the defective design of the DTP vaccine caused their child's disabilities and the manufacturer was subject to both strict and negligence liability for defective design under Pennsylvania common law. Upon removal of the action to federal court, the United States District Court for the Eastern District of Pennsylvania granted summary judgment for defendant, holding that Pennsylvania law was expressly preempted by an NCVIA provision that "[n]o vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side-effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." Plaintiffs appealed and the United States Court of Appeals for the Third Circuit affirmed. The United State Supreme Court granted certiorari to address the scope of the NCVIA's preemption provision.

The Court held that the NCVIA preempts all design defect claims seeking compensation for injury or death caused by a vaccine's side-effects. The Court reasoned that the language of the provision referring to side-effects that were "unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings" took the vaccine's particular design as a given and thus extinguished liability for injuries arising out of that design. In addition, the three traditional bases for product liability are defects in design, manufacture and warnings, and the provision's mention only of the latter two suggested that claims arising from the first were what Congress intended to preempt. By contrast, plaintiffs' argument that the NCVIA preempts only claims arising from side-effects that were unavoidable by the adoption of feasible alternative designs was not supported by the statutory language. Further, plaintiffs' contention that design defect claims were immunized only if the manufacturer had properly manufactured the vaccine and warned about its risks was not grammatically supported, as the statute used the phrase "even though" rather than "and" after the word "unavoidable."

Beyond the language of the preemption clause itself, the Court noted that other provisions of the statute, and of the United States Food and Drug Administration regulations thereunder, impose various requirements on both vaccine manufacture and vaccine warnings, while there are no provisions about vaccine design. Thus both the statutory structure and language supported the result reached by the Court. In light of this, the Court stated there was no need to resort to consideration of legislative history, but in any event examination of that history provided no support for plaintiffs' arguments. Indeed, part of a House committee report counseled claimants who could not prove a manufacturing or warning defect to pursue the compensation scheme rather than a tort remedy, again supporting the conclusion that there was no tort remedy for design defects.

United States Supreme Court Holds State Tort Suits Claiming Automobile Manufacturers Should Have Installed Lap-and-Shoulder Belts Not Impliedly Preempted by Federal Motor Vehicle Safety Standard Because Preserving Manufacturer Choice of Safety Restraints Was Not Significant Federal Regulatory Objective

In *Williamson v. Mazda Motor of America, Inc.*, 131 S. Ct. 1131 (Feb. 23, 2011), decedent was killed in an automobile accident while wearing a lap belt in the rear aisle seat of a minivan. Decedent's family brought a state law design defect suit against the vehicle's manufacturer claiming decedent died because the seat had only a lap belt instead of a lap-and-shoulder belt.

Federal Motor Vehicle Safety Standard 208 ("FMVSS 208") requires, among other things, that automobile manufacturers install seatbelts on the rear seats of passenger vehicles. Manufacturers must install lap-and-shoulder belts on seats next to a door frame, but are given a choice of installing either simple lap belts or lap-and-shoulder belts on rear inner seats.

The trial court dismissed the tort claim on the pleadings, finding the state law claim preempted by FMVSS 208, and the California Court of Appeal affirmed. The courts relied on *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), in which the United States Supreme Court held that a different portion of a previous version of FMVSS 208, which required manufacturers to equip their vehicles with passive restraint devices, preempted a state tort suit seeking to hold a manufacturer liable for failing to install airbags. The Court found that a fundamental objective of the federal regulation was to give manufacturers a choice of several different passive restraint devices so that, over time, market forces would determine which devices were most effective and economical. As forcing manufacturers to exercise their choice in favor of airbags would defeat the federal objective, the state law tort suit was preempted. The California Court of Appeal found considerable similarity between the tort suit in this case and the one in *Geier*, and concluded that FMVSS 208 also impliedly preempted a suit seeking to force manufacturers to install lap-and-shoulder belts on rear inner seats.

The United States Supreme Court granted certiorari in light of the fact that several other courts also had interpreted *Geier* as indicating that FMVSS 208 preempts state tort suits such as the one at issue here, and the Court reversed. The Court first observed that under ordinary conflict preemption principles a state law that "stands as an obstacle to the accomplishment and execution of the full purposes and objectives" of a federal law conflicts with such law and is therefore impliedly preempted. In *Geier*, the maintenance of manufacturer choice was a significant federal regulatory objective, a conclusion that was supported by the regulatory history, the agency's contemporaneous explanation of its objectives and the agency's current views of the regulation's pre-emptive effect.

In the present case, however, the Department of Transportation's ("DOT") decision to require manufacturers to install lap-and-shoulder belts for rear outer seats but not inner seats was not based on a fundamental objective of promoting manufacturer choice. Unlike in *Geier*, here the DOT was not concerned about a lack of consumer acceptance of lap-and-shoulder belts, which already were widely used, or about using the regulation to spur the market's development of alternative safety devices; rather, DOT thought lap-and-shoulder belts would increase safety and not pose additional risks, but was concerned that lap-and-shoulder belts on rear inner seats were not cost-effective. The mere fact that DOT made a negative judgment about cost effectiveness, however, could not by itself show that the agency sought to forbid tort suits requiring a different result. For one thing, DOT did not believe that costs would remain frozen. Further, many federal safety regulations make cost-effectiveness judgments, and to infer pre-emptive intent in all such cases would eliminate the possibility that an agency only sought to impose minimum standards that state law could find to be inadequate. Finally, the Court found relevant the agency's own view that FMVSS 208 did not preempt the plaintiff's suit.

Massachusetts Appeals Court Notes, But Does Not Address, Admissibility of Plaintiff's Expert Testimony That "Each and Every Exposure to Asbestos" Is "Substantial Contributing Factor" to Disease; Declines to Decide Whether Manufacturer Has Duty to Warn of Dangers of Another Manufacturer's Product

In *Morin v. Autozone Northeast, Inc., et al.*, 79 Mass. App. Ct. 39 (Mar. 14, 2011), plaintiff's mother worked over the course of many years in offices near loading bays where her company's delivery trucks were maintained. After her mother died of mesothelioma, plaintiff sued 40 vehicle parts manufacturers and retailers for wrongful death in Massachusetts Superior Court, asserting claims of breach of express and implied warranties of merchantability and negligence and alleging decedent's mesothelioma was caused by exposure to defendants' asbestos-containing parts in the trucks. After the court granted summary judgment to twelve defendants on the ground plaintiff had presented insufficient evidence that their products contributed to her mother's death, plaintiff appealed the judgment as to three defendants.

The Massachusetts Appeals Court reversed as to two defendants but affirmed as to the third. The court first noted that to prove causation in an asbestos case, plaintiff must establish (1) that defendant's product contained asbestos, (2) to which the victim was exposed and (3) such exposure was a substantial contributing factor in causing the victim's harm. The court also noted that the evidence as to the second element would generally be sufficient if it "permit[ted] the reasonable inference of the presence at a work site of both the [victim] and the defendant's asbestos-containing product for an appreciable period of exposure." The adequacy of plaintiff's proof on the third element was not at issue because her expert had testified at deposition that "each and every exposure to asbestos that [the decedent] received as a bystander . . . was a substantial contributing factor in causing [her] malignant mesothelioma," and the admissibility of this opinion apparently was not challenged in the summary judgment proceedings.

Addressing plaintiff's claims against two defendants, both suppliers of replacement brakes and clutches, the court

found that plaintiff had presented sufficient evidence to establish the element of asbestos content. In so finding, the court cited the deposition testimony of two of decedent's co-workers that they had purchased from each of the defendants replacement brakes and clutches with the word "asbestos" on the packaging, and defendants' admissions that their stores carried some asbestos-containing brakes and clutches in the 1970s and 1980s when the maintenance work at issue was done. Additionally, the two co-workers testified that: (i) each defendant was one of eight suppliers from whom they bought replacement brakes and clutches; (ii) the co-workers had performed "hundreds" such replacements, generally one every two or three days in the decades in question; and (iii) they had used air hoses to blow brake dust from the company vehicles during brake replacement. Moreover, decedent's office was only thirty feet from the vehicle bays and she walked through the area ten or more times a day. Considered alongside plaintiff's expert's testimony that asbestos fibers can remain airborne for long periods and drift considerable distances, the court found a jury could infer decedent had been "in close proximity" to defendants' asbestos-products "on numerous occasions," so that there was sufficient evidence of exposure.

As to the third defendant, a trailer manufacturer, the court found there was insufficient evidence for a jury to conclude that its originally installed brakes, even if they contained asbestos, were still in the trailer at the time decedent's company acquired it. As to plaintiff's claim defendant should have warned of the danger of using compressed air in removing replacement brakes of any manufacturer, the court found it unnecessary to decide whether Massachusetts law would hold that a manufacturer has a duty to warn about the foreseeable risks of a product supplied by others. The court held that even if such a duty were to be recognized, there was insufficient evidence here to find decedent was exposed to anything other than "insignificant or de minimis" asbestos from other manufacturers' brakes, as the trailer's brakes were worked on only six or seven days during the seven years decedent's company owned it and there was no evidence as to which, if any, of the replacement brakes contained asbestos.

First Circuit Holds Expert Opinion That Benzene Causes Rare Leukemia Subtype Admissible Because Applying "Bradford Hill" or "Weight of the Evidence" Criteria to Conclude Association Between Benzene and Disease Was Causal Is Scientifically Reliable; Court, However, Appears to Ignore Lack of Scientifically Reliable Evidence of Association

Plaintiffs in *Milward v. Acuity Specialty Products Group, Inc.*, 2011 U.S. App. LEXIS 5727 (1st Cir. Mass. Mar. 22, 2011), sued three chemical companies in the United States District Court for the District of Massachusetts, claiming workplace exposure to their benzene-containing products had caused the plaintiff husband to develop acute promyelocytic leukemia ("APL"). After a four-day evidentiary hearing, the district court excluded plaintiffs' expert's "general causation" opinion that benzene is capable of causing APL in humans generally, ruling that plaintiffs had not demonstrated the testimony to be reliable as required by *Daubert v. Merrill Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Based on the lack of essential expert testimony, the court entered judgment for defendants.

The United States Court of Appeals for the First Circuit reversed. The court held that the expert had indeed applied a reliable methodology, namely making a scientific judgment that the "weight of the evidence," considering generally accepted criteria enumerated years ago by the British epidemiologist Sir Arthur Bradford Hill as well as additional similar criteria, "supported the inference that the association between benzene exposure and APL is genuine and causal." The Bradford Hill criteria include such factors as the temporal relationship between exposure and disease, strength of the association between the two, presence of a dose-response relationship and biological plausibility of causation in light of existing scientific knowledge.

At the outset, the court acknowledged that APL was a relatively rare subtype of acute myeloid leukemia ("AML"), which was itself one of four broad leukemia types, and that while there was a scientific consensus that APL was in part caused by a particular genetic mutation there was no consensus as to the cause(s) of that mutation. In addition, while there was epidemiologic evidence of a statistically significant association between benzene exposure and AML generally, there was no such evidence specifically with respect to APL.

The district court had found the expert's causation opinion unreliable because, among other things, it relied upon data concerning the genetic mutations involved in other AML subtypes, as well as animal and in vitro studies about the possible role of benzene metabolites in causing those mutations, to support the conclusion that benzene caused APL even though it involved a different mutation. The appeals court held, however, that in so doing the district court had "placed undue weight on the lack of general acceptance of [the expert]'s conclusions and crossed the boundary between gatekeeper and trier of fact" by making its own "evaluation of the weight of the evidence." The appellate court also suggested the trial judge had misunderstood the Bradford Hill/weight of the evidence methodology as requiring that each criterion analyzed by the expert by itself reliably demonstrate causation, rather than merely that the criteria cumulatively do so.

It appears from the court's opinion, however, that the court committed precisely the error of which it accused the trial court—namely, of misunderstanding the Bradford Hill methodology, which is only intended to guide the determination of causality where epidemiological studies have demonstrated a statistically significant association between the exposure and disease at issue. Indeed, many of the Bradford Hill criteria themselves—such as the strength of the association and the presence of a dose-response relationship—only underscore this fact. Here, there was no such association, and the court did not purport to analyze whether there was any methodology that supports drawing scientifically reliable conclusions, as opposed to merely offering hypotheses for further investigation, about the causation of one disease or genetic mutation from evidence about another.

Massachusetts Federal District Court Holds Defense Expert's Testimony on Lack of Causal Link Between Drug and Suicide Attempts Admissible Because Expert Relied On His Own Peer-Reviewed Study, But Precludes Testimony on Suicidal Thoughts as Study Was Limited to Suicide Attempts

In *In re Neurontin Marketing and Sales Practices and Products Liability Litigation*, 2011 WL 1048971 (D. Mass. Mar. 18, 2011), over one hundred individuals experienced behavioral disturbances, depression and ultimately suicidal actions, including completed suicide, after their doctors prescribed an anti-epileptic drug, gabapentin. The individuals and their estates' representatives sued the drug's manufacturers in the United States District Court for the District of Massachusetts alleging the drug caused the individuals' injuries and deaths.

Since 2004, gabapentin has been the subject of a protracted multi-district litigation with two distinct parts: (1) "sales and marketing" actions brought by consumer purchasers and third party payors stemming from an alleged fraudulent off-label marketing scheme (*see October 2010 Foley Hoag Product Liability Update; In re Neurontin Marketing and Sales Practices and Products Liability Litigation*, 2010 WL 3169485 (D. Mass. Aug. 10, 2010)); and (2) "products liability" actions, such as this one, alleging injuries resulting from the use of gabapentin. In the latter type of action, plaintiffs bear the burden of establishing both general and specific causation. As explained in the Federal Judicial Center's Reference Manual on Scientific Evidence, cited by the court, "General causation is established by demonstrating, often through a review of scientific and medical literature, that exposure to a substance can cause a particular disease . . . . Specific, or individual, causation, however, is established by demonstrating that a given exposure is the cause of an individual's disease . . . ."

In support of their theory of general causation, plaintiffs relied upon a meta-analysis by the United States Food and Drug Administration ("FDA") of various manufacturers' clinical trials. The analysis supported an association between one class of anti-epileptic drugs - which included gabapentin and four others - and an elevated risk of suicidal thoughts and behavior short of an actual suicide attempt. Defendants' expert, however, conducted studies specifically of gabapentin, which were published in a peer-reviewed journal, from which he concluded that, regardless of whether the drug causes an increase in suicidal thoughts or behavior, there was no increased risk of actual suicide attempts. In an unpublished supplemental report, the expert expanded his conclusion, opining the drug did not even increase the risk of suicidal thinking or behavior.

Plaintiffs moved to partially exclude the testimony of defendants' expert because the methodology of his studies was unreliable. Specifically, plaintiffs argued the expert's findings should be characterized in terms of

"associations" rather than "causal inferences," and attacked his methodology on the basis that it did not take into account the concomitant effect of certain other drugs taken by the gabapentin patients.

The court denied the motion to exclude defendants' expert's testimony despite finding that plaintiffs' criticisms "undermined" the expert's opinion. Citing the publication of the expert's study in a peer-reviewed journal, the court explained that the expert's opinion was not so fundamentally unsupported that it must be excluded. Instead, the conflicting views of plaintiffs' and defendants' experts should be explored through cross-examination and submitted for a jury's consideration. However, the court did preclude defendants' expert from testifying that his studies supported any conclusion relating to suicidal thoughts (as discussed in his unpublished supplemental report), as the studies had been specifically limited to the issue of suicide attempts.

This Update was prepared by Foley Hoag's Product Liability and Complex Tort Practice Group, which includes the following members:

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