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# Update

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## U.S. Supreme Court Holds That FDA Approval Process for Medical Devices Preempts Common Law Tort Claims

On February 20, 2008, the United States Supreme Court held that the Medical Device Amendments of 1976, 21 U.S.C. § 360c *et seq.*, (“MDA”) bars common law claims challenging the safety or effectiveness of a medical device marketed in a form that received premarket approval from the FDA. *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999 (2008).

At issue in *Riegel* was the Evergreen Balloon Catheter, a prescription medical device used to open patients’ arteries during coronary angioplasties; the device had received premarket approval from the FDA in 1994. Riegel and his wife alleged that Medtronic’s catheter was designed, labeled, and manufactured in a manner that violated New York common law, and that these defects caused Riegel to suffer severe and permanent injuries. The complaint raised a number of common law claims, including claims for strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the catheter.

In an opinion written by Justice Antonin Scalia, the Supreme Court held that the Riegels’ claims were preempted by the MDA, which expressly prohibits states from establishing, with respect to medical devices, any requirement which is “different from, or in addition to, any requirement applicable... to the device” and “which relates to the safety or effectiveness of the device.” 21 U.S.C. § 360k(a).

In reaching this holding, the Court engaged in a two-part analysis. First, it was necessary to determine whether the FDA had established requirements applicable to the Medtronic catheter. 128 S.Ct. at 1006. The catheter, a Class III device under the MDA, was subjected to a demanding premarket approval process, which was specific to the individual device and focused on the safety of the device. The Court found that this premarket approval process “imposes ‘requirements’ under the MDA” as interpreted by the Court in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). *Id.* at 1007.

Second, it was necessary to determine whether the Plaintiffs’ common law claims were based upon state requirements which were “different from, or in addition to” the federal requirements and that related to safety and effectiveness. *Id.* at 1006. Citing to *Lohr*, the Court held that that common law causes of action for negligence and strict liability impose “requirements” and would therefore be preempted by federal requirements specific to the medical device. *Id.* at 1007. Specifically, the court found that “[s]tate tort law that requires a manufacturer’s catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect.” *Id.* at 1008.

Chief Justice Roberts and Justices Kennedy, Souter, Thomas, Breyer, and Alito, joined in the opinion. Justice Stevens filed an opinion concurring in part and concurring in the judgment. Justice Ginsburg filed a dissenting opinion.

Pittsburgh

Philadelphia

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Firm News

## E.D.Pa. Court Conducts Pre-Trial Review to Determine Whether Product Is Unreasonably Dangerous

In *Cicoello v. Caterpillar, Inc.*, 2008 U.S. Dist. LEXIS 4568 (E.D.Pa. January 22, 2008), the injured plaintiff-husband and his wife filed suit, claiming that a tool used during the course of his employment was defective and caused his injuries. The court conducted a pre-trial review to determine whether the alleged defect, “if proven, would render the product unreasonably dangerous.” Under Pennsylvania law, a defendant is entitled to such a pre-trial determination, comparing the risk and utility of the product, as designed with the risk and utility of an alternative design. The Third Circuit applies the Wade Factors, a seven-step analysis, considering: (1) the product’s usefulness and desirability; (2) the product’s safety aspects; (3) the availability of a safer substitute product; (4) the ability to eliminate the product’s unsafe elements without impairing its usefulness or making it too expensive to maintain its utility; (5) the user’s ability to avoid danger with due care; (6) the user’s anticipated awareness of the product’s inherent dangers and their ability to be avoided; and (7) the manufacturer’s ability to spread the risk of loss through price setting or liability insurance.

In *Cicoello*, the court noted that factor seven, the feasibility of the defendant’s ability to spread the loss was not in dispute. However, the court heard from the parties’ experts on the remaining six factors and determined that, even based on a review of the facts in the light most favorable to the plaintiffs, the product’s general utility and the user’s awareness of dangers inherent to the product and their ability to be avoided were both factors that favored the defendant. However, the remaining factors, including consideration of the product’s safety aspects; consideration of the manufacturer’s ability to eliminate the unsafe character of the product; and consideration of user’s actual ability to avoid danger all favored the plaintiffs. Accordingly, the court concluded that it could not, as a matter of law, find that the product was not unreasonably dangerous at the preliminary stage. Under the plaintiffs’ version of the facts, their recovery would be justified. Therefore, the matter will proceed to trial to determine whether the evidence actually supports the plaintiffs’ allegations.

## W.D.Pa. Court Limits Testimony From Plaintiff’s Expert

In *McAndrew v. Garlock Equipment Co.*, 2008 U.S. Dist. LEXIS 9144 (W.D.Pa. February 7, 2008), the court granted, in part, the defendant’s motion *in limine* to preclude testimony from the plaintiff’s expert. During the course of his employment, the plaintiff applied heat to a piece of steel tubing used in the roofing industry (“melt out procedure”) and was injured when it exploded. The plaintiff’s expert had no experience in commercial roofing or mechanical engineering; yet, the court decided during an earlier summary judgment proceeding that the expert qualification standard should be liberally applied and that the expert was qualified because of his experience with chemical engineering, forensic engineering and explosions. The issue presented in the motion *in limine* was limited to whether the plaintiff’s expert’s opinions were based on sufficient facts/data and were the product of reliable methodology.

The court precluded the expert’s testimony as to product identification after finding that his opinion was not based on scientific or specialized knowledge. Plaintiff’s expert simply compared and determined that the product in question had dimensions that were consistent with an exemplar produced by the purported manufacturer. Plaintiff’s expert never examined exemplars from any of the manufacturer’s competitors. The court determined that he could not differentiate the defendant’s product from those of other manufacturers.

Plaintiff’s expert was also precluded from testifying as to the existence of a manufacturing defect. When considering whether the product was insufficiently annealed or inadequately welded, the plaintiff’s expert simulated a hydrostatic burst instead of an explosion. The defendant argued that the two methods are distinguishable and cannot be interchanged. The court noted that the plaintiff’s expert provided no support for his assumption that the two methods would result in equivalent displacement. Noting the absence of a solid foundation, the court precluded plaintiff’s expert’s opinion on the existence of a manufacturing defect.

Because the court had already determined that the plaintiff’s expert possessed adequate qualifications, it permitted testimony as to the necessity of warning users of the expulsion hazard created during the melt out procedure. However, because the plaintiff had previously advised the Court that he would not produce evidence that the use of protective equipment would have prevented or minimized his injury, his expert was precluded from testifying as to the effect of such equipment.

## PA Supreme Court Grants Allocatur in Asbestos Case to Determine Whether the Court Should Adopt Section 2 of the Restatement (Third) of Torts

On February 27, 2008, the Pennsylvania Supreme Court granted allocatur in *Bugosh v. I.U. North America, Inc.*, to consider whether the court should apply Section 2 of the Restatement (Third) of Torts in place of Section 402A of the Restatement (Second) of Torts. No. 350 WAL 2007 (Pa. Feb. 27, 2008).

Since 1978, Pennsylvania courts have adhered to a strict products liability standard. See *Azzarello v. Black Brothers Co. Inc.*, 391 A.2d 1020 (Pa. 1978). Under the current law, a product is deemed defective if it left the manufacturer lacking any element necessary to make it safe for its intended use. This standard does not allow for any consideration of reasonableness or foreseeability with respect to the product's safety.

This strict liability standard will be revisited in *Bugosh*, in which the court will consider adopting the Restatement Third on Torts, thereby importing concepts of negligence into Pennsylvania's products liability law.

The allocatur petitioner in *Bugosh*, I.U. North America, Inc. ("IUNA"), formerly Pittsburgh Gage and Supply Co., is a supplier and distributor of construction materials. IUNA is challenging a \$1.4 million dollar judgment awarded to the estate of Edward J. Bugosh, based on allegations that he contracted malignant mesothelioma from exposure to the defendant's asbestos-containing products.

In 2007, the Superior Court rejected IUNA's argument that the Third Restatement negligence product liability concepts should apply, stating "Pennsylvania's judicature in the area of strict liability rests on the premise that where a plaintiff has been injured by a defective product, 'as between the innocent consumer and a manufacturer of a defective product, the manufacturer should bear the loss.' Until and unless our Supreme Court alters its approach to strict liability, we will continue to adhere to established principles." *Bugosh v. Allen Refractories Co.*, 932 A.2d 901, 911 (Pa. Super. 2007) (internal citations omitted).

## In a Failure to Warn Case, Philadelphia County Court of Common Pleas Holds That Federal Law Does Not Preempt State Court Claims Based on the Adequacy of Prescription Drug Label

In *Collins v. Smithkline Beecham Corporation d/b/a Glaxosmithkline*, No. 0762, 2008 Phila. Ct. Com. Pl. LEXIS 57, \*1 (Ct. Com. Pl. March 11, 2008), the plaintiffs sued Smithkline Beecham Corporation d/b/a Glaxosmithkline ("GSK") under the state tort claim of failing to warn their husband/father (the "decedent") of the alleged relationship between the drug, Paxil, and suicide. The plaintiffs alleged that the decedent was prescribed Paxil, a medication manufactured by GSK, and took his recommended dosage until he committed suicide. GSK filed a motion for summary judgment, in which it contended that the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 ("FDCA") preempted any state tort claims regarding the adequacy of the Paxil label. Upon consideration of these claims, the Philadelphia County Court of Common Pleas held that while the U.S. Constitution's Supremacy Clause preempts state laws that expressly or impliedly interfere with or contradict federal law, it does not preempt state laws where Congress has failed to clearly and manifestly demonstrate

its intent for the federal law at issue to supersede state police powers. With respect to the FDCA, Congress expressed its intent not to preempt state law not only during the Congressional hearings regarding the FDCA's passage, but also in failing to reference preemption within the text of the FDCA. The court also relied on *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804 (1986) to demonstrate that the U.S. Supreme Court has permitted plaintiffs to raise inadequate labeling claims in state court under the FDCA, even though the FDCA did not provide for any cause of action. The court determined that the fact that the FDCA did not provide for a federal cause of action further supports the notion that the plaintiffs' claims are not preempted. The court believed that Congress specifically chose not to provide a federal remedy under the FDCA due to the availability of a state law right of action, and that if it precluded the plaintiffs' right to recovery, GSK would be immune from liability for its tortious conduct. The court denied GSK's motion for summary judgment.

## Philadelphia Court of Common Pleas Holds That to Be Admissible, Co-Worker Testimony Must Meet the Requirements of Eckenrod

In *Weible v. Brake & Clutch Co. et al.*, No. 3073, 2008 Phila. Ct. Com. Pl. LEXIS 69, \*1 (Ct. Com. Pl. March 18, 2008), the estate of the decedent filed suit claiming the decedent developed mesothelioma and died as a result of his exposure to asbestos-containing products manufactured and/or supplied by certain defendants when the decedent visited automotive mechanics at the garage of the PECO facility in which the decedent worked. The defendants filed, and the court granted, motions for summary judgment on the ground that the plaintiff had failed to assert sufficient product identification as required by *Eckenrod v. GAF Corp.*, 544 A.2d 50 (Pa. Super. Ct. 1988). In opposition to the motions for summary judgment and in response to the court's request for a statement of matters complained of on appeal, the plaintiff proffered the decedent's deposition testimony and the deposition testimony of two of the decedent's co-workers to establish that the decedent was exposed to the defendants' products. In reviewing its decision to grant the defendants' motions for summary judgment, the Philadelphia County Court of Common Pleas determined that the decedent's and the decedent's co-workers' testimony failed to establish the regularity, proximity and frequency requirements of *Eckenrod* because neither the decedent nor the co-workers could testify as to the number of years the decedent visited the garage, the length of time in which he visited, the products used while the decedent was in the garage or the projects being performed while the decedent was visiting. This testimony was insufficient to allow the court to interpret the regularity of decedent's visits without engaging in inappropriate speculation. The court also addressed the plaintiff's attempts to introduce deposition testimony where the plaintiff's counsel used leading questions to elicit product identification testimony. The court held that in reviewing its decision to grant the defendants' motions for summary judgment, the court was required to consider only that evidence which was properly introduced. The court held that answers to inappropriate leading questions by the plaintiff's counsel are not admissible and may not serve as the basis for surviving a summary judgment motion.

*Product Liability Update* is a publication of Thorp Reed & Armstrong's Product Liability Group. The following attorneys defend product liability claims both regionally and nationally, handling cases ranging from single claims to nationwide class actions:

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## Firm News

**Kittredge, Donley, Elson, Fullem & Embick, LLP and Thorp Reed & Armstrong, LLP are pleased to announce that they have combined their practices, effective March 1, 2008.**

**The combined firm will operate under the name of Thorp Reed & Armstrong, LLP.**

As our clients' businesses and geographies have expanded, so has their need for top-flight legal counsel throughout the Commonwealth of Pennsylvania and the Northeastern United States.

The combination bolsters both firms' already strong presence in Philadelphia, New Jersey and New York, while also creating a truly statewide presence for the combined firm. What's more, the new Thorp Reed & Armstrong, which already has a national representation for some clients, will expand our service to clients with national and international representation in the areas of insurance and reinsurance, and international trade, as well as bolster Thorp Reed & Armstrong's existing litigation, labor and employment, environmental law and product liability practices.

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