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Product Liability Litigation Update

Recent Developments in the Law

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Federal District Court Applying Georgia Law Protects Branded Prescription Drug Manufacturer From Design Defect Claim

In 2013, the United States Supreme Court announced that state law claims for design defects against generic drug manufacturers are preempted by federal law. *See Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013). Since that time, commentators have speculated regarding the possible ramifications for branded prescription drug manufacturers. Applying *Bartlett* to claims under Georgia law, the United States District Court for Western District of Ohio recently held that design defect claims against a branded pharmaceutical manufacturer are preempted just as claims against generic manufacturers.

In *Booker v. Johnson & Johnson*, --- F. Supp. 3d ---, No. 12-cv-40000, 2014 WL 5113305 (W.D. Ohio Oct. 10, 2014), Plaintiff brought suit against branded pharmaceutical manufacturers alleging that her daughter suffered from a pulmonary embolism and died as a result of taking Defendants' product, Ortho Evra birth control patch. Under Georgia law, design defect claims focus on the feasibility of alternative designs, as well as on the availability of effective substitutes for the product at issue that meet the need but that are safer. *Id*. at *3. Plaintiff's design defect claim was premised on the idea that defendants manufactured and marketed Ortho Evra despite the existence of safer and effective substitutes -- namely, oral birth control pills. *Id*. at *4.

Defendants moved for summary judgment, arguing that Plaintiff's design defect claims are preempted under *Bartlett* because a state tort law duty to adopt a different design conflicts with federal law mandating use of the FDA-approved design. Despite finding that Plaintiff had "otherwise stated a valid design defect cause of action under Georgia law," *id*. at *5, the court nonetheless granted Defendants' motion for summary judgment. Relying on *Bartlett*, the court held that it "was impossible for the Defendants to comply with both its state-law duty to alter the composition of the drug, and its federal-law duty not to alter an FDA approved design." *Id*. Moreover, the court found that the "remedial 'alternative design' requirement" at issue was "precisely the type contemplated by the United States Supreme Court" in *Bartlett*. *Id*.

The *Booker* decision does not limit its holding to its facts and is a significant decision for branded pharmaceutical manufacturers. This issue is one to watch as branded companies continue to argue preemption of design defect claims under *Bartlett*.

Colorado Federal Court Applies Restatement (Third) of Torts § 6 To Bar Design Defect Claim Against Medical Device Manufacturer

In *Haffner v. Stryker Corp.*, No. 14-cv-186, 2014 WL 4821107 (D. Colo. Sept. 29, 2014), the United States District Court for the District of Colorado issued a significant opinion applying the Restatement (Third) of Torts § 6 to preclude a design defect claim against a medical device manufacturer.

In *Haffner*, Plaintiff alleged he was injured by the implantation of a Stryker Triathlon Total Knee System (Knee System), a medical device, because he was allergic to two of its components -- cobalt and nickel. *Id*. at *1. Based on these allegations, Plaintiff asserted several claims, including a cause of action for design defect under a theory of strict product liability. *Id*. Relying in part on a Colorado Court of Appeals case that had cited the Restatement (Third) of Torts § 6 regarding the learned intermediary doctrine, *O'Connell v. Biomet, Inc.*, 250

P.3d 1278, 1281 (Colo. App. 2010), the court predicted that the Colorado Supreme Court would adopt that section's test for design defect with respect to prescription drugs and medical devices: "'A prescription drug or medical device is not reasonably safe due to defective design if . . . reasonable health-care providers . . . would not prescribe the drug or medical device for any class of patients.'" *Id*. at *3 (quoting Restatement (Third) of Torts § 6(c)) (emphasis added). In addition, the court noted that the drafters' comment states that "'a prescription drug or medical device that has usefulness to any class of patients is not defective in design even if it is harmful to other patients.'" *Id*. (quoting Restatement (Third) of Torts § 6 *cmt*. b) (emphasis added).

In applying that test, the court rejected Plaintiff's contention that the Knee System was defectively designed because it contained cobalt and nickel, substances to which 19% of the population was alleged to be allergic or sensitive, despite the availability of hypoallergenic alternatives. *Id*. "Simply because a product would not be compatible with a certain class of individuals—in this case, those with cobalt and nickel allergies—does not mean the medical device is defectively designed." *Id*. Thus, the court dismissed Plaintiff's design defect cause of action. *Id*.

The Restatement (Third) of Torts § 6 limits liability against pharmaceutical and medical device manufacturers by recognizing that drugs and medical devices are not one-size-fits-all medical solutions. The *Haffner* decision joins a growing number of courts that have adopted that rationale to bar design defect claims against pharmaceutical and medical device manufacturers.

FDA Issues Final Guidance Omitting Reporting Requirements for Certain Medical Device Enhancements

On October 15, 2014, the U.S. Food and Drug Administration (FDA) issued a final guidance document, *Distinguishing Medical Device Recalls from Medical Device Enhancements* (Final Guidance), revising a draft document that had been issued on February 22, 2013, *Distinguishing Medical Device Recalls from Medical Device Enhancements and Associated Reporting Requirements* (Draft Guidance). The Final Guidance, like the Draft Guidance, clarifies when a change to a device constitutes a recall, as well as the difference between a medical device recall and a "product enhancement." Notably, however, the FDA removed from the Final Guidance a discussion of several reporting requirements under 21 C.F.R. Part 806 for corrections that do not meet the FDA's definition of a recall, resulting in the change to the title of the guidance.

The Draft Guidance had proposed requiring reporting of any enhancement intended to reduce health risks, which could have forced medical device makers to report minor product changes that are not connected to recalls or serious safety concerns. In contrast, in the Final Guidance, the FDA removed a section requiring 806 reports for device enhancements and specifically stated that "[m]edical device enhancements do not require the submission of an 806 report." In addition, the FDA removed many of its proposals with respect to recall reporting requirements.

The removal of reporting requirements for medical device enhancements from the Final Guidance should be well received by industry not only because it lessens the need for additional reports to the FDA compared to the draft, but also because it adds a layer of clarity to the FDA's existing policy on the subject. While the FDA's position in the 2013 draft guidance, that some enhancements initiated to reduce a risk of health posed by the device, was unpopular with industry, it was not inconsistent with the practices of some manufacturers. By explicitly clarifying that medical device enhancements do not require the submission of an 806 report, the FDA has resolved an open question on which device manufacturers had previously reached differing conclusions.

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