

Products Liability & Mass Torts Alert

An informational newsletter from Goodwin Procter's Products Liability & Mass Torts Group

Medical Device Preemption After *Riegel*

Prior to the U.S. Supreme Court's 2008 landmark decision in *Riegel v. Medtronic, Inc.*¹, courts disagreed whether 21 U.S.C. § 360k(a) preempted state law tort claims against manufacturers of medical devices.² That section involves medical devices approved by the FDA pursuant to the Medical Device Amendments Act ("MDA") of 1976 that requires manufacturers of devices presenting potentially serious health risks to obtain the agency's pre-market approval.

In an 8-1 decision, the Supreme Court in *Riegel* concluded that the MDA preempted state common law to the extent that the application of common law duties would impose requirements "different from, or in addition to" requirements imposed under the MDA. Because manufacturers of class III devices must comply with extensive conditions prior to marketing their devices, including design specifications, manufacturing processes and labeling wording, and cannot modify approved devices without supplemental agency permission, the court concluded that pre-market approval places "requirements" on devices.

Next, the *Riegel* court decided that state common law tort duties establish "requirements." It reasoned that permitting state courts to adjudicate products liability claims against medical device manufacturers based on common law tort duties would disrupt Congress' purpose when enacting the MDA of establishing requirements that apply uniformly to medical devices. The court opined 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."

Although the court denied plaintiff Riegel recovery on his claim that a defective catheter caused his injuries because the MDA preempted his New York state common law tort claims, the court noted that persons injured by defective medical devices could recover by properly asserting "parallel" claims. Because the MDA preempts only claims based on state common law duties that would impose requirements "different from, or in addition to" requirements established by pre-market approval, claims "premised on a violation of FDA regulations" may go forward because they complement rather than conflict with pre-market approval.

The plaintiffs' bar has attempted to seize upon the "green-light" the court gave plaintiffs to bring parallel claims. Plaintiffs' lawyers will frequently contend that a defendant medical device company deviated from the pre-market approved manufacturing process for the device, and the manufacturer's failure to follow the

pre-approved process tainted the product. Post-*Riegel* decisions, however, suggest that courts will scrutinize closely plaintiffs' claims to ensure that they do not present MDA preempted claims and are only masquerading as "parallel" claims.

Recent Post *Riegel* Cases

The court in *In re Medtronic, Inc. Sprint Fidelis Leads Product Liability Litigation*³ held that the plaintiffs' products liability claims against the manufacturer of allegedly defective implantable cardiac defibrillator leads were preempted by the MDA. The plaintiffs claimed that the manufacturing process for the leads, despite receiving pre-market approval, was unsound and caused the plaintiffs' injuries. The court had little difficulty concluding that this claim, because it found fault with an MDA approved manufacturing process, was preempted. The plaintiffs contended that their defective manufacturing claims paralleled MDA guidelines because Medtronic's testing and quality assurance systems allegedly violated the FDA's Current Good Manufacturing Practices ("CGMPs") and Quality System Regulation ("QSR") guidelines. Because the generic CGMPs and QSR guidelines are not specifically applicable to particular medical devices and "require manufacturers to develop *their own* quality system controls," these "inherently flexible" guidelines could not provide a basis for the plaintiffs' "parallel" manufacturing defect claims according to the court.

The Supreme Court of Wisconsin in *Blunt v. Medtronic, Inc.*⁴ similarly held that the MDA preempted negligence and strict liability claims brought by the user of a defibrillator experiencing battery shorting problems. Because Medtronic's original Marquis 7230 defibrillator received pre-market approval, claims challenging the safety and effectiveness of the device were preempted. The opinion of the Wisconsin court is notable because it concluded that supplemental pre-market approval for design changes to a previously approved medical device does not affect the original approval. The plaintiff Blunt argued that Medtronic acted negligently by continuing to sell the previously approved defibrillator after it achieved supplemental pre-market approval for a new version of the device that presumably operated more safely by correcting the shorting problem. Rejecting the plaintiff's argument, the court noted that supplemental approval does not terminate the manufacturer's right to market the original device. Rather, the FDA must affirmatively act to withdraw a grant of pre-market approval and provide the manufacturer with notice of its decision and a hearing to contest that determination.

In re Medtronic and *Blunt* illustrate the significant protection from liability *Riegel* provides to medical device manufacturers. It would be a mistake, however, to overlook the potential for mischief in allowing plaintiffs to bring parallel claims. One federal court judge, pointing to *Riegel's* limitations, rejected the defendant's preemption argument. In *Hofts v. Howmedica Osteonics Corporation*⁵, Judge David Hamilton held that the plaintiff's claims against the manufacturer of an artificial hip were not preempted because they were based on allegations that the manufacturer failed to meet the FDA's requirements. The court permitted the plaintiff's defective manufacturing and breach of warranty claims to proceed to the extent that they were "parallel" claims premised on the defendant manufacturer's failure to comply with FDA requirements.

Medical device manufacturers should also be aware of the recent decision in *Horowitz v. Stryker Corporation*.⁶ In *Horowitz*, the court dismissed the plaintiff's claims against the manufacturer of an artificial hip because the claims, based on state common law duties that might impose requirements "different from, or in addition to" the requirements placed on the artificial hip in pre-market approval, were preempted by the MDA. The case is particularly noteworthy because the court articulated a causation hurdle that plaintiffs must overcome to recover against a medical device manufacturer. A plaintiff, in addition to demonstrating that the manufacturer failed to comply with pre-market approval requirements for a medical device, must show that this failure resulted in the device's defective nature and that the defect caused by the manufacturer's failure to comply with pre-market approval requirements caused his or her injury.

In sum, *Riegel* ended the disagreement between courts over the preemptive extent of 21 U.S.C. § 360k(a). The U.S. Supreme Court established that that provision preempts not only conflicting state statutes but also common law tort duties enforced through litigation. Because state court monetary damages awards to persons harmed by defective medical devices impose requirements on medical device manufacturers as surely as state legislation, Congress' aim to create a uniform system of regulation for medical devices through the MDA would be frustrated by allowing state common law tort claims to proceed against medical device manufacturers. Only claims that parallel the MDA's pre-market approval requirements for medical devices and neither impose different nor additional requirements on approved devices can escape preemption after *Riegel*. Medical device companies should also challenge the causal connection alleged by plaintiffs pursuing products liability claims. The causal chain between a device manufacturer's failure to comply with pre-market approval guidelines and a plaintiff's injury is often attenuated and can present a weak link in the plaintiff's case that defendant manufacturers should attack.⁷

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Over the past 25 years our products liability and mass torts litigators have defended against some of the largest controversies in the field. We ensure our clients' interests are optimally protected by integrating medical, scientific and engineering expertise with sophisticated litigation management and trial strategies. Each of our senior litigators has more than 20 years' experience in the field, and extensive contacts in the medical and scientific communities. We are well prepared to defend litigation involving medical devices.

¹ 128 S.Ct. 999 (2008)

² 21 U.S.C. §360k(a) states, “Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.”

³ 2009 WL 35467 (D. Minn.)

⁴ 2009 WL 36778, 2009 WI 16 (Wisconsin)

⁵ 2009 WL 331470 (S.D. Ind.)

⁶ 2009 WL 436406 (E.D.N.Y.)

⁷ Emboldened by the March 4, 2009 U.S. Supreme Court decision in *Wyeth v. Levine*, 2009 WL 529172, which found that FDA labeling requirements for pharmaceuticals do not preempt state products liability claims premised on a drugmaker’s failure adequately to warn the patient of a drug’s risks, Democrats have reintroduced a bill in the House of Representatives to overturn *Riegel*. Representative Frank Pallone Jr. (NJ-D), co-sponsor of the proposed legislation with Representative Henry Waxman (CA-D), commented, “There should not be any distinction between the legal treatment of pharmaceuticals and medical devices, and without action by Congress this unfortunate decision [*Riegel*] will continue to exist.” See <http://productliability.law360.com/articles/90318> (viewed March 6, 2009). Medical device manufacturers should monitor the progress of the proposed legislation. If enacted, this bill would expose medical device companies to increased litigation and eliminate their ability to rely on pre-market approval as a complete defense to many types of state law tort claims.

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