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Parallel Claims: Exact Contours Will Continue to Be Litigated

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In *Riegel v. Medtronic, Inc*., 128 S. Ct. 999 (2008), decided in February 2008, the United States Supreme Court held that the Medical Device Amendments ("MDA") to the Food Drug and Cosmetic Act ("FDCA") expressly pre-empted common-law state claims involving Class III medical devices that had received FDA premarket approval. Relying on an express pre-emption clause contained in the MDA, 21 U.S.C. Section 360k(a), the Court held that state lawsuits were expressly pre-empted because they would impose requirements on Class III medical device manufacturers that were "different from, or in addition to," the requirements already imposed by the FDA. But, relying on language in *Medtronic v. Lohr,* 518 U.S. 470, 495 (1996), the Court stopped just short of holding that all personal injury actions involving Class III medical devices were expressly pre-empted. As the Court explained:

> Thus, Section 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements.

With this single sentence, the Supreme Court recognized a new type of claim commonly referred to as the "parallel claim." The Court, however, provided almost no guidance on the exact nature and scope of such a claim. Over the 20 months since *Riegel* was decided, numerous plaintiffs have seized on this language and characterized their claims as parallel claims, trying to avoid *Riegel*'s pre-emption. In response, trial courts, mostly in the federal arena, have had to determine what constitutes a permissible parallel claim. Although this area of law is still evolving, the validity of certain types of parallel claims has been addressed, and some practical guidance can be drawn from these cases.

Fraud on the FDA and Other Claims of Violating FDA Reporting Requirements

Since *Riegel*, some plaintiffs have tried to create a parallel claim by alleging that the defendant violated FDA regulations by not disclosing certain safety information to the FDA as part of the premarket approval process, or by failing to properly report post-market adverse events. The Supreme Court in *Buckman Co. v. Pl.'s Legal Committee*, 531 U.S. 341, 352-53 (2001), previously ruled that the FDCA does not provide individuals with a private right of action, and that these types of claims are barred by implied pre-emption principles. *Riegel* did not change *Buckman*'s holding; there is still no independent cause of action under federal law for alleged violations of the FDCA or FDA regulations. See, e.g., *Covert v. Stryker Corp.*, WL2424559 (M.D.N.C. Aug.5, 2009). For this reason, in addition to being barred by implied pre-emption principles, these types of claims for alleged violations of FDA reporting regulations have also been held to be barred under *Riegel*'s express pre-emption principles unless there is some state law basis for recovery. See, e.g., *Miller v. DePuy Spine, Inc.*, WL 1767555 (D. Nev. May 1, 2009). A valid parallel claim cannot be based solely on a violation of FDA regulations. The claim must be predicated on an existing state common law or statute that provides a basis for

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recovery. Therefore, unless plaintiff can refer to a state common law or statute specifically permitting recovery for violations of FDA regulations, these types of claims should also be expressly pre-empted under *Riegel.*

Manufacturing Defect Claims

On the other end of the spectrum, most courts have held that manufacturing defect claims, if pled properly, may constitute a valid parallel claim. See, e.g., *Delaney v. Stryker Orthopaedics*, 2009 WL 564243 (D.N.J. Mar. 5, 2009) (holding that manufacturing defect claims are one of the few types of claims that may not be pre-empted under *Riegel*). Courts have generally permitted these types of claims to proceed because a typical manufacturing defect claim asserts that the defendant manufactured the product in a manner that deviated from FDA-mandated processes or specifications and, therefore, the claim would not impose additional or different requirements on the manufacturer. As long as the plaintiff provides detail on how the device deviated from manufacturing processes or specifications established by the FDA, either through the premarket approval process or through Current Good Manufacturing Practice (CGMP) regulations, most courts have found that these claims are not expressly pre-empted.

To date, the vast majority of parallel claims that have survived motions to dismiss alleged manufacturing defect claims. See *Purcel v. Advanced Bionics Corp.*, WL 3874713 (S.D. Tex. 2008). Some manufacturing defect claims have been dismissed, however, either because the claims were not adequately pled pursuant to *Bell Atlantic Corp. v. Twombly* or because the alleged manufacturing defect had no relation to the device at issue or to plaintiff's injuries. Courts have made it clear that the alleged regulatory violation must be related to the device at issue, and bear some relation to plaintiff's injury, for a parallel claim to survive a motion to dismiss.

Design Defect and Failure To Warn Claims

Thus far, the vast majority of post-*Riegel* decisions have dismissed plaintiffs' design defect and failure to warn claims under *Riegel*'s express pre-emption principles. The reason behind these decisions is clear. Plaintiffs can no longer assert that Class III medical devices should be designed or labeled in a manner that differs from FDA approval specifications. At least one court, however, has held that a plaintiff may assert a parallel failure to warn claim in connection with the off-label use of a Class III device. In *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769 (D. Minn. 2009), the court held that plaintiff may have a valid parallel claim if the plaintiff alleged that the defendant promoted the device for off-label uses in violation of FDA regulations and failed to provide adequate warnings and instructions relating to the off-label use.

Express Warranty Claims

The biggest divergence in reported opinions discussing parallel claims involves express warranty claims. The problem exists because in *Riegel*, the Supreme Court did not address whether express warranty claims were pre-empted because the lower courts dismissed that claim due to a lack of evidence. Post-*Riegel*, some courts, including those in the Third Circuit, have held that express warranty claims are not pre-empted under *Riegel* because such claims "arise from voluntary representations of the parties and not from the independent operation of state law." See *Huber v. Howmedica Osteonics Corp*., 2008 WL 5451072 (D. N.J. Dec. 31, 2008).

Other courts have addressed the express warranty issue by analyzing whether the defendant's representations were approved or mandated by the FDA. For example, in *Riley* and *Horowitz v. Stryker Corp.,* 613 F. Supp. 2d 271 (E.D. N.Y. 2009), the courts held that express warranty caims were only pre-empted if the warranties were based on FDA approved or mandated language. The *Riley* court explained that express warranty claims based on representations not approved or mandated by the FDA would not impose additional or different requirements on manufacturers because federal law permits, but does not require, manufacturers to provide express warranties. Lastly, a few courts have found that all express warranty claims are pre-empted under *Riegel*.

Although the exact contours of the parallel claim will continue to be litigated, the parallel claim doctrine is likely here to stay in some form. It is unlikely that the Supreme Court will step in any time soon to further clarify this issue. As a result, the trial and lower appellate courts will bear the burden of establishing the framework by which parallel claims involving Class III medical devices will be judged. ■