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APPEALS COURT RULING EMBRACES "PMA" DEVICE PREEMPTION

by
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In May, the U.S. Court of Appeals for the Second Circuit joined a strong and convincing majority of federal appellate courts in upholding medical device preemption for Premarket Approval (PMA) devices in *Riegel v Medtronic, Inc.*, 451 F. 3d 104 (2d Cir. 2006). To the extent a circuit split remains, it grows increasingly stale. *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), remains the lone minority case on point, and it has failed to persuade any other circuit in the seven years since it was decided.

The *Riegel* majority held "that tort claims that allege liability as to a PMA-approved medical device, notwithstanding that device's adherence to the standards upon which it obtained premarket approval from the FDA, are preempted."

The majority explained that the PMA process involves "interaction between the FDA and the manufacturer," and approval means "the applicant is required to comply with the standards in the PMA approval order" and also any Conditions of Approval. It adopted the majority position that the PMA process "utterly diverges from the 510(k) process," and also concluded that the FDA mandated compliance for this particular device, even though the record involved "generic letters" from the FDA telling Medtronic its device had won approval.

The majority also concluded that state law tort claims can be preempted where "the liability-creating premise" is "that the [device] itself, in its present PMA-approved form, is in some way defective and therefore requires modification."

The court further noted that a jury verdict would place manufacturers in an untenable position because they still could not act without FDA approval. Moreover, it is conceivable that different juries might reach different conclusions. In the Second Circuit's view, upholding preemption upheld the purpose of the MDA – to avoid stifling innovation with a welter of contrary requirements.

One judge did dissent, however. The dissent's analysis began by presuming that Congress would not have intended preemption of what it viewed as a basic state health and safety issue. As most recently noted by the FDA [*see* 21 Fed. Reg. 3922 (Jan. 24, 2006)], however, medical device regulation has historically been the subject of pervasive federal regulation, thus undermining any presumption that may exist against preemption of matters of traditional state concern. The dissent also viewed Congress' intent to preempt state law tort claims to be unclear, and found it improbable that Congress meant to protect consumers by placing their fate in the hands of the FDA, which it viewed as less than competent.

Despite the skepticism in the *Riegel* dissent, the majority opinion is further affirmation of the importance of the preemption defense for medical device manufacturers. Moreover, to the extent past cases are any guide, the Supreme Court has shown little appetite for addressing the issue whenever plaintiff have pursued review. *See McMullen v. Medtronic, Inc.*, 421 F.3d 482 (7th Cir. 2005), *cert. denied*, 126 S. Ct. 1464 (2006); *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir.), *cert. denied* sub. nom. *Knisley v. Medtronic, Inc.*, 126 S. Ct. 420 (2005); *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 799 (8th Cir. 2001) (en banc), *cert. denied*, 535 U.S. 1056 (2002); *Martin v. Medtronic, Inc.*, 254 F.3d 573, 584–585 (5th Cir. 2001), *cert. denied*, 534 U.S. 1078 (2002); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 224-27 (6th Cir. 2000), *cert. denied*, 534 U.S. 818 (2001); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911–914 (7th Cir. 1997), *cert. denied*, 523 U.S. 1020 (1998).

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