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Can a Plaintiff Thread the Preemption Needle by Alleging Off-Label Promotion?

About the Author

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In 2008, the United States Supreme Court held in *Riegel v. Medtronic, Inc*. that a federal statute, the Medical Device Amendments of 1976, barred (or preempted) state tort law claims against manufacturers of FDA-approved medical devices. In the years since the *Riegel* decision, many plaintiffs have attempted to avoid preemption by basing their claims against medical device manufacturers on that manufacturer's alleged off-label promotion.

Although some courts have recognized a 'narrow gap' of non-preempted claims, including potential claims arising from off-label promotion, most courts have applied a very demanding standard to such claims. The Minnesota State District Court addressed the pleading requirements for such a claim in an August 2013 order. In that case, *Lawrence v. Medtronic, Inc.*, the plaintiff alleged he was injured by a Class III medical device, called 'the Infuse Device,' which is designed for implantation into vertebrae to fuse those vertebrae. The court found that the bulk of the plaintiff's claims were preempted, including claims of negligence, strict liability, warranty, and breaches of various Minnesota state statutes, based on *Riegel* and on the Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*.

However, more interestingly for medical device manufacturers, the court held that 'plaintiffs' fraud-based claims may not be preempted, if they are pleaded with the requisite particularity.' (In non-legalese, this means that, instead of just making general allegations, the plaintiff must actually provide specific factual allegations — who said what to whom and when — that prove their claims.)

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There is some good news, however. While *Lawrence v. Medtronic* allowed for the possibility for a such a non-preempted claim, the court set a demanding pleading standard for plaintiffs to meet. The *Lawrence* plaintiffs' fraud claims were based on allegations that 'defendants provided false and misleading information to them in the process of promoting the off-label use of the Infuse Device,' and that

plaintiffs relied on those misrepresentations in agreeing to have the device implanted. But the plaintiffs' allegations were not specific and were little more than boilerplate allegations, what we might refer to as 'fraud in the air':

Plaintiffs identify alleged representations made by Defendants in promoting the off-label use of the Infuse device, and contrast those representations with various published medical research that reveal risks of such off-label use. Plaintiffs do not, however, identify what representations were made to them or their physicians and allegedly relied on by them in deciding to go ahead with the surgical procedure at issue in this case. It is unclear from the Complaint which specific alleged misrepresentations allegedly caused Steven Lawrence and his doctors to choose an off-label use of the Infuse device for Mr. Lawrence's surgery performed on September 12, 2011. Plaintiffs' allegations regarding what Mr. Lawrence's physicians knew and what they relied upon in deciding to recommend an off-label use of the Infuse device in his case are conclusory, at best, and are stated upon information and belief, signaling that they are not within Plaintiffs' personal knowledge.

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The Court held that these allegations failed to plead fraud with the requisite particularity. Allegations that the product was used off-label, or that the defendant had made allegedly false statements in certain medical literature, are not adequate: 'In order to give rise to a claim of fraud in such a case, the Plaintiff must plead facts to show that his or her physician was affirmatively mislead in assessing the potential risk by misrepresentations made by the Defendant' and that those alleged misstatements were not included in the FDA-approved labeling. Because the plaintiffs failed to plead such facts, the Court dismissed the complaint without prejudice, allowing them to re-plead with sufficient facts, if possible.

So what is the takeaway? Medical device manufacturers need to be aware that the Lawrence decision is part of a growing body of case law that recognizes that a plaintiff may allege a parallel claim, and thus avoid preemption under Riegel, based on fraudulent misrepresentation made during off-label promotion. However, Lawrence still requires plaintiffs to allege specific facts showing that the doctor who made the decision to use the Class III medical device actually was misled by a specific false statement attributable to the manufacturer. That was the holding of a Massachusetts State Court in a case that we handled, *Scoggins v. Boston Scientific Corporation,* Middlesex County Superior Court, (2010), and is the holding of several other cases as well, including *Riley v. Cordis Corp.*(2009); *Houston v. Medtronic, Inc.*(2013); and *Caplinger v. Medtronic, Inc.*, (2013).

In sum, these cases recognize that there may be a 'narrow gap' of non-preempted claims based on off-label promotion, but it is no easy feat to plead facts that would establish such a claim, and thereby thread the preemption needle.