Legal Opinion Letter

Vol. 22 No. 16 October 25, 2013

Washington Legal Foundation
Advocate for Freedom and Justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
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Ramirez v. Medtronic, Inc.: The Perils of Off-Label Promotion Allegations in Medical Device Preemption Cases

by Matthew A. Reed

The twin doctrines of express preemption and implied preemption create a scissors that cut off most state-law tort claims involving medical devices marketed pursuant to the Food and Drug Administration's ("FDA") rigorous pre-marketing approval ("PMA") process. In *Riegel*, the United States Supreme Court held that Section 360k of the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA") expressly preempts any state-law claim that requires anything different from, or additional to, the requirements of medical device manufacturers set forth in the MDA and the FDA regulations implementing it. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008). And in *Buckman*, the Court held that the FDA had to be free to enforce the MDA pursuant to its difficult and competing objectives, so that state-law claims in which the existence of the MDA was a "critical element" were impliedly preempted because they amounted to private attempts to enforce federal regulations. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348-53 (2001). Thus, "*Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010).

Plaintiffs have sought to avoid the *Riegel*/*Buckman* pincers by alleging in their state-law claims that manufacturers were promoting off-label uses of their devices. A device is used "off-label" when a physician uses it in a manner, or for a purpose, different than those approved by the FDA for inclusion in the device's label. According to plaintiffs, allegations of off-label promotion remove their claims from the preemptive power of the MDA because the FDA's approval, and thus regulation, applies only to "on-label" uses. Most courts have held, however, that the FDA regulates devices, not just their particular uses, and thus allegations of off-label promotion do nothing to obviate the *Riegel*/*Buckman* analysis. *See*, *e.g.*, *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206 (W.D. Okla. 2013); *Houston v. Medtronic, Inc.*, --- F. Supp. 2d ---, 2013 WL 3927839 (C.D. Cal. Jul. 30, 2013); *Otis-Wisher v. Fletcher Allen Health Care, Inc.*, --- F. Supp. 2d ---, 2013 WL 3214714 (D. Vt. Jun. 25, 2013).

In *Ramirez*, the District of Arizona recently held that allegations of off-label promotion do exempt state-law claims from preemption. *Ramirez v. Medtronic, Inc.*, --- F. Supp. 2d ---, 2013 WL 4446913 (D. Ariz. Aug. 21, 2013); *see also Alton v. Medtronic, Inc.*, 2013 WL 4786381 (D. Ore. Sept. 6, 2013). The analysis it employed in reaching that conclusion, however, required the court to take positions on off-label promotion and preemption that not only contradicted other positions in its opinion, but also basic regulations and preemption law. Moreover, it led to a rule that allows a plaintiff to avoid preemption merely by alleging off-label promotion. As a result, rather than lighting an alternative path to that employed by most courts, it serves primarily to demonstrate the wisdom of the majority rule.

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Ramirez involved Medtronic's Infuse, a three-piece spinal fusion device PMA-approved by the FDA for use in a specific spinal surgery when all three pieces were used. Plaintiff alleged that Medtronic promoted the use of Infuse in a different, off-label manner to her surgeon, and that, as a result, she suffered injury. Medtronic moved to dismiss Plaintiff's claims as expressly and impliedly preempted.

The court began by asserting that the plaintiff "premises her state law claims on her physician's off-label use of the Infuse device, which she claims resulted from Medtronic's active promotion of that use. Her claims thus seek to hold Medtronic liable for injuries that trace back to its off-label promotion." While acknowledging that a physician may properly use a device off-label, and that a manufacturer can do nothing to stop such use, the court made clear that a manufacturer's promotion of off-label use "violates federal law." Express preemption, however, only applies to claims that a defendant violated state tort law despite compliance with federal law. Thus, the allegation of illegal off-label promotion was the "crucial difference" that caused *Riegel*'s shield against state-law claims to drop.

In short, *Ramirez* held express preemption did not apply because the core of the plaintiff's state-law claims was the existence of a federal infraction. But it was that precise conclusion that directly contradicted its *Buckman* analysis. The court acknowledged that implied preemption arises from the fact that the FDA alone is responsible for enforcing the FDCA, and that in doing so it must have leeway to balance its difficult and competing objectives as it sees fit. As a result, "federal regulations cannot be hijacked by private plaintiffs" who use state-law claims essentially to enforce federal law "under the guise of negligence actions." Therefore, the court held, *Buckman* impliedly preempts state-law claims the core of which "turn[s] on the existence of a federal infraction." Yet the court held that the plaintiff's claims were not impliedly preempted, despite having just held they turned on the federal infraction of off-label promotion in allowing them to escape express preemption.

Furthermore, the court acknowledged that *Buckman* sought to ensure that manufacturers would only be held to the FDA's interpretation of the FDCA, not those of fifty different states. Otherwise, manufacturers' attempts to comply with the FDCA, "though deemed appropriate by the Administration, [might] later be judged insufficient in state court." Yet despite its admission that *Buckman* reserved interpretation of the FDCA for the FDA, and specifically not for the courts, it refused to impliedly preempt plaintiff's claims in part because "*Buckman* does not foreclose claims that would require a court to interpret federal law."

Ramirez's analysis proceeded from the flawed premise that the plaintiff's allegations of off-label promotion entailed a new use beyond the scope of federal regulation and its preemptive effect—despite the court's acknowledgment that off-label promotion is in fact subject to federal regulation. That core contradiction led to the confused analysis discussed above, in which the court struggled to explain how plaintiff's claims simultaneously were, and were not, predicated on a violation of federal law. Rather than follow *Ramirez* down that analytical rabbit hole, courts would be better served in following the majority of courts in holding that allegations of off-label promotion fall squarely within the existing regulatory scheme, and thus cannot remove state-law claims beyond the reach of *Riegel* and *Buckman*.

 ISBN 1056 3059