

Stengel v. Medtronic, Inc.: The Riegel/Buckman Gap Narrows in the Ninth Circuit

Medical Device Law Update

May 2012 by [Matthew Reed](#)

The Ninth Circuit Court of Appeals has further curtailed the universe of state law claims pertaining to Class III medical devices that are neither expressly preempted by *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008) nor impliedly preempted by *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349-50 (2001). In *Stengel v. Medtronic, Inc.*, --- F.3d ---, 2012 WL 1255040 (9th Cir. Apr. 16, 2012), the court ruled that a state law failure-to-warn claim premised on Food and Drug Administration (FDA) regulations was impliedly preempted by the Supreme Court's decision in *Buckman* because it was analytically indistinct from the "fraud-on-the-FDA" claim with which *Buckman* dealt. To wit, both claims revolved around allegations that the defendant misled the FDA, whether by commission (*Buckman*) or omission (*Stengel*).

When considered in conjunction with *Riegel's* express preemption of state law claims that add to or change the duties of Class III medical device manufacturers under the Medical Device Amendments to the Food, Drug, and Cosmetic Act, the Ninth Circuit's robust view of *Buckman* implied preemption leaves very little room for a plaintiff to state a cognizable state law cause of action against the manufacturer of a medical device cleared through the FDA's premarket approval (PMA) process. The court recognized the sharpened dilemma it left potential plaintiffs, but identified state law manufacturing defect actions as a category of claims that had passed through the *Riegel/Buckman* gauntlet unscathed, at least in the Seventh Circuit Court of Appeals. This is because such claims parallel federal duties (and thus skirt *Riegel*) without relying solely on the breach of duties created by federal regulation (which would run afoul of *Buckman*).

The *Stengel* opinion explicitly acknowledged that federal appellate courts were divided on the issue of whether state law failure-to-warn claims were preempted by *Buckman*. Interestingly, it aligned itself with the Eighth Circuit Court of Appeals' view, while spending a good amount of space explaining why the Fifth Circuit Court of Appeals' countervailing view was unpersuasive. Whether the Supreme Court takes note of the brewing circuit split, or the Ninth Circuit's justification of its decision, remains to be seen.

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