Legal Opinion Letter

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COURT REJECTS EFFORT TO "PREEMPTION-PROOF" MEDICAL DEVICE LAWSUIT

by
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A growing number of courts have held that medical devices marketed pursuant to the Food and Drug Administration's ("FDA") rigorous pre-market approval ("PMA") process are so heavily regulated by the federal government that nearly all state law claims regarding such devices are preempted, expressly or impliedly, by federal law. In *Caplinger v. Medtronic, Inc.*, the plaintiff attempted to "preemption-proof" her state law claims by alleging that Medtronic engaged in "off-label promotion" of its medical devices – that is, sold them specifically for uses that were not indicated on the FDA-approved label, in contravention of FDA regulations. --- F. Supp. 2d ---, 2013 WL 453133 at *9 (W.D. Okla. Feb. 6, 2013). The federal district court dismissed the plaintiff's complaint anyway, holding that, while such allegations might allow a few of her claims to escape express preemption, they were still impliedly preempted. In so doing, the court relied upon a logical construction of the Supreme Court's much-debated implied preemption doctrine in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), which other courts facing similar "off-label" allegations, and seeking to give full preemptive force to FDA regulatory authority, would do well to follow.

Caplinger involved Medtronic's Infuse Device, a Class III medical device used in spinal fusion surgeries to treat degenerative disc disease. The Infuse consists of three parts: "(1) a recombinant human bone morphogenetic protein, (2) a collagen scaffold, and (3) an interbody fusion device (essentially, a cage)." It was approved by the FDA through the PMA process for spine surgeries performed through the abdomen, but had not been approved for the same surgeries performed through the back. Plaintiff alleged the Infuse, which was implanted through her back, had caused "exuberant bone growth," which in turn caused leg and back problems and associated surgeries.

Plaintiff brought claims – replete with allegations of off-label promotion – against Medtronic for fraudulent misrepresentation and inducement, constructive fraud, strict products liability under failure to warn and design defect theories, breach of express and implied warranties, negligence, and negligent misrepresentation. Medtronic moved to dismiss Plaintiff's complaint on two grounds. First, each cause of action was expressly preempted by the Medical Device Amendments of 1976 ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA") – as interpreted by the Supreme Court in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) – "because they seek to impose state-law requirements on the design, manufacture, or labeling of the Infuse Device that are different from or in addition to the federal requirements imposed by the FDA." Second, to the extent Plaintiff's claims were predicated upon allegations that Medtronic promoted "off-label" uses of the Infuse in contravention of the FDCA, they were seeking privately to enforce federal law and thus were impliedly preempted by *Buckman*.

The court began its discussion by setting forth the express preemption principles that governed its analysis. In *Riegel*, the Supreme Court provided two important interpretations of MDA section 360k(a),

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which expressly preempts any state "requirement" pertaining to medical devices different from, or in addition to, the federal government's requirements under the MDA. First, "federal requirements" meant those imposed by the PMA process (as opposed to the less rigorous "510(k) clearance" process). Second, "state requirements" included state common law claims (in addition to state legislation, regulations, etc.). Thus, state-law claims pertaining to PMA-approved medical devices are preempted unless they are premised upon a violation of FDA regulations, and thus "parallel" federal requirements.

The court's implied preemption analysis turned on its interpretation of *Buckman*. There, the Supreme Court found "clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government." The *Buckman* plaintiffs' state law "fraud-on-the-FDA" claims were therefore preempted because it was the FDCA, not state law, which prohibited fraud on the FDA. Thus the plaintiffs were necessarily seeking to enforce the FDCA because it was "a critical element" to their claims. *Caplinger* construed *Buckman*'s "critical element" language logically to preempt *any* state-law claim when it is "in substance (even if not in form) a claim for violating the FDCA – that is, when the state claim would not exist if the FDCA did not exist."

Caplinger then summarized the practical effect of the Supreme Court's medical device preemption jurisprudence: "*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*)." Thus, the court concluded, a viable state-law claim pertaining to a PMA-approved medical device "must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA."

The *Caplinger* plaintiff argued her claims were exempt from express preemption because "defendant's intentional promotion of the Infuse Device for [] off-label uses was in violation of federal law and FDA regulations." Noting that *Buckman* found off-label usage "accepted and necessary," the court rejected this contention as inconsistent with the MDA's express preemption provision, which applies to PMA-approved devices *themselves*, regardless of how they are used or promoted. Neither did plaintiff's allegations of off-label promotion create "parallel" claims that escaped express preemption, because the federal ban on off-label promotion is "not genuinely equivalent" to the state law duties to manufacture products with adequate warnings and non-defective designs. Put another way, "[i]t is possible to violate the state law requirement while complying with the federal requirements and vice versa." Thus, the majority of the plaintiff's claims were expressly preempted despite their allegations of off-label promotion, because they would impinge on the FDA's exclusive regulatory power by imposing state-law liability despite Medtronic's compliance with federal regulations.

Moreover, to the extent the plaintiff's fraudulent misrepresentation/inducement and negligent promotion claims were premised on off-label promotion (and thus escaped express preemption because they alleged violations of the FDCA and were therefore "parallel" to federal requirements), they were nonetheless impliedly preempted by *Buckman*'s preclusion of private enforcement of the FDCA. Because "even the concept of 'off-label use' is a creature of the FDCA," the court held, a determination of whether promotion of such use was improper would necessarily require "reliance on the requirements of the FDCA." Thus, while ostensibly based on state law, each of plaintiff's claims was "in substance a claim for violating the FDCA" and was therefore "clearly preempted under *Buckman*." In short, *Caplinger*'s application of *Buckman* to *any* private attempt to enforce the FDCA, regardless of form, allowed it properly to recognize – and impliedly preempt – the plaintiff's claims premised upon off-label allegations as incursions into the FDA's exclusive jurisdiction.

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