PUBLICATION

Federal District Court Rules Favorably for Medical Device Manufacturer in Off-Label Promotion Lawsuits

Authors: Robert F. Tom
April 17, 2015

On April 13, 2015, in the case of *Kathleen Hafer v. Medtronic, Inc.*, the United States District Court for the Western District of Tennessee issued a favorable opinion to a medical device manufacturer in the context of preemption and alleged off-label promotion.

On the whole, Judge John T. Fowlkes Jr.'s opinion reinforces the strength of a preemption defense in a medical device case even where there are allegations of off-label use and promotion of a pre-market approved medical device. Medtronic is represented by Baker Donelson, along with the firms of Mayer Brown and Pepper Hamilton.

In a 30-page opinion, Judge Fowlkes found that plaintiffs' claims for strict liability-failure to warn, strict liability-design defect, negligence and breach of express and implied warranties were preempted by the Medical Device Amendments of 1976 (MDA). As to plaintiffs' claims for fraudulent concealment and misrepresentation, negligent misrepresentation and breach of express warranty, the court also dismissed these claims with leave to amend under Rule 9(b) for failure to allege with particularity the specific misrepresentations and warranties relied upon by plaintiffs.

These lawsuits originated in state court in Memphis, Tennessee, where Kathleen Hafer and 140 other plaintiffs from around the country individually sued Medtronic, Inc. and/or Medtronic Sofamor Danek USA, Inc. (collectively, Medtronic) based on Medtronic's pre-market approved Infuse Bone Graft Device (Infuse). Plaintiffs' lawsuits uniformly alleged that Medtronic had improperly and illegally promoted and sold Infuse in an off-label manner, which resulted in various injuries to the plaintiffs. Medtronic subsequently removed all of the lawsuits to federal court, and the lawsuits were then transferred to Judge Fowlkes. The plaintiffs thereafter filed a Master Complaint and asserted seven causes of action for fraudulent concealment and misrepresentation, strict liability-failure to warn, strict liability-design defect, negligent misrepresentation, negligence, and breach of express and implied warranties. Medtronic moved to dismiss the Master Complaint, arguing that the claims were either expressly or impliedly preempted and that the individual claims were subject to dismissal on independent state law grounds.

After the parties fully-briefed Medtronic's motion to dismiss and subsequently filed a number of supplemental authorities, the court issued a 30-page opinion finding favorably for Medtronic. The court began its analysis with an overview of preemption generally under the MDA and stated that there is a "narrow gap" within which a state law claim must fit in order to avoid express and 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*)." Regarding off-label use/promotion, the court recognized that "if there are [federal] requirements applicable to the device, off-label use/promotion will not remove federal preemption" and that the "use of medical devices in an off-label manner 'is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine.'"

In a ruling very significant to medical device manufacturers facing strict liability-failure to warn, strict liability-design defect, negligence, and breach of express and implied warranty claims, the court found that such claims were preempted. As to the plaintiffs' failure-to-warn claim, the court found that claim expressly preempted under 21 U.S.C. § 360k(a), as it would impose labeling requirements "different from, or in addition to" the federal requirements. The court found that the FDA-approved label clearly warns of the risks associated with the use of Infuse—both off-label and on-label—experienced by the plaintiffs and that the plaintiffs' failure-to-warn claim would require Medtronic "to provide warnings above and beyond those . . . that were specifically approved by the FDA as part of the PMA process." The court also found that the plaintiffs' design defect claim was expressly preempted as such a claim "would permit a finding that . . . the Infuse Device [is] unreasonably dangerous, even if defendants complied with all FDA regulations addressed to design," which in turn would provide requirements "different from, or in addition to" federal requirements.

As to the plaintiffs' claims for breach of express and implied warranties based on Medtronic's FDA-approved label, the court found that such claims were expressly preempted because they "directly contradict the FDA's analysis of safety and effectiveness" and provide a requirement "different from, or in addition to" federal requirements. However, the court did find that, to the extent that the plaintiffs relied upon express warranties voluntarily made to the individual plaintiffs, the plaintiffs would be given leave to amend to allege the specifics of any such warranties.

The court noted that the plaintiffs' basis for their negligence claim was unclear, but it stated that if the claim was that Medtronic was negligent in failure to warn or in the design, such a claim would be expressly preempted, and if it were based on Medtronic's failure to comply with federal law, it would be impliedly preempted. To the extent the negligence claim was based on misrepresentations, the plaintiffs would be granted leave to amend to state with particularity which misrepresentations the plaintiffs relied upon. The court also granted the plaintiffs leave to amend their fraud claim to allege with particularity the misrepresentations made during the promotion and marketing of Infuse.

The *Hafer* opinion can be accessed here.