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Massachusetts District Court Dismisses FCA Claims Based on Fraudulent Off-Label Promotion for Lack of Particularity

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On May 23, 2016, the US District Court for the District of *Massachusetts* dismissed several of the claims in a ***False Claims Act (FCA)*** whistleblower suit against Medtronic, Inc. and its wholly-owned subsidiary *Medtronic MiniMed, Inc. (Medtronic)* related to its insulin pumps and integrated diabetes management systems.

In ***United States ex rel. Witkin v. Medtronic, Inc.***, the relator, Witkin (a former employee of Medtronic) alleged that certain of Medtronic's promotional activities related to its insulin pumps and the pediatric use of its integrated diabetes management systems designed for adult use were false or misleading, resulting in false claims for reimbursement. The district court held that Witkin failed to plead his claims with sufficient particularity pursuant to Fed. R. Civ. P. 9(b). The district court emphasized the particularity requirement in this case, observing that "the alleged fraudulent promotional activity permits only a weak inference of resulting false claims." Specifically, the district court held that, with respect to allegations that Medtronic promoted its insulin pumps for use with a type of insulin that is not approved for administration with a pump, Witkin failed to connect allegations of fraudulent promotion to any false claims for reimbursement of either the pumps or the insulin. In addition, with respect to the pediatric use of adult integrated diabetes management systems, the District Court invoked the often-cited principle that "Witkin had alleged an elaborate fraudulent scheme with some detail, but without particularity as to the 'who, what, where, and when' of the underlying fraudulent promotion or eventual false claims."

Accordingly, the district court dismissed the claims that relied on a theory of off-label promotion on Rule 9(b) grounds. Notably, the district court distinguished the alleged off-label promotion at issue in this case from claims in other cases that premise FCA liability on *truthful* off-label promotion, noting that there is a question about whether imposing liability in such circumstances would run afoul of the First Amendment (citing the Second Circuit's 2012 holding in *United States v. Caronia*, which we discussed in our post on May 26).

The particularity of the pleading was also an issue in a claim unrelated to off-label promotion. The district court also dismissed, on Rule 9(b) grounds, Witkin's claims that Medtronic assisted patients in fabricating eligibility criteria for pump therapy because Witkin failed to include particularized allegations of patient targets or when or what information was falsified "let alone allegations of doctors who endorsed the fabricated certifications of medical necessity and thereafter made false

claims to the government health care programs.”

The decision was not a total loss for Witkin, however, as the district court permitted certain FCA claims to continue, based on payments to physicians allegedly in violation of the Anti-Kickback Statute (AKS). In addition, the district court allowed Witkin’s retaliatory discharge claims to continue. As to the dismissed claims, however, the district court indicated that it was not inclined to allow Witkin to amend. The district court warned that, as Witkin had already been allowed two amended complaints, the court was unlikely to grant any additional requests to amend the complaint, stating that, absent unforeseen circumstances, Witkin would not be allowed to “try to reformulate his allegations, yet again, to avoid their legal deficiencies.”

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