

Medical Marketing Plans May Run Afoul of False Claims Act; Third Circuit Reverses Dismissal of Complaint

A recent Third Circuit case may signal serious legal repercussions for medical device companies as well as hospitals and physicians as a result of marketing programs employed by medical device manufacturers in their efforts to increase market share. *U.S. ex rel. Schmidt v. Zimmer, Inc. et al.* was handed down on October 6, 2004.

In reversing the lower court's dismissal of the complaint, the Third Circuit held that Zimmer, a medical device manufacturer, may be liable under the False Claims Act (FCA) for causing or conspiring with a hospital to falsely certify compliance with the federal Anti-Kickback and Anti-Self-Referral (Stark) laws. (The hospital had previously settled and was not the focus of the appeal.) The court's opinion apparently extends current law and warrants a review by manufacturers of their marketing programs and a review by hospitals and physicians of the roles they play in those programs.

The Complaint's Allegations

Dr. Richard G. Schmidt, an orthopedic surgeon, brought a *qui tam* ("whistleblower") action pursuant to the False Claims Act against defendant Zimmer, a manufacturer, seller and distributor of orthopedic implants. He sued on behalf of the government to recover losses incurred because of what he believed were fraudulent claims presented for Medicare reimbursement. A private plaintiff in a *qui tam* action, like Dr. Schmidt, is referred to as a relator.

Dr. Schmidt alleged that Zimmer entered into a contract with Premier Purchasing Partners (Premier), a group purchasing organization for entities, including the hospital, that provide medical services for which reimbursement may be sought under the Medicare program. Under the contract, Zimmer provided its medical devices to Premier participants. The marketing practices at issue in the case were implemented through Premier and included the following:

When a customer purchased from Zimmer more than the total number of implants it had purchased the year before, each additional implant could be purchased at a reduced price.

The customer would receive a 2% bonus on purchases after meeting pre-set market share and volume purchase commitments relating to Zimmer products.

Additional incentives were provided "to offset the costs associated with competitive conversion," if the provider switched from using a competitor's product to the Zimmer product.

In the *qui tam* complaint, Dr. Schmidt alleged that Zimmer and its hospital customer induced physicians and orthopedic departments to assist in meeting Zimmer's prescribed volume and market share levels by sharing with

them all or part of the rewards received under the contract.

The complaint also alleged that the Zimmer marketing program constituted the giving of kickbacks to induce purchases that would be reimbursed under federal programs. The sharing of rewards with surgeons was alleged to implicate the Stark law because a participating physician then referred patients to an entity with which s/he had a financial relationship.

In ruling on Zimmer's motion to dismiss the complaint, the district court held simply that Zimmer could not be liable under the FCA because it did not cause the hospital to file a false claim. The district court did not reach the issue of whether the Zimmer marketing program violated the anti-kickback or Stark laws.

Third Circuit Reasoning

In reviewing the factual allegations of the complaint, which for the purposes of the appeal the court deemed to be true, the appellate court "conclude[d] that these [anti-kickback and Stark] issues cannot be resolved in the context of a motion to dismiss." Thus, the court of appeals implicitly ruled that the described practices, if proven, could violate the anti-kickback and Stark laws.

Because this action was framed as a *qui tam* lawsuit under the False Claims Act, the central issue decided by the court was whether Zimmer could be liable under the FCA for *causing* a false claim to be presented or *conspiring* to obtain payment of a false claim from the United States. In its most far-reaching ruling, the Third Circuit interpreted this liability standard to be met by anyone who knowingly or recklessly "assisted in" causing the government to pay false claims, or claims that were grounded in fraud.

Dr. Schmidt, the *qui tam* relator, apparently did not argue that Zimmer could be liable for submission by the hospital of an actual false claim, *i.e.*, that the hospital sought reimbursement from the United States for more than it paid Zimmer. Thus, the issue posed was whether Zimmer knowingly assisted the hospital in falsely making the required certification on a Medicare cost report that the services identified in the cost report were not provided or procured directly or indirectly through payment of a kickback.

The appellate court ruled that Zimmer could potentially be held liable because, as alleged, it "created and pursued a marketing scheme that it knew would, if successful, result in the submission by [the hospital]... of compliance certifications required by Medicare that Zimmer knew would be false." Stated slightly differently, the court reversed the dismissal of the complaint against Zimmer because "Zimmer must have known that [the hospital] could not purchase its implants, receive kickbacks, and share the kickbacks with its physicians, in the manner provided by the contract unless [the hospital] falsely certified itself to be in compliance with federal law."

A Cautionary Note

Because the court's opinion is based solely on the allegations of the complaint and assumes those allegations to be true, the opinion does not give full consideration to Zimmer's defense that the challenged marketing practices are protected by the discount safe harbor to the anti-kickback statute. Nor does the court seem to distinguish between marketing practices focused specifically on conversion costs and increasing of market share as opposed to those intended, for example, to induce the use or purchase of a type of product or procedure never previously used or viewed as medically necessary by the hospital or surgeons. Typically, conversion-type incentives are viewed as having less impact on utilization and federal health care costs. Upon remand, these and other defenses

may yet result in the dismissal of the whistleblower complaint.

The Third Circuit opinion stands, however, as a warning to manufacturers, hospitals and physicians that strict compliance with anti-kickback and Stark laws is still an essential part of doing business where reimbursement by federal health care programs is involved. In light of this ruling, manufacturers in particular may want to consider documenting their understanding of how their customers will treat marketing incentives in statements to the government so that they can refute any suggestion that they have participated in a scheme to submit false certifications.

For Further Information

If you have any questions about the information in this Alert, please contact Philip H. Lebowitz at 215.979.1819 or lebowitz@duanemorris.com, or any of the Health Law attorneys listed below, or the attorney in the firm with whom you are regularly in contact.

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