FDA Law Blog

Hyman, Phelps & McNamara, P.C.

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Recent Developments in Drug and Device-Related False Claims Act Cases where Alleged Fraud Was Not Properly Pleaded

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In a March 17, 2009 opinion in United States ex rel Roop v. Hypoguard USA, Inc., the United States Court of Appeals for the Eighth Circuit held that the Relator's qui tam allegations concerning Defendant's alleged failure to submit FDA-required medical device reports ("MDRs") for defective blood glucose monitors was insufficient to meet the Fed.R.Civ.P. 9(b) requirements for pleading fraud with specificity. Affirming the lower court's dismissal of Relator's pre- and post-judgment motions to file a First Amended Complaint, the Eight Circuit determined that Relator's proposed First Amended Complaint "failed to cure deficiencies in the initial Complaint" because it "did not plead with particularity the details of any false Medicare reimbursement claim presented to, or paid by, the United States or its agent. Nor did it allege with particularity how any product defect or failure to submit MDR reports to the FDA was material to . . . the government's decisions to pay countless unidentified Medicare reimbursement claims submitted by Hypoguard distributors."

In a March 20, 2009 opinion in United States ex rel Poteet v. Lenke, the United States District Court for the District of Massachusetts held that Relator's qui tam action against multiple spine surgeons and device distributors alleging receipt of kickbacks from Medtronic, Inc. and Medtronic Sofamor Danek U.S.A. in exchange for off-label promotion of INFUSE Bone Graft/LT-CAGE® was barred by the prior public disclosure of Relator's allegations in previously filed lawsuits and the media, and by the Relator's failure to meet the Fed.R.Civ.P. 9(b) requirements for pleading fraud with specificity. In its application of the Rule 9(b) specificity requirement, the court found that Relator's Amended Complaint was "devoid of specific allegations linking the distributor defendants to the general allegations of kickbacks and the filing of false claims with the government." It further observed that the Relator had failed to specify "which distributors were involved in the scheme, and how they were involved," or "whether the recipients of the gifts ever purchased Medtronic products or filed a claim for medicare benefits," "[ ]or . . . that these gifts caused a false filing with Medicare." Quoting a leading First Circuit FCA/Rule 9(b) opinion, United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 733 (1st Cir. 2007) (see our post about that case here), the court further found that the Relator's Amended Complaint "contains 'no factual or statistical evidence to strengthen the inference of fraud beyond possibility.'"

We have earlier reported on the case of Hopper and Hutto v. Solvay Pharmaceuticals, Inc., where the United States District Court for the Middle District of Florida dismissed a qui tam False Claims Act case involving allegations that the defendants had engaged in an alleged off-label marketing scheme with regard to the drug Marinol. On March 13, 2009, the defendants filed their appellate brief with the United States Court of Appeals for the Eleventh Circuit. On March 24, 2009, the Washington Legal Foundation filed an amicus curiae brief in that Court supporting the defendants' position that the Eleventh Circuit should affirm the lower court's dismissal. Hyman, Phelps & McNamara P.C. is one of the counsel of record for the defendants in that case.

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