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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA
ex rel. KASSIE WESTMORELAND,

Plaintiff,

v.

AMGEN, INC.; INTERNATIONAL
NEPHROLOGY NETWORK renamed
INTEGRATED NEPHROLOGY NETWORK,
a d/b/a of DIALYSIS PURCHASING
ALLIANCE, INC.; and ASD
HEALTHCARE,

Defendants.

CIVIL ACTION
NO. 06-10972-WGY

MEMORANDUM

YOUNG, D.J.

September 15, 2011

I. INTRODUCTION

Relator Kassie Westmoreland ("the Relator") brings this qui tam action against Amgen, Inc. ("Amgen"), International Nephrology Network ("INN"), and ASD Healthcare ("ASD") (collectively, "the Defendants") for violations of the federal False Claims Act, 31 U.S.C. §§ 3729-33. In her Fourth Amended Complaint, the Relator alleges that the Defendants knowingly caused health care providers to make false representations material to the payment of Medicare claims and conspired to get

false claims paid by Medicare. Specifically, the Relator alleges that, in violation of the federal Anti-Kickback Statute, the Defendants encouraged providers to submit claims for payment by Medicare for the value of the excess product, or "overfill," contained in the vials of their drug Aranesp but not included in Aranesp's average sales price ("ASP"). This Court has upheld the Relator's allegations as sufficient to state a claim under the False Claims Act.

There are now a number of other motions pending decision by the Court. First, the Defendants move for partial judgment on the pleadings under Federal Rule of Civil Procedure 12(c). It is undisputed that health care providers, in signing mandatory Medicare Enrollment Form CMS-855 ("the Provider Agreement"), agree to comply with the Anti-Kickback Statute as a precondition of Medicare payment. The Defendants, however, argue (1) that the clause in the Provider Agreement requiring a certification of compliance with the Anti-Kickback Statute is contrary to the Medicare statutes and regulations, which do not establish Anti-Kickback Statute compliance as a precondition of payment, and (2) that the adoption by the Centers for Medicare and Medicaid Services ["CMS"] of the version of the Provider Agreement that includes the certification clause was procedurally improper and outside the scope of its authority. The Relator, in opposition to the Defendants' motion, argues (1) that the Anti-Kickback

Statute itself establishes compliance as a precondition of Medicare payment, and (2) that the certification of compliance in the Provider Agreement is a valid agency interpretation of the regulations. The United States, while not a party to the action, has filed a statement of interest supporting the Relator's position.

Second, the Relator and Amgen bring cross-motions for partial summary judgment as to Count IV of the Fourth Amended Complaint, which alleges that Amgen artificially inflated Aranesp's ASP by failing to include overfill as a "price concession," in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A). In her memorandum in support of her motion, the Relator argues that, because Aranesp's ASP was artificially inflated, claims submitted by providers based on this ASP were false and fraudulent as matter of law. Amgen asserts that federal rules and regulations make clear that overfill is not to be included in a drug's ASP and that there is no evidence that Amgen intended to submit an inaccurate ASP for Aranesp.

Third, INN and ASD move for partial summary judgment on the theory that they are shielded from liability by the Anti-Kickback Statute's "safe harbor" provisions for group purchasing organizations ("GPOs"), 42 U.S.C. § 1320a-7b(b)(3)(C), and discounts, *id.* § 1320a-7b(b)(3)(A). The Relator brings a cross-motion for partial summary judgment, arguing that the GPO safe

harbor is inapplicable to INN due to its failure to comply with the formalities set forth in the federal regulations and due to its impermissibly close relationships with Amgen and ASD. With respect to ASD and the discount safe harbor, the Relator argues that the "pass through" of an administrative fee paid by Amgen to INN to ASD, who utilized the funds to provide discounts to providers, was unlawful and indicative of the conspiracy to defraud Medicare in which the Defendants allegedly have engaged.

A. Procedural Posture

In June 2006, the Relator filed this qui tam action against Amgen, INN, ASD, and two other corporate defendants under the federal False Claims Act and various related state laws on behalf of the United States, fifteen states, and the District of Columbia. Relator's Compl., ECF No. 1. In September 2009, the United States notified the Court that it was not intervening in the action at that time. U.S. Notice Non-Intervention, ECF No. 71. The states and the District of Columbia (collectively, the "States") intervened by filing a separate Multi-State Complaint in October 2009, which they amended in December 2009. Multi-State Compl. Intervention, ECF No. 85; Multi-State First Am. Compl., ECF No. 112. Subsequently, several states voluntarily dismissed, including Delaware, Florida, Louisiana, Nevada, New Hampshire, and Texas. Notices Voluntary Dismissal, ECF Nos. 120, 123, 148, 153, 156, 163.

The Relator filed her Third Amended Complaint in December 2009, bringing claims on behalf of herself, the United States, Georgia, and New Mexico. Relator's Third Am. Compl., ECF No. 113. The Defendants subsequently moved to dismiss Counts I-VI of the Third Amended Complaint and the entirety of the Multi-State First Amended Complaint. Amgen's Mot. Dismiss Relator's Third Am. Compl., ECF No. 139; Amgen's Mot. Dismiss Multi-State First Am. Compl., ECF No. 142; INN & ASD's Mot. Dismiss Relator's Third Am. Compl., ECF No. 138; INN & ASD's Mot. Dismiss Multi-State First Am. Compl., ECF No. 135. The Court dismissed the Multi-State First Amended Complaint and some of the Relator's federal claims under the federal False Claims Act's first-to-file bar and the remainder of her claims without prejudice under Federal Rule of Civil Procedure 12(b)(6). United States ex rel. Westmoreland v. Amgen, Inc., 707 F. Supp. 2d 123 (D. Mass. 2010). The First Circuit has since reversed the dismissal of the States' claims under the state False Claims Acts of California, Illinois, Indiana, Massachusetts, New Mexico, and New York, and affirmed the dismissal of the States' claims under Georgia's False Claims Act. New York v. Amgen, Inc., Nos. 10-1629, 10-1630, 10-1633, 10-1634, 10-1635, 10-1636, 10-1954, 10-1955, 2011 WL 2937420 (1st Cir. July 22, 2011).

In May 2010, the Relator filed her Fourth Amended Complaint, and the Defendants again moved to dismiss. Relator's Fourth Am.

Compl., ECF No. 238; Amgen's Mots. Dismiss Relator's Fourth Am. Compl., ECF Nos. 251, 253; INN & ASD's Mot. Dismiss Relator's Fourth Am. Compl., ECF. No. 256. On July 21, 2010, the Court denied the Defendants' Motions to Dismiss the Relator's Fourth Amended Complaint. See United States ex rel. Westmoreland v. Amgen, Inc., 738 F. Supp. 2d 267 (D. Mass. 2010). On August 4, 2010, the Defendants answered the Relator's Fourth Amended Complaint. Amgen's Answer Relator's Fourth Am. Compl., ECF No. 286; INN & ASD's Answer Relator's Fourth Am. Compl., ECF No. 285. INN and ASD asserted their compliance with certain safe harbor provisions of the federal Anti-Kickback Statute as their Ninth Affirmative Defense. INN & ASD's Answer Relator's Fourth Am. Compl., Affirmative Defenses ¶ 15.

On February 18, 2011, INN and ASD filed their Motion for Partial Judgment on the Pleadings. INN & ASD's Mot. Partial J. Pleadings, ECF No. 367; Mem. Supp. INN & ASD's Mot. Partial J. Pleadings, ECF No. 368. Amgen then moved to join INN and ASD's motion on March 1, 2011, and this Court allowed it the following day. Amgen's Mot. Joinder INN & ASD's Mot. Partial J. Pleadings, ECF No. 385; Mem. Supp. Amgen's Mot. Joinder INN & ASD's Mot. Partial J. Pleadings, ECF No. 387. On March 11, 2011, the Relator opposed the Defendants' joint motion. Mem. Opp'n Defs.' Mot. Partial J. Pleadings, ECF No. 408. The Court granted the Defendants leave to file a joint reply brief, which they did on