IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF GEORGIA ATLANTA DIVISION

UNITED STATES OF AMERICA ex rel. FOX RX, INC.,

Plaintiff,

v.

OMNICARE, INC. and NEIGHBORCARE, INC., 1:11-cv-962-WSD

Defendants.

OPINION AND ORDER

This matter is before the Court on Relator's Motion for Clarification of the Court's Order, or for Leave to Amend [119] ("Motion to Amend").

I. BACKGROUND

On March 25, 2011, Relator Fox Rx, Inc. ("Relator") initiated this *qui tam* action under the False Claims Act ("FCA") against Defendants Omnicare, Inc. and NeighborCare, Inc. ("Defendants"). On May 27, 2011, Relator filed, as a matter of right, its First Amended Complaint [6] (the "Second Complaint"), and on August 4, 2011, before Defendants were served with process, Relator filed, with the Court's leave, its Second Amended Complaint [7] (the "Third Complaint").

In the eight (8)-count Third Complaint, Relator alleged that Defendants,

specialty pharmacies providing services to long-term care facilities throughout the United States, engaged in four (4) separate schemes to defraud the Medicare Part D program by seeking reimbursement for prescriptions, filled on behalf of Part D beneficiaries, that are not covered or are not reimbursable by Part D:

(i) prescriptions for atypical antipsychotic drugs ("AAP") for "off-label" use of such drugs—that is, a use not authorized by the Food and Drug Administration or supported in the authorized medical literature (Counts I and II); (ii) partially-filled prescriptions ("split prescriptions") requiring multiple refills and allowing Defendants to charge unnecessary dispensing fees (Counts III and IV);
(iii) prescriptions filled without obtaining "prior authorization" (Counts V and VI); and (iv) waiver of patients' co-payments (Counts VII and VIII).

On December 21, 2011, Defendants filed their Motion to Dismiss the Third Complaint [33] (the "First Motion to Dismiss") on the grounds that Counts I through VI failed to state a claim under the FCA and that all of the counts failed to be pleaded with particularity as required by Rule 9(b) of the Federal Rules of Civil Procedure. On August 29, 2012, the Court granted in part and denied in part the First Motion to Dismiss. The Court dismissed Counts III, IV, V, VI, and VIII for failure to state a claim. The Court held that Part D does not reimburse claims for "off-label" AAP and that, therefore, Counts I and II stated claims for relief. The Court found, however, that Counts I, II, and VII were not pleaded with the particularity required by Rule 9(b) of the Federal Rules of Civil Procedure. The Court dismissed Counts I, II, and VII without prejudice and granted Relator leave to "file an amended complaint . . . to re-plead Counts I, II, and VII."

On September 18, 2012, Relator filed its Third Amended Complaint [98] (the "Fourth Complaint"). Counts I and II of the Fourth Complaint corresponded to Counts I and II of the Third Complaint and alleged that, since January 1, 2006, Defendants submitted "thousands" of false claims for "off-label" AAP prescriptions through Relator and "other PDP Sponsors."¹ Spreadsheets attached to the Fourth Complaint provided detailed information on a sample of alleged "offlabel" claims for prescriptions filled in 2009 and 2010, and submitted through Relator. The Fourth Complaint did not include any detail of prescriptions filled in other years or though other PDP Sponsors.

On October 2, 2012, Defendants filed their Motion to Dismiss the Fourth Complaint [99] (the "Second Motion to Dismiss") on the ground, among others, that Counts I and II again were not pleaded with particularity, including because the Fourth Complaint did not include any detail for prescriptions filled before 2009

¹ The Fourth Complaint also included a claim for "reverse" false claims (Count III) and a claim based on improper waiver of co-payments (Count IV).

or after 2010 or for prescription claims submitted through PDP Sponsors other than Relator. On May 17, 2013, the Court granted, in part, the Second Motion to Dismiss and dismissed the claims in Counts I and II based on claims for "off-label" prescriptions submitted outside the 2009 to 2010 time period and through PDP Sponsors other than Relator.²

On June 11, 2013, Relator filed its Motion to Amend seeking leave to file a fifth complaint to re-plead all of its "off-label" claims by alleging detail, that it excluded from its previous pleadings, of "off-label" prescriptions submitted from 2006 to 2011.³

II. DISCUSSION

Plaintiff's Motion to Amend is untimely under the existing schedule in this case. See LR 7.1(A)(2), NDGa (providing that, with certain exceptions not relevant here, "motions must be filed WITHIN THIRTY (30) DAYS after the

² The Court also dismissed Counts III and IV of the Fourth Complaint.

³ In the Motion to Amend, Relator also seeks "clarification" on whether the Court's May 17, 2013, dismissal of the improperly pleaded claims was with or without prejudice. The Court's order, dismissing Relator's claims and not granting leave to re-plead, speaks for itself, and the Court considers here only Relator's request for leave to amend. <u>See</u> Fed. R. Civ. P. 41(b) (providing that an involuntary dismissal for failure to state a claim "operates as an adjudication on the merits").

beginning of discovery").⁴ Although Rule 15 of the Federal Rules of Civil Procedure generally governs leave to amend pleadings, the Court first must determine whether the schedule may be modified, under Rule 16, to allow the late filing of the Motion to Amend. <u>See Sosa v. Airprint Sys., Inc.</u>, 133 F.3d 1417, 1419 (11th Cir. 1998) (per curiam) (holding that courts evaluating untimely motions to amend should determine whether to alter the scheduling order under Rule 16 before determining whether the amendment is proper under Rule 15). "A schedule may be modified only for good cause and with the judge's consent." Fed. R. Civ. P. 16(b)(4). "This good cause standard preludes modification unless the schedule cannot 'be met despite the diligence of the party seeking extension.'" <u>Sosa</u>, 133 F.3d at 1418 (quoting Fed. R. Civ. P. 16 advisory committee's note (1983 Amendment, Discussion of subdivision (b))).

Relator seeks leave to file an amended complaint now to allege particularly that Defendants submitted "off-label" reimbursement claims not just in 2009 and 2010 but in the entire period from 2006 to 2011. Relator does not argue that, despite its diligence, it was not able to assert these allegations in earlier

⁴ The Motion to Amend is also untimely under the Preliminary Report and Discovery Plan (the "Plan") filed by the parties on January 20, 2012, and approved by the Court on February 23, 2012. The Plan required any amendments to the pleadings to be filed not "LATER THAN THIRTY (30) DAYS after the [Plan] [was] filed." (Plan [39] ¶ 6(b), at 10.)

complaints.⁵ The only reason Relator offers for not including its additional allegations in its earlier complaints is that Defendants did not, in their First Motion to Dismiss, assert this exact pleading deficiency as a basis for dismissal.⁶ Relator does not cite, and the Court is not aware of, any authority requiring either a defendant or the court to parse through a defective complaint to identify all possible pleading deficiencies in addition to those that serve as the basis for the dismissal of the complaint. A plaintiff, however, always has the obligation to file a complaint that fully satisfies the pleading requirements imposed by the Rules, including Rule 9(b). See Corsello v. Lincare, Inc., 428 F.3d 1008, (11th Cir. 2005) ("Failure to satisfy Rule 9(b) is a ground for dismissal of a complaint."). Relator has not shown "good cause" for its failure to include its additional allegations in earlier complaints, and the Motion to Amend is denied. Cf. Angiolillo v. Collier County, 394 F. App'x 609, 611-12 (11th Cir. 2010) (affirming district court's finding that plaintiff lacked good cause to amend because plaintiff did not

⁵ In its brief, Relator ignores its obligation to show "good cause" for its proposed amendment and argues only that leave should be granted under Rule 15. The Court previously admonished Relator that Rule 16's "good cause" standard now governs motions to amend in this matter. (See Order [116] at 11 n.8, May 15, 2013.)

⁶ In their first Motion to Dismiss, Defendants argued, and the Court subsequently found, that Relator's Third Complaint failed to allege with particularity the submission to the government of *any* off-label reimbursement claims and that *all* of Relator's off-label claims were thus required to be dismissed.

sufficiently identify newly-learned facts supporting new claims and failed to

establish that new claims could not have been asserted in the original complaint).⁷

III. CONCLUSION

Accordingly, for the foregoing reasons,

IT IS HEREBY ORDERED that Relator's Motion for Clarification of the

Court's Order, or for Leave to Amend [119] is **DENIED**.

⁷ Because the Court finds that Realtor's Motion to Amend does not satisfy Rule 16, the Court does not reach the appropriateness of leave to amend under Rule 15. The Court notes that, although Rule 15(a)(2) provides that "[t]he court should freely give leave when justice so requires," leave to amend may be denied because of the plaintiff's "repeated failure to cure deficiencies by amendments previously allowed." See Equity Lifestyle Props., Inc. v. Fla. Mowing & Landscape Serv., Inc., 556 F.3d 1232, 1241 (11th Cir. 2009) (quoting Foman v. Davis, 371 U.S. 178, 182 (1962)). In this case, Relator's failure to fully cure earlier pleading deficiencies in its Fourth Complaint warrants denying leave to file a fifth complaint. See, e.g., Corsello, 428 F.3d at 1014 (affirming the district court's denial of leave to file a fourth complaint where relator had previously been given the opportunity to re-plead in conformity with Rule 9(b)); see also United States ex rel. Fowler v. Caremark Rx, L.L.C., 496 F.3d 730, 740 (7th Cir. 2007) ("Despite the fact that the deficiencies could be cured through an appropriate pleading, a district court properly exercises its discretion in dismissing the case when the plaintiff continually fails to provide a valid pleading in compliance with the federal rules."), overruled on other grounds by Glaser v. Wound Care Consultants, Inc., 570 F.3d 907 (7th Cir. 2009).

SO ORDERED this 26th day of September, 2013.

William S. My EY, JR. UNITED STATES DISTRICT JUDGE