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.,** **Defendants.**	**1:11-cv-962-WSD**

OPINION AND ORDER

This matter is before the Court on Defendants' Motion for Summary Judgment [165].

I. BACKGROUND

In this *qui tam* action, Relator Fox Rx, Inc. ("Relator") alleges that Defendants Omnicare, Inc. and NeighborCare, Inc. (collectively, "Defendants"), specialty pharmacies, violated the False Claims Act ("FCA") by seeking reimbursement for non-covered prescriptions from the Medicare Part D program. The United States declined to intervene.

A. Medicare Part D[1]

Medicare Part D ("Part D") is the federally funded prescription drug benefit program available to Medicare participants who voluntarily enroll. The program is administered by the Centers for Medicare and Medicaid Services ("CMS"), a federal agency within the Department of Health and Human Services. CMS provides drug coverage to Part D enrollee beneficiaries through private Part D Plans ("PDP") offered and administered by private PDP sponsors authorized by CMS.

To participate in Part D, beneficiaries enroll in a PDP of their choice. Beneficiaries pay premiums to their PDP sponsors. Their PDP coverage is limited by certain deductibles, co-payments, and benefit caps. Beneficiaries have their prescriptions filled at private pharmacies, which are generally within a PDP's contract network. The pharmacies submit their PDP bills for payment by the PDP sponsor, or the PDP sponsor's subcontractor, which pays the prescription costs not paid directly by the beneficiary. CMS ultimately reimburses the PDP sponsor for varying portions of the prescription costs. See generally Omnicare, Inc. v.

[1] This brief background to Medicare Part D is not a complete overview of the program or its intricacies. It is offered simply to provide general context for Relator's allegations.

UnitedHealth Group, Inc., 594 F. Supp. 2d 945, 948–49 (N.D. Ill. 2009) (providing an overview of Medicare Part D).

B. Procedural History

On March 25, 2011, Relator initiated this action. On May 27, 2011, Relator filed, as a matter of right, its First Amended Complaint [6], and on August 4, 2011, Relator filed, with the Court's leave, its Second Amended Complaint [7]. In the Second Amended Complaint, Relator alleged that Defendants, specialty pharmacies providing services to long-term care facilities ("LTCFs") throughout the United States, engaged in several 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. Relator specifically alleged, in Counts I and II, that Defendants filled, and sought reimbursement for, prescriptions for atypical antipsychotic drugs ("AAP") for "off-label" use of such drugs—a use not authorized by the Food and Drug Administration ("FDA") or supported in the authorized medical literature, known as the "compendia."[2, 3]

[2] The Court uses the term "off-label" to include the use of a drug that is neither authorized by the FDA nor supported in the compendia.

[3] The Second Amended Complaint also alleged that Defendants sought reimbursement for partially-filled prescriptions ("split prescriptions"),

On December 21, 2011, Defendants moved to dismiss the Second Amended Complaint on the grounds, among others, that Counts I and II failed to state a claim under the FCA and failed to be meet the pleading particularity requirement of Rule 9(b) of the Federal Rules of Civil Procedure. On August 29, 2012, the Court granted in part and denied in part Defendants' motion to dismiss. 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 and II were not pleaded with particularity. The Court dismissed Counts I and II and granted Relator leave to re-plead Counts I and II.[4]

On September 18, 2012, Relator filed its Third Amended Complaint [98]. Counts I and II of the Third Amended Complaint correspond to Counts I and II of the Second Amended Complaint. Count I alleges that Defendants violated 31 U.S.C. § 3729(a)(1)(A) by submitting claims for reimbursement for "off-label" AAP prescriptions, and Count II alleges that Defendants violated 31 U.S.C. § 3729(a)(1)(B) by making "false records or statements" in connection with claims

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prescriptions filled without obtaining "prior authorization," and prescriptions filled after waiving patients' co-payments.

[4] The Court also dismissed, for failure to state a claim, Relator's claims based on split prescriptions and failure to obtain prior authorizations. The Court dismissed, for failure to plead with particularity, Relator's claim based on co-payment waivers and granted Relator leave to re-plead the co-payment waiver claim.

for reimbursement for "off-label" AAP prescriptions. Relator alleges that Counts I and II consist of "thousands" of claims submitted, since January 1, 2006, to Relator and "other PDP Sponsors." With the Third Amended Complaint, Relator submitted spreadsheets detailing a "sample" of the alleged off-label AAP prescriptions for twenty (20) specific patients. These spreadsheets detail prescriptions filled only in 2009 and 2010, and submitted only to Relator, as opposed to any other PDP sponsor.[5]

On October 2, 2012, Defendants moved to dismiss the Third Amended Complaint on the ground, among others, that Relator again failed to plead its claims with particularity as required by Rule 9(b). On May 17, 2013, the Court granted, in part, Defendants' motion to dismiss and dismissed the claims in Counts I and II based on claims for "off-label" AAP prescriptions submitted outside the 2009 to 2010 time period and through PDP Sponsors other than Relator.[6] The Court thus limited the claims at issue in this action to alleged "off-label" AAP

[5] The Third Amended Complaint also included two additional claims: (i) a claim based on co-payment waiver, corresponding to Count VII of the Second Amended Complaint (Count IV); and (ii) a previously unasserted claim that Defendants made "reverse false claims" in violation of 31 U.S.C. § 3729(a)(1)(G) (Count III).

[6] On different grounds, the Court also dismissed Relator's co-payment waiver claim in Count IV and "reverse false claims" claim in Count III.

prescriptions submitted for reimbursement by Defendants to Relator in 2009 and 2010.

On December 2, 2013, Defendants filed their Motion for Summary Judgment seeking judgment in their favor on all of Relator's remaining claims.

C. Relevant Facts[7]

1. *Defendants' Business*

Defendants are specialty pharmacies that provide services in long-term care facilities ("LTCFs"), such as nursing homes. (See SUMF ¶¶ 1, 29.) In 2009 and 2010, Defendants staffed LTCFs with "dispensing pharmacists" and, in some instances, "consultant pharmacists." (See id. ¶¶ 29, 30, 50–51; SAMF ¶ 18.)

Dispensing pharmacists filled prescriptions for the LTCFs' residents, including Part D beneficiaries enrolled in PDPs offered by Relator ("Fox members"). (See SUMF ¶ 46.) After a dispensing pharmacist filled a prescription

[7] These facts are taken from the following statements of facts submitted in accordance with Local Civil Rule 56.1: Defendants' Statement of Undisputed Material Facts [165-2] ("SUMF"), Relator's Response to Defendants' SUMF [167] ("Resp. SUMF"), Relator's Statement of Additional Material Facts [168] ("SAMF"), and Defendants' Response to Relator's SAMF [184] ("Resp. SAMF"). Where a party disputed a factual assertion contained in a statement of facts, the Court also considered the specific exhibits cited in support of the assertion. See L.R. 56.1(B) (3), NDGa (providing that the court deems a party's SUMF citation as supportive of the asserted fact "unless the respondent specifically informs the court to the contrary in the response").

for a Fox member, Defendants submitted a claim for payment to Relator's subcontractor ProCare Rx. (Id.) ProCare Rx then submitted the claim to Relator, which ultimately submitted the claim for reimbursement by CMS. (Id. ¶ 48.)

Defendants' consultant pharmacists fulfilled LTCFs' obligations under CMS regulations to provide certain pharmacy services. (Id. ¶¶ 50–51.) The consultant pharmacists worked with LTCF staff to create, implement, and manage "medication regimens" for LTCF residents. (Id. ¶ 52.) In performing these duties, the consultant pharmacists regularly reviewed the residents' medical records, including the residents' medical diagnoses. (Id. ¶¶ 53–56; SAMF ¶ 32.) The consultant pharmacists recorded the diagnoses in Defendants' computer system. (SAMF ¶ 32.)

2. *Remaining Claims*

During discovery, Relator identified approximately 13,755 claims submitted by Defendants for AAP prescriptions filled on behalf of Fox members in 2009 and 2010. (SUMF ¶ 79.) Relator's retained expert, Barry Rovner ("Rovner"), reviewed these claims and opined in his report that 243 claims, filled for 71 Fox members, were for off-label AAP. (See id. ¶ 81.) Rovner subsequently testified that, based on additional information he received, 63 of the claims he previously identified as being for off-label prescriptions were in fact for prescriptions with

medically accepted indications. (Id. ¶ 89; see also Defs.' Tab 80 (showing claims per beneficiary).) Based on Rovner's testimony, Relator now concedes that these 63 claims, and an additional 35 claims, were for prescriptions with medically accepted indications. (Relator's Br. [166] at 23.[8]) Relator now maintains that 145 of the claims identified in Rovner's report (the "Remaining Claims"), filled on behalf of 47 Fox members, were for off-label prescriptions.

II. DISCUSSION

A. Legal Standard

A court "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Parties "asserting that a fact cannot be or is genuinely disputed must support that assertion by . . . citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials." Fed. R. Civ. P. 56(c)(1).

The party seeking summary judgment bears the burden of demonstrating the absence of a genuine dispute as to any material fact. Herzog v. Castle Rock

[8] Citations are to ECF page numbers.

Entm't, 193 F.3d 1241, 1246 (11th Cir. 1999). Once the moving party has met this burden, the non-movant must demonstrate that summary judgment is inappropriate by designating specific facts showing a genuine issue for trial. Graham v. State Farm Mut. Ins. Co., 193 F.3d 1274, 1282 (11th Cir. 1999). Non-moving parties "need not present evidence in a form necessary for admission at trial; however, [they] may not merely rest on [their] pleadings." Id.

The Court must view all evidence in the light most favorable to the party opposing the motion and must draw all inferences in favor of the non-movant, but only "to the extent supportable by the record." Garczynski v. Bradshaw, 573 F.3d 1158, 1165 (11th Cir. 2009) (quoting Scott v. Harris, 550 U.S. 372, 381 n.8 (2007)). "[C]redibility determinations, the weighing of evidence, and the drawing of inferences from the facts are the function of the jury . . . ." Graham, 193 F.3d at 1282. "If the record presents factual issues, the court must not decide them; it must deny the motion and proceed to trial." Herzog, 193 F.3d at 1246. But, "[w]here the record taken as a whole could not lead a rational trier of fact to find for the non-moving party," summary judgment for the moving party is proper. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986).

B. Analysis

Relator alleges that, by submitting the 145 Remaining Claims for off-label

AAP, Defendants are liable under two provisions of the FCA: subsections (a)(1)(A) and (a)(1)(B) of 31 U.S.C. § 3729. Those provisions impose liability on "any person who—(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or] (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1) (2012). Relator specifically contends that the Remaining Claims were "false or fraudulent" because the prescriptions underlying the claims were off-label and thus not covered under Part D. Relator further contends that Defendants had actual or constructive knowledge that the Remaining Claims' prescriptions were off-label.

Defendants argue that they are entitled to summary judgment because the record does not support that they acted "knowingly" with respect to the submission of the Remaining Claims.[9] To act "knowingly" under the FCA means that the

[9] Defendants further argue that the record does not support the existence of a "false claim" because the evidence is not sufficient to show that any of the Remaining Claims is for an off-label prescription. Defendants specifically contend that Relator's expert Barry Rovner applied an unreliable method in determining whether a prescription was off-label. Defendants acknowledge that their argument is a challenge to the admissibility of Rovner's opinions, governed by Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Defendants' Daubert challenge is not properly before the Court because, under the Court's Local Rules, such challenges must be made in a motion. See L.R. 26.2(C), N.D. Ga. ("Any party objecting to an expert's testimony based on Daubert . . . shall file a motion no later than the date the proposed pretrial order is submitted."). To consider

defendant "(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." Id. § 3729(b)(1). Relator argues that the record is sufficient at least to show a genuine dispute on either the issue of whether Defendants had actual knowledge that the Remaining Claims were for off-label prescriptions or the issue of whether Defendants acted in "reckless disregard" or "deliberate ignorance" of the off-label nature of the prescriptions.

1. *"Actual Knowledge" of Off-Label Prescriptions*

To support that Defendants had "actual knowledge" that the Remaining Claims consisted of off-label prescriptions, Plaintiff cites evidence that Defendants obtained, prior to filling and seeking reimbursement for the prescriptions, the patients' diagnostic information. The record evidence shows, at most, that Defendants' consultant pharmacists regularly reviewed their LTCF patients'

Defendants' Daubert challenge, raised only in their summary judgment submissions, would deprive the Court of meaningful briefing on the issue. See McCurdy v. Ford Motor Co., No. 1:04-CV-155 (WLS), 2006 WL 2793167, at *2 (M.D. Ga. Sept. 26, 2006) (explaining that the reason courts require separate Daubert and summary judgment motions "is that the standards for resolving the two motions are different, and . . . the resolution of the Daubert motion has serious implications upon the resolution of the motion for summary judgment"). For purposes of the pending Motion for Summary Judgment, the Court considers Rovner's opinions, that the Remaining Claims consisted of off-label prescriptions, sufficient to show a genuine dispute over the issue of whether the Remaining Claims constituted "false claims" under the FCA.

medical records and recorded the patients' various medical diagnoses into Defendants' computer system.[10] Based solely on this knowledge of diagnostic information, Plaintiff argues that Defendants had "actual knowledge" that the Remaining Claims were for off-label prescriptions.[11] The Court disagrees.

First, there is no direct evidence in the record that Defendants' dispensing pharmacists, who filled the prescriptions comprising the Remaining Claims, had knowledge of the patients' diagnostic information.[12] In its submission to the Court, Relator argues that patient diagnoses, as recorded in Defendants' computer system by consultant pharmacists, were "available to [Defendants'] dispensing pharmacists." (Relator's Br. [166] at 15.) Relator, however, has not cited any

[10] Plaintiff has not submitted evidence that this process was applied to the patients whose prescriptions comprise the Remaining Claims.

[11] Although not explicit in its submissions, Relator's argument appears to be based on its contention that AAP prescribed to patients with certain diagnoses are necessarily off-label.

[12] Relator specifically states that it does not rely on "collective knowledge," or a combination of the knowledge of Defendants' dispensing and consultant pharmacists, to establish knowledge here. (Relator's Br. [166] at 20.) The Court therefore does not decide whether the application of "collective knowledge" is appropriate in this case and limits its evaluation to whether any particular employee of Defendants had the requisite knowledge. The Court notes that, although the Eleventh Circuit has not considered the issue, the courts of appeals to have considered "collective knowledge" have held that its application is not proper under the FCA. See, e.g., United States v. SAIC, 626 F.3d 1257, 1274–77 (D.C. Cir. 2010).

record evidence to support this contention. The Court may draw inferences in Relator's favor only to the extent supportable by the record, see Garczynski 573 F.3d at 1165, and the record does not support that dispensing pharmacists had access to the diagnosis information recorded by consultant pharmacists.

Second, even if the record supported that the dispensing pharmacists had access to, and knowledge of, patient diagnoses, there is no evidence that any dispensing pharmacist had knowledge that any prescription was off-label. The parties do not dispute that a prescription is off-label if it is for a use not expressly authorized by FDA regulations or not recognized in the compendia. To know whether a particular prescription is off-label, the dispensing pharmacist therefore must know not only the patient's diagnoses but also whether the prescribed drug is authorized by FDA regulations for the diagnoses, either individually or in combination, or recognized in the compendia for the diagnoses. The record does not contain any evidence that any of Defendants' pharmacists, or other employees, had this knowledge.[13] The Court thus finds that the record does not support that

[13] The record shows that Defendants did not even provide their dispensing pharmacists with access to the compendia during the relevant time periods. (SUMF ¶ 69.) Because a prescription is not off-label if its use is supported in any of the compendia, Relator concedes that access to the compendia is necessary to determine whether a prescription has a medically accepted indication. (See Resp. SUMF ¶ 63.)

Defendant's had "actual knowledge" that the Remaining Claims were for off-label prescriptions.[14]

2. *"Reckless Disregard" or "Deliberate Ignorance" of Off-Label Prescriptions*

To support that Defendants acted in "reckless disregard" or "deliberate ignorance" of the off-label nature of the Remaining Claims, Plaintiff again argues that Defendants' dispensing pharmacists had access to, but ignored, patients' diagnostic information. As discussed above, the record does not support that the dispensing pharmacists had access to patients' diagnoses. Even if it did, such access is not evidence of "reckless disregard" or "deliberate ignorance." The diagnoses alone do not establish whether a particular prescription is for a medically accepted indication. As noted, to make this determination requires comparing the diagnoses to the relevant FDA regulations and to each of the compendia. The record contains no evidence that the dispensing pharmacists, or any other employees of Defendants, had access to, let alone ignored, such a comparison.

Relator argues that Defendants failed to proactively make the determination

[14] Plaintiff essentially argues that Defendants' dispensing pharmacists had a duty to do an independent investigation of the prescriptions they were presented to fill as the ground that Plaintiff believes there was sufficient information available for the dispensing pharmacists to investigate whether the prescription was a proper one. The authorities do not support that dispensing pharmacists had this duty and there is no evidence to support that the duty could be fulfilled even if it existed.

comparison. Although Relator argues generally that Defendants were required to comply with CMS regulations governing PDPs, Relator has not cited, and the Court is not aware of, any authority imposing a duty on the dispensing pharmacists, or any other employees of Defendants, to make this comparison. As the Court noted in its August 29, 2012, Order [96], CMS has issued official guidance stating that Defendants did *not* have such a duty. See Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4229 (CMS Jan. 28, 2005) (responding to public comments on proposed Part D regulations and "clarify[ing] that pharmacists will not be required to contact each physician to verify whether a prescription is being used for other than a medically accepted indication"). The Court concludes that Defendants did not have a duty to evaluate whether any prescriptions were off-label. Accordingly, the Court finds that the record does not support that Defendants acted in "reckless disregard" or "deliberate ignorance" of the off-label nature of the Remaining Claims.

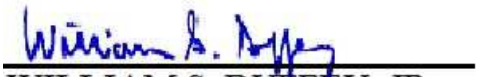
Having concluded that the record does not support that Defendants had "actual knowledge" of false claims, or acted "reckless disregard" or "deliberate ignorance" of the falsity of any claims, the Court concludes that Defendants are entitled to summary judgment on Relator's claims.

III. CONCLUSION

Relator commenced this litigation by alleging that Defendants knowingly submitted to CMS claims for "thousands" of off-label AAP prescriptions. After multiple motions to dismiss and extensive discovery, Relator's expert determined that, despite Relator's initial allegations, Defendants filled 243 off-label AAP prescriptions for Part D beneficiaries. Of these, Realtor itself later conceded that the evidence was sufficient to show that just 145 off-label AAP prescriptions, for 47 patients, were filled. There is no evidence to show that Defendants, as opposed to physicians, treated these 47 patients and prescribed the AAP at issue. Relator nevertheless argues that Defendants must have had actual or constructive knowledge of the patients' diagnoses and thus were able to determine if the AAP prescriptions were for off-label use. The undisputed evidence here does not support that Defendants or their employees knew or had access to information that allowed them to know if doctors had prescribed off-label use of AAP, and there is no evidence or authority to support that Defendants had a duty to undertake this evaluation. Accordingly,

IT IS HEREBY ORDERED that Defendants' Motion for Summary Judgment [165] is **GRANTED**.

SO ORDERED this 23rd day of May, 2014.



WILLIAM S. DUFFEY, JR.
UNITED STATES DISTRICT JUDGE