UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF FLORIDA TAMPA DIVISION

UNITED STATES OF AMERICA ex rel. NILES ROSEN, M.D.,

Plaintiff,

v.

Case No. 8:19-cv-1526-MSS-AAS

EXACT SCIENCES CORPORATION and EXACT SCIENCES LABORATORIES, LLC,

Defendant.

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ORDER

Plaintiff United States of America *ex rel*. Niles Rosen, M.D. (collectively, the plaintiffs) move to compel documents and testimony from Defendants Exact Sciences Corporation and Exact Sciences Laboratories, LLC (collectively, Exact Sciences). (Doc. 85). Exact Sciences responds in opposition. (Doc. 87).

I. BACKGROUND

The plaintiffs initiated this *qui tam* action alleging Exact Sciences violated the False Claims Act (FCA) through its violation of the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320. (Doc. 1). The plaintiffs allege Exact Sciences offered illegal kickbacks through their Patient Compliance Program (PCP), wherein Exact Sciences offered \$75 Visa gift cards to patients in exchange for

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their use of Cologuard, a colon cancer screening exam. (Id. at \P 48–65).

On September 26, 2022, the court denied Exact Sciences' motion to dismiss. (Doc. 78). Exact Sciences answered the complaint on October 24, 2022. (Doc. 80). The plaintiffs now move to compel Exact Sciences to produce responses to two interrogatories. (Doc. 100, Ex. 1).

II. LEGAL STANDARD

A party may obtain discovery about any nonprivileged matter relevant to any party's claim or defense and proportional to the needs of the case. Fed. R. Civ. P. 26(b)(1). Discovery helps parties ascertain facts that bear on issues. *ACLU of Fla., Inc. v. City of Sarasota*, 859 F.3d 1337, 1340 (11th Cir. 2017) (citations omitted).

A party may move for an order compelling discovery from the opposing party. Fed. R. Civ. P. 37(a). The party moving to compel discovery has the initial burden of proving the requested discovery is relevant and proportional. *Douglas v. Kohl's Dept. Stores, Inc.*, No. 6:15-CV-1185-Orl-22TBS, 2016 WL 1637277, at *2 (M.D. Fla. Apr. 25, 2016) (quotation and citation omitted). The responding party must then specifically show how the requested discovery is unreasonable or unduly burdensome. *Panola Land Buyers Ass'n v. Shuman*, 762 F.2d 1550, 1559–60 (11th Cir. 1985).

III. ANALYSIS

The plaintiffs request the court compel Exact Sciences to produce

information involving a "SuperCertificate" program the plaintiffs allege Exact Sciences started after halting the PCP program. (Doc. 100, Ex. 1, p. 2). The plaintiffs describe this SuperCertificate program as Exact Sciences' distribution of "gift cards just like the Visa gift cards" issued as part of the PCP program, but with a more limited number of vendors and merchants through which the gift cards may be utilized. (*Id.* at 3). The plaintiffs specifically request the court compel Exact Sciences to answer two interrogatories asking for "the number of SuperCertificate cards offered and paid" by Exact Sciences and "the number of claims to federal health care programs [made by Exact Sciences] in connection with such offers and payments." (*Id.* at 6).

Complaints filed by a *qui tam* relator under the FCA must comply with Federal Rule of Civil Procedure 9(b). *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1012 (11th Cir. 2005); *U.S. ex rel. Clausen v. Lab Corp. of Am., Inc.*, 290 F.3d 1301, 1308–10 (11th Cir. 2002). Rule 9(b) does not permit a relator to "allege simply and without any stated reason for this belief that claims requesting illegally payments must have been submitted, were likely submitted, or should have been submitted to the Government." *Clausen*, 290 F.3d at 1311. "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Although Rule 9(b) does not abrogate the concept of notice pleading, it requires a complaint to set forth: (1) precisely what statements or omissions were made in which documents or oral representations; (2) the time and place of each such statement and the person responsible for making (or, in the case of omissions, not making) them; (3) the content of such statements and the manner in which they misled the plaintiff; and (4) what the defendant obtained as a consequence of the fraud.

Garfield v. NDC Health Corp., 466 F.3d 1255, 1257 (11th Cir. 2006) (*quoting Brooks v. Blue Cross and Blue Shield of Florida, Inc.*, 116 F.3d 1364, 1371 (11th Cir. 1997)); *see also U.S. ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1357 (11th Cir. 2006).

For FCA cases, the actual submission of the claim must be pleaded with particularity and not simply inferred from the circumstance. *Corsello*, 428 F.3d at 1013. "The particularity rule serves an important purpose in fraud actions by alerting defendants to the precise misconduct with which they are charged and protecting defendants against spurious charges of immoral and fraudulent behavior." *Durham v. Bus. Mgmt. Assoc.*, 847 F.2d 1505, 1511 (11th Cir.1988) (internal citations omitted). As such, "discovery in *qui tam* actions must be limited and tailored to the specificity of the complaint." *United States ex rel. Bane v. Breathe Easy Pulmonary Servs., Inc.*, No. 8:06-cv-40-T24MAP, 2008 WL 4057549, at *1 (M.D. Fla. Aug. 27, 2008).

This particularity requirement of *qui tam* actions under the FCA trumps the plaintiffs' request that the court compel Exact Sciences to answer the two interrogatories. The plaintiffs do not dispute that the SuperCertificate

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program goes unmentioned by name in the plaintiffs' amended complaint (Doc. 23). The plaintiffs instead argue the allegations in their complaint "broadly reached all forms of financial incentives and unlawful remuneration Exact Sciences offered and/or paid as part of the kickback scheme Relator described" and was "not limited to the pre-paid Visa reward cards" utilized in the PCP. (Doc. 100, Ex. 1, pp. 12).

Though the plaintiffs are correct that portions of their amended complaint more broadly allege "Exact Sciences offered cash equivalent financial inducements to federal health beneficiaries in violation of the AKS and submitted false and fraudulent claims for payments for such tests in violation of the FCA," the only relevant conduct the plaintiffs specifically describe Exact Sciences engaging in involves the \$75 Visa cards allegedly distributed as part of the PCP program. (Doc. 100, Ex. 1, p. 10). The plaintiffs' contention thus runs counter to "[t]he public policy underpinnings of Rule 9(b), the FCA, and *qui tam* actions." *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1359 (11th Cir. 2006).

This conclusion comports with the case law cited in the plaintiffs' motion. That case law uniformly holds plaintiffs may "proceed to discovery on the entire fraudulent scheme" while only providing "examples of specific false claims submitted to the government pursuant to that scheme." U.S. ex rel. Bledsoe v. Community Health Systems, 501 F.3d 493, 510 (6th Cir. 2007). Although the plaintiffs plausibly connect the PCP and SuperCertificate programs, the amended complaint contains "no detailed allegations, such as who, what, when, where, and how fraudulent practices occurred regarding the [SuperCertificate program], as required by Rule 9(b) in pleading fraud." *U.S. ex rel. Holland v. Davita, Inc.*, No. 6:17-cv-1592-Orl-37GJK, 2020 WL 10700153, at *3 (M.D. Fla. Dec. 11, 2020).

The plaintiffs have not established the two interrogatories are relevant and proportional to the specific claims and allegations in their amended complaint. The plaintiffs' Motion to Compel (Doc. 89) is thus **DENIED**.

ORDERED in Tampa, Florida on February 7, 2023.

Enanda Arnold Samme

AMANDA ARNOLD SANSONE United States Magistrate Judge