

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

UNITED STATES
OF AMERICA, *et al.*

Case No. 1:13-cv-586

Plaintiff,
vs.

Judge Timothy S. Black

ALPHATEC SPINE, INC., *et al.*,

Defendant.

**ORDER DENYING
DEFENDANT'S MOTION FOR SUMMARY JUDGMENT (Doc. 44)**

This civil action is before the Court on Defendant Journey Lite of Cincinnati, LLC's motion for summary judgment (Doc. 44) and the parties' responsive memoranda (Docs. 58, 63).

I. INTRODUCTION

Defendant Journey Lite of Cincinnati, LLC ("Journey Lite") is a multi-specialty outpatient surgery center located in Evansdale, Ohio, that has been in operation since 2007. (Doc. 44, at 4). From June 2011 to December 2013, Journey Lite was owned by Defendant Center for Advanced Spine Technologies ("CAST"). (*Id.*). Defendant Dr. Atiq Durrani is an orthopedic surgeon who formerly operated in the Cincinnati, OH, area, and was the president and CEO of CAST. (*Id.*). Dr. Durrani performed surgeries on patients at Journey Lite. Journey Lite, Dr. Durrani, and CAST are the only remaining Defendants in this civil action.

Plaintiffs all allege that they are former patients of Dr. Durrani who were subjected to unnecessary surgeries either ordered or directly performed by Dr. Durrani. Plaintiffs further allege that these unnecessary surgeries involved the use of a product called PureGen. PureGen is a medical device designed for use in orthopedic surgeries. PureGen was entered into clinical trials on or around February 9, 2011 which were scheduled to last until September of 2013. (Doc. 1, at 8). Plaintiffs' Complaint alleges that Defendants used PureGen in surgeries without Plaintiffs' consent, and beyond the scope of the approved clinical trial. The Complaint further alleges that Alphatec Spine, Inc., the manufacturer of PureGen, made "direct payments and concealed kickbacks" to doctors to influence them to use PureGen in surgeries. (*Id.* at 12–13). Alphatec claims to have removed PureGen from the market in February 2013 in response to FDA concerns about its safety, but Plaintiffs allege that Alphatec has nevertheless continued to push to have PureGen used in surgeries since that time. (*Id.* at 11–13).

Several of the claims in this civil action are *qui tam* claims filed by Plaintiffs on behalf of the United States. Plaintiffs allege that, in addition to using PureGen in surgeries without patients' informed consent, Defendants perpetrated a fraud on the federal government by billing these surgeries to Medicaid and Medicare. The allegations claim that Defendants Journey Lite and CAST "knowingly created false medical records, bills, and cost reports that included charges for off label uses of PureGen, which resulted in inflated outlier payments to be paid by the government[.]" (*Id.* at 20). The United States, through the U.S. Attorney's Office, has declined to intervene in this action. (Doc. 22).

Plaintiffs' Complaint raises the following claims against Defendants:

- 1) Multiple claims for violation of the False Claims Act (31 U.S.C. § 3729 *et seq.*) (Counts I–III);
- 2) Claim for violation of 42 U.S.C. § 1320a–7b(b) (federal “anti-kickback statute”) (Count IV);
- 3) Claim for “civil penalties or awards arising from criminal conduct” (Count V);
- 4) Claim for violation of 45 C.F.R. § 46 *et seq.* (standards governing use of human subjects in medical research) (Count VI);
- 5) Claim of unjust enrichment, equitable, and general relief (Count VII).

II. STANDARD OF REVIEW

A motion for summary judgment should be granted if the evidence submitted to the Court demonstrates that there is no genuine issue as to any material fact, and that the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986). The moving party has the burden of showing the absence of genuine disputes over facts which, under the substantive law governing the issue, might affect the outcome of the action. *Celotex*, 477 U.S. at 323. All facts and inferences must be construed in a light most favorable to the party opposing the motion. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

A party opposing a motion for summary judgment “may not rest upon the mere allegations or denials of his pleading, but . . . must set forth specific facts showing that there is a genuine issue for trial.” *Anderson*, 477 U.S. at 248 (1986).

III. ANALYSIS

A. The Use of PureGen at Journey Lite

Whether PureGen was actually used in surgeries performed at Journey Lite is a fundamental element of all of Plaintiffs' claims. Defendant's motion for summary judgment argues that PureGen was not used at Journey Lite and there is no genuine dispute of material fact on this question. Accordingly, Defendant argues that all of Plaintiffs' claims must be dismissed on summary judgment.

To support their claim that PureGen was not used at Journey Lite, Defendant has submitted 10 affidavits of Journey Lite employees who each state that PureGen was not used at Journey Lite. (Docs. 44-2 to 44-11). Additionally, Plaintiffs deposed six witnesses, all also employees at Journey Lite, who each stated that PureGen was not used at the facility. (Docs. 44-12 to 44-17).

Plaintiffs' response to Defendant's motion disputes the allegation that there is no genuine issue of material fact regarding whether PureGen was used in surgeries performed at Journey Lite. Plaintiffs point to five "operative reports" filled out by Dr. Durrani, each containing information about a specific surgical procedure that he performed at Journey Lite. (*See* Doc. 63-2).¹ Each of these operative reports indicated at the time they were created (which in each case was contemporaneous with the corresponding surgery) that PureGen was used in a surgery at Journey Lite. (*Id.*) However, each of the reports was modified on the same date, November 12, 2013, many

¹ Plaintiffs actually provided copies of six operative reports. However, after reviewing the reports, the Court does not see how the operative report of one of the surgeries (performed on a Ms. Erin Greelish) states, as Plaintiffs claim, that PureGen was used during the surgery.

months after the surgeries at issue, and three months after the Complaint in this case was filed, to remove the portion of the report that indicated PureGen was used during surgery. (*See id.*). Defendant claims that all five of the operative reports initially erred in the indication that PureGen was used during surgeries at Journey Lite, alleging that Dr. Durrani inadvertently used an incorrect template designed for surgeries performed at a different location than Journey Lite. (Doc. 44, at 6–7). This claim of clerical error is supported by the testimony of a Journey Lite employee. (Doc. 44-11).

Viewing the disputed facts in the light most favorable to the non-moving party, there remains a genuine dispute of material fact over whether PureGen was in fact used in surgical procedures at Journey Lite. A reasonable juror could determine that the operative reports indicating that PureGen was used during surgeries at Journey Lite (at least when they were filled out at the time of the surgeries in question) are more persuasive than the testimony of employees that could be determined to have a demonstrable bias. In the case of a genuine dispute of material fact such as this, the Court cannot find at the summary judgment stage that PureGen was not used in any procedure performed at Journey Lite.

Accordingly, the Court declines to grant summary judgment on any claims based on Defendant's contention that PureGen was not used in any procedures at Journey Lite.

B. Billing of Medicare/Medicaid

Defendant further claims that Plaintiffs have failed to demonstrate any material fact that would allow a jury to find that Defendant actually billed Medicare or Medicaid for any of the procedures from the Complaint. Defendant's alleged fraud against the

government is a necessary element of Plaintiffs' *qui tam* claims. If the moving Defendant is correct, and there is no dispute of material fact as to whether Defendants fraudulently billed the federal government, Plaintiffs' *qui tam* claims must be dismissed at the summary judgment stage.

In support of Plaintiffs' claim that Journey Lite did not bill Medicare or Medicaid for any of the procedures listed in the Complaint, Plaintiffs have provided the affidavit of the controller at Journey Lite, who testified that neither Medicare or Medicaid were billed for any of those procedures. (Doc. 44-19).

Plaintiffs cannot point to any direct evidence that Medicare or Medicaid were billed for any Journey Lite procedures. However, they claim that this is the fault of Defendant's insufficient responses to discovery requests. Plaintiffs' response to the motion for summary judgment includes a declaration from Plaintiffs' attorney pursuant to Rule 56(d) of the Federal Rules of Civil Procedure that Plaintiffs cannot provide facts essential to justify its opposition to the motion with regard to the issue of Medicare or Medicaid billing. (Doc. 58-1). Plaintiffs argue that in response to their requests for itemized billing records of procedures performed on Plaintiffs, Defendants have only provided "account ledgers" without sufficient information to determine who was billed for any of the procedures. (*Id.*). There is currently a separate lawsuit pending in federal court against Defendant over whether these account ledgers are sufficiently detailed medical billing records as required under Ohio law.

The Court has reviewed these account ledgers, which have been entered into the record. (Doc. 59-21). Based upon these ledgers, it is not possible to determine which

entities were billed for any of the disputed procedures. The entries all have general descriptions such as “Insurance Billing,” “Insurance Payment,” and “Secondary Insurance Billing.” (*See id.*). There are no names of any specific entity, be it private insurance, the federal government, or otherwise, that was billed or that made payments to Journey Lite.

Defendant argues that the inquiry into billing must end there, characterizing Plaintiffs’ argument regarding the vague account ledgers as an “issue[] related to billing practices that [is] not relevant to this lawsuit.” (Doc. 63, at 7). Defendants further state that “if there was nothing billed to Medicare and Medicaid, it is obvious that no billing can be identified showing what was billed to either entity.” (*Id.*). The issue, however, is not that the account ledgers fail to specify that Medicare or Medicaid were billed, but rather that the ledgers fail to specify *any* entity that was billed. Currently the only piece of evidence in the record that makes a definitive statement about whether Medicaid or Medicare was billed is the affidavit of the Journey Lite controller. (Doc. 44-19). However, the Court cannot see how he can testify to that fact with any certainty if there is no responsive documentary evidence to provide information on who specifically was billed for medical procedures at Journey Lite. Defendant’s cursory dismissal of this legitimate discovery issue without attempting to clarify their billing practices leads the Court to the conclusion that Plaintiffs’ Rule 56(d) declaration is meritorious.

Accordingly, the Court declines to grant summary judgment based on the issue of whether Medicaid or Medicare were billed for the procedures in question, as additional discovery appears to be required.

C. Subject Matter Jurisdiction

Defendant argues in its motion for summary judgment that Plaintiffs' claims under the False Claims Act should be dismissed for lack of subject matter jurisdiction. (Doc. 44, at 11). The motion alleges that "nowhere in Plaintiffs' Complaint do they assert they have standing pursuant to 31 USC § 3030(b)."² (*Id.*). In order to bring an action for violation of the False Claims Act, the action must either be initiated by the Attorney General under 31 U.S.C. § 3730(a) or by private persons under the *qui tam* provisions of 31 U.S.C. § 3730(b).

Plaintiffs have sufficiently alleged jurisdiction in this case, especially given the Court's preference to evaluate cases on their merits. Count I of Plaintiffs' Complaint states that "[t]his Count is brought by Plaintiffs/Relators in the name of the United States under the Qui Tam provisions of 31 U.S.C. § 3730 for Defendant's violations of 31 U.S.C. 31 § 3729 [sic]." (Doc. 1, at 30). Furthermore, the section of the Complaint labeled "Jurisdiction and Venue" (*Id.* at 7–8) claims jurisdiction based on 31 U.S.C. § 3732, which states:

Any action under [31 U.S.C. § 3730] may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any act proscribed by [31 U.S.C. § 3729] occurred.

31 U.S.C. § 3732(a).

² Although Defendant's motion consistently claims that Plaintiff needed to cite jurisdiction under "31 U.S.C. § 3030(b)" (*see* Doc. 44, at 11), it is clear from context and Defendant's reply memorandum that Defendant is referring to 31 U.S.C. § 3730(b) with this argument.

Accordingly, it is evident from the Complaint that Plaintiffs' claims under the False Claims Act are *Qui Tam* claims properly raised in federal court on behalf of the United States government.

IV. CONCLUSION

For the reasons outlined above, Defendant Journey Lite of Cincinnati, LLC's motion for summary judgment (Doc. 44) is **DENIED**.

IT IS SO ORDERED.

Date: 9/28/16

s/ Timothy S. Black
Timothy S. Black
United States District Judge