## IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

| UNITED STATES OF AMERICA | : | <b>CIVIL ACTION</b> |
|--------------------------|---|---------------------|
| ex rel. YOASH GOHIL,     | : |                     |
| Plaintiff                | : |                     |
|                          | : |                     |
| vs.                      | : | NO. 02-2964         |
|                          | : |                     |
| AVENTIS, INC., et al.,   | : |                     |
| Defendants               | : |                     |

## **MEMORANDUM**

## STENGEL, J.

#### **January 9, 2017**

Relator Yoash Gohil brings this False Claims Act lawsuit on behalf of the United States against his former employer Sanofi-Aventis U.S., Inc. (Aventis) and its subsidiaries. Mr. Gohil alleges that Aventis engaged in a fraudulent pharmaceutical marketing scheme, which caused numerous healthcare providers to submit false claims to federally-funded health insurance programs. Aventis has moved for a partial judgment on the pleadings, asserting a statute of limitations bar and a First Amendment defense. I will deny this motion.

# I. BACKGROUND<sup>1</sup>

Mr. Gohil was employed by Aventis and its predecessor companies from February 1982 until his resignation in June 2002. At all relevant times, Mr. Gohil was a Senior Oncology Sales Specialist whose duties included the marketing, promotion, and sale of pharmaceuticals manufactured by Aventis. This case concerns the marketing of

<sup>&</sup>lt;sup>1</sup> The information contained in this section is taken from the Third Amended Complaint, unless otherwise noted.

Taxotere, a chemotherapy agent manufactured by Aventis which Mr. Gohil was assigned to promote and sell in the Philadelphia region.

Originally, the Food and Drug Administration (FDA) approved Taxotere for the treatment of patients with Non-Small Cell Lung Cancer and Breast cancer, but only after the failure of prior platinum based chemotherapy. This is also known as second line treatment. In November 2002, the FDA approved Taxotere for first line treatment of Non-Small Cell Lung Cancer. There were no other approved medical indications. Between 1996 and 2004, Taxotere was the most expensive taxane on the market. A substantial portion of individuals who are treated with Taxotere are participants in a federal insurance program including Medicare, Medicaid, CHAMPUS/Tricare, and the Federal Employee Health Benefit Plan (FEHBP).<sup>2</sup>

In 2000, Aventis was formed through the merger of RPR and Hoechst Marion Roussel. Rhone-Poulenc Rorer Pharmaceuticals, Inc. (RPR) had manufactured and marketed Taxotere. The plaintiff was an employee of Hoechst and then became an employee of Aventis. After the merger, he was assigned to market Taxotere.

The plaintiff alleges that, from 1996 until 2004, Aventis engaged in a marketing plan which promoted Taxotere for off-label uses. Gohil alleges that Aventis trained and directed its employees to misrepresent the safety and effectiveness of the off-label use of Taxotere to expand the market for Taxotere into unapproved settings. He claims Aventis also paid healthcare providers illegal kickbacks—i.e., sham unrestricted grants, speaking

<sup>&</sup>lt;sup>2</sup> CHAMPUS/Tricare provides medical care for members of the Uniformed Services. 10 U.S.C § 1071 (West 2015). CHAMPUS is an acronym for Civilian Health and Medical Program of the Uniformed Services.

fees, travel, entertainment, sports and concert tickets, preceptorship fees, and free samples and free reimbursement assistance—to incentivize providers to prescribe Taxotere for off-label uses. By the means of this fraudulent marketing scheme, Aventis dramatically increased revenue on sales of Taxotere from \$424 million in 2000 to \$1.4 billion in 2004.

Federal Insurance Programs will pay for an off-label use of a prescription drug if the drug is used for a medically accepted indication or the drug is medically necessary. Aventis marketed Taxotere for off-label use in the first line treatment of Breast Cancer and Non-Small Cell Lung Cancer, for the second line treatment of Ovarian Cancer, and for the treatment of other unspecified medical indications. According to Gohil, the prescription of Taxotere in these settings would not be eligible for reimbursement. Additionally, prescriptions of Taxotere which were "produced through the payment directly or indirectly of a kickback" were ineligible for reimbursement. As a result, Aventis' fraudulent marketing scheme allegedly caused a substantial number of healthcare providers to submit claims for reimbursement to Governmental medical reimbursement systems for the use of Taxotere, which would not have otherwise been paid had the Government reimbursement programs known of Aventis' fraudulent marketing scheme.

3

#### **II. RELEVANT PROCEDURAL HISTORY**

Mr. Gohil filed his original False Claims Act (FCA) *qui tam* complaint under seal on May 17, 2002.<sup>3</sup> He filed his First Amended Complaint on July 19, 2002 under seal. In June 2002, Mr. Gohil resigned from Aventis, and he initiated a wrongful termination action against Aventis in New Jersey Superior Court pursuant to New Jersey's Conscientious Employee Protection Act and New Jersey's Law Against Discrimination. In the state court lawsuit, Mr. Gohil alleged that Aventis retaliated against him because he objected to sales activities which violated federal and state laws, including FDA regulations.

The parties engaged in discovery in the New Jersey action. Aventis produced tens of thousands of pages of training materials, manuals, and journal abstracts about Taxotere. Mr. Gohil took depositions of several current and former Aventis employees. After the close of discovery but before any judgment was entered, the parties settled the New Jersey action on October 19, 2005. The settlement agreement included a broad release of liability in favor of Aventis.

On August 15, 2006, the Government declined to intervene in this *qui tam* case. The case was unsealed and a summons issued to Aventis on September 11, 2006. With leave of court, Mr. Gohil filed the Second Amended Complaint under seal on February 9, 2007; the Government again declined to intervene. The Second Amended Complaint was unsealed on February 29, 2008.

<sup>&</sup>lt;sup>3</sup> This case was originally assigned to Chief Judge Tucker. It was then transferred to Judge Ditter and then to my docket in 2013.

The First Amended Complaint outlined facts regarding FCA violations for sales of both Taxotere and Anzemet (another oncological drug product marketed by Gohil while working for Aventis). The Second Amended Complaint deleted the majority of facts and claims related to the sale of Anzemet, leaving claims and facts regarding the sale of Taxotere as the primary focus.<sup>4</sup> The Second Amended Complaint also added more detail about the Taxotere claims laid-out in the First Amended Complaint. The Second Amended Complaint defined the applicable timeframe as 1996 to 2004.

After a contentious jurisdictional discovery period (which included an interlocutory appeal), the defendants moved to dismiss the Second Amended Complaint based on several theories: the general release the plaintiff executed in connection with the settlement of the New Jersey lawsuit, the original source requirements of the FCA, and the plaintiff's failure to allege Aventis' supposed fraudulent conduct with particularity as required under Rule 9(b). I denied that motion in part and granted it in part. I dismissed

<sup>&</sup>lt;sup>4</sup> Mr. Gohil had been informed by the U.S. Government that another relator had already asserted FCA claims regarding Anzemet. His claims likely would have been dismissed under the "first-filed rule." In deciding the defendants' motion to dismiss the Second Amended Complaint, I rejected the defendants' argument—which they raise again here—that this shift in focus amounts to a "new legal theory" warranting dismissal. <u>See</u> Memorandum Denying in Part, Granting in Part Defendants' Motion to Dismiss the Second Amended Complaint, Mar. 30, 2016, Doc. No. 125 at 14. If anything, Mr. Gohil's withdrawal of the Anzemet claims prevented the court and parties from expending time and resources on claims which likely would have been dismissed.

The Second Amended Complaint also added a conspiracy claim based on the same details outlined in the First Amended Complaint. It is based on the same common core of facts and relates back to the 2002 complaints. See, e.g., United States ex rel. Kolchinsky v. Moody's Corp., 162 F.Supp.3d 186, 199 (S.D. N.Y. 2016)("[A] new legal theory applied to the same facts set out in the earlier pleading will relate back."). The defendants' arguments on this point are more in the vein of a "failure to state a claim" than a limitations argument. I've already determined that the conspiracy claim is sufficient under Rules 12(b)(6) and 9(b). See Memorandum Granting in Part, Denying in Part Defendants' Motion to Dismiss the Second Amended Complaint, Mar. 30, 2015, Doc. No. 125 at 30.

Counts III and IV of the plaintiff's Second Amended Complaint without prejudice because those Counts were factually deficient.<sup>5</sup>

The defendants filed a motion for reconsideration of my decision regarding the public disclosure bar's effect on claims related to years 1996-1999 and 2002-2004. I denied that motion.<sup>6</sup>

I granted the plaintiff leave to file a Third Amended Complaint. The defendants again moved to dismiss Counts III and IV of that complaint, arguing again that these claims were factually deficient and did not meet the heightened pleading standard of Rule 9(b), required of *qui tam* pleading. <u>See U.S. ex rel. LaCorte v. SmithKline Beecham</u> <u>Clinical Labs., Inc.</u>, 149 F.3d 227, 234 (3d Cir. 1998). I denied this motion and placed the parties on a discovery schedule.<sup>7</sup>

The defendants now move once more for the dismissal of Counts III and IV under Rule 12(c)(i.e., a motion for judgment on the pleadings), based on two legal defenses not previously presented.<sup>8</sup>

<sup>6</sup> <u>See</u> Memorandum Denying Motion for Reconsideration, May 4, 2015, Doc. No. 132.

<sup>&</sup>lt;sup>5</sup> <u>See</u> Memorandum Granting in Part, Denying in Part Defendants' Motion to Dismiss the Second Amended Complaint, Mar. 30, 2015, Doc. No. 125.

The defendants then filed a motion for reconsideration of this decision based on their arguments about the public disclosure bar. I denied this motion finding no basis for reconsideration. <u>See</u> Order Denying Motion for Reconsideration, May 4, 2015, Doc. No. 132.

<sup>&</sup>lt;sup>7</sup> I determined that the plaintiff's Third Amended Complaint cured the deficiencies noted in my decision dismissing the Second Amended Complaint. I also addressed the defendants' argument that the plaintiff's allegations of "false statements" provided no basis for relief. <u>See</u> Order Denying Defendants' Motion to Dismiss the Third Amended Complaint, Aug. 20, 2015, Doc. No. 151.

<sup>&</sup>lt;sup>8</sup> As the plaintiff alludes in his briefing, the assertion of these defenses now—which were not raised previously despite ample opportunity—does appear to be somewhat suspect. While I

#### **III. STANDARD OF REVIEW UNDER RULE 12(C)**

"After the pleadings are closed--but early enough not to delay trial--a party may move for judgment on the pleadings." FED. R. CIV. P. 12 (c). When a defendant moves to dismiss a claim because it fails to offer a basis upon which relief can be granted under Rule 12(c), the same standard used in deciding motions under Rule 12(b)(6) is applied to motions brought under Rule 12(c). See, e.g., Turbe v. Gov't of V.I., 938 F.2d 427, 428 (3d Cir. 1991); United States v. Cephalon, --- F. Supp. 3d ---, No. 08-287, 2016 WL 398014, at \*2 (E.D. Pa. Feb. 2, 2016). District courts may grant a motion for judgment on the pleadings under Rule 12(c) "only if, viewing all the facts in the light most favorable to the nonmoving party, no material issue of fact remains and the moving party is entitled to judgment as a matter of law." Knepper v. Rite Aid Corp., 675 F.3d 249, 257 (3d Cir. 2012)(citing Rosenau v. Unifund Corp., 539 F.3d 218, 221 (3d Cir. 2008)). See also Sikirica v. Nationwide Ins. Co., 416 F.3d 214, 220 (3d Cir. 2005); Society Hill Civic Ass'n v. Harris, 632 F.2d 1045, 1054 (3d Cir. 1980). "[I]f the pleadings do not resolve all of the factual issues in the case, a trial on the merits would be more appropriate than an attempt at resolution of the case on a Rule 12(c) motion." 5A C. Wright & A. Miller, Federal Practice and Procedure § 1367, at 515 (1990).

recognize defense counsel has the duty to zealously advocate for their clients, I cannot help but wonder whether this motion is nothing more than a delay tactic and another "bite at the apple." I caution counsel going forward to be mindful of the dictates of all of the Federal Rules of Civil Procedure, especially Rule 11.

#### **IV. DISCUSSION**

The defendants offer two grounds for dismissal: (1) they argue that the plaintiff's claims dating between 1996 and 2000 are barred by the statute of limitations; and (2) the parts of plaintiff's Counts III and IV of the Third Amended Complaint based on "truthful, non-misleading speech" are barred by First Amendment free speech protections.

#### A. The False Claims Act Statute of Limitations

Under the False Claims Act (FCA), persons who submit fraudulent applications for payment to the United States are liable to the Government in a civil action for civil penalties and treble damages. 31 U.S.C. § 3729(a)(1) (West 2015). The *qui tam* provisions of the act empower private individuals, like Mr. Gohil, to file lawsuits on behalf of the United States seeking damages sustained by the Government for the payment of false claims.<sup>9</sup> 31 U.S.C. § 3730(b). Relators, the citizen plaintiff in a FCA action, must file their complaints under seal and serve the Government with a copy of the complaint and disclosure of all material evidence. 31 U.S.C. § 3730(b)(2). The court cannot lift the seal until the Government investigates the claims and either decides to take over the action or notifies the court that it declines to intervene in the case. 31 U.S.C. § 3730(b)(4). If the Government declines to intervene, it retains the right to veto any

<sup>&</sup>lt;sup>9</sup> "*Qui tam* is short for '*qui tam pro domino rege quam pro se ipso in hac parte sequitur*,' which means 'who pursues this action on our Lord the King's behalf as well as his own.'" <u>Rockwell</u> <u>Int'l Corp. v. United States</u>, 549 U.S. 457, 463 (2007). Congress enacted the *qui tam* provisions to employ citizens in the quest to recover money depleted from the national treasury as a result of fraud against the Government. <u>U.S. ex rel. Springfield Terminal Ry. Co. v. Quinn</u>, 14 F.3d 645, 650 (D.C. Cir. 1994)(discussing legislative history).

settlement negotiated by the relator, and it may move to intervene at a later date upon a showing of good cause. 31 U.S.C. § 3730(b)(1);(b)(3).

The defendants argue that the "new" FCA claims dating from 1996 to 2000 appeared for the first time in the plaintiff's Second Amended Complaint and should be barred by the FCA's six-year statute of limitations because the Second Amended Complaint was filed in 2007 and unsealed in 2008. <u>See</u> 31 U.S.C. § 3731(b)(1).<sup>10</sup> The plaintiff argues that the amended claims "relate back" to the claims laid out in the original complaint, filed within the statutory period, making them timely.

## **B.** Relation Back is Appropriate Under Rule 15(c)(1)(B)

In qui tam cases where relators amend their own pleadings without Government

intervention, courts have applied Rule 15(c)(1)(B) of the Federal Rules of Civil

Procedure to determine whether the proposed new claims and allegations "relate back,"

for statute of limitations purposes, to a previously-filed complaint.<sup>11</sup>

(2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed,

whichever occurs last.

<sup>&</sup>lt;sup>10</sup> 31 U.S.C. § 3731(b) states:

A civil action under Section 3730 may not be brought--(1) more than 6 years after the date on which the violation of section 3729 is committed, or

Because the Government did not intervene, 31 U.S.C. § 3731(b)(1) applies.

<sup>&</sup>lt;sup>11</sup> <u>See, e.g.</u>, <u>United States v. Premier Education Group, L.P.</u>, No. 11-3523 (RBK/AMD), 2016 WL 2747195, at \*22 (D.N.J. May 11, 2016); <u>Hericks v. Lincare Inc.</u>, No. 07–387, 2014 WL

If Rule 15(c) can be applied and later amended complaints can "relate back" to the original complaint, the amended complaint's filing is essentially treated as being filed on the date of the initial complaint, for the purpose of calculating the statute of limitations.

The hallmark of the relation back inquiry is fair notice to the defendant. <u>See, e.g.</u>, <u>Glover v. F.D.I.C.</u>, 698 F.3d 139, 145-47 (3d Cir. 2012)("[F]actual overlap alone is not enough, because the original complaint must have given fair notice of the amended claim to qualify for relation back under Rule 15(c).") Rule 15(c)(1)(B) only permits relation back of untimely FCA claims if they clearly arose out of the "conduct, transaction, or occurrence pled occurrence set out--or attempted to be set out--in the original pleading." FED. R. CIV. P. 15(c)(1)(B).<sup>12</sup>

Courts have liberally construed the relation back doctrine in order to comport with the general presumption favoring amendment under Rule 15. <u>See USX Corp. v.</u> <u>Barnhart</u>, 395 F.3d 161, 167 (3d Cir. 2004)("Allowing relation back under Rule 15(c) also comports with the general presumption in favor of allowing a party to amend pleadings."); <u>Bensel v. Allied Pilots Ass'n</u>, 387 F.3d 298, 310 (3d Cir. 2004)("In

<sup>1225660,</sup> at \*13 (E.D. Pa. Mar. 25, 2014); <u>U.S. ex rel. Repko v. Guthrie Clinic, P.C.</u>, 557 F.Supp.2d 522, 529-31 (M.D. Pa. 2008). <u>See also U.S. ex rel. Miller v. Bill Harbert Intern.</u> <u>Const., Inc.</u>, 608 F.3d 871, 877-80 (D.D.C. 2010)(discussing FCA and Rule 15 generally); <u>U.S.</u> <u>ex rel. Bledsoe v. Community Health Systems, Inc.</u>, 501 F.3d 493, 516-19 (6th Cir. 2007).

<sup>&</sup>lt;sup>12</sup> See also Glover v. F.D.I.C., 698 F.3d 139, 145-47 (3d Cir. 2012); USX Corp. v. Barnhart, 395 F.3d 161, 166-67 (3d Cir. 2004)("[A]mendments that restate the original claim with greater particularity or amplify the factual circumstances surrounding the pertinent conduct, transaction or occurrence in the preceding pleading fall within Rule 15(c). In essence, application of Rule 15(c) involves a search for a common core of operative facts in the two pleadings. As such, the court looks to whether the opposing party has had fair notice of the general fact situation and legal theory upon which the amending party proceeds." (quoting Bensel v. Allied Pilots Ass'n, 387 F.3d 298, 310 (3d Cir. 2004)).

accordance with the general theory of liberalized pleading in the federal system, Rule 15(c) is premised on the notion that a party is not entitled to the protection of the statute of limitations based upon the later assertion by amendment of a claim or defense that arises out of the same conduct, transaction, or occurrence set forth in the timely filed original pleading.").<sup>13</sup> "The relation back provision of Rule 15(c) aims to ameliorate the harsh result of the strict application of the statute of limitations." <u>Garvin v. City of Philadelphia</u>, 354 F.3d 215, 220 (3d Cir. 2003).

"[T]he underlying question for a Rule 15(c) analysis is 'whether the *original* complaint adequately notified the defendants of the basis for liability the plaintiffs would later advance in the amended complaint." <u>Glover v. F.D.I.C.</u>, 698 F.3d 139, 146 (3d Cir. 2012)(citations omitted)(emphasis in original). Put another way, Rule 15(c) considers whether the facts and claims of the amended pleadings are a natural outgrowth of the original pleading, which put the defendants on notice of possible liability.

I see no reason why the amended complaints in this action would not relate back to the timely-filed original complaint.<sup>14</sup> The allegations made in the Original and First

<sup>&</sup>lt;sup>13</sup> See also Blatt v. Merrill Lynch, 916 F. Supp. 1343, 1351 (D.N.J. 1996)("Courts have liberally construed Rule 15(c) to allow amendments to relate back to the original pleading provided that the opposing party had notice of the claim and would not be prejudiced by the amendment" (citing In re Chaus Sec. Litig., 801 F.Supp. 1257, 1264 (S.D.N.Y.1992); FDIC v. Conner, 20 F.3d 1376, 1385–86 (5th Cir.1994); Fuller v. Marx, 724 F.2d 717, 720 (8th Cir. 1984)).

<sup>&</sup>lt;sup>14</sup> The defendants argue that they were not on actual notice of the FCA claims until 2006, when the First Amended Complaint (the first complaint of the series to be served on the defendants) was unsealed. I see no reason why the initial sealed complaint, which commenced this action, would not be considered the "original pleading" under Rule 15. <u>See United States v. Premier</u> <u>Education Group, L.P.</u>, No. 11-3523 (RBK/AMD), 2016 WL 2747195, at \*22 (D.N.J. May 11, 2016)("Rule 15(c)(1)(b) provides that an amendment to a pleading relates back to the date of the original pleading when 'the amendment asserts a claim or defense that arose out of the conduct,

transaction, or occurrence set out—or attempted to be set out—in the original pleading.' Here, Relators commenced this action on June 20, 2011, with the filing of the sealed original complaint, within the statute of limitations. Therefore, so long as the allegations in the subsequent complaints relate back to the original complaint, Relators claims are not timebarred."); <u>U.S. ex rel. Repko v. Guthrie Clinic, P.C.</u>, 557 F.Supp.2d 522, 530 (M.D. Pa. 2008)("As a preliminary matter, we believe that the date the initial complaint was filed, not the date the third amended complaint was filed, is the operative date for the purposes of our calculation pursuant to Rule 15(c)(1)(B) of the Federal Rules of Civil Procedure. Rule 15(c)(1)(B) states that an amendment relates back to the date of the original pleading when 'the amendment asserts a claim or defense that arose out of the conduct, transaction, or occurrence set out ... in the original pleading.'... Therefore, we find that Rule 15(c)(1)(B) is applicable and will relate the pleading back to the date of the original complaint, which is July 19, 2004.").

I cannot find support for the defendants' argument that the sealing provision of the FCA should somehow prevent the court from allowing amended complaints to "relate back." See U.S. ex rel. Parikh v. Premera Blue Cross, 2007 WL 1031724, at \*4 (W.D. Wash. Apr. 3, 2007)("[T]he language of the FCA suggests that the statute of limitations is tolled when the original complaint is filed [not when it is unsealed].")(discussing the applicability of a statute of limitations defense in a FCA action in which the Government did not intervene); In re Pharmaceutical Industry Average Wholesale Price Litigation, 498 F.Supp.2d 389, 395 (D. Mass. 2007)("The government argues that the statute of limitations provision in the FCA provides that the period of limitations is measured against when the action is 'brought,' not when it is unsealed. See 31 U.S.C. § 3731(b). The government's view is consistent with the holdings of trial courts that an FCA commences when the relator filed suit." (citations omitted)(collecting cases)); U.S. ex rel. Cericola v. Fed. Nat'l Mortgage Assoc., 529 F. Supp. 2d 1139, 1150-51 (C.D. Cal. 2007)("Fannie Mae also argues that because FCA complaints are filed under seal while the Government investigates the claims made therein, FCA complaints are fundamentally incompatible with the relation back doctrine because they do not impart fair notice upon the defendant. Again, no case so holds and the case relied on by Fannie Mae, United States v. The Baylor Univ. Med. Ctr., 469 F.3d 263, 269-71 (2d Cir. 2006), appears to be an outlier case and, in any event, is distinguishable because it focused on the application of the doctrine to the Government's complaint-in-intervention. The Second Circuit concluded that the application of the statute of limitations to the Government's complaint-in-intervention runs from the date that it files its complaint, and does not relate back to the qui tam relator's filing.... Accordingly, Baylor is not controlling in the present circumstances." (citations omitted)).

This argument is somewhat disingenuous. The defendants themselves have discussed the plaintiff's New Jersey employment lawsuit in their briefing. That case was based on the allegations in this case. They note in briefing this motion that the employment lawsuit involved discovery of both Aventis' and RPR's training manuals. <u>See</u> Defendants' Memorandum Supporting Motion for Partial Judgment on the Pleadings, Doc. No. 183 at 2 n. 1. In their motion to dismiss the Second Amended Complaint, they argued that the release of liability in the New Jersey settlement agreement barred this suit. That agreement was likely negotiated because it put the defendants on notice that a FCA action was imminent. The defendants knew or should have known that a FCA lawsuit was forthcoming and what it involved.

Amended Complaints involve the same conduct detailed more fully in the Second Amended Complaint.<sup>15</sup> Though the Second Amended Complaint no longer included FCA allegations regarding Anzemet, the basic FCA allegations regarding Taxotere remained and the additional details regarding these claims further substantiated the claims made in the First Amended Complaint.

Furthermore, as I explained in my previous decisions regarding the Second and Third Amended Complaints, the Third Amended Complaint also asserts claims that arise out of the same conduct alleged in the Original, First, and Second Amended Complaints.<sup>16</sup> The Third Amended Complaint makes additional factual allegations that are natural offshoots of the original allegations. Aventis had fair notice of these claims and suffers no prejudice from the prosecution of these claims.<sup>17</sup>

<sup>&</sup>lt;sup>15</sup> The First Amended Complaint was the first complaint actually served on the defendants. This is the complaint to which the defendants refer for purposes of notice. It was filed two months after the Original Complaint. The defendants do not argue that the First Amended Complaint cannot relate back to the Original Complaint. Even if they did, the two also involve similar allegations and relation back would be appropriate, if there were a concern about the statute limitations running from the time the Original Complaint was filed.

<sup>&</sup>lt;sup>16</sup> The defendants also argue that the plaintiff's Third Amended Complaint included a "new" claim regarding kickbacks to researchers and physicians. They move to dismiss this "new" claim as untimely. This new "claim" is related to the same misleading, off-label promotion alleged in earlier complaints. "[A] new legal theory applied to the same facts set out in the earlier pleading will relate back." <u>United States ex rel. Kolchinsky v. Moody's Corp.</u>, 162 F.Supp.3d 186, 199 (S.D. N.Y. 2016). Allegations in the earlier complaints also allude to this aspect of the marketing scheme. In that way, this "new claim" appears to be a natural off-shoot of allegations already made. The defendants' argument is unavailing.

<sup>&</sup>lt;sup>17</sup> I also point out that the defendants' raising this issue now, almost eight years after they received the unsealed First Amended Complaint and discovery has begun, seems more prejudicial to the plaintiff. I recognize that the defendants can raise their statute of limitations defense at any time. However, the timing of this motion is rather suspect.

The defendants claim that the First Amended Complaints did not put them on notice of allegations preceding 2000, because Mr. Gohil did not sell Taxotere nor work for Aventis' predecessor RPR between 1996 and 1999; as such, later complaints cannot relate back to it.<sup>18</sup> The First Amended Complaint made clear that Mr. Gohil brings his *qui tam* action as an employee of Aventis and *its predecessors*.<sup>19</sup> Though Mr. Gohil was technically an employee of Aventis from 2000 to 2002, he outlines events preceding the merger of Hoechst and RPR in his First Amended Complaint as part of an ongoing practice of off-label promotion.<sup>20</sup> See Gutierrez v. Johnson & Johnson, 227 F.R.D. 255, 256-59 (D.N.J. 2005)(allowing relation back to expand statutory period to two years prior because a "pattern and practice" was alleged and conduct dating back to that timeframe was at issue in the initial pleading).

<sup>18</sup> The defendants support this argument with <u>Anderson v. Bondex Int'l, Inc.</u>, No. 10–2306, 552 F.App'x 153, 157-58 (3d Cir. Jan. 7, 2014). That case is distinguishable. <u>See id.</u> at 158 ("We likewise reject Anderson's contention that her original complaint put Appellees on notice of her amended claim. The original complaint made no mention of workplace exposure during the 1960s and '70s, and in fact explicitly disclaimed any cause of action related to her employment within federal enclaves.").

<sup>19</sup> See First Amended Complaint at ¶ 5; Second Amended Complaint at ¶¶ 1, 5; Third Amended Complaint at ¶¶ 1, 5.

<sup>20</sup> <u>See</u> Original Complaint at ¶¶ 108, 125, 137; First Amended Complaint at ¶¶ 22, 108 (discussing RPR's Taxotere marketing actions in 1999).

The defendants argue that the Second Amended Complaint is the first time Gohil makes FCA allegations against Aventis' predecessor RPR. This is not true. While the references to RPR in the First Amended Complaint are scant, the Original and First Amended Complaints indicate that the practices alleged were ones undertaken by Aventis' predecessor RPR (which previously marketed Taxotere prior to the merger).

The plaintiff has requested documents from 1996 to 2004 since the parties began discovery which was also after the Second Amended Complaint was filed and the relevant timeframe stated at 1996 to 2004.

The defendants' motion regarding its statute of limitations defense is denied.<sup>21</sup>

#### C. First Amendment Defense is Not Ripe for Disposition

The defendants argue that dismissal of parts of the plaintiff's Counts II and IV of the Third Amended Complaint are based on allegations of truthful, non-misleading offlabel promotion of Taxotere. Liability for truthful, non-misleading speech related to offlabel marketing may be protected by the First Amendment. See Sorrell v. IMS Health Inc., 564 U.S. 552, 577-78 (2011). I do not read the plaintiff's allegations as asserting claims based on truthful or non-misleading speech. Throughout the Third Amended Complaint, the plaintiff asserts that the defendants' off-label promotion of Taxotere was false and/or misleading. See, e.g., Third Amended Complaint, Doc. No. 134 at ¶ 15, § 2 (pp. 6-90), ¶¶ 29, 30, 31, 38, 60-64, 67. That sort of speech is not necessarily protected by the First Amendment. See Sorrell v. IMS Health Inc., 564 U.S. 552, 583 (2011) ("[T]he Court has found that 'sales practices' that are 'misleading, deceptive, or aggressive' lack the protection of even this 'intermediate' standard."); United States v. Caronia, 703 F.3d 149, 164 (2d Cir. 2012)("[T]o warrant First Amendment protection, the speech in question must not be misleading and must concern lawful activity."); United States v. Bell, 414 F.3d 474, 480 (3d Cir. 2005)("The threshold inquiry is whether

<sup>&</sup>lt;sup>21</sup> <u>See Gutierrez v. Johnson & Johnson</u>, 227 F.R.D. 255, 256-59 (D.N.J. 2005)(allowing relation back to expand putative time frame by two years); <u>Freedman v. Fisher</u>, 89 F. Supp. 3d 716, 720 (E.D. Pa. 2015)(holding new statutory claim related back because "facts underpinning" claim were "pled in the original complaint" and defendant had "fair notice" that such "claim was possible"). <u>See also Simplex Time Recorder Co. v. Sec. of Labor</u>, 766 F.2d 575, 585 (D.C. Cir. 1985)("In situations where 'the citation as amended alleged the same basic facts and circumstances and complained of the same omission by the employer as had the original citation and complaint,' the courts have allowed amendment to cover periods prior to those originally listed in the complaint and more than six months before the date of the amendment.")

the commercial speech involves unlawful activity or is misleading. If so, the government may restrict it and the inquiry ends." (citation omitted)).<sup>22</sup>

The parties' arguments raise the question: was the off-label promotion actually false and/or misleading.<sup>23</sup> This is a genuine dispute which is material to the outcome of this case. Under Rule 12(c), I cannot render judgment with this dispute unresolved.<sup>24</sup> This question is better answered by a jury. At this point, I must accept the plaintiff's

<sup>&</sup>lt;sup>22</sup> <u>See also Sorrell v. IMS Health Inc.</u>, 564 U.S. 552, 579 (2011)("The State nowhere contends that detailing is false or misleading within the meaning of this Court's First Amendment precedents.... Nor does the State argue that the provision challenged here will prevent false or misleading speech." (citation omitted)).

<sup>&</sup>lt;sup>23</sup> The factual context of the statements made in promoting Taxotere off-label is especially important to answering this question. <u>See, e.g., McMahan & Co. v. Wherehouse Entm't, Inc.</u>, 900 F.2d 576, 579 (2d Cir. 1990)("The district court concluded that defendants had not misled plaintiffs because the information they included in the written and oral representations was "literally true". We think, however, that when read as a whole, the defendants' representations connoted a richer message than that conveyed by a literal reading of the statements. The central issue on all three claims is not whether the particular statements, taken separately, were literally true, but whether defendants' representations, taken together and in context, would have [been misleading].")

<sup>&</sup>lt;sup>24</sup> In a footnote, the defendants explain that the Third Amended Complaint is "ambiguous" in whether it is seeking liability based on truthful and non-misleading speech. <u>See</u> Defendants' Motion for Partial Judgment on the Pleadings, Doc. No. 183, at 11 n. 8. This footnote further supports a denial of their motion. I am required to view the plaintiff's complaint in the light most favorable to him. Any ambiguity would be resolved to indicate liability predicated on false, misleading speech.

allegations as true for the purpose of this motion.<sup>25</sup> Whether a First Amendment defense is permissible is a question to be answered after fact findings have been made.<sup>26</sup>

Thus, I will deny the defendants' motion without prejudice based on their First Amendment defense.<sup>27</sup>

# V. CONCLUSION

For the foregoing reasons, the defendants' motion for partial judgment on the

pleadings is DENIED.

An appropriate Order follows.

<sup>&</sup>lt;sup>25</sup> <u>See DiCarlo v. St. Mary Hosp.</u>, 530 F.3d 255, 262-63 (3d Cir. 2008)("A motion for judgment on the pleadings will be granted, pursuant to Fed.R.Civ.P. 12(c), if, on the basis of the pleadings, the movant is entitled to judgment as a matter of law.... The court will accept the complaint's well-pleaded allegations as true, and construe the complaint in the light most favorable to the nonmoving party, but will not accept unsupported conclusory statements." (citation omitted)).

<sup>&</sup>lt;sup>26</sup> See also Camreta v. Greene, 563 U.S. 692, 705 (2011)("[A] 'longstanding principle of judicial restraint requires that courts avoid reaching constitutional questions in advance of the necessity of deciding them.'"); Common Cause of Pennsylvania v. Pennsylvania, 558 F.3d 249, 257 (3d Cir. 2009)("A federal court '[a]lways ... must balance the heavy obligation to exercise jurisdiction against the deeply rooted commitment not to pass on questions of constitutionality unless adjudication of the constitutional issue is necessary."")(citation omitted).

<sup>&</sup>lt;sup>27</sup> See United States ex rel. Cestra v. Cephalon, Inc., No. 14-1842, 2015 WL 3498761, at \*12 (E.D. Pa. June 3, 2015)("I agree with the Court in Bergman that the question of First Amendment protection is therefore not properly disposed of on a motion to dismiss and will deny Cephalon's motion seeking to dismiss relator's claims on First Amendment grounds."); United States ex rel. Bergman v. Abbot Labs., 995 F. Supp. 2d 357, 376 (E.D. Pa. 2014) ("Because Relator has alleged that Defendant's marketing of TriCor included false and misleading statements, and, under a 12(b)(6) analysis, these allegations must be accepted as true, this Court finds that Abbott's commercial speech does not warrant First Amendment protection at this stage."). See also U.S. ex rel. Nevyas v. Allergan, Inc., No. 09–432, 2015 WL 3429381, at \*1 (E.D. Pa. May 26, 2015).