****FOR PUBLICATION****

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: PLAVIX MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION (NO. II)	MDL No. 2418
This Document Relates to:	
UNITED STATES OF AMERICA, *et al.*, *ex rel.* JKJ Partnership 2011, LLP, Plaintiffs, v. SANOFI AVENTIS, U.S., LLC, *et al.*, Defendants.	Civil Action No. 11-6476 (FLW) **OPINION**

WOLFSON, United States District Judge:

Before the Court is the motion of Defendants Sanofi-Aventis U.S., LLC; Sanofi US Services, Inc.; Aventis Pharmaceuticals, Inc.; Bristol-Myers Squibb Company; and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership (collectively "Defendants"), to dismiss the Second Amended Complaint of *qui tam* Plaintiff and relator JKJ Partnership 2011, LLP ("JKJ"), for lack of jurisdiction, pursuant to Fed. R. Civ. P. 12(b)(1), and for failure to state a claim, pursuant to Fed. R. Civ. P. 12(b)(6). Defendants contend (i) that JKJ's claims based on conduct occurring prior to the 2010 amendment to the False Claims Act ("FCA") by the Patient Protection and Affordable Care Act ("PPACA") are barred by the jurisdiction-stripping, pre-PPACA version of the FCA's "public disclosure bar," 31 U.S.C. § 3730(e)(4), because, *inter alia*, JKJ is not an original source of information learned, in the first instance, by JKJ's members

before JKJ's formation; (ii) that JKJ's claims based on conduct occurring after the 2010 amendment fail to state a claim under the non-jurisdictional, post-PPACA version of the public disclosure bar for the same reasons; and (iii) that all of JKJ's claims in the Second Amended Complaint are barred by the FCA's "first-to-file bar," 31 U.S.C. § 3730(b)(5), because of the impermissible replacement of one of JKJ's members, between the filing of the Original Complaint in 2011 and the filing of the Second Amended Complaint in 2017. JKJ opposes the motion, and, in the alternative, cross-moves to file a Third Amended Complaint, under Fed. R. Civ. P. 15(a)(2), 15(c)(1)(C), and 17(a)(3), naming its individual members as the realtor plaintiffs. For the reasons that follow, the Court finds that the public disclosure bar does not apply to JKJ's claims, that the first-to-file bar precluded, and prevents, JKJ from proceeding as the plaintiff in this action after its change in membership, and that the first-to-file bar prevents the joinder of JKJ's members as additional plaintiffs in this action, rendering JKJ's requested amendment futile. The Second Amended Complaint is therefore dismissed and JKJ's cross motion for leave to amend is denied.

I. FACTUAL BACKGROUND & PROCEDURAL HISTORY

On October 26, 2011, two doctors and a Sanofi sales representative formed JKJ, a Delaware Limited Partnership. JKJ was formed for the purpose of bringing the present litigation. On November 4, 2011 — nine days after it was formed — JKJ filed the Original *qui tam* Complaint, identifying its partners anonymously as "Partner A," "Partner B," and "Partner C." Original Compl., ¶¶ 20-24. In the Original Complaint, JKJ alleged, *inter alia*, that

> the Sanofi Defendants failed to disclose material adverse efficacy data regarding Plavix®, as required by 21 C.F.R. § 314.80 (governing post-marketing reporting of adverse drug experiences), causing physicians to prescribe, and Government Programs to reimburse, Plavix® for millions of patients who were genetically predisposed to experience diminished or no responsiveness to Plavix®, rendering it little more than a placebo and placing the patients at significant risk.

Id. at ¶ 5.

On February 22, 2017, JKJ filed a Second Amended Complaint, further developing its claim of Plavix's ineffectiveness for certain patients based on their genetic makeup. In the Second Amended Complaint, JKJ alleges that

> Defendants promoted [Plavix] as *the* standard of care for *all* antiplatelet and antithrombotic patients—including patients who received stents—notwithstanding their knowledge that the drug had little or no effect, and was therefore medically contraindicated, for over 30% of patients. . . . Defendants knew, but concealed the fact that their blockbuster drug Plavix had no demonstrable pharmacodynamics effect for many patients who had been prescribed the drug. They also knew that these "non-responders" or "low responders" were not entirely genetically random. Individuals whose ethnic background was African-American or Asian-American had a much higher risk of non-response to Plavix than other ethnicities. . . . Defendants referred to this as the Plavix "Variability of Response" (or "VOR") issue.

Second Amended Compl. ("SAC"), ¶¶ 1-2 (emphasis in original).

In that respect, JKJ claims that Defendants made affirmative misrepresentations by "systematically and deliberately promot[ing] Plavix through false and misleading advertising [and other marketing materials] that overstated efficacy, and minimized critical adverse event and risk information. Defendants would brand this their 'Expand and Protect' strategy." SAC, ¶ 249. Indeed, JKJ avers that Defendants created a logo used on Sales and Marketing material to stress and reflect this strategy. *Id.* According to JKJ, based upon such a strategy, Defendants "protected" Plavix by selling the drug's safety and efficacy in *all* patients in spite the fact that Defendants knew it was false. *Id.*

At some point between the filing of the Original Complaint in November 2011, and the filing of the Second Amended Complaint in February 2017, Partner B left the JKJ partnership, and Dr. Paul A. Gurbel joined the JKJ partnership to replace him or her. After the substitution in membership came to light, the Court, at an August 9, 2017 status conference, asked the parties to brief whether JKJ was a proper relator capable of continuing the litigation. In response to the

Court's inquiry, on October 11, 2017, Defendants filed a motion to dismiss, pursuant to Fed. R. Civ. P. 12(b)(1) and Fed. R. Civ. P. 12(b)(6). In their motion, Defendants argue that, (i) if JKJ is construed as the relator in its own right, the FCA's public disclosure bar precludes JKJ's claims,[1] (ii) if JKJ is construed as a pass-through entity for its members, who are the real relators in this action, then JKJ lacks Article III associational standing to proceed as the plaintiff in this case,[2] (iii) JKJ's continuation as the plaintiff after the substitution of Dr. Gurbel for Partner B is prohibited by the FCA's first-to-file bar, and (iv) any curative amendment to add JKJ's members as plaintiff relators is also prohibited by the first-to-file bar. Also, on October 11, 2017, JKJ opposed Defendants' motion and cross-moved, in the alternative, for leave to amend in order to name its current members, as well as JKJ, as the relator plaintiffs in this action. The parties' cross motions have been fully briefed and are ripe for the Court's consideration.

II. STANDARD OF REVIEW

A. Federal Rule of Civil Procedure 12(b)(1)

Under Federal Rule of Civil Procedure 12(b)(1), a court must grant a motion to dismiss if it lacks subject matter jurisdiction to hear a claim. *See* Fed. R. Civ. P. 12(b)(1). "A motion to dismiss for want of standing is also properly brought pursuant to Rule 12(b)(1), because standing

[1] As noted, *supra*, Defendants' motion is brought under both Rule 12(b)(1) and Rule 12(b)(6) because the FCA's public disclosure bar was jurisdictional before 2010, but continues to allow for non-jurisdictional challenges thereafter.

[2] The Court finds Defendants' arguments concerning associational standing inapposite to the facts of this case, where the JKJ partnership is clearly attempting to proceed as the relator in its own right. ECF No. 62, Opp. Br. & Cross Mot., 1-4 (explaining that in the Second Amended Complaint, JKJ, not its individual members, is the relator). The FCA does not limit relator standing to natural persons. 31 U.S.C. § 3730(b)(1) ("[a] person may bring a civil action for a violation of section 3729 for the person and for the United States Government"). And, indeed, the Third Circuit has adjudicated matters with partnership/association relators without observing a jurisdictional standing obstacle. *See, e.g., U.S. ex rel. Moore & Co., P.A., v. Majestic Blue Fisheries, LLC,* 812 F.3d 294 (3d Cir. 2016) (involving professional association relator).

is a jurisdictional matter." *Ballentine v. United States*, 486 F.3d 806, 810 (3d Cir. 2007); *see St. Thomas–St. John Hotel & Tourism Ass'n v. Gov't of the U.S. Virgin Islands*, 218 F.3d 232, 240 (3d Cir. 2000) ("The issue of standing is jurisdictional."). "On a motion to dismiss for lack of standing, the plaintiff bears the burden of establishing the elements of standing, and each element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation." *Ballentine*, 486 F.3d at 810 (citations and internal quotation marks omitted).

In evaluating a Rule 12(b)(1) motion to dismiss, the court must first determine whether the motion "presents a 'facial' attack or a 'factual' attack on the claim at issue, because that distinction determines how the pleading must be reviewed." *Constitution Party of Pennsylvania v. Aichele*, 757 F.3d 347, 357 (3d Cir. 2014) (quoting *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 243 (3d Cir. 2012)). "A facial 12(b)(1) challenge, which attacks the complaint on its face without contesting its alleged facts, is like a 12(b)(6) motion in requiring the court to 'consider the allegations of the complaint as true.' " *Hartig Drug Co. Inc. v. Senju Pharm. Co.*, 836 F.3d 261, 268 (3d Cir. 2016) (citation omitted); *see Gould Elecs. Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000), *modified by Simon v. United States*, 341 F.3d 193 (3d Cir. 2003) (observing that in reviewing a facial challenge, which contests the sufficiency of the pleadings, "the court must only consider the allegations of the complaint and documents referenced therein and attached thereto, in the light most favorable to the plaintiff."). A factual challenge, on the other hand, "attacks allegations underlying the assertion of jurisdiction in the complaint, and it allows the defendant to present competing facts." *Hartig Drug Co.*, 836 F.3d at 268. The "trial court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case" and "the plaintiff will have the burden of proof

that jurisdiction does in fact exist." *Petruska v. Gannon Univ.*, 462 F.3d 294, 302 n. 3 (3d Cir. 2006) (quoting *Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977)).

"Therefore, a 12(b)(1) factual challenge strips the plaintiff of the protections and factual deference provided under 12(b)(6) review." *Hartig Drug Co.*, 836 F.3d at 268.

B. Federal Rule of Civil Procedure 12(b)(6)

In reviewing a motion to dismiss for failure to state a claim upon which relief can be granted, pursuant to Federal Rule of Civil Procedure 12(b)(6), "courts accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (internal quotation marks and citation omitted). While Federal Rule of Civil Procedure 8(a) does not require that a complaint contain detailed factual allegations, "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citation omitted). Thus, to survive a Rule 12(b)(6) motion to dismiss, the Complaint must contain sufficient factual allegations to raise a plaintiff's right to relief above the speculative level, so that a claim "is plausible on its face." *Id.* at 570; *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). While the "plausibility standard is not akin to a 'probability requirement,' . . . it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (citation omitted).

To determine whether a plaintiff has met the facial plausibility standard mandated by *Twombly* and *Iqbal*, courts within the Third Circuit engage in a three-step progression. *Santiago v. Warminster Twp.*, 629 F.3d 121, 130 (3d Cir. 2010). First, the reviewing court "outline[s] the elements a plaintiff must plead to a state a claim for relief." *Bistrian v. Levi*, 696 F.3d 352, 365 (3d Cir. 2012). Next, the court "peel[s] away those allegations that are no more than conclusions and thus not entitled to the assumption of truth." *Id.* Finally, where "there are well-pleaded factual allegations, [the] court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Iqbal*, 556 U.S. at 679. This last step of the plausibility analysis is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679.

III. ANALYSIS

A. Public Disclosure Bar

Defendants argue that JKJ's claims are precluded by the FCA's public disclosure bar, which limits a plaintiff's ability to bring claims based on information previously disclosed in, *inter alia*, government reports and investigations; public hearings, including court proceedings; and the news media. The FCA was amended in 2010, altering the public disclosure bar's limitation on claims. JKJ's claims cover a period spanning both prior to and after the amendment, requiring the Court to apply both versions of the statute. Before its 2010 amendment, the FCA's "public disclosure bar," 31 U.S.C. § 3730(e)(4)(A), provided:

> No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office [sic] report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

Under that version of the statute, an "original source" under 31 U.S.C. § 3730(e)(4)(B) was defined as:

> an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

31 U.S.C. § 3730(e)(4)(B); *See, e.g.*, *U.S. ex rel. Atkinson v. Pa. Shipbuilding Co.*, 473 F.3d 506, 518–19 (3d Cir. 2007).

In 2010, Congress amended the bar as part of the PPACA, such that it now reads as follows:

> (4)(A) The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—
>
> (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party*;*
>
> (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit or investigation; or
>
> (iii) from the news media,
>
> unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
>
> (B) For purposes of this paragraph, "original source" means an individual who either (i) prior to a public disclosure under subsection (e)(4)(A), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

31 U.S.C. § 3730(e)(4)(A), (B) (2012). *See, e.g., U.S. ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 298 (3d Cir. 2016).

After the amendment, § 3730(e)(4) "does not set forth a jurisdictional bar." *Id.* at 300. Additionally, as relevant to this case, "information that was disclosed in a criminal, civil, or administrative hearing now qualifies as a public disclosure only if the information was disclosed

in a federal case to which the government was a party. As a result, information that was disclosed in a federal case between private parties no longer constitutes publicly disclosed information." *Id.* at 299 (citation omitted). Finally, after the amendment "[a] relator no longer must possess 'direct . . . knowledge' of the fraud to qualify as an original source. . . . The focus now is on what independent knowledge the relator has added to what was publicly disclosed." *Id.* at 299.

Applying the foregoing, under either version of the statute, to determine whether the claims in JKJ's Second Amended Complaint are barred by the FCA's public disclosure provisions, the Court must first assess whether JKJ's claim is *based on* publicly disclosed allegations or transactions. "This, in turn, requires a twofold analysis. First, [courts] determine whether the information was disclosed via one of the sources listed in § 3730(e)(4)(A). Second, [courts] decide whether the relator's complaint is based on those disclosures." *U.S. ex rel. Atkinson*, 473 F.3d at 519. "To be 'based upon' the publicly revealed allegations or transactions the complaint need only be 'supported by' or 'substantially similar to' the disclosed allegations and transactions." *Id.* (citing *United States ex rel. Mistick PBT v. Housing Auth.*, 186 F.3d 376, 385–88 (3d. Cir. 1999) (rejecting a rule that "based upon" means "actually derived from," because such a rule would render the original source exception superfluous)). The Third Circuit has explained the proper application of the bar as a standard formula:

> To aid our analysis we are guided by an algebraic representation of the nature and extent of disclosure required to raise the jurisdictional bar. *U.S. ex rel. Dunleavy v. City of Delaware*, 123 F.3d 734, 741 (3d Cir. 1999) (quoting *U.S. ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 654 (D.C. Cir. 1994)).
>
> > [I]f X + Y = Z, Z represents the allegation of fraud and X and Y represent its essential elements. In order to disclose the fraudulent transaction publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, i.e., the conclusion that fraud has been committed.

> *Id.* To draw an inference of fraud, both a misrepresented [X] and a true [Y] state of facts must be publicly disclosed. *Id.* at 741. So, if either Z (fraud) or both X (misrepresented facts) and Y (true facts) are disclosed by way of a listed source, then a relator is barred from bringing suit under § 3730(e)(4)(A) unless he is an original source.

U.S. ex rel. Atkinson, 473 F.3d at 519. *See also U.S. ex rel. Zizic v. Q2Administrators, LLC*, 728 F.3d 228, 235–36 (3d Cir. 2013) ("An allegation of fraud is an explicit accusation of wrongdoing. A transaction warranting an inference of fraud is one that is composed of a misrepresented state of facts plus the actual state of facts.").

Applied here, Defendants identify four qualifying public disclosure sources under § 3730(e)(4)(A): (i) a letter order issued following discovery hearings held before the Magistrate Judge in *Hall v. Bristol-Meyers Squibb Co.*, No. 3:06-CV-5203 (D.N.J. Mar. 24, 2011); (ii) the proposed Amended Complaint in *Mills v. Bristol-Myers Squibb Co.*, No. 2:11-CV-968 (D. Ariz. Sept. 2, 2011); (iii) news articles discussing the District Judge's denial of leave to file the proposed Amended Complaint in *Mills*, including *Patient Is Not Entitled to File Second Amended Complaint Against Drug Manufacturers*, Health Law Week, Oct. 28, 2011 ("Health Week"); and Michael F. Bahler, *District Judge Looks to Restatement (Third) of Torts in Throwing Out Plavix Suit*, Bloomberg Law, Oct. 13, 2011 ("Bloomberg"); and (iv) a news article concerning a label change for Plavix, Jared A. Favole & Alicia Mundy, *FDA Considers Updating Plavix Label*, Wall St. J., Dec. 31, 2008, at D6 ("WSJ"). The Court notes that the news articles remain qualifying public disclosures under both the pre and post-amendment versions of the public disclosure bar. 31 U.S.C. § 3730(e)(4)(A). The Court proceedings in *Hall* and *Mills*, however, were litigated between private parties, without the intervention of the Government, and therefore are qualifying public disclosures only under the pre-2010 iteration of the bar. *U.S. ex rel. Moore*, 812 F.3d at 300. The Court is therefore called upon to determine whether substantially the same allegations or transactions of fraud from JKJ's Second Amended

Complaint were publicly disclosed in these sources, considering all sources for JKJ's pre-2010 allegations and the news articles alone for the post-2010 allegations. The Court addresses each category of disclosures in turn.

In *Hall*, the plaintiffs brought a product liability class action against BMS and Sanofi, which alleged, among other things, that Plavix was marketed as more effective and safer than aspirin, when in fact BMS and Sanofi knew that it was not more effective and actually carried greater safety risks, including heart attack, stroke, and internal bleeding. *Hall*, ECF No. 1, Original Compl., ¶¶ 13-14; ECF No. 54, Am. Compl., ¶¶ 13-14. Notably, the Complaint and Amended Complaint in *Hall* do not mention the issue of genetic variability at all. In support of the present motion, therefore, Defendants rely upon a letter order issued by the Magistrate Judge assigned to the case, following two hearings on discovery disputes concerning matters outside the four corners of the Amended Complaint. Specifically, the Letter Order states in relevant part that "Plaintiffs further contend that, while Defendants Bristol-Meyers Squibb, Company, et al. ("Defendants") knew for many years that over 30% of people taking Plavix incur no benefit, this information was not disclosed to the public until late 2009." *Hall*, ECF 106, Mar. 24, 2011 Letter Order (Bongiovanni, M.J.), p.1. Firstly, the Court finds that, on its face, the Magistrate Judge's summary of the plaintiffs' argument does not itself provide both essential elements of an allegation of fraud. While the Y is present in the form of the true set of facts — that defendants knew that over 30% of people taking Plavix incur no benefit — the X, or alleged misrepresented fact is absent.[3] The plaintiffs in *Hall* apparently represented in their request for more extensive

[3] I stress that because on a motion to dismiss I must take all allegations as true, I assume as true JKJ's allegation that Defendants knowingly misrepresented the efficacy of Plavix; that is "Defendants promoted [Plavix] as *the* standard of care for *all* antiplatelet and antithrombotic patients—including patients who received stents—notwithstanding their knowledge that the drug had little or no effect, and was therefore medically contraindicated, for over 30% of patients."

discovery that defendants knew, but did not disclose the aspect of the genetic variability issue that some patients did not respond to the drug. The plaintiffs there did not, as JKJ does in this case, allege that Defendants actively promoted Plavix as efficacious for *all* antiplatelet and antithrombotic patients while aware that this was not true. SAC, ¶¶ 1-2.

Looking to the transcripts of the oral arguments concerning the *Hall* plaintiffs' discovery request confirms this view. At the October 26, 2010 hearing on the plaintiffs' discovery request, the issue of patients possessing genetic variations affecting Plavix's effectiveness was extensively discussed. Specifically, the parties in *Hall* divided the genetic variability issue into cases of "hypo responders," for whom Plavix was ineffective, and "hyper responders" for whom Plavix was too effective, creating heightened risk of bleeding. As relevant to this case, the parties' discussion of hypo responders never raised the specter of fraud by suggesting that the *Hall* defendants misrepresented Plavix's effectiveness for such patients. Much to the contrary, plaintiffs' counsel in *Hall* noted that defendants had been discussing the cause of the hypo responder issue since May of 2007, and "had an enormous interplay with the FDA on this, before the FDA forced them to black box it." *Hall*, ECF No. 98, October 26, 2010 Hearing Tr., 28:7-11. Defense counsel added, of the hypo responder issue, that "[t]his issue about genetic variability of response has been in medical articles and in the press since 2008. It was added to the label initially in 2009. It was supplemented again another time in 2009. And then even the black box warning was added to the label in March of 2010." *Id.* at 32:3-7. In the entire discussion of the label change, there was no suggestion by plaintiffs' counsel or otherwise, that defendants denied

SAC, ¶¶ 1-2 (emphasis in original). Moreover, JKJ alleged that Defendants made material misrepresentations by overstating Plavix's efficacy and minimized critical adverse event and risk information. *Id.* at ¶ 249. I make no comment as to the merits of JKJ's allegation of Defendants' misrepresentations in this regard.

or misrepresented the hypo responder phenomenon. To the contrary, the alleged fraud with which plaintiffs' counsel professed to be concerned was one related to "hyper responders," a different category of persons for whom Plavix was alleged to cause excessive bleeding:

> Plaintiffs' Counsel: "And for some people they're hypo responders. That is to say they don't metabolize it correctly, and the drug doesn't work at all, and they have double the risk of heart attack or – or stroke because they're hypo responders . . .
>
> The Court: "But I think what the defendants have said is that none of these plaintiffs are alleging that they're in the category of genetic hype – hypo responders."
>
> Plaintiffs' Counsel[4]: "Exactly. We are in the category of variable responders. We are hyper responders. Which we've already found within the documents up through May of 2007, they knew about the hyper responder. The variability of response is the larger issue. And our people are all hyper responders who were never warned about the variability of response."

Id. at 25:8-12; 25:14-22. The hypo-responder issue was mentioned only once at the second, February 22, 2011 hearing, and then only by defense counsel, who noted that such persons, referred to again in those proceedings as "hypo responders," were not alleged to be relevant to the case. *Hall*, ECF No. 105, February 22, 2011 Hearing Tr., 25:9-13 ("The second point is I think at the last hearing Mr. Miller conceded that all issues relating to hypo-response, that is a lack of efficacy, were not relevant to these particular Plaintiffs and he focused instead on this hyper-response genetic variation.").

Interpreting the Magistrate Judge's summary about a "failure to disclose" in this context, the *Hall* discovery issue clearly did not raise a question of any actual misrepresentation or fraud concerning Plavix's effectiveness for hypo responders before an alleged public admission of the problem in 2009 — presumably the label change. Defense counsel represented, without contradiction by plaintiffs' counsel, that the issue was already public as early as 2008, and

[4] The transcript contains a typographical error, where the comments of Plaintiffs' counsel are attributed to the Court. The context and content of the exchange, however, make clear that Plaintiffs' counsel is speaking.

plaintiffs' counsel themselves represented that defendants were in discussions with the FDA concerning the issue between 2007 and 2010. Moreover, the *Hall* plaintiffs limited their additional allegations of fraud to information surrounding hyper responders who are at increased bleeding risk, not hypo responders whose genetic makeup rendered Plavix ineffective. The Order and the transcript therefore firmly establish the existence of Y, the true state of facts, that Defendants were aware that a category of persons existed whose genetic variations reduced or eliminated the efficacy of Plavix. What is missing from the Magistrate Judge's Letter Order, and from the transcripts of the hearings it referenced, is any mention of X, the alleged misrepresentation by defendants, contradicting Y, that would give rise to an inference of fraud. Plaintiffs counsel in *Hall* did not, for example, as JKJ does in this case, allege that defendants advertised Plavix as being equally effective for all patients, or otherwise publicly denied that the hypo responder phenomenon was a problem with the product. In the absence of a misrepresentation, the Court finds that the *Hall* Letter Order does not support an inference of fraud.

The *Mills* Complaint is even weaker evidence of prior public disclosure. There, the Complaint concerns exclusively the risks of excessive bleeding for, in the parlance of *Hall*, hyper responders. That Complaint does support an inference of fraud concerning hyper responders, but that is not of the kind of fraud alleged in the Second Amended Complaint here. In *Mills*, the plaintiffs contended that defendants knew of the risk of bleeding and other complications to hyper responders caused by Plavix, but nevertheless failed to disclose those risks *and* marketed Plavix as safe and not causing the very conditions Plavix was known to cause in hyper responders. Comparable allegations for the hypo responders are nowhere to be found in *Mills*. They are simply not discussed. The Complaint in *Mills* alleged:

34. However, in specific patient populations Defendants knew that Plavix would not prevent clotting, and exposure to Plavix would in fact, cause a heightened risk of:

a. Serious excessive and fatal spontaneous bleeding;

b. Increased risk of colectomy (surgical intervention to stem spontaneous bleeding);

c. A decrease in the number of platelets in the blood (thrombocytopenia);

d. Hypotension;

e. Circulatory problems; and,

f. Respiratory distress and cardiovascular problems.

35. Nevertheless, Defendants marketed Plavix to be superior in design and effect than Aspirin and claimed that *Plavix, unlike Aspirin, did not cause the adverse side effects listed in paragraphs 34(a) to (f) above*.

36. During the period of 1997 to the time of Plaintiff's ingestion of said drug, Plavix was heavily marketed directly to consumers through television, magazine and Internet advertising. It was touted as a "super-aspirin," that would give a person even greater cardiovascular benefits than a much less expensive, daily aspirin *while being safer* and easier on a person's stomach *than aspirin*. Those assertions have proven to be false by scientific studies. p. 8

. . .

42. Additionally, Plavix is a prodrug that requires biotransformation in the human body to an active metabolite by cytochrome P-450 (CYP enzymes). Once in the body the enzymes push the majority of Plavix into an inactive pathway, with the remaining prodrug requiring two separate CYP –dependent oxidative steps. Given this chemical structure, *patients carrying a genetic variant of CYP incur a greater risk of adverse events such as death, cardiovascular problems, circulatory problems, and spontaneous excessive and potentially fatal bleeding*.

43. *Defendants Sanofi and BMS knew or should have known that the genetic variants occurred in 30% of the Caucasian population* and suggested to Physicians and the medical community that patients be tested for the genetic variant. However, *Defendants failed to disclose the potential risk posed to carriers of the genetic variant*.

Mills v. Bristol-Myers Squibb Co., No. 2:11-CV-968 (D. Ariz. Sept. 2, 2011), ECF No. 30-1, Proposed Am. Compl. at ¶¶ 34-36, 42-43 (emphasis added). Again, reviewing these allegations, it is clear that the fraud alleged in *Mills* concerned the defendants' alleged misrepresentation of the *safety* of Plavix for *hyper responders*, including roughly 30% of the *Caucasian* population.

By contrast, JKJ's Second Amended Complaint in this action alleges a fraud in which Defendants supposedly misrepresented the *efficacy* of Plavix for *hypo responders,* including roughly 30% of the patient population who are predominantly *African American* and *Asian*. SAC, ¶¶ 1-2.

Defendants make much, however, of the fact that the Complaint in *Mills*, in its consideration of misrepresented bleeding risk for hyper responders, relied upon the same study upon which JKJ now relies for its claims based on misrepresented efficacy for hypo responders. Compare *Mills* Complaint, p. 10 ¶ 42 n.5, with Original Compl., ¶¶ 157-58; SAC, ¶¶ 157-58. Defendants therefore appear to argue that *Mills'* prior disclosure of the genetic variability of response or "VOR" issue, writ large, is sufficient for the application of the public disclosure bar, regardless of whether the allegations concerned that Plavix worked too well for some persons, such that it was not safe, or did not work well enough for some persons, such that it was not an effective medical treatment. The Court disagrees. Reading this shared reliance on the same study as expansively as possible, again yields only the Y — the true factual circumstance that Plavix was not effective for a substantial portion of the population based on their genetics — not the X — any misrepresentation by Defendants.

The news articles concerning *Mills* disclose no more than the Complaint. *See* Health Week ("Mills alleged that the chemical structure of Plavix is defective because it carries a higher risk of adverse events for patients who carry the genetic variant CYP, who are poor metabolizers of the drug."); Bloomberg ("The new complaint specifically alleged that Plavix's chemical structure was more dangerous and less effective for people who carried the CYP generic variant. A medical study had reported that CYP carriers who used Plavix experienced higher rates of

death from cardiovascular causes, heart attack, and stroke."). The allegations reproduced therein also do not disclose any allegations of misrepresentations made by Defendants (the X).

Finally, like all other sources discussed above, the news article concerning the 2009 label change also discloses, at best, the existence of the variability of response efficacy issue — the Y. *See* WSJ ("The three studies last week -- two in the New England Journal of Medicine and one in the Lancet -- identified a genetic abnormality in some heart patients that could interfere with their liver's ability to completely process Plavix in the bloodstream, but they differed on the number of patients affected. Two of the studies suggested the drug was less effective in about 30% of the population that has the mutated gene from one parent, while one study indicated the drug is less effective in the 5% of the population that has the gene from both parents."). But, the same article did not disclose any alleged misrepresentation by Defendants leading up to or surrounding the change — the X — that could give rise to an inference of fraud. That is, the article did not disclose that Defendants allegedly marketed Plavix by touting that the drug is efficacious for *all* antiplatelet and antithrombotic patients. In sum, the Court finds that because the allegations in JKJ's Second Amended Complaint are not *based on* prior public disclosures regarding alleged misrepresentations (the X), the public disclosure bar does not apply to bar JKJ's claims. However, that is not the end of this Court's inquiry. I turn next to the FCA's first-to-file bar.

B. First-to-File Bar

"The first-to-file bar provides that, once a *qui tam* action has been brought on a claim, 'no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.'" *U.S. ex rel. Heath v. AT & T, Inc.*, 791 F.3d 112, 120 (D.C. Cir. 2015) (quoting § 3730(b)(5)). "The text speaks . . . to who may bring a private action and when .

. . .” *Id.* The question presented to the Court in determining the bar’s application to JKJ’s Second Amended Complaint is whether the substitution of Dr. Gurbel for the original Partner B in JKJ’s partnership brought about an “intervention” of a new private party into the case. This question in turn requires a two-part analysis. First, the Court must determine whether the departure of Partner B from the original JKJ partnership, and the addition of Dr. Gurbel to the partnership created a new legal entity, distinct from the original JKJ partnership that filed the Original Complaint in this action. Second, if the post-Gurbel JKJ partnership is indeed a new entity, the Court must determine whether the new JKJ’s substitution as the Plaintiff in the Second Amended Complaint constituted an “intervention” barred by the first-to-file bar.

This Court finds, and the parties agree, that whether the change in JKJ’s membership gave rise to a new legal entity is a question of Delaware State law. *See* ECF No. 58-1, Def. Mot. Br., p. 13-14; ECF No. 62, Opp. & Cross Mot., p. 19-20. Specifically, JKJ argues that under Del. Code Tit. 6 § 15-103(a), “relations among partners and between partners and the partnership are governed by the partnership agreement.” Section 1.03 of JKJ’s Partnership Agreement in turn provides that JKJ “shall not be a separate legal entity distinct from its Partners.” ECF No. 62-3, August 1, 2011 JKJ Partnership 2011 LLP Partnership Agreement (“Agreement”), p. 2, Section 1.03. The Agreement also states in Section 8.01, that “withdrawal of a Partner shall not cause a dissolution of the Partnership,” and, in Section 1.07, that the “term of the Partnership . . . shall continue until the final resolution or settlement of the Action without further right of appeal.” From these provisions, JKJ argues that the departure of the original Partner B did not dissolve the original partnership and the addition of Dr. Gurbel did not result in the creation of a new partnership under Delaware law.

Defendants, looking to the same body of law, reach the opposite conclusion. Defendants contend that the Delaware Revised Uniform Partnership Act ("DRUPA"), under which JKJ was formed, provides as a default rule that Delaware partnerships are separate entities surviving the addition or subtraction of partners, but that the original members of JKJ exercised their option under § 15-201(a) to opt out of the "entity partnership" structure, when they adopted the language in Section 1.03 of their Partnership Agreement that JKJ "shall not be a separate legal entity distinct from its Partners." Defendants therefore argue that JKJ, as an aggregate, or non-entity partnership, is subject to the pre-DRUPA partnership regime, in which the subtraction of a member dissolves the partnership and the addition of a member gives rise to a new partnership.

As a threshold matter, the Court agrees that under DRUPA, the language of the Partnership Agreement governs the nature of the legal entity created. Del. Code Tit. 6 § 15-103(a); Del. Code Tit. 6, § 15-201(a). Under JKJ's partnership agreement, the JKJ partnership does not exist as a legal entity separate and distinct from its three members. Partnership Agreement, Section 1.03. Indeed, this legal artifice was potentially essential to JKJ's claims in this case. Were the Court to have found JKJ's claims in the Second Amended Complaint to be based upon prior public disclosures, JKJ would only have been able to proceed if it were an "original source" of the information. 31 U.S.C. § 3730(e)(4)(B).[5] JKJ, of course, was formed in 2011, and therefore did not exist at the time of the events underlying JKJ's claims in the Second Amended Complaint. JKJ therefore has "knowledge" of the fraud for which it claims to serve as a whistleblower, if at all, only through its constituent members. Although the Third Circuit has not resolved the issue, the consensus of persuasive precedent suggests that, were JKJ a separate

[5] The parties extensively briefed the issue of JKJ's status as an original source in anticipation of a finding that JKJ's claims were based on prior public disclosures.

legal entity, the fact that it did not exist at the time the alleged fraud occurred would prevent it from being an "original source" with direct knowledge of the fraud under the pre-amendment FCA. *See, e.g., Fed. Recovery Servs., Inc. v. United States*, 72 F.3d 447, 452 (5th Cir. 1995) (entity "incorporated with the express purpose of pursuing qui tam litigation based on the information that others, . . . had already obtained" "had no 'direct and independent' knowledge of the information upon which this qui tam action is based."); *U.S. ex rel. Precision Co. v. Koch Indus., Inc.*, 971 F.2d 548, 554 (10th Cir. 1992) (corporate entity can make "no showing it has a legitimate claim to information gathered by [its shareholders] prior to its formation" and "cannot seriously argue it qualifies as an original source" of that information). By contrast, although the Third Circuit has not yet reached the issue, at least one appellate court has found that an unincorporated association with no legal distinction from its members, can proceed in a *qui tam* action on the basis of its members' knowledge of the fraud. *See Minnesota Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1049–50 (8th Cir. 2002) ("Unincorporated associations derive their rights from the rights of their members. Thus, associations can have standing to assert their members' rights in court . . . . An association's knowledge is in no way parasitic of its members and is 'direct' within the meaning of the original source clause." (citation omitted)). In its briefing concerning the public disclosure bar, JKJ, relying upon *Minnesota Ass'n of Nurse Anesthetists*, argues that it should be able to impute the knowledge of, and act upon, the rights of its members because it has no separate legal existence from them under its Partnership Agreement.

Looking then to the legal status of the JKJ entity that filed the Original Complaint in this matter, that Court finds that, pursuant to § 15-201(a) of DRUPA and Section 1.03 of the Partnership Agreement, the original JKJ had no separate legal existence from its members,

Partners A, B, and C. The Court will also accept JKJ's position that this original JKJ partnership was able to serve as a relator in this case on the basis of its members' knowledge and legal rights, since the partnership was not legally distinct from these members. *See Minnesota Ass'n*, 276 F.3d at 1049–50. The problem for JKJ, however, is that the necessary consequence of there being no legal distinction between the original JKJ partnership and its members — Partners A, B, and C — is that there was not a separate, JKJ legal entity that could persist as the nominal plaintiff in this matter when Partner B left the partnership and Dr. Gurbel joined into the new JKJ partnership. Accordingly, although purportedly proceeding as a single entity in this action, JKJ has actually been two partnerships. At the time of the filing of the original complaint JKJ was a partnership of A, B, and C, alleged to possess their knowledge and proceeded with their legal rights as relators. Sometime after the filing of the Original Complaint, and before the filing of the Second Amended Complaint, JKJ became a partnership of A, Dr. Gurbel, and C, alleged to possess their different combination of knowledge and legal rights.

JKJ of course contends that other provisions of its partnership agreement prevent this result. *See* Partnership Agreement, Section 1.07 (the "term of the Partnership . . . shall continue until the final resolution or settlement of the Action without further right of appeal"); Section 8.01 ("withdrawal of a Partner shall not cause a dissolution of the Partnership"). The Court finds these provisions unpersuasive, however, because the benefits of a persistent, separate legal entity for litigation purposes are inextricably intertwined with the entity model of partnership that DRUPA adopted. Once JKJ's original members opted out of the entity model, as permitted by § 15-201(a), they could not retain the benefits of a legally separate JKJ entity for litigation purposes. Any finding to the contrary would lead to the absurd result that JKJ would be permitted to proceed as a relator because it is legally indistinguishable from, and therefore

directly possesses the knowledge of, its members, but would also be permitted to change its membership without becoming a different legal entity because it is legally independent and distinguishable from its present membership. Put simply, JKJ cannot have it both ways. As part of a litigation strategy to maintain their anonymity, JKJ's original partners formed a non-entity partnership arguably capable of serving as a source of information concerning events which transpired before its formation on the basis of its partners' personal knowledge. Having obtained these benefits at filing, JKJ cannot now be treated as an entity partnership capable of persisting in the litigation through a change in membership.

This result is compelled by the structure and history of DRUPA itself. "Historically, the common law considered partnerships to be collections of individuals rather than distinct jural entities with their own interests." *HB Gen. Corp. v. Manchester Partners, L.P.*, 95 F.3d 1185, 1192 (3d Cir. 1996) (citing *Silliman v. DuPont,* 302 A.2d 327, 331 (Del. Super. Ct. 1972), *aff'd, F.I. Du Pont, Glore, Forgan & Co. v. Silliman,* 310 A.2d 128 (Del. 1973) and *Puerto Rico v. Russell & Co.*, 288 U.S. 476, 480 (1933)). This conception of partnerships as legally indistinct from their individual members is known as the aggregate model of partnership, which is distinguished from the entity model, which holds that the partnership is a legally distinct entity, independent of its individual members. *Id.* In 1947, Delaware adopted the Uniform Partnership Act ("UPA"), 6 Del. C. § 1501, *et seq*. The UPA retained most features of the aggregate model of partnership, but introduced some features of the entity model. *HB Gen. Corp.*, 95 F.3d at 1192 (quoting *Silliman,* 302 A.2d at 332 n. 4 (noting that the evolution of the Uniform Partnership Act has been viewed as a "realistic accommodation of entity theory to aggregate practice which leaves unresolved many problems concerning the legal nature of partnerships....")). The UPA remained the law until 1999, when it was repealed and replaced with DRUPA, which became

effective January 1, 2002. *Hynansky v. Vietri*, No. 14645-NC, 2003 WL 21976031, at *5 n. 35 (Del. Ch. Aug. 7, 2003).

DRUPA significantly revised many aspects of the UPA, and transformed the law of Delaware partnerships from primarily following the aggregate model to primarily following the entity model as a default. For example, as relevant to this case, under Delaware's version of the UPA, a partnership was defined as "*an association of 2 or more persons* to carry on as coowners a business for profit." 6 Del. C. § 1506 (emphasis added). As noted above, DRUPA, however, provides that "[a] partnership is *a separate legal entity which is an entity distinct from its partners* unless otherwise provided by the partnership's formation documents." Del. Code Ann. Tit. 6, § 15-201 (a) (emphasis added). The Official Comments to the RUPA, the model code version upon which DRUPA is based, clearly spell out the benefits of this entity model compared to the prior aggregate model:

> RUPA embraces the entity theory of the partnership. In light of the UPA's ambivalence on the nature of partnerships, the explicit statement provided by subsection (a) is deemed appropriate as an expression of the increased emphasis on the entity theory as the dominant model. . . .
>
> Giving clear expression to the entity nature of a partnership is intended to allay previous concerns stemming from the aggregate theory, such as the necessity of a deed to convey title from the 'old' partnership to the 'new' partnership every time there is a change of cast among the partners. Under RUPA, there is no 'new' partnership just because of membership changes.

RUPA § 201, Official Cmt. (2017-2018 ed.). The comments to the RUPA provision concerning the dissolution of partnerships cast the difference in the treatment of partnership membership changes in even starker light.

> Under UPA Section 29, a partnership is dissolved every time a partner leaves. That reflects the aggregate nature of the partnership under the UPA. Even if the business of the partnership is continued by some of the partners, it is technically a new partnership. The dissolution of the old partnership and creation of a new partnership causes many unnecessary problems.

. . .

> RUPA's move to the entity theory is driven in part by the need to prevent a technical dissolution or its consequences. Under RUPA, not every partner dissociation causes a dissolution of the partnership.

RUPA § 801 Official Cmt. 1 (2017-2018 ed.).

Delaware's UPA, the pre-DRUPA statute, reflected the same difficulties inherent in aggregate partnerships during membership changes. The subchapter on dissolution provided that "[t]he dissolution of a partnership is the change in the relation of the partners caused by any partner ceasing to be associated in the carrying on as distinguished from the winding up of the business." 6 Del. C. § 1529. The provision on the continuation of partnership business after a change in membership similarly reinforced the point:

> When any new partner is admitted into an existing partnership, or when any partner retires and assigns (or the representative of the deceased partner assigns) the rights in partnership property to 2 or more of the partners, or to 1 or more of the partners and 1 or more third persons, if the business is continued without liquidation of the partnership affairs, creditors of the first or dissolved partnership are also creditors of the partnership so continuing the business.

6 Del. C. § 1541(a). In short, when Delaware followed the more-aggregate dominant model of the UPA, its law reflected that the addition or subtraction of members from the partnership created new partnerships.

DRUPA brought an end to this phenomenon by embracing the entity model of partnership, but, as noted above, DRUPA predominantly sets forth only a series of default rules. The statutory text explicitly permits partners to opt out of the majority of DRUPA's provisions enshrining the entity model. Del. Code Ann. Tit. 6, § 15-103(a) (empowering partners to opt out of DRUPA provisions through amendments to the partnership agreement); § 15-103(b) (enumerating the provisions from which partners may not opt out; § 15-201(a) is not enumerated). As one commentator on the RUPA succinctly put it, "Section 201(a), which states

that a partnership is an entity distinct from its partners, is not mentioned in the Section 103(b) list of rules that cannot be varied by agreement. Therefore, the partnership agreement may govern the relations among partners and between the partnership and the partners according to an aggregate model." RUPA, § 201, Partnership as Entity, Rev. Uniform Partnership Act Section 201 (2017-2018 ed.), Annotated Cmt. 3. "Delaware made this point explicit when it adopted R.U.P.A. in 1999 by amending R.U.P.A. § 201(a) to provide: 'A partnership is a separate legal entity … distinct from its partners *unless or to the extent otherwise provided in a statement of partnership existence and in a partnership agreement*.'" *Id.* at Annotated Cmt. 3, n. 10 (emphasis in original).

Against that backdrop, JKJ's partners argue that, despite having opted out of the entity model of partnership under § 15-201(a), JKJ may nevertheless retain the benefits of the entity model to persist as a party to litigation while changing membership. Such an argument is plainly contrary to the letter and intent of DRUPA. As I have explained, two distinct models of partnership structure exist — aggregate and entity. No other form of partnership has been recognized by Delaware law in this regard. As such, when JKJ voluntarily made an election to opt out of the entity structure of § 15-201 (a), the partnership necessarily became the aggregate form; that is, the members of the partnership are legally *indistinct* from the partnership entity itself. In other words, under this approach, each JKJ partner is fully accountable for his/her share of the business' operations, and the business itself exists only to be a vehicle for the members to operate under a single business entity. Such an aggregate partnership, which exists as an association of individuals rather than a separate legal entity, does not survive changes in membership, but becomes a new partnership between the new and remaining members. Consequently, it logically follows that JKJ cannot opt out of an entity partnership — as it is

permitted to do under DRUPA — but then chooses to retain the partnership as a separate entity when the membership changed. To adopt Plaintiff's position would eviscerate the very legal difference between an entity and aggregate partnership. Accordingly, I find that the current JKJ partnership of Partner A, Dr. Gurbel, and Partner C, which purports to be the relator plaintiff in the Second Amended Complaint, is not the same relator partnership composed of Partners A, B, and C that filed the Original Complaint in this action.

Having determined that, as a matter of state law, JKJ has attempted to proceed as two, legally distinct partnerships in this action, the Court must proceed to the question of whether this is permitted, as a matter of federal law, under the FCA's first-to-file bar. As noted above, the first-to-file bar provides that "[w]hen a person brings an action under this subsection, *no person other than the Government may intervene* or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5) (emphasis added). The Supreme Court has clearly defined the contours of party intervention in the FCA context:

> A "party" to litigation is "[o]ne by or against whom a lawsuit is brought." Black's Law Dictionary 1154 (8th ed.2004). An individual may also become a "party" to a lawsuit by intervening in the action. See *id.,* at 840 (defining "intervention" as "[t]he legal procedure by which ... a third party is allowed to become a party to the litigation"). As the Court long ago explained, "[w]hen the term [to intervene] is used in reference to legal proceedings, it covers the right of one to interpose in, *or become a party to,* a proceeding already instituted." *Rocca v. Thompson,* 223 U.S. 317, 330, 32 S.Ct. 207, 56 L.Ed. 453 (1912) (emphasis added). The Court has further indicated that intervention is the requisite method for a nonparty to become a party to a lawsuit. See *Marino v. Ortiz,* 484 U.S. 301, 304, 108 S.Ct. 586, 98 L.Ed.2d 629 (1988) *(per curiam)* (holding that "when [a] nonparty has an interest that is affected by the trial court's judgment ... the better practice is for such a nonparty *to seek intervention* for purposes of appeal" because "only parties to a lawsuit, or those that properly become parties, may appeal an adverse judgment" (internal quotation marks omitted; emphasis added)).

U.S. ex rel. Eisenstein v. City of New York, New York, 556 U.S. 928, 933 (2009). The Supreme Court further clarified that a non-party can become a party to litigation only through intervention even where the nonparty is a real party in interest under Rule 17. *Id.* at 935. Applying this broad

and comprehensive definition of intervention to the present case, it is clear that the current JKJ partnership of Partner A, Dr. Gurbel, and Partner C, as a non-party to the Original Complaint — having not yet come into existence — cannot, pursuant to the FCA's first-to-file bar, intervene in this action by being joined as a plaintiff in the Second Amended Complaint.

C. Amendment

In the event that, as the Court has decided, JKJ cannot proceed as the relator in the Second Amended Complaint, JKJ asks that it be allowed to file a Third Amended Complaint to name its individual members, as well as JKJ, as the plaintiff relators. JKJ contends that such amendment should be permitted as a permissive amendment under Fed. R. Civ. P. 15, or as an amendment to substitute a real part in interest under R. 17. On its face, the first-to-file bar would appear to preclude any such amendment. 31 U.S.C. § 3730(b)(5) ("no person other than the Government may intervene"); *U.S. ex rel. Eisenstein*, 556 U.S. at 933 ("intervention is the requisite method for a nonparty to become a party to a lawsuit."). JKJ therefore asks the Court to follow the holding of the Tenth Circuit in *U.S. ex rel. Precision Co. v. Koch Indus., Inc.*, 31 F.3d 1015 (10th Cir. 1994) ("*Precision II*"). There, the Tenth Circuit narrowed the application of the first-to-file bar only to Rule 24 intervention, and found the joinder of parties through a Rule 15(a) amendment permitted under the FCA. *Id.* at 1017-18 ("when § 3730(b)(5) speaks of intervention, it means to prohibit parties unrelated to the original plaintiff from joining the suit to assert a claim based on the same facts relied upon by the original plaintiff"). *Precision II* has been followed by a number of district courts, but has never been cited by the Third Circuit or any court in this District.

The Tenth Circuit's holding however, is in clear tension with the Supreme Court's decision in *Eisenstein*, discussed *supra*. Indeed, during the briefing of the present motions, the

Tenth Circuit revisited its *Precision II* holding in *United States ex rel. Little v. Triumph Gear Sys., Inc.*, 870 F.3d 1242 (10th Cir. 2017), *cert. denied sub nom. U.S. ex rel. Little v. Triumph Gear Sys., Inc.*, 138 S. Ct. 1298 (2018). There, the court observed that *Precision II* was likely no longer good law, in the wake of the intervening Supreme Court precedent in *Eisenstein*, but nevertheless managed an elaborate savings construction to find that *Precision II* need not be directly overruled in the particular factual circumstances presented. *Id.* at 1247 ("But we aren't writing on a blank slate; our analysis must account for this court's decision in *Precision*, 31 F.3d 1015."). Specifically, in discussing the continued precedential effect of *Precision II*, the Court observed:

> In the FCA context, the Supreme Court has defined "intervention" as "the requisite method for a nonparty to become a party to a lawsuit." *United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 933, 129 S.Ct. 2230, 173 L.Ed.2d 1255 (2009) . . . Under that broad formulation, intervention takes place when a non-party becomes a party—regardless of the mechanism by which that occurs. . . . Rigidly applying that definition here would make for an easy resolution. Before the amended complaint was filed, Little and Motaghed weren't parties. After its filing, they were. Thus, under *Eisenstein*'s definition, they intervened—and the first-to-file rule would bar their claims.

Triumph Gear, 870 F.3d at 1247. The Court nevertheless salvaged *Precision II* by noting that, unlike the joined parties in *Precision II*, the new plaintiffs in *Triumph Gear* entered the action by some means other than a Rule 15 amendment. *Id.* at. 1248. I agree with the Tenth Circuit's own initial interpretation that *Precision II* on its face is inconsistent with *Eisenstein*, but decline to follow that Circuit Court's tortuous legal gymnastics in reconciling *Precision II* to the Supreme Court's clear pronouncement on intervention. *Precision II* was never the law in this Circuit, nor has it been cited as authority by the Third Circuit or any court in this District for any proposition. In light of its conflict with governing law, I find it to be neither binding nor persuasive authority. Accordingly, at the filing of the Original Complaint in this action, the only party plaintiff was the JKJ partnership of A, B, and C, not Partner A, B, or C as individuals, and certainly not Dr.

Gurbel, who was a stranger to the litigation. The joinder of Partner A, Partner B, Partner C, or Dr. Gurbel through any procedural device at this juncture would constitute a party intervention under *Eisenstein*. Because the FCA's first to file bar unambiguously bars all such intervention, it applies in this case to prevent any further amendment to add the individual partners as plaintiffs. JKJ's cross motion for leave to file a Third Amended Complaint is therefore denied.

IV. CONCLUSION

For the foregoing reasons, the public disclosure bar does not apply to JKJ's claims, the first-to-file bar prevents JKJ from proceeding as the plaintiff in this action after its change in membership, and the first-to-file bar prevents the joinder of JKJ's members as additional plaintiffs in this action, rendering JKJ's amendment to add additional parties futile. The Second Amended Complaint is therefore dismissed and JKJ's cross motion for leave to amend is denied.

Date: May 30, 2018

/s/ Freda L. Wolfson
FREDA L. WOLFSON
UNITED STATES DISTRICT COURT