IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,
ex rel. JOHN R BORZILLERI, M.D. et al.,

Plaintiffs,

vs.

ABBVIE, INC., et al.,

Defendants.

Case No. 15-cv-7881(JMF)

MEMORANDUM OF LAW IN SUPPORT OF
THE PHARMACY BENEFIT MANAGER DEFENDANTS' JOINT MOTION
TO DISMISS RELATOR'S SECOND AMENDED COMPLAINT

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In this *qui tam* action, in which all governmental entities have declined to intervene, Relator John Borzilleri, M.D., alleges that "secretive" "service fees" paid by drug manufacturers to pharmacy benefit managers ("PBMs") and plan sponsors are to blame for the high cost of prescription drugs. Relator's theory is that, for years, drug manufacturers have agreed to pay excessive service fees to PBMs and plan sponsors in exchange for favorable placement on the PBMs' covered drug lists (formularies) and to ensure the acquiescence of the PBMs in the manufacturers' price increases. Relator contends, in turn, that these excessive fees have not been reported to the government as discounts, thus causing the government to overpay Medicare Part D ("Part D") plans for the drugs those plans provide to enrollees.

Despite its length, the Second Amended Complaint ("SAC") fails to satisfy the most elemental pleading standards for bringing a fraud case. It does not contain a *single* specific allegation about any of the defendants or any of the particular fees in their contracts with the manufacturers for the Part D drugs. Instead, the SAC is based on speculation about what Relator might "ascertai[n]" by pursuing this lawsuit and how he "anticipates" that discovery might confirm his hypotheses about the relationship between service fees and drug prices. That kind of "fishing expedition" approach to litigation is insufficient under governing federal pleading standards.

The reason for the SAC's shortcomings is obvious. Relator is not a well-meaning *qui tam* plaintiff who used inside information to build his case. Relator is instead a former hedge fund manager, with access only to public information, whose only connection to the Defendants was that he specialized in "short selling" their stocks, thereby profiting from bad news about them. As a related lawsuit recently brought against Relator by his former employer shows, this case is about entrepreneurial opportunism, not sincere whistleblowing activity aimed at remedying fraud against the government.

These pleading deficiencies warrant dismissal with prejudice. Relator filed his initial complaint on October 6, 2015, and amended his complaint two times after the government had investigated his case over a period of years (and at considerable cost to the Defendants). But the United States, every State named in the SAC, and the District of Columbia declined to intervene after their investigations. If Relator had viable theories to pursue or relevant facts to offer, he would have included them in the SAC.

Beyond its overarching pleading deficiencies, the SAC also fails for two additional and independent reasons under the False Claims Act ("FCA") that bar this action. First, it violates the FCA's "public disclosure" bar because service fees are a well-known form of compensation that is routinely reported to the Centers for Medicare & Medicaid Services ("CMS") by manufacturers and plan sponsors, and allegations that such fees are allegedly excessive or misreported have been the subject of multiple public reports. Indeed, some of the very sources upon which Relator bases his allegations in the SAC constitute public disclosures. Second, the SAC violates the FCA's "first-to-file" bar, since Relator indisputably filed a previous lawsuit making the very same allegations.[1] For these reasons, too, as well as those set forth in the Manufacturer Defendants' Motion to Dismiss, the SAC should be dismissed.

BACKGROUND

I. FACTUAL BACKGROUND

Relator filed this *qui tam* action on October 6, 2015, more than a year and a half after filing a nearly identical case in Rhode Island federal court.[2] After the government (federal and state)

[1] A dismissal under the "first to file" bar would be without prejudice. *See e.g.*, *United States ex rel. Wood v. Allergan, Inc.*, 899 F.3d 163, 175 (2d Cir. 2018).

[2] Though that case has been unsealed, Relator's initial complaint in the District of Rhode Island has not been unsealed and is unavailable on the public docket. The case docket lists the "Date Filed" as January 16, 2014 (No. 1:14-cv-00031). Relator's first (May 2014) and second amended complaints (July 2018) in that action are unsealed, and he is proceeding to litigate that action despite the government's decision not to intervene.

investigated both matters and declined to intervene, the cases were unsealed.

During this time, Relator managed a health care hedge fund with a short-side focus at Shepherd Kaplan Krochuk, LLC ("SKK"). Relator was also the fund's largest investor. After SKK learned about the unsealing of these *qui tam* actions, it summarily terminated Relator, liquidated his fund, and sued him in Massachusetts state court.[3] According to its lawsuit, SKK found that "throughout 2016 and 2017, and escalating in early 2018, Borzilleri established highly significant short positions" against the "stock value" of certain of the Defendants in this FCA lawsuit and those in the nearly identical suit he filed in Rhode Island. *See* Ex. A, SKK Compl. at 1, 33, 35. SKK also found that Relator increased his short positions through early April 2018 while he had "non-public information both that the lawsuits had been filed, and that they would soon be unsealed." Ex. B, SKK Mot. to Dismiss Counterclaims at 4. By April 17, 2018, the seven largest short positions in the fund were against the securities of the defendants in this case, including a number of the PBM Defendants. Ex. A ¶ 37.

This case was unsealed on April 13, 2018. ECF No. 19. Just four days later, Relator authored and distributed a press release to major media outlets and financial institutions to which he attached both of his now-public *qui tam* complaints. Relator admits that his complaints "make substantially negative allegations about the defendants . . . against which [he] had established large short positions in the Fund," Ex. A ¶ 40; Ex. C, Borzilleri Ans. & Counterclaim at 9 ¶ 40, and he has described these cases as "the greatest financial opportunity of his career." Ex. C at 24 ¶ 70.

[3] Relator and SKK currently are engaged in two lawsuits, one in Massachusetts Superior Court and one in the Southern District of New York (Sullivan, J.). This Court may rely on items in the public record in evaluating a motion to dismiss, including pleadings in other actions. *See, e.g.*, *Pani v. Empire Blue Cross Blue Shield*, 152 F.3d 67, 75 (2d Cir. 1998) ("It is well established that a district court may rely on matters of public record in deciding a motion to dismiss under Rule 12(b)(6), including case law and statutes."); *see also Rahman v. Schriro*, 22 F. Supp. 3d 305, 311 (S.D.N.Y. 2014) ("'Courts that consider matters of public record in a Rule 12(b)(6) motion are limited to things such as statutes, case law . . . or pleadings in another action.'") (brackets omitted) (quoting *Moore U.S.A., Inc. v. Standard Register Co.*, 139 F. Supp. 2d 348, 363 (W.D.N.Y. 2001)).

Unsurprisingly, given his intent, Relator named as Defendants in this case the holding companies that issue shares to the public, such as UnitedHealth Group, Inc., Humana, Inc., CVS Health Corporation, and Express Scripts Holding Co., rather than their respective operating subsidiaries that actually perform the activities challenged in the SAC. [4]

II. REGULATORY BACKGROUND

This case concerns Part D of the Medicare program, under which the federal government makes prescription drug benefits available to the elderly and disabled.[5] To deliver these benefits, CMS contracts with private insurance companies, often referred to as plan sponsors, who then agree to administer drug benefits to Part D beneficiaries in accordance with CMS rules. *See* 42 U.S.C. § 1395w-102(e).

PBMs play an important role in the administration of Part D. PBMs may provide a variety of services to plan sponsors, including negotiating and administering drug rebate programs, establishing and administering claims processing systems, offering formulary design and management tools, and negotiating reimbursement rates with pharmacies. SAC ¶ 154.[6] PBMs are compensated for these services. *E.g.*, *id.*

CMS pays plan sponsors in part based on their cost to acquire drugs for their Part D

[4] The PBM and Part D Plan Sponsor Defendants ("PBM Defendants") are: Aetna Inc., Cigna Corporation, CVS Health Corporation, Express Scripts Holding Company, Humana, Inc., and UnitedHealth Group, Inc. Notably, these entities are not correctly named. In each case, the proper party would be the applicable subsidiary of each that operates as a PBM or Part D plan sponsor. Several of these Defendants have raised this issue with Relator, identified the correct subsidiary, and requested that the correct party be named; however, Relator's counsel has refused.

[5] Part D Plans ("PDPs") offer coverage for "covered part D drugs." *See* Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108–173, 117 Stat. 2066. "[C]overed part D drugs" excludes various categories of drugs, such as drugs prescribed for the treatment of erectile dysfunction and drugs that are payable under Part A (hospital insurance) or Part B (medical insurance). *See* 42 U.S.C. § 1395w-102(e). Relator's multiple references to the prices of Viagra fail to recognize that Viagra, when prescribed for the treatment of erectile dysfunction, is statutorily excluded from Part D coverage.

[6] *See* Ex. D, CMS Pub 100-18, Ch. 9, § 20, Definitions at 3 (2018), available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf.

enrollees as reported in annual cost estimates called "bids" and cost data submitted periodically by plans to CMS during the year. *See* 42 C.F.R. § 423.265. Because CMS pays plan sponsors based on their costs, CMS also needs to know about discounts that plan sponsors receive from manufacturers that offset the cost paid by the plan sponsors.[7] *E.g.*, SAC ¶ 30. While discounts often take the form of rebates from the manufacturers to the plan sponsors, CMS also considers as discounts other payments that plan sponsors, or in this case PBMs, receive from drug manufacturers. *See* 42 C.F.R. § 423.308.[8]

One common form of payment by drug manufacturers to PBMs is known as a "service fee."[9] A PBM might, for example, provide data services to a manufacturer or assist with rebate program management, and be paid a service fee as a result. SAC ¶ 155. There is nothing new or unusual about this form of payment. CMS has recognized the existence and legitimacy of fees manufacturers pay for PBMs' services, including bona fide service fees ("BFSFs"),[10] and has considered how those fees should be reported for various drug pricing purposes, for more than

[7] *See, e.g.*, Ex. E, Final Medicare Part D DIR Reporting Requirements for Plan Year 2017.

[8] Plan sponsors, typically via their contracted PBMs, negotiate with manufacturers to reduce the price paid by the plan sponsor for the manufacturers' drugs, often in the form of rebates. These rebates may be retained by the PBMs or passed through to the plan sponsor. Over time, plan sponsors have obtained a higher percentage of manufacturer rebates (and PBMs have retained a lower share). Regardless of whether the plan sponsor actually obtains the rebate, all manufacturer rebates are reported by the plan sponsor to CMS as discounts. SAC ¶ 162.

[9] There are various types of service fees that manufacturers may pay to PBMs (and other entities) that are recognized and regulated by CMS. See for example the discussion in CMS, Medicare Part D Reporting Requirements for Payment Reconciliation (2018), available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/CY2018_Part-D-Reporting-Requirements-12072017.pdf.

[10] *See* 77 Fed. Reg. 22170 (Apr. 12, 2012) (regulatory definition of BFSF for purposes of Part D, incorporated into 42 C.F.R. § 423.501).

twenty years—first in Medicaid,[11] then in Medicare Part B,[12] and most recently in Medicare Part D.[13] BFSFs are wholly permissible under Part D and are not treated as discounts by CMS when they are consistent with fair market value ("FMV"). *See* 42 C.F.R. § 423.501. Indeed, even if service fees exceed FMV, they still are permissible so long as they are disclosed to CMS through a process known as Direct and Indirect Remuneration ("DIR") Reporting.[14] CMS, in fact, reduces payments to plan sponsors—and therefore benefits from—the portion of such fees that may exceed FMV, so long as they are properly reported.[15]

III. RELATOR'S ALLEGATIONS

The core premise of the SAC is that drug manufacturers have agreed for years to pay PBMs excessive service fees, thereby increasing the price of drugs paid by CMS. *See, e.g.*, SAC ¶ 26. The SAC alleges that these excessive service fees are paid by pharmaceutical companies in exchange for favorable placement on the PBMs' formularies and for acquiescence by the PBMs in manufacturer price increases. *See, e.g.*, *id.* ¶ 79. And the SAC contends that these excessive service fees were not disclosed to CMS through the DIR reporting process. *See, e.g.*, *id.* ¶ 86.

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[11] *See* Drug Rebate Program, Medicaid Release No. 14, at 1 (Dec. 21, 1994), https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-014.pdf (discussing services and fees paid by manufacturers for them).

[12] *See* 71 Fed. Reg. 69624, 69667 (Dec. 1, 2006) (regulation defining BFSF for purposes of determining the "Average Sales Price" used in the Medicare Part B program).

[13] *See supra* note 7 and *infra* note 15.

[14] DIR includes, for example, discounts, chargebacks or rebates, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies or similar entities, obtained by an intermediary contracting organization with which the Part D plan sponsor has contracted (such as a PBM), regardless of whether the intermediary has retained or passed on to the plan sponsor all or a portion of those discounts or other benefits. 42 C.F.R. § 423.308.

[15] *See* Ex. F, CMS, Final Medicare Part D DIR Reporting Requirements for 2009 Payment Reconciliation, at 9 (June 10, 2010). Prior to this time, CMS was well aware of BFSFs, as reflected in sub-regulatory program guidance. For example, CMS discussed these fees in its 2007 guidance and has required reporting of BFSFs since the 2009 Plan Year. *See* Ex. G, CMS, Final Medicare Part D DIR Reporting Requirements for 2007 Payment Reconciliation, at 2 (June 13, 2008); Ex. F at 9.

Based on the existence of this alleged scheme, the SAC alleges that all Defendants must be submitting a "myriad of false claims . . . for reimbursement in the Medicare Part D program, including Prescription Drug Event (PDE) reports, [DIR] reports, Part D annual plan bids, . . . [and] financial data required for Part D subsidy reconciliation." *Id.* ¶¶ 86, 87; *accord, e.g.*, *id.* ¶¶ 28–29. Relator also appears to present the alternative theory that Manufacturer Defendants forgave unidentified debts allegedly owed by the PBM Defendants' affiliated Part D plan sponsors in connection with expensive drugs that trigger "catastrophic coverage" requirements, and then failed to report those forgiven amounts to the government as discounts or rebates. *See, e.g.*, *id.* ¶¶ 395–444.

ARGUMENT

I. THE SAC FAILS BASIC PLEADING REQUIREMENTS AND SHOULD BE DISMISSED WITH PREJUDICE.

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Wood ex rel. United States v. Applied Research Assocs. ("ARA")*, 328 F. App'x 744, 746 (2d Cir. 2009) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). "'The plausibility standard . . . asks for more than a sheer possibility that a defendant has acted unlawfully.'" *Id.* at 746–47 (quoting *Iqbal*, 556 U.S. at 678). A statement of facts that "merely creates a suspicion [of] a legally cognizable right of action," is insufficient, *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007), and "stops short of the line between possibility and plausibility of entitlement to relief," *ARA*, 328 F. App'x at 747 (quoting *Iqbal*, 556 U.S. at 678).

In addition, Rule 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). The requirement applies to complaints, like this one, that assert violations of the FCA and its state-law

analogues. *See, e.g.*, *United States ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 26 (2d Cir. 2016); *Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1477 (2d Cir. 1995). And because one essential element of any such violation is the submission of a false claim or statement to the government, Rule 9(b) demands that Relator "(1) specify the statements that the [he] contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Ladas*, 824 F.3d at 25 (internal quotation marks omitted). While Relator need not have direct personal knowledge of the actual submission of the claims to the government, he must offer "plausible allegations creating a strong inference that *specific* false claims were submitted to the government." *United States ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 86 (2d Cir. 2017) (emphasis added).

A. The SAC's Speculative Allegations Lack Plausibility and Particularity as to Even the Most Basic Elements of the Schemes It Purports to Plead.

The SAC is a textbook example of the sort of speculative allegations Rules 12(b)(6) and 9(b) exist to foreclose. Far from identifying facts that could plausibly support his allegations or specific instances of fraud by specific defendants in connection with specific drugs, the SAC pleads literally no facts specific to any of the PBM Defendants or their Part D contracts. Instead, the SAC espouses pure hypothesis in repeatedly seeking to conduct "discovery of unknown wrongs." *Madonna v. United States*, 878 F.2d 62, 66 (2d Cir. 1989) (internal quotation marks omitted); *see, e.g.*, SAC ¶ 122 ("For all the PBM Defendants, we expect discovery to determine that the manufacturer 'service fee' scheme has been a primary driver of both their PBM and overall corporate profit growth over the past decade.").[16]

[16] *See also* SAC ¶ 218 ("Close scrutiny of the financial terms and transactions related to these secretive arrangements will be a key part of case discovery."); *id.* ¶ 296 ("[A] detailed review of all financial transactions between the Manufacturer Defendants and a given PBM Defendant for a particular drug product, at the corporate level, will be required in a thorough investigation."); *id.* ¶ 433 ("[W]e expect discovery to uncover wide-ranging 'cost-sharing' reporting and financial fraud for Gleevec and other extreme-priced 'specialty' oral cancer drugs."); *id.* ¶ 720 ("We expect discovery to uncover even less legitimate 'support services' for the Defendant 'traditional' drugs.").

This approach puts the cart before the horse. A plaintiff may not, under Rule 9(b), plead speculative generalizations on the off chance that discovery will theoretically prove those allegations correct. *Madonna*, 878 F.2d at 66. Yet that is *precisely* what Relator has done here. Over the course of almost 200 pages, Relator offers little more than generalized, industry-wide assertions that lack connection to any of the drugs at issue here, any of the contractual relationships between the Defendants, any of the disclosures made by any of the Defendants to CMS, or, for that matter, any specific conduct of any PBM Defendant.

The lack of actual facts is staggering. Relator never *once* identifies a particular Part D contract or sub-contract, an allegedly false statement made by any Defendant, or a specific false claim submitted, or caused to be submitted, by any of the PBM Defendants (or anyone else); never once identifies the services performed or service fees actually paid in connection with any of the drugs at issue for Part D beneficiaries; never once identifies what he believes the FMV for those services truly was; and never once explains how or why any alleged excessive service fee was not disclosed to CMS. On Relator's ancillary theory regarding "catastrophic coverage" debt forgiveness, he does not identify a single forgiven debt that he claims was not properly reported to the government. Particularly given the government's own investigation and declination of this case, this Court should decline Relator's request to submit the Defendants to further discovery so he can further explore whether his hypotheses are anything more than a flight of fancy.

1. The SAC Recites Alleged Elements of the FCA Yet Offers No Plausible Allegations.

Relator asserts that the "PBM Defendants have caused or directly submitted a myriad of false claims via the array of submissions required for reimbursement in the Medicare Part D program." SAC ¶¶ 86, 170. Without connecting the alleged fraudulent scheme to any actual claims or other submissions, Relator merely recites *alleged* legal requirements and labels the

submissions as "false."[17] *Id.*; *see also id.* ¶¶ 808–09. Pleading such "labels and conclusions" or "a formulaic recitation of the elements of a cause of action" is insufficient to survive a motion to dismiss. *Twombly*, 550 U.S. at 555. Because Relator has only advanced bald assertions and conclusions of law, the SAC should be dismissed. *Leeds v. Meltz*, 85 F.3d 51, 53 (2d Cir. 1996).

2. The SAC Also Lacks Particularized Allegations as Required by Rule 9(b) about the Allegedly Unlawful Service Fees.

Relator's theory relies on at least three key factual premises that must be pled with particularity under Rule 9(b). *First*, Relator must identify the service fees a particular PBM Defendant received for services provided to a Manufacturer Defendant in connection with a particular drug provided under a particular Part D plan. *Second*, Relator must identify the actual (and lower) FMV of those services. *Third*, Relator must allege that the PBM Defendant did not report (or, more precisely, caused the contracted plan sponsor not to report) the difference between those figures to CMS. The SAC does not contain particularized allegations about *any* of those essential facts and thus fails to satisfy the rigorous pleading standard set by Rule 9(b). *See, e.g.*, *United States ex rel. Polansky v. Pfizer, Inc.*, No. 04-cv-0704, 2009 WL 1456582, at *4 (E.D.N.Y. May 22, 2009) ("Rule 9(b) requires that a plaintiff set forth the who, what, when, where and how of the alleged fraud." (internal quotation marks omitted)).

a. Relator Admits He Does Not Know the Amounts of Any Service Fees.

Relator acknowledges that the compensation structure for service fees can vary from one contract to the next, with many industry participants using "[a] 'percent of revenue' arrangement"

[17] Relator references pre-2009 violations of the FCA but does not explain why the pre-2009 statute applies. *See, e.g.*, SAC ¶¶ 87, 92. In the Second Circuit, § 3729(a)(1)(B) of the FCA "applies retroactively to any claim pending before a court on or after June 27, 2008." *United States v. N.Y. Soc'y for the Relief of the Ruptured & Crippled, Maintaining the Hosp. for Special Surgery*, No. 07-cv-292 (PKC), 2014 WL 3905742, at *9 (S.D.N.Y. Aug. 7, 2014) (internal citation omitted).

while others employ "flat fees and lump sum payments" instead. SAC ¶ 660. He thus recognizes (as he must) that "the PBM Defendant compensation for any particular . . . drug will depend upon specific contractual terms." *Id.* ¶¶ 242, 243. Yet Relator concedes that he does not know what the terms of *any* of those contracts are. *Id.* ¶ 180.

Relator tries to paper over his patent pleading deficiency by relying on what he claims are the "*average* contract terms for 'service fees'" in the *private* insurance market as reported in an advocacy piece published by PhRMA, a nonprofit organization that asserts the interests of pharmaceutical manufacturers. *Id.* ¶ 179. But *average* fees in the *private* insurance market, even if they were accurate, have no bearing on *specific* fees related to particular *Part D* contracts.[18]

Relator next inserts that "average" service fee rate into a series of three examples that purport to "illustrate" how his theory works in connection with specific drugs—Enbrel, Gleevec, and Premarin. *See id.* ¶¶ 246–75. But in each case, the SAC makes clear that it is just *assuming* that the supposed industry-wide "average" rate for the private insurance market is: (a) applicable to contracts with the manufacturer of each of the three drugs; and (b) specifically relates to contracts regarding Part D. *See, e.g., id.* ¶ 250 ("*Using the '8% of sales' PhRMA average 'specialty' contract rate*, the annual PBM/specialty pharmacy 'service fee' payment from Defendant Amgen *would be* $1,479 for each Enbrel-treated patient in 2006 . . . ."); *id.* ¶ 259 (substantively identical allegation regarding Gleevec); *id.* ¶ 271 (similar allegation regarding Premarin, "[u]sing the '4% of sales' PhRMA average 'traditional' contract rate"). Relator does

[18] Prescription drug coverage may be provided by private insurance companies that offer policies in the commercial market, employer-based market, or under government programs, or by employers or unions—all of which are subject to very different laws, regulations, and financial arrangements. A fundamental flaw throughout the SAC is that Relator assumes that national revenue and rebate data reflects the financial aspects of the Part D program. *See, e.g.*, SAC ¶¶ 242–44. For example, the "incriminating" PhRMA report, *id.* ¶¶ 177–91, and the "incriminating" PCMA report, *id.* ¶¶ 198–213, do not report on Part D drug costs, rebates, or fees. The three examples of financial relationships given in the PhRMA report pertain specifically to commercial insurance and employer-sponsored insurance, which is why Relator admits that the data relates to "private insurance." *Id.* ¶ 190.

not allege with any specificity the relevant contract terms or fee rates—let alone actual fees paid for the services provided. And Relator does not explain on what factual basis he extrapolates these averages to Part D contracts.

Industry-wide averages are the antithesis of the "particularity" that Rule 9(b) demands. For this reason, courts have repeatedly rejected the use of industry-wide assertions that any given participant in the industry is more likely than not to have engaged in the alleged conduct. This sort of "probabilistic reasoning," they have concluded, "fails under Rule 9(b)'s heightened pleading standard." *Republic Bank & Tr. Co. v. Bear Stearns & Co.*, 683 F.3d 239, 257 (6th Cir. 2012) (reasoning that plaintiff's reliance on "the industry-wide existence of questionable appraisal practices" is insufficient because "this argument involves only probabilities"); *see also, e.g.*, *Plumbers' Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp.*, 632 F.3d 762, 774 (1st Cir. 2011) (allegation that "other banks engaged in such practices, some of which probably distorted loans, and therefore this may have happened in this case" was insufficient because "there is no allegation that any specific bank that supplied mortgages to the trusts did exert undue pressure"). Relator has not alleged—and has no basis to say—whether any given Defendant's contractual fee rate for Part D services resembles the industry-wide "average" figure that he asserts—and without that, his claims fail.

Unaware of any specific terms or fees in the PBM-Manufacturer Part D contracts supposedly at issue, Relator resorts to a pair of contracts to which CVS and Express Scripts allegedly were parties—specifically contracts with *private employers* providing their employees insurance coverage. *See* SAC ¶¶ 689–713. But Relator's references to the CVS contract make no allegation or any reference *at all* to the amount of service fees that CVS was receiving from manufacturers. *See id.* ¶¶ 704–05. According to Relator's allegations, the Express Scripts contract

provides a ceiling for service fees it receives from manufacturers, but does not identify the fees paid in connection with any particular drug (which, of course, could be significantly lower than the ceiling described). *Id.* ¶ 692. These contracts are thus irrelevant and add nothing to Relator's theory in this case, against CVS and Express Scripts or otherwise.

Relator cannot satisfy even the most basic pleading requirements. The SAC does not allege with any specificity the amount of any service fees paid by a Manufacturer Defendant to any PBM Defendant related to Part D, or the terms of any Part D contractual relationships between these parties. Relator has a hypothesis, but a hypothesis does not state a cause of action for false claims or kickbacks—both sounding in fraud—under Rules 12(b)(6) and 9(b). *Ladas*, 824 F.3d at 26–27 ("hypotheses," "conclusory statements," and assertions "not supported by particularized allegations of fact" do not satisfy Rule 9(b)).

b. Relator Does Not Allege the FMV of the Services PBMs Provided and Does Not Even Know What Those Services Were.

The second essential component of Relator's theory is that the PBM Defendants were paid more than they should have been paid or, put another way, that the PBM Defendants were paid in amounts that exceeded FMV. Relator does not back up this claim with any of the requisite particularity. In fact, it appears that Relator—a former hedge fund manager—does not even know the services PBMs generally (let alone these PBM Defendants specifically) provide in exchange for services fees. *See, e.g.*, SAC ¶ 720 (describing what he "expect[s] discovery to uncover" about what "support services" the PBM Defendants supply to their clients).

This failure, too, warrants dismissal. Courts have consistently held that where a relator asserts that a defendant has violated the FCA by paying or receiving compensation in excess of FMV without disclosing that compensation, the relator "must allege a benchmark of FMV against which Defendants' [compensation arrangements] . . . can be tested." *United States ex rel.*

Schaengold v. Mem'l Health, Inc., No. 4:11-cv-58, 2014 WL 7272598, at *11 (S.D. Ga. Dec. 18, 2014) (bracket and internal quotation marks omitted); *see also United States ex rel. Schubert v. All Children's Health Sys., Inc.*, No. 8:11-cv-1687, 2013 WL 6054803, at *11 (M.D. Fla. Nov. 15, 2013); *United States ex rel. Dennis v. Health Mgmt. Assocs., Inc.*, No. 3:09-cv-484, 2013 WL 146048, at *13 (M.D. Tenn. Jan. 14, 2013); *United States ex rel. Osheroff v. Tenet Healthcare Corp.*, No. 09-22253, 2012 WL 2871264, at *7 (S.D. Fla. July 12, 2012).

Relator offers no such comparative benchmark here, nor does he allege what the FMV payment should have been for any specific contract. To the contrary, the SAC admits that CMS has "purposely not defin[ed] methods for BFSF FMV assessment in the Part D program" and that as a result "each drug manufacturer must determine its own process based upon acceptable practices in the private marketplace." SAC ¶ 653.

Relator attempts to salvage this assertion by claiming that "the appropriate 'arm's length' compensation to the PBM Defendants for providing manufacturer services should be very modest, even for 'complex' specialty drugs." *Id.* In support, Relator points to a statement by an entity he identifies as Diplomat Pharmacy—"the largest remaining independent specialty pharmacy"—made in an SEC filing: "[W]e incur significant costs in providing these services and receive minimal service fees in return." *Id.* ¶¶ 668, 671 (emphasis omitted). But Diplomat Pharmacy is not a PBM akin to any of the Defendants in this case. It is, the SAC acknowledges, a specialty pharmacy and, in this role, provides a different scope and type of services than the PBM Defendants provide. *See id.* ¶¶ 668–69. Even as to the service it does provide, it avers it is undercompensated as it incurs "significant costs." *Id.* ¶ 671. In addition, Diplomat's statements do not relate to services provided in connection with the Part D program. Even as to the services Diplomat provides, the SAC lacks any actual description of how much Diplomat charges for its

services or how those fees compare to the service fees received by the PBM Defendants. The SAC never offers a particularized allegation of the services at issue under any Part D contract; what the FMV of those services was for even a single one of the drugs at issue; or whether or why any particular payments by particular Defendants for particular services under particular contracts exceeded FMV.[19]

c. Relator Lacks Any Particularized Allegations that the PBM Defendants' Service Fees Were Not Properly Reported to CMS.

Relator equally fails to plead that any PBM Defendant's service fees were not properly reported to CMS. In a plan sponsor's Part D DIR reports to CMS, the plan sponsor is required to report as a price concession any portion of a service fee that exceeded FMV. *See, e.g.*, SAC ¶ 30. ("As per [CMS] regulations, 'service fees' in excess of FMV should be reported by the Drug Manufacturer to the plan sponsor in Medicare Part D. In turn, the plan sponsor should report 'service fees' in excess of FMV to CMS in its [DIR] report as a 'discount,' leading to lower Part D 'negotiated' drug prices."). In other words, CMS regulations *permit* fees to be set at above FMV, so long as the difference is reported to CMS as a discount (and thus inures to CMS's benefit by lowering its costs). Relator's FCA theory depends on establishing not only that any service fees charged by the PBM Defendants were excessive, but also that these excessive fees—through the actions of the PBM—were not reported to CMS as required under Part D DIR guidance and regulations and thus led to the submission of false claims by the plan sponsors. Relator fails to plead any such allegations, with particularity or otherwise.

Relator offers only a vague and cursory allegation that "[t]he Defendants are intentionally not doing so"—i.e., not reporting service fees in excess of FMV to the government. *Id.* But he

[19] Even if the "cost approach" were the only acceptable method for determining FMV in the Part D context, as Relator suggests, *see* SAC ¶¶ 460, 471, Relator still never describes what an FMV payment for the PBM Defendants' services on any of the drugs in question would be using the "cost approach" method.

alleges *zero* facts to support this crucial aspect of his case. For this reason, too, Relator's claims fail Rule 9(b).[20]

3. Relator Also Fails to Present Particularized Allegations About Supposed Catastrophic Coverage Payment Waivers.

Relator's catastrophic coverage theory fails under Rule 9(b) for the same reasons as his service fees theory, and the Court should readily dispose of these allegations for failure to satisfy Rule 9(b). As discussed above, this theory depends on Relator's claim that the Manufacturer Defendants forgave unspecified debts allegedly owed by the PBM Defendants' affiliated Part D plan sponsors in connection with expensive drugs that trigger "catastrophic coverage" requirements, and then failed to report those forgiven amounts to the government as discounts or rebates. *See, e.g.*, SAC ¶¶ 395–444. Like his allegations about the service fees, however, Relator fails to plead any particularized allegations to support the key factual components of that theory. This theory, as well, is purely speculative.

First, Relator offers no particularized allegations that any catastrophic coverage payments were actually owed by any of the PBM Defendants, nor that any of the Manufacturer Defendants has ever forgiven any such debts, let alone as to any of the drugs at issue in this suit or in relation to a Part D contract or subcontract. Instead, he merely hypothesizes that (a) the PBMs are more profitable than his analysis of their SEC disclosures suggests that they should be, and (b) receiving massive debt forgiveness from the Manufacturer Defendants (apparently, in addition to excessive service fees) must be the explanation. *See, e.g.*, SAC ¶¶ 413–21. Based on that speculation,

[20] While *qui tam* relators can sometimes plead a viable FCA complaint even in circumstances where they do not have access to the actual claims documents the defendants submitted to the government, the Second Circuit has held that to do so, the relator must still allege that he has reason to know that the false statements or claims were made and point to "reliable indicia that lead to a strong inference that claims were actually submitted." *See United States ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 89 (2d Cir. 2017) (citation and internal quotation marks omitted). Relator has none of that here. He is not, as in *Chorches*, a corporate insider who has seen fraud first-hand but simply lacks access to the specific billing documents on which the fraud was consummated. *See, e.g.*, *id.* at 84–85.

Relator alleges that "[w]e concluded that the Manufacturer Defendants, *in many instances*, are 'forgiving' the PBM Defendants for this 'catastrophic exposure' in order to further the 'service fee' pricing scheme."[21] *Id.* ¶ 352 (emphasis added); *see also id.* ¶ 422 ("We concluded that, *in many instances*, manufacturers are fraudulently excusing the PBM Defendants from their 15% 'catastrophic' cost-sharing exposure . . . ."). Relator does not claim to have ever seen or heard about any document reflecting forgiven "catastrophic coverage" debt. Nor does he offer any explanation for his leap from his (unsupported) speculation that the Manufacturer Defendants are forgiving debts "in many instances," *id.* ¶¶ 352, 422, to his conclusion that they have forgiven debt owed by PBM Defendants. Without such particularized allegations to connect his amorphous hypotheses to the claims he is actually pursuing here, he cannot satisfy Rule 9(b).

Second, Relator has not identified any instances in which such forgiveness occurred but was not properly reported to CMS under the Part D program. As with his service fee theory, particularized pleading of those facts is necessary because—as he acknowledges—there is nothing wrong with debt-forgiveness so long as it is properly reported to CMS on the designated forms as a rebate or discount. *See id.* ¶ 432 ("If the Manufacturer Defendants are commonly 'forgiving' the PBM Defendants from their Part D 'catastrophic' exposure, these amounts should be properly reported as discounts via DIR reports to CMS . . . ."). The most Relator can say is that "*we expect discovery to uncover* wide-ranging 'cost sharing' reporting and financial fraud for Gleevec and other extreme-priced 'specialty' oral cancer drugs." *Id.* ¶ 433 (emphasis added). That amounts to a concession that he filed his SAC "as a pretext for discovery of unknown wrongs," *Madonna*, 878 F.2d at 66, which Rule 9(b) forbids.

[21] Relator refers throughout his SAC to an undefined "we." *See, e.g.*, SAC ¶¶ 21, 23, 75. As he is the only Relator in this case, the PBM Defendants presume he drafted his complaints with the expectation (now proven to be mistaken) that the U.S. government and various state governments would be joining his crusade and has simply failed to modify his pleadings to reflect that he is alone in propounding the "conclusions" in his SAC.

4. Relator Fails to Allege Scienter.

The Supreme Court has emphasized that the scienter requirement under the FCA is a "rigorous" one and that complaints may be dismissed at the pleading stage for failure to allege it adequately. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2001 (2016). To survive a motion to dismiss, a *qui tam* relator must allege facts sufficient to establish a strong inference that the defendant acted "knowingly." 31 U.S.C. § 3729(b)(1)(A) (2012). Although knowledge may be alleged generally, "under Rule 9(b), the proponent of an FCA claim must allege facts that give rise to a strong inference of fraudulent intent." *United States ex rel. Grubea v. Rosicki, Rosicki & Assocs., P.C.*, 318 F. Supp. 3d 680, 694 (S.D.N.Y. 2018) (emphasis in original); *see also Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1128 (2d Cir. 1994), *superseded by statute on other grounds, as recognized in Norguard Ins. Co. v. RCJ Constr. Servs. Corp.*, No. 14-cv-432, 2018 WL 1178034, at *3 (E.D.N.Y. Jan. 19, 2018). Despite including 923 paragraphs in the SAC, Relator fails to allege any facts giving rise to a "strong inference" that the PBM Defendants had knowledge of the alleged wrongdoing. Relator offers only speculative inferences of a supposed industry-wide "secretive" scheme paired with his own conclusory say-so that the PBM Defendants acted "intentionally" or "knowingly." SAC ¶¶ 30, 808–09. His threadbare SAC falls well short of establishing the critical scienter element of an FCA claim. *Accord, e.g.*, *Grubea*, 318 F. Supp. 3d at 695 (granting motion to dismiss because complaint lacked "particularized information" as to scienter). The SAC should accordingly be dismissed.

5. Relator Fails to Make Specific Allegations Against Any of the PBM Defendants, in Violation of Rule 9(b).

Relator consistently aggregates entirely separate companies, with entirely separate postures vis-à-vis manufacturers and Part D, under the rubric "PBM Defendants." *See* SAC ¶¶ 1, 147. Relator does not distinguish conduct purportedly attributable to any one of the PBM Defendants

(Aetna, Cigna, Humana, CVS Health, Express Scripts, or UnitedHealth Group), each of which are large corporations with wide-ranging business operations and functions and disparate organizational structures. *See* SAC ¶¶ 141–46. Relator's generalized and undifferentiated allegations against all PBM Defendants as a group are neither credible nor legally sufficient and, on this basis alone, should be dismissed. *Kermanshah v. Kermanshah*, 580 F. Supp. 2d 247, 258 (S.D.N.Y. 2008) ("[A] complaint alleging fraud against multiple defendants must state the allegations specifically attributable to each individual defendant."); *United States ex rel. Corp. Compliance Assocs. v. N.Y. Soc'y for the Relief of the Ruptured & Crippled, Maintaining the Hosp. for Special Surgery*, No. 07 Civ. 292 (PKC), 2014 WL 3905742, at *19 (S.D.N.Y. Aug. 7, 2014) (dismissing claims under Rule 9(b) where relators' causes of action made blanket allegations against all three defendants collectively and failed to set "forth *separately* the acts complained of by *each defendant*" (emphasis in original) (internal quotation marks omitted)). Without identifying each Defendant's conduct, Relator's claims must fail.

B. Relator's Anti-Kickback Statute (AKS) Theory Fails for the Same Reasons as His FCA Theory, and for Several Other Reasons.

Relator also alleges that the PBM Defendants engaged in criminal conduct in violation of the AKS. While a violation of the AKS can serve as a predicate for an FCA violation, to survive a motion to dismiss, Relator would need to allege plausibly and specifically the elements of both the AKS and the FCA.[22] Relator alleges that "[t]he PBM Defendants . . . receive fraudulent 'service fees', as 'kickbacks', for favorable Manufacturer Defendant drug inclusion/handling in Part D drug formularies." SAC ¶ 79. Relator asserts throughout the SAC the conclusory mantra

[22] The AKS makes it a crime to: (1) knowingly and willfully, (2) offer or pay, (3) any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person, (4) to induce such person, (5) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service, (6) for which payment may be made in whole or in part under a Federal health care program. 42 U.S.C. § 1320a-7b(b)(2)(A). For a further discussion regarding the AKS, *see* Mem. of Law in Support of Manufacturer Defendants' Jt. Mot. to Dismiss Borzilleri's SAC, at 9–10.

that purported "service fee" payments must have been "kickbacks" because they exceeded FMV for the services rendered. *See, e.g.*, *id.* ¶¶ 332, 634, 639, 646, 648, 673. As a result, according to Relator, "[v]irtually all Part D submissions for reimbursement pertaining to the Manufacturer Defendant drugs over the past 12 years-plus have been 'tainted' by kickbacks and have been false claims." *Id.* ¶ 87. Relator also appears to allege that manufacturers' supposed forgiveness of "catastrophic coverage" debts was also exchanged for formulary placement of their drugs. *Id.* ¶¶ 79, 81, 395–437.

Relator's AKS claim can be easily rejected, on the same basic grounds that necessitate dismissal of his FCA claims. He has failed to allege with particularity: (1) any of the supposed services provided in exchange for "service fees" on which his whole theory of liability is based; (2) why these services were "not necessary" or were a "sham"; (3) the FMV of the services; (4) the amount actually paid for the services; (5) why the amount paid exceeded FMV and by how much; or (6) whether service fees should have been or were reported to Medicare Part D. For these reasons alone, his AKS theory fails.

Relator's AKS theory suffers additional fundamental flaws, however. First, the AKS requires proof that the Manufacturer Defendants paid (or were solicited to pay) "service fees" to the PBM Defendants to "induce" illegal referrals of Part D business. 42 U.S.C. § 1320a-7b(b)(1), (b)(2)(A); *United States ex rel. Nunnally v. W. Calcasieu Cameron Hosp.*, 519 F. App'x 890, 894 (5th Cir. 2013) ("[A]ctual inducement is an element of the AKS violation . . . and [relator] must provide reliable indicia that there was a kickback provided in turn for the referral of patients."). All Relator appears to allege is that the service fees (which Relator hypothesizes must have been excessive) must have been intended to secure favorable formulary placement. But he does not allege any particular facts even suggesting that this actually occurred between any Defendants, let

alone in the Part D Program. It is at least equally plausible that any service fees were paid in exchange for legitimate services provided by PBMs.

Second, even if Relator had alleged that a drug manufacturer paid above-FMV service fees with the intent to sway formulary decisions, Relator makes no plausible allegation that any PBM Defendant "*knowingly and willfully*" participated in any such conduct. *See* 42 U.S.C. § 1320a-7b(b)(2)(A) (emphasis added). Relator cannot adequately allege knowledge or willfulness under the AKS without plausibly setting forth facts showing that the Defendants knew their conduct was unlawful. *Bryan v. United States*, 524 U.S. 184, 196 (1998) (holding that willfulness requires that the defendant had "knowledge that the conduct is unlawful"); *United States v. Bishop*, 740 F.3d 927, 932–33 (4th Cir. 2014); *United States v. Vernon*, 723 F.3d 1234, 1256 (11th Cir. 2013) (an AKS violation requires proof that the defendant "acted with the intent to do something that the law forbids" (internal quotation marks omitted)). Here, Relator uses the word "willful" just *once* in a 191-page pleading. SAC ¶ 170(2).

C. The SAC Fails to State a Claim for Conspiracy to Submit False Claims.

To allege conspiracy under the FCA, a plaintiff must plausibly allege "(1) an unlawful agreement by the defendant to violate the FCA, and (2) at least one overt act performed in furtherance of that agreement." *United States ex rel. Scharff v. Camelot Counseling*, No. 12-CV-3791, 2016 WL 5416494, at *9 (S.D.N.Y. Sept. 28, 2016) (quotation omitted).[23] Although Count II of the SAC purports to allege an FCA conspiracy, Relator has failed to meet these essential pleading requirements, in addition to other deficiencies of the SAC discussed above. There is no particularized allegation of an agreement between any Defendants (or anyone else, for that matter)

[23] 31 U.S.C. § 3729(a)(3) (2006) imposed liability on anyone who "conspire[d] to defraud the Government by getting a false or fraudulent claim allowed or paid." Now, 31 U.S.C. § 3729(a)(1)(C) imposes FCA liability on anyone who "conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)."

to violate the FCA. Relator makes only the conclusory statement that "Defendants conspired with others known and unknown, including without limitation Service Vendors, to defraud the United States by inducing the United States to pay and/or approve false and fraudulent claims." SAC ¶ 815. This is clearly insufficient under both Rule 12(b)(6) and Rule (9)(b). *See, e.g.*, *United States ex rel. Piacentile v. Amgen, Inc.*, No. 04-CV-3983, 2018 WL 4409838, at *13 (E.D.N.Y. Sept. 17, 2018) (dismissing conspiracy claim under Rule 12(b)(6) where relator failed to "specify 'the defendants' who allegedly participated in the alleged conspiracy" and failed to alleged defendants "shared the objective of getting claims paid by the Government"); *Ladas*, 824 F.3d at 27 (upholding dismissal of FCA conspiracy claim where complaint failed "to identify a specific statement where [defendants] agreed to defraud the government"); *Camelot Counseling*, 2016 WL 5416494, at *9 (dismissing conspiracy claim where complaint failed to allege agreement to violate the FCA).

Relator also does not make any plausible factual allegations of an "overt act" in furtherance of an agreement to violate the FCA, let alone with the sufficient particularity demanded by Rule 9(b). As elsewhere in the SAC, Relator relies on a boilerplate allegation, without any facts, that defendants "took substantial steps in furtherance of the conspiracy, inter alia, by making false and fraudulent statements and representations, by preparing false and fraudulent records, and/or by failing to disclose material facts." SAC ¶ 815. This summary allegation does not stave off dismissal, *see Iqbal*, 556 U.S. at 678, and falls well short of meeting the heightened pleading requirements of Rule 9(b). *See Ladas*, 824 F.3d at 27. Without plausible and particularized allegations of facts supporting violations of § 3729(a)(1)(C) or § 3729(a)(3) (2006), the Court should dismiss Count II.

D. The Ancillary State Law Claims Fail to Allege Any Plausible Claims Under Any State FCA.

Relator's state law claims, Counts 5 through 32, are subject to the same Rule 12(b)(6) and (9)(b) pleading standards applicable to his federal claims, *see, e.g.*, *United States ex rel. Blaum v. Triad Isotopes, Inc.*, 104 F. Supp. 3d 901, 912–13 (N.D. Ill. 2015), and they are premised on the same thin factual allegations he offers to support his federal FCA counts. Therefore, this Court should dismiss all analogous state FCA counts for the same reasons outlined above.[24]

E. Relator's Common Law Claims for Unjust Enrichment and Common Law Fraud Must Be Dismissed Because Relator Lacks Standing to Bring Them on Behalf of the Government.

Relator does not have standing to bring common law claims here, because the FCA does *not* "give relators the right to assert common law claims on behalf of the United States." *United States ex rel. Phipps v. Comprehensive Cmty. Dev. Corp.*, 152 F. Supp. 2d 443, 451 (S.D.N.Y. 2001) (internal citation omitted). Therefore, Count 33 and Count 34 must be dismissed with prejudice.

II. RELATOR'S FCA CLAIMS ARE PRECLUDED BY THE STATUTE'S PUBLIC DISCLOSURE BAR.

The FCA's "public disclosure" bar prevents "'parasitic lawsuits' based upon publicly disclosed information in which would-be relators 'seek remuneration although they contributed nothing to the exposure of the fraud.'" *United States ex. rel Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1157 (2d Cir. 1993) (quoting *United States ex rel. Doe v. John Doe Corp.*, 960 F.2d 318, 319 (2d Cir. 1992)). That is precisely what Relator is doing here—indeed, he blatantly pleads that his allegations are based on various public disclosures cited in the SAC.

[24] Alternatively, the Court could dismiss the federal FCA claims and decline to retain supplemental jurisdiction over Relator's state law claims. *See Ruotolo v. Fannie Mae*, 933 F. Supp. 2d 512, 527 (S.D.N.Y. 2013) ("[N]othing [] separates this case from the usual case where courts typically decline to exercise jurisdiction over state law claims when all federal claims are dismissed before trial.").

The Affordable Care Act (ACA) amended the public disclosure bar effective March 2010. Thus, to the extent the Relator alleges false claims made between 2006 and March 23, 2010, the pre-ACA version governs. *See, e.g.*, *United States ex rel. Amico v. Deutsche Bank AG*, No. 15-CIV-9551 (CM), 2017 WL 2266988, at *4 n.4 (S.D.N.Y. May 8, 2017) ("Public disclosure" bar is not retroactive.). As to post-March 2010 false claims, the amended version controls. *See, e.g.*, *United States ex rel. Patriarca v. Siemens Healthcare Diagnostics, Inc.*, 295 F. Supp. 3d 186, 195 (E.D.N.Y. 2018) (noting that every federal court of appeals to consider the issue has held that "the pre-2010 version of the public disclosure bar applies to any conduct that occurred prior to the amendment and that the post-2010 version applies to any conduct that occurred after the effective date of the 2010 amendment" (internal quotation marks, alterations, and citation omitted)).

Under either version, the Court must perform a two-step analysis and determine: (1) whether the allegations in the complaint are "substantially similar" to the allegations contained in prior "public disclosures," and, if so, (2) whether the suit may nonetheless go forward because the relator is an "original source" of the information on which he bases his allegations. *United States ex rel. Ping Chen v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282, 296–97 (S.D.N.Y. 2013). "Public" is defined broadly. *See Kreindler*, 985 F.2d at 1158 (deciding that discovery material in a lawsuit is public). Relator's SAC should be dismissed with prejudice in its entirety because prior public disclosures are substantially similar to the allegations in the SAC and Relator is not an original source. *See* 31 U.S.C. § 3730(e)(4)(A).[25]

[25] Pre-ACA, prior public disclosures deprived the court of subject-matter jurisdiction and required dismissal pursuant to Rule 12(b)(1), whereas after the 2010 amendments, such public sources instead constitute failure to state an FCA claim and thus justify Rule 12(b)(6) dismissal. *See Chorches*, 865 F.3d at 80; *United States ex rel. JDJ & Assocs. LLP v. Natixis*, No. 15-cv-5427 (PKC), 2017 WL 4357797, at *5 (S.D.N.Y. Sept. 29, 2017).

A. Factual Allegations and Fraud Inferences Substantially Similar to Those in Relator's SAC Were Publicly Disclosed Before He Filed This *Qui Tam* Action.

Whether a prior disclosure involved allegations "substantially similar" to those made in the operative *qui tam* complaint depends on whether the "information conveyed could . . . at least have alerted law-enforcement authorities to the likelihood of wrongdoing." *Ping Chen*, 966 F. Supp. 2d at 298 (quoting *United States ex rel. Springfield Term. Ry. Co. v. Quinn*, 14 F.3d 645, 654 (D.C. Cir. 1994)). Claims that are even partly based on public disclosures are deficient under the statute. *See, e.g.*, *Kreindler*, 985 F.2d at 1158. The same is true where the relator's "independent investigation" or analysis of publicly-disclosed material forms the basis for his allegations. *See, e.g.*, *id.* at 1158–59; *JDJ*, 2017 WL 4357797, at *11 ("[C]ombining publicly available information with specialized expertise is not sufficient to overcome the first step of the public disclosure bar . . . ."); *United States ex rel. Alcohol Found. v. Kalmanovitz Charitable Found., Inc.*, 186 F. Supp. 2d 458, 461–62 (S.D.N.Y. 2002) (applying public disclosure bar where relator gathered information from articles published by third parties and obtained a unique "perspective" by "spending hundreds of hours compiling facts into a 'mosaic'"). So long as the "material aspect[s] of [the] alleged scheme" appeared in prior public disclosures, the FCA claim fails. *Ping Chen*, 966 F. Supp. 2d at 298.

As demonstrated below, Relator's allegations regarding PBMs' and drug manufacturers' "service fees" involve a long-disclosed subject of public (and government) scrutiny.

2011 OIG Report. In March 2011—more than four years before Relator filed this *qui tam* action—the U.S. Department of Health and Human Services Office of Inspector General ("OIG") released a report entitled, "Concerns with Rebates in the Medicare Part D Program." *See* Ex. H, OIG Report OEI 02-08-00050, "Concerns with Rebates in the Medicare Part D Program" (Mar. 2011). In all material respects, Relator's SAC contemplates the same potential for fraud as the

OIG recognized in its report. Indeed, Relator cites that very OIG report as support for his suspicions. *See* SAC ¶¶ 227–30. The OIG Report described the results of OIG's examination of administrative fees received by PBMs, noting that: (a) PBMs were receiving "fees from drug manufacturers," (b) in exchange for "services that the PBM provided to the manufacturer, such as negotiating rebates, calculating rebate amounts, and distributing rebates to sponsors," and (c) the fees "were generally based on a fixed percentage of [Wholesale Acquisition Cost (WAC)]." Ex. H at ii, 18–19. A majority of the PBMs receiving such fees "did not pass them on to the sponsors" and, "[a]s a result, the sponsors did not report the fees to CMS and therefore they were not passed on to the [Medicare Part D] program," all because the "PBMs considered these fees to be bona fide service fees, which CMS does not consider price concessions if they are at fair market value." *Id.* at 19. OIG concluded that reporting of such fees to CMS "may be inaccurate[]" and *recommended an assessment of "whether these fees should actually be considered rebates." Id.* (emphasis added). That same spring, OIG's Semiannual Report to Congress noted that some PBMs "collected fees from drug manufacturers that were not always passed on to the Part D program." Ex. I, OIG, Semiannual Report to Congress, Oct. 1, 2010–Mar. 31, 2011, at I-16. Two years later, in OIG's Fall 2013 Semiannual Report to Congress, it was publicly disclosed that OIG had begun undertaking reviews of BFSFs. Ex. J, OIG, Semiannual Report to Congress, Apr. 2013–Sep. 2013, at 95–96 (App'x B).

These OIG reports, which squarely qualify as administrative "report[s], . . . audit[s], or investigation[s]," 31 U.S.C. § 3730(e)(4)(A), publicly disclosed the inference of fraud that Relator postulates and asks the Court to draw in this case—i.e., that the PBM Defendants received service fees based on a percentage of sales price (namely, WAC) and did not pass those fees on to Medicare Part D, and that that conduct amounted to "inaccurate" reporting and wrongful retention of those

funds if they did not constitute BFSFs. Ex. H at 18–19. These OIG reports vividly demonstrate the government's awareness of the potential fraud alleged by Relator and are quintessential public disclosures that bar Relator's claims. *See* 31 U.S.C. § 3730(e)(4)(A).

Other Pre-2015 Public Disclosures. OIG's reports were not the first or only public disclosures that pondered whether service fees paid by drug manufacturers to PBMs might be improperly reported. Both Relator's conclusory inferences and the raw materials from which he draws them were a subject of open discussion dating back to the early 2000s.[26]

- September 1, 2002, Managed Care, *When Success Sours: PBMs Under Scrutiny* (Ex. K), at 4: "PBMs receive other payments from manufacturers that are not rebates and which are paid separately. These include *administrative fees for services rendered in connection with rebate agreements*. . . . Halbert told analysts that administrative fees don't exceed 3 percent of the *amount spent for the branded drugs covered by the fees . . . . The company retains . . . the administrative fees paid by the drug makers*.

- Spring 2003, Journal of Health Law, *The Spotlight on PBMs: Federal Enforcement of the Anti-Kickback Statute on the Pharmaceutical Benefit Management Industry*, 36 J. HEALTH L. 213, 218 (Ex. L): "PBMs . . . typically receive both an administrative fee and a rebate from drug manufacturers. . . . As noted in a HCFA report, '[r]ebates and *administrative fees are commonly paid as a percent of the drug's wholesale acquisition cost (WAC)—which represents the manufacturer's sale price*.'"

- January 28, 2005, 70 Fed. Reg. 4194, 4308–4309 (Medicare Prescription Drug Benefit Final Rule) (Ex. M): "In the preamble to the proposed rule, we said that to the extent the administrative fees paid to Part D plans (or their subcontractors, such as PBMs) are above the fair market value of the services rendered, this differential will be considered a price concession. . . . [A]s fiduciaries of the Medicare trust fund, we have a responsibility to ensure that price concessions are not *masked as administrative fees*."

- September 8, 2005, News Release, U.S. Attorney's Office, *AdvancePCS to Pay $137.5 Million to Resolve Civil Fraud and Kickback Allegations* (Ex. N), at 1: "The civil settlement resolves claims under the False Claims Act . . . arising from (1) *payments made by pharmaceutical manufacturers to AdvancePCS in the form of excessive administrative fees* and over-priced products and services agreements as an improper

[26] The sources referenced here properly may be considered by the Court on this Motion. With respect to false claims alleged to have been made prior to March 2010, the Court's inquiry is jurisdictional and thus it may look beyond the SAC. As to false claims alleged to have been made after March 2010, this Court can and should take judicial notice of these public disclosures. *See, e.g., Staehr v. Hartford Fin. Servs. Grp., Inc.*, 547 F.3d 406, 425 (2d Cir. 2008) ("[I]t is proper to take judicial notice of the *fact* that press coverage, prior lawsuits, or regulatory filings contain[] certain information, without regard to the truth of their contents . . . ."); *Ping Chen*, 966 F. Supp. 2d at 294.

reward for favorable treatment of the manufacturers' drugs in connection with the contracts." *See also* Dep't of Health & Human Servs. & Dep't of Justice, Health Care Fraud & Abuse Control Program, Annual Report for FY 2005 (Aug. 2006) (Ex. O), at 7–8 (describing AdvancePCS settlement).

- January 2007, Congressional Budget Office (CBO), *Prescription Drug Pricing in the Private Sector* (Ex. P), at 12: "Manufacturers also make other types of payments to PBMs in addition to rebate payments. For example, *manufacturers commonly pay a fee to PBMs for the service of administering formularies. Such fees are frequently equal to about 3 percent of wholesale list prices*."

- March 6, 2009, Business Wire, *State of Maryland's CVS Caremark Contract Audit Reveals More than $10 Million in Potential Overpayments, Undisclosed Rebates, Improper Drug Switching, According to CtW* (Ex. Q), at 1: "In 2006, the United States Office of Personnel Management . . . [determined CVS's predecessor, AdvancePCS,] kept $13 million in administrative fees that should have been considered drug rebates and returned to the federal agency."

- January-February 2013, Specialty Pharmacy Times, *Why We Care About Bona Fide Service Fees* (Ex. R), at 1–2: "Bona Fide Service Fees (BFSFs) is one of the most important industry terms today, with a dramatic impact across pharmaceutical manufacturers, . . . specialty pharmacy and specialty distributors, and GPOs, as well as CMS and oversight agencies such as the [OIG] and [DOJ]. . . . *The price that the government reimburses for pharmaceutical products under . . . Medicare . . . is impacted by the fees the manufacturer pays to trading partners and how those fees are treated. If a fee is considered a legitimate administrative fee, or a BFSF, it is excluded from statutory pricing calculations that the manufacturer submits to the government, which in turn defines the 'Government Price.' If the price is a price incentive (not an excluded BFSF), it also affects pricing. Therefore, the treatment of fees moves pricing and reimbursement up or down. . . . If the government pays more than it thinks it should for pharmaceutical products under these programs, it can apply the False Claims Act, which is legal action related to the pharmaceutical manufacturer submitting incorrect data which causes the government to pay more than it should. . . . [T]he treatment of fees impacts all of the statutory pricing. . . .*"

- October 7–8, 2013, CBI Conference, *Fair Market Value of Bona Fide Service Fees: Ensure Accuracy of Reported Government Pricing and Compliant Documentation Practices*: An industry conference conducted by CBI on the subject of "[a]pproaches to determining fair market value (FMV) and bona fide service fees (BFSF)," which "continue to be a challenge due to limited guidance . . . [and] heavy government scrutiny," was open to anyone who paid the registration fee. (Ex. S) All presenters' presentation materials were subsequently available online for purchase as a "Compendia." (Exs. T, U). According to Relator, "[a]ll key components of the fraud were verified via presentations . . . at the conference." SAC ¶ 460.

CBO reports, DOJ press releases, and articles published in BusinessWire and various healthcare industry and academic publications clearly constitute "news media." *See, e.g.*, *Ping Chen*, 966 F. Supp. 2d at 291, 297–98 ("news media" extends "to 'smaller' or 'professionally specialized' reader bases"); *cf., e.g.*, *Alcohol Found.*, 186 F. Supp. 2d at 463 ("news media" encompasses published information in "scholarly or scientific periodicals"). Likewise, a written presentation, advertised and available online (even for a fee), counts as a public disclosure under the broad definition of "news media." *See, e.g.*, *United States ex rel. Osheroff v. Humana, Inc.*, 776 F.3d 805, 813 (11th Cir. 2015) (collecting cases finding that public or promotional websites, legal notices, and advertisements count as "news media"); *cf., e.g.*, *Patriarca*, 295 F. Supp. 3d at 200 (public disclosure not impacted by required "annual subscription fee" to access journal); *United States ex rel. Brown v. BankUnited Trust 2005-1*, 235 F. Supp. 3d 1343, 1354–56 (S.D. Fla. 2017) (public disclosure not impacted by procedural necessity of filing formal requests to obtain materials). Thus, notwithstanding Relator's dramatic characterizations of a conference that he attended, organized by CBI, as a conspiratorial meeting solely of "industry expert[s]" and "insider[s]," SAC ¶¶ 446, 452, the written presentations from that conference (which Relator describes in SAC ¶¶ 452–89) are public disclosures because they were available for online sale to the public. *See Patriarca*, 295 F. Supp. 3d at 200. These sources publicly disclosed both the "essential elements" of the supposed scheme, from which readers could infer the potential fraud, *and* the "crux of the alleged fraud" itself. *See Ping Chen*, 966 F. Supp. 2d at 298–99 (internal quotation marks and citation omitted).

Moreover, it is irrelevant that these public sources did not identify each of the specific PBM Defendants because, as Relator admits, PBMs are a concentrated group of readily-identifiable major players. SAC ¶ 15. Where the methodology of the supposed fraud and the types of entities

involved have been generally aired in prior disclosures, a relator cannot reap a *qui tam* recovery merely by performing the straightforward task of using public information to name particular defendants. *See, e.g.*, *In re Natural Gas Royalties*, 562 F.3d 1032, 1043 (10th Cir. 2009); *United States v. Emergency Med. Assocs. of Ill., Inc.*, 436 F.3d 726, 728–29 (7th Cir. 2006) (application of the public disclosure bar was "not [even] a close question" where "since the mid-1990s" there had been "public allegations that Medicare was being billed for services provided by residents as if attending physicians had actually performed the services" and the relator had merely asserted that false-claims theory against specific defendants).

This principle is particularly applicable when the government itself has ready access to documents from which it could identify particular participants in an industry-wide practice. *See, e.g.*, *United States v. Alcan Elec. & Eng'g, Inc.*, 197 F.3d 1014, 1019 (9th Cir. 1999) (barring FCA claims where prior complaint alleged the same general scheme against different defendants because the government "presumably would have ready access to documents identifying [the] contractors" and "could easily identify the contractors at issue" itself); *United States ex rel. Fine v. Sandia Corp.*, 70 F.3d 568, 569–72 (10th Cir. 1995) (dismissing FCA claims when prior disclosures necessarily implicated a group of unnamed laboratories because "the government has already identified the problem and has an easily identifiable group of probable offenders").

The public documents identified disclose the possibility of PBMs receiving fees that might not be BFSFs and failing to pass them along as price concessions to plan sponsors and ultimately CMS. Further, the PBM market contains just a handful of "readily identifiable" companies, and the government—not Relator—was well positioned to consult Medicare Part D submissions already in its possession to identify any particular PBMs that may have engaged in the "service fee" practices described in the public disclosures between 2002 and 2013. Therefore, Relator's

claims are barred unless he is an "original source" of his allegations. 31 U.S.C. § 3730(e)(4). He is not.

B. Relator Is Not an "Original Source."

With respect to Relator's pre-2010 claims, Relator is only an "original source" if he had "direct and independent knowledge" of that information. 31 U.S.C. § 3730(e)(4) (2006). As to post-2010 claims, relator must have had "knowledge that is independent of and *materially adds to* the publicly disclosed allegations or transactions." 31 U.S.C. § 3730(e)(4)(B) (2010) (emphasis added). To be "direct," Relator must have "knowledge obtained from actually viewing source documents, or first-hand observation of the fraudulent activity," *Ping Chen*, 966 F. Supp. 2d at 300, which is not the case where a public disclosure or a "third party is 'the source of the core information' upon which the *qui tam* complaint is based," *United States v. N.Y. Med. Coll.*, 252 F.3d 118, 121 (2d Cir. 2001) (internal citation omitted). The "original source" rule differentiates "between those individuals who . . . simply stumble upon a seemingly lucrative nugget and those actually involved in the process of unearthing important information about a false and fraudulent claim." *Ping Chen*, 966 F. Supp. 2d at 299. Additionally, under both the pre- and post-ACA versions of the statute, Relator must also have "voluntarily provided the information to the Government *before* filing an action." *N.Y. Med. College*, 252 F.3d at 120; *Ping Chen*, 966 F. Supp. 2d at 299. Relator is not an original source for three reasons.

First, the SAC gives no indication that Relator voluntarily shared his information with the government *before* initiating this *qui tam* suit in October 2015, which dooms his FCA claims. *See, e.g.*, *Phipps*, 152 F. Supp. 2d at 454; *A1 Procurement, LLC v. Hendry Corp.*, No. 11-cv-23582, 2013 WL 12061864, at *8 (S.D. Fla. June 24, 2013) (rejecting "original source" solely on this basis).

Second, Relator here falls well short of possessing the "independent" knowledge necessary to qualify as an "original source" under either version of the statute. Relator is an "investment fund manager and physician" who has worked as a "professional healthcare industry investment analyst for 25+ years." SAC ¶ 132. He was never employed by any Defendant and did not have any "business relationship with [Defendants] through which [he] gained insider information." *JDJ*, 2017 WL 4357797, at *10; *accord, e.g.*, *Amico*, 2017 WL 2266988, at *5 ("Amico could not have had direct and independent knowledge of the Defendants' RMBS fraud because he never worked for Deutsche Bank. . . . [E]ven if Amico had worked for Deutsche Bank, he admits that the allegations underlying the Complaint are based on knowledge he derived from third-party sources, including public records."). Thus, Relator cannot claim "direct" or "independent" knowledge of the scheme he now alleges. To the contrary, Relator concedes in his Rhode Island *qui tam* complaint that he "is *not an insider* at any of the Defendants, but rather an industry expert who has filed this case based upon extensive expertise, investigation and supporting factual evidence."[27] First Am. Compl. ¶ 92, ECF No. 6, *United States ex rel. Borzilleri v. Bayer AG, et al.*, No. CV-14-03 (D.R.I. filed May 1, 2014) (hereafter "RI Am. Compl."). Relator's job, until he was recently fired for improper trading linked to his serial *qui tam* actions, entailed collecting and evaluating publicly available information about healthcare companies. By his own admissions, that is all he has done in this case.[28]

[27] Relator's 2014 Rhode Island *qui tam* complaint may be properly considered by this Court at least as to Relator's pre-2010 allegations and claims, because the pre-ACA "public disclosure" bar is a *jurisdictional* barrier. *E.g.*, *Hamm v. United States*, 483 F.3d 135, 137 (2d Cir. 2007) ("In resolving the question of jurisdiction, the district court can refer to evidence outside the pleadings . . . ." (internal quotation marks and citation omitted)); *see also supra* note 3.

[28] To be sure, in exceptional circumstances a non-insider may conduct such beneficial first-hand observations and investigations as to render himself an "original source." *See, e.g.*, *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1017–18 (7th Cir. 1999) (relator alleging fraud conducted extensive first-hand observational tracking of whether city bussing practices lived up to public descriptions of those practices). But Relator falls far from that tree in this case.

Third, under the current version of the statute, Relator's SAC does not "materially add" to the existing public record. Stitching together facts and reiterating inferences already set out in publicly available documents adds nothing at all to the state of knowledge preceding Relator's *qui tam*. Relator's allegations that he had limited *oral* and supposedly *private* conversations and conferences with "insiders" do not assist him as they reveal that even his non-published information was still patently second-hand. *See, e.g.*, SAC ¶¶ 128(a)–(c), 445–89. At best, the facts Relator learned in those conferences and conversations merely confirmed what the OIG and others already had noted years earlier: a significant number of PBMs were (a) calculating their administrative service fees based on drugs' list prices and (b) keeping the fees for themselves. *See infra* Part II.A. Not only is that practice proper, but also these are hardly facts that materially add to the prior public record.

Relator's own "speculation and conjecture" does not satisfy the "original source" requirement for him to proceed with a *qui tam* action notwithstanding prior public disclosures. *United States ex rel. Morgan v. Express Scripts, Inc.*, No. 2:05-cv-1714, 2013 WL 6447846, at *13 (D.N.J. Dec. 9, 2013). Relator epitomizes the tag-along, opportunistic litigant that Congress intended to discourage when it established the original source doctrine. This Court should dismiss Relator's FCA claim on public disclosure grounds.

III. THE COURT SHOULD DISMISS RELATOR'S SAC UNDER THE FCA'S FIRST-TO-FILE RULE BECAUSE IT IS RELATOR'S SECOND-FILED ACTION PLEADING THE SAME ALLEGATIONS AGAINST THE SAME PBM DEFENDANTS.

This case presents a straightforward application of the first-to-file bar. As Relator concedes, his allegations merely repackage—and often directly parrot—claims he previously asserted in a near-identical *qui tam* suit filed in the District of Rhode Island in early 2014. This is

a transparent attempt to hedge his bets by proceeding simultaneously in separate jurisdictions. The FCA does not allow or reward this strategy.

When an FCA *qui tam* action has been filed, "no person other than the Government may intervene or bring a related action based on the facts underlying the pending action."[29] 31 U.S.C. § 3730(b)(5). This "first-to-file" rule aims to encourage meaningful whistleblowing while avoiding the "dilution of 'copycat actions that provide no additional material information'" to the Government regarding a potential fraud. *Wood*, 899 F.3d at 169–70 (quoting *United States ex rel. Batiste v. SLM Corp.*, 659 F.3d 1204, 1210 (D.C. Cir. 2011)). It seeks to deter and prevent "opportunistic suits," *United States ex rel. LaCorte v. SmithKline Beecham Clin. Labs., Inc.*, 149 F.3d 227, 233 (3d Cir. 1998), recognizing that "[a] later-filed complaint that mirrors the essential facts as the pending earlier-filed complaint does nothing to help reduce fraud of which the government is already aware," *United States ex rel. Heineman-Guta v. Guidant Corp.*, 718 F.3d 28, 36 (1st Cir. 2013). There is no dispute that the Rhode Island matter was pending when this action was filed.

The first-to-file rule applies whenever a later-filed FCA case alleges the "same material elements of fraud" as the pending earlier-filed claim, "even if the allegations incorporate additional or somewhat different facts or information." *Wood*, 899 F.3d at 169 (quoting *United States ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112, 121 (D.C. Cir. 2015)). What matters is whether the "essential facts" are sufficiently the same that the government would have had notice, based on the earlier-filed claim, "to initiate an investigation into allegedly fraudulent practices." *Heineman-Guta*, 718

[29] After the passage of the ACA, the first-to-file bar no longer deprives a court of subject-matter jurisdiction, but rather constitutes a failure to state a viable claim. *United States ex rel. Hayes v. Allstate Ins. Co.*, 853 F.3d 80, 86 (2d Cir. 2017). Nevertheless, this defect in Relator's SAC cannot be cured by amendment or supplement, and thus dismissal—rather than leave to amend—is the appropriate course. *Wood*, 899 F.3d at 172–73; *United States ex rel. Shea v. Verizon Comm'cns, Inc.*, 160 F. Supp. 3d 16, 30 (D.D.C. 2015) ("No matter how many times Plaintiff amends his Complaint, it will still be true that he 'br[ought] a related action based on the facts underlying the [then] *pending* action.'" (quoting 31 U.S.C. § 3730(b)(5) (alteration in original)).

F.3d at 36–37. The first-to-file rule is "'designed to be quickly and easily determin[ed], simply requiring a side-by-side comparison'" of the allegations in the two actions. *United States ex rel. Wood v. Allergan*, 246 F. Supp. 3d 772, 791 (S.D.N.Y. 2017), *rev'd on other grounds*, 899 F.3d 163. That comparison is dispositive in this case.

In early 2014, Relator filed a sealed *qui tam* complaint in the District of Rhode Island. On May 1, 2014, he amended that complaint, asserting federal false claims, federal AKS, and state false claims counts. *See* RI Am. Compl. As here, Relator summarized his Rhode Island allegations in a "Summary of Fraud Allegations," alleging that the "Manufacturer Defendants of multiple sclerosis (MS) drugs have made fraudulent overpayments of 'Bona Fide Service Fees' (BFSFs) far in excess of the legally-required 'Fair Market Value' (FMV) to the PBM Defendants, as part of a nationwide collusive scheme in the Medicare Part D program." *Id.* ¶ 10; *see also id.* ¶ 85 ("The cornerstone of this complaint pertains to the handling in Medicare Part D of 'Bona Fide Service Fees' (BFSFs) . . . ."). More than 17 months later, on October 6, 2015, Relator filed this *qui tam* action under seal in this Court. *See* ECF No. 1. Even after multiple amendments, his SAC alleges the exact same theory and material facts that he pleaded in Rhode Island—i.e., that "Manufacturer Defendants of brand drugs have and continue to make fraudulent overpayments of illegitimate 'Bona Fide Service Fees' (BFSFs) far in excess of legally-required 'Fair Market Value' (FMV) to the PBM Defendants, as part of a nationwide collusive price inflation scheme in the Medicare Part D program." *See* SAC ¶ 26.

Relator's two *qui tam* actions are not merely "related," as prohibited by the statute; the claims in this case derive from Relator's Rhode Island claims and directly parrot them in all material respects. In both suits, Relator pleads that PBMs now make the majority of their compensation through service fees from manufacturers that far exceed FMV and are not properly

reported to the government. *Compare* RI Am. Compl. ¶¶ 10, 12, 22, 26, 28–31, 36–47, 59, 83, 95, 167, 242, 252, *with* SAC ¶¶ 13, 26, 35, 59–60, 86, 161–64, 170, 632, 646, 673. And in both cases, Relator asserts an ancillary theory that drug manufacturers have improperly forgiven PBMs' debts associated with "catastrophic coverage" rules and then failed to report that debt-forgiveness. *See, e.g.*, RI Am. Compl. ¶¶ 50–58; SAC ¶¶ 32, 33, 347, 352.

The *only* difference between this case and the Rhode Island *qui tam* action is that Relator swaps out the alleged drugs at issue, focusing on multiple sclerosis drugs in Rhode Island and on medications that treat cancer, diabetes, and rheumatoid arthritis in this case. For purposes of the first-to-file rule, this distinction is immaterial. Indeed, Relator's earlier-filed Rhode Island *qui tam* allegations were rife with references to drugs treating cancer, rheumatoid arthritis / inflammatory conditions, and diabetes, including those manufactured by the Manufacturer Defendants named in this case. *See, e.g.*, RI Am. Compl. ¶¶ 10, 75–77, 124, 285 & Exs. 17–19, 23, 26, 34, 46. In the SAC, in fact, Relator explicitly recognizes that the various drug categories are part and parcel of one broad alleged fraud. *See* SAC ¶¶ 8–9 ("The pricing abuse among 'old' blockbuster and new drugs has been particularly severe in the largest-spending US drug categories, including multiple sclerosis (MS), rheumatoid arthritis, cancer and diabetes," and "*[t]he latter three therapeutic categories are the focus of this Qui Tam action*."). In fact, Relator's allegations of violations of state false claims statutes in this case have been cut-and-pasted from the Rhode Island pleadings without modification, such that they refer solely to states' losses from overpayments on multiple sclerosis drugs. *See* SAC ¶¶ 614, 617, 620, 623, 626, 629, 632, 635, 638, 641, 644, 647, 650, 653, 656, 659, 661, 664, 667, 670, 673, 676, 679, 682, 685, 688, 691, 694, 697, 700, 707.

There can be no dispute that the two complaints are based on the "same essential facts" and that the Rhode Island complaint easily put the government on notice of the potential for fraud

relating to services fees. *See, e.g.*, *Wood*, 246 F. Supp. 3d at 792 (concluding that where FCA and AKS claims were based on general practice of improperly distributing drugs through surgical kits, "[w]hether Allergan unlawfully distributed one drug or more than one drug through those customer care kits is of no moment; either way the [first-filed] Complaint contained enough material facts to alert the government to [the] potential fraud alleged here") (internal quotation marks and citation omitted); *accord Heineman-Guta*, 718 F.3d at 37 (applying first-to-file bar where second complaint "described the same types of kickbacks" as had been disclosed in the first-filed complaint); *Grynberg v. Koch Gateway Pipeline Co.*, 390 F.3d 1276, 1280 (10th Cir. 2004) (applying first-to-file bar where second-filed complaint raised "same essential claim" that defendant "employed various fraudulent techniques" to mismeasure natural gas it produced and then "avoid or decrease its obligation to pay royalties to the United States"). And the fact that Relator himself filed the prior *qui tam* that activates the first-to-file bar here in no way saves his claims. Courts routinely dismiss successive *qui tam* actions by the same relator. *See, e.g.*, *United States ex rel. Shea v. Cellco P'ship*, 748 F.3d 338, 342–43 (D.C. Cir. 2014), *vacated and remanded on other grounds*, 135 S. Ct. 2376 (2015); *United States ex rel. Moore v. Pennrose Properties, LLC*, No. 3:11-cv-121, 2015 WL 1358034, at *15–18 (S.D. Ohio Mar. 24, 2015); *United States ex rel. Bane v. Life Care Diags.*, No. 8:06-cv-467, 2008 WL 4853599, at *7 (M.D. Fla. Nov. 10, 2008) ("Piecemeal litigation by a relator is not allowed under the FCA."); *United States ex rel. Smith v. Yale-New Haven Hosp., Inc.*, 411 F. Supp. 2d 64, 74–75 (D. Conn. 2005).

In sum, this case presents one of the clearest-cut examples of a violation of the FCA's first-to-file bar in the federal case law, and this case should be dismissed.

CONCLUSION

This Court should dismiss Relator's claims with prejudice as inadequately pleaded under Rules 12(b)(6) and 9(b) and incurably barred by prior public disclosures. Only if the Court's sole ground for dismissal is the FCA's first-to-file bar should the dismissal be without prejudice. Given Relator's status as a short-seller outsider, who does not—and cannot—rely on anything other than publicly available information, any prospective amendment would be futile to cure *any* of the dispositive defects raised in this Motion. *See AEP Energy Servs. Gas Holding Co. v. Bank of Am., N.A.*, 626 F.3d 699, 726 (2d Cir. 2010) ("Leave to amend may be denied on grounds of futility if the proposed amendment fails to state a legally cognizable claim or fails to raise triable issues of fact."). Relator filed his initial complaint on October 6, 2015, and has already amended his complaint on two separate occasions over a two-year period. ECF Nos. 1, 58, 148. Accordingly, the Court should dismiss all Relator's claims with prejudice, or, alternatively, without prejudice if the Court relies *solely* on the first-to-file bar.

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Respectfully submitted,

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