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*, v. ABBVIE, INC., et al., *Defendants*.	Case No. 15-civ-7881(JMF)

PHARMACY BENEFIT MANAGER DEFENDANTS' REPLY IN SUPPORT OF MOTION TO DISMISS

INTRODUCTION

The Pharmacy Benefit Manager ("PBM") Defendants advanced three independent grounds on which Relator's SAC[1] should be dismissed. First, by proffering nothing more than a series of hypotheticals and industry-wide generalities, the SAC fails to allege violations of the False Claims Act ("FCA") with the required plausibility and particularity. Second, the FCA's public disclosure bar precludes Relator's claims because he constructed his theory based on publicly available information, and he possesses no first-hand knowledge of his own. Third, under the FCA's first-to-file bar, the SAC must be dismissed because Relator's allegations in this case are materially identical to those he made in a separate federal case that was pending in the District of Rhode Island when he filed this one.

Relator's Opposition (ECF No. 271) fails adequately to address any of these defects. The PBM Defendants' Motion described how Relator failed to allege with any specificity (or at all) key facts relating to any particular Defendant. Examples of crucial missing facts include the actual fees or rates charged under any Part D contract, descriptions of the actual fees and services exchanged, the supposed true fair market value of services provided under the contracts in question, and actual reports submitted to CMS that allegedly failed to properly report these fees. The Opposition largely ignores these pleading deficiencies, and Relator does not (and cannot) identify particularized allegations as to any of them. Instead, he merely insists that he "sees no significant deficiencies in his understanding of the broad mechanics of the scheme" and is "confident of confirming his allegations expeditiously in discovery." Opp. 29–30. His defense of the SAC is wholly insufficient and ignores the Second Circuit's admonition that Rule 9(b) exists

[1] In this brief, all abbreviations have the same meaning assigned to them in the PBM Defendants' Memorandum in Support of their Motion to Dismiss, ECF No. 261 ("PBM Defendants' Motion" or "PBM MTD").

to prevent just such "filing of complaints 'as a pretext for discovery of unknown wrongs.'" *Madonna v. United States*, 878 F.2d 62, 66 (2d Cir. 1989).

Relator's responses to the public disclosure and first-to-file bars are equally unavailing. As for the public disclosure bar, Relator's continued, extensive reliance on public sources validates the PBM Defendants' argument that his claims are based entirely on facts and theories that were publicly disclosed before he filed this case, and Relator repeatedly concedes in his Opposition and exhibits that he lacks any insider or first-hand insight that might make him an "original source." *See*, *e.g.*, Opp. 1, 14, 23, 26, 30. Furthermore, Relator's only attempt to overcome the first-to-file bar relies on a manifestly artificial and immaterial distinction between his Rhode Island and S.D.N.Y. complaints—namely, differences in the particular drugs pleaded in each case. Relator concedes that the two *qui tams* are otherwise identical.

As the PBM Defendants argued in their Motion, Relator appears to have filed this lawsuit to facilitate and profit from a short-selling scheme, which resulted in his termination from his position as an investment fund manager. His scheme and the duplicative lawsuits it spawned has caused a significant expenditure of financial resources not only by the Defendants, but also by the United States, which explains in its separate motion to dismiss under 31 U.S.C. § 3730(c)(2)(A) that it undertook "a careful and wide-ranging investigation into Relator's core allegations." Mem. of Law in Supp. of U.S. Motion to Dismiss 5 ECF No. 275 ("U.S. Motion" or "U.S. MTD"). Rules 12(b) and 9(b) and the FCA itself should make this the end of the line for Relator's tactics. This Court should dismiss the SAC with prejudice on the grounds asserted in the PBM Defendants' and

the Manufacturer Defendants' respective motions and the independent grounds asserted in the U.S. Motion under 31 U.S.C. § 3730(c)(2)(A).[2]

ARGUMENT

I. THE COURT SHOULD DISMISS RELATOR'S COMPLAINT BECAUSE IT FAILS TO SATISFY THRESHOLD PLEADING REQUIREMENTS

A. Relator Fundamentally Misunderstands the Pleading Requirements Applicable to This Case.

To withstand a motion to dismiss, the SAC must offer more than just "'labels and conclusions' or . . . 'naked assertion[s]' devoid of 'further factual enhancement.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (brackets in original) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 557 (2007)). Moreover, because he is asserting clams for fraud, Relator must, under Rule 9(b), plead his claims with "particularity." Fed. R. Civ. P. 9(b).

Rule 9(b) imposes this particularity requirement for multiple reasons, two of which are especially relevant here. First, it is intended to "discourage plaintiffs from making a cavalier decision to accuse a defendant of fraud," *SEC v. One or More Unknown Traders in Sec. of Onyx Pharm., Inc.*, 296 F.R.D. 241, 247 (S.D.N.Y. 2013), and thereby "safeguard [defendants'] reputation[s] from improvident charges of wrongdoing," *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 99 (2d Cir. 2007). Second, it deters so-called "strike suits," in which a plaintiff files suit in the hope that the defendant will choose to settle meritless claims rather than incur the significant expense of defending against them on the merits. *Id.*

Given Rule 9(b)'s role as a shield against abusive litigation, courts have long held that where Rule 9(b) applies, a plaintiff cannot use "conclusory generalizations" of fraud to "set off on

[2] The time set by this Court for any further amendments to Relator's pleadings has now passed, *see* ECF. No. 265, and dismissal—rather than leave to amend—is the appropriate course. Moreover, all but one of the grounds for dismissal asserted by the Defendants calls for dismissal with prejudice; only if this Court relies *solely* on the first-to-file bar should the dismissal be without prejudice. *See* PBM MTD 2 n.1, 34 n.29, 38.

a long and expensive discovery process in the hope of uncovering some sort of wrongdoing or of obtaining a substantial settlement." *Decker v. Massey-Ferguson, Ltd.*, 681 F.2d 111, 116 (2d Cir. 1982); *see also, e.g.*, *Madonna*, 878 F.2d at 66 ("One of the purposes of Rule 9(b) is to discourage the filing of complaints 'as a pretext for discovery of unknown wrongs.'" (citation omitted)); *Johnson v. Univ. of Rochester Med. Ctr.*, 686 F. Supp. 2d 259, 267 (W.D.N.Y. 2010) ("One of the primary purposes of Rule 9(b) is to prevent the prosecution of lawsuits that merely seek to establish the factual basis for some nebulous, unknown crime.").

The strictures of Rule 9(b) are fundamental. In this case, however, the SAC contains *no* specific allegations of fraudulent conduct by any of the PBM Defendants, and instead posits broad, generalized hypotheses about the pharmaceutical and PBM industries and about what Relator "expect[s] discovery to determine." PBM MTD 8 (quoting SAC ¶ 122). Relator reaffirms that approach in his Opposition. He does not (and cannot) point to any specifics in the SAC about *any* of the supposedly unlawful bilateral Part D-related arrangements between PBM Defendants and Manufacturer Defendants that form the basis for his allegations. Rather, he offers this Court only his "confiden[ce]" that the "product-specific 'service fee' contracts" will be "easily accessible in discovery." Opp. 29–30. But Relator's "contention[] that discovery will unearth information tending to prove his contention of fraud[] is precisely what Rule 9(b) attempts to discourage." *Madonna*, 878 F.2d at 66.

Relator attempts to evade his obligation to plead particularized facts by arguing that the Defendants failed to offer in their motions to dismiss any facts to *contradict* the SAC. Specifically, the Opposition claims that "[t]he lack of any 'factual' challenge to the Relator's allegations supports Relator's theory of the participation of all the Defendants in this extensively detailed and documented 'service fee' scheme." Opp. 14. Of course, the burden of pleading sufficient facts

falls squarely on Relator, not on Defendants. When moving to dismiss, Defendants are required to accept "well-pleaded factual allegations" as true. *Iqbal*, 556 U.S. at 679. Relator cannot rescue his poorly pled SAC by arguing that at the pleading stage of this case, and contrary to the Federal Rules of Civil Procedure and binding case law, the Defendants are somehow responsible for asserting any facts—let alone contradictory facts—in support of a motion to dismiss.

B. Relator Still Fails to Provide the Specific Facts that Would Be Necessary to Plead His Claims Adequately.

Relator's basic theory is that (a) the Manufacturer Defendants paid "excessive fees" to the PBM Defendants in exchange for favorable treatment of the Manufacturers' drugs on the PBM Defendants' formularies, and (b) all Defendants then caused inaccurate reporting of those excessive service fees (namely, failing to identify them as discounts) in submissions to the Government. It is apparent that Relator's complaint "broadly hypothesiz[es] that the same pattern of conduct applies to the numerous bilateral relationships between each of the PBMs and each of the drug manufacturers he has named as defendants." U.S. MTD 15. To satisfy Rule 9(b), Relator would have needed to allege at least three critical facts with particularity for *each* of the bilateral relationships at issue. *First*, Relator needed to identify and quantify the particular service fees a particular PBM Defendant received from a particular Manufacturer Defendant in exchange for particular services provided in connection with a particular drug under a particular Part D plan. *Second*, Relator needed to identify the actual FMV of those particular services, in order to compare the FMV with the rate that was actually paid. *Third*, Relator needed to allege that the particular PBM Defendant did not report—or caused the contracted plan sponsor not to report—the difference between these amounts to CMS as a discount. Relator's Opposition does not identify any allegations (in the SAC or elsewhere) that would fill *any* of those fundamental holes, let alone the others identified in the PBM Defendants' Motion. *See, e.g.*, PBM MTD 9.

1. Amount of Any Service Fees

In a complaint built exclusively around the assertion that the PBM Defendants each received more than FMV for the services they provided under a Part D contract, Relator must allege how much each of the PBM Defendants actually received. The SAC does not do so for any of the PBM Defendants. Instead, as the PBM Defendants explained in their motion to dismiss, it relies on fictionalized hypotheticals to "illustrate" Relator's allegations using a supposed industry-wide "average" service fee rate. PBM MTD 11 (citing SAC ¶¶ 246–75). Such "industry-wide" averages, by definition, do not provide the particularity that Rule 9(b) demands. *See, e.g., Rep. Bank & Tr. Co. v. Bear Stearns & Co.*, 683 F.3d 239, 257 (6th Cir. 2012); *Plumbers' Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp.*, 632 F.3d 762, 774 (1st Cir. 2011).

Relator now effectively concedes that he cannot supply anything more specific than these averages. *See* Opp. 9. And lacking that, he makes the remarkable argument "that the exact 'service fee' contract rate for any individual Defendant drug is not of major consequence, *unless the contract rate is properly decreased to maintain FMV*." *Id.* (emphasis added). In other words: The specific rate does not matter, unless it was set at FMV. But Rule 9(b) requires that Relator allege the specific rate under a Part D contract to show, with particularity, that the payments were above FMV. He cannot merely assert that the rate must have been above FMV, then insist that because "[t]he Defendants never make th[e] factual argument" in their motion to dismiss that the rate was consistent with the FMV of the services provided (an argument that would be improper under Rule 12(b) and *Iqbal*), his conclusory allegations must be correct. Opp. 9.

2. FMV of PBM Services

The second essential component of Relator's theory would be pleading the actual FMV of the services for which he claims the PBM Defendants were overpaid. As stated in the PBM Defendants' Motion, courts consistently require plaintiffs making FMV-based claims to offer a

specific "benchmark of [FMV] against which Defendants' [payments] . . . 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); *see also* PBM MTD 13–14 (collecting cases).[3]

Relator offers no such benchmark here. Citing a 50-paragraph range in the SAC, Relator claims that he has "provided the Court with the first detailed analysis of FMV in any *qui tam* action." Opp. 54 (citing SAC ¶¶ 623–73). But nowhere in that range of allegations (or anywhere else in the SAC) does Relator plead specifics about the FMV of any particular services provided by any particular PBM Defendant (or even the FMV of any commonly provided PBM service in general). The Opposition claims that the "primary FMV 'benchmark' for each Defendant product is simply the level and rate of legitimate 'service fee' payments for the same product before the massive price increases ensued." *Id.* But Relator neither identifies the amount of those supposed pre-scheme fees nor explains the basis for his apparent assumption that services themselves have not evolved over time.[4] Relator simply "avers that FMV determination will not be a complex endeavor in most instances in an investigation of these allegations." Opp. 54. As discussed above, *see supra* pp. 3–4, such "contention[s]" about what "discovery will unearth" do not satisfy Rule 9(b). *Madonna*, 878 F.2d at 66.

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[3] Relator cites a pending District of Massachusetts case to suggest that pleading a "benchmark" is unnecessary. *See* Opp. 56. But in that case, a benchmark was unnecessary precisely because the relator provided "numerous specific allegations that, if true, are sufficient to support the conclusion that the consulting and speaking programs that Defendant contracted for did exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the service." *United States ex rel. Bawduniak v. Biogen Idec, Inc.*, No. 12-cv-10601-IT, 2018 WL 1996829, at *3 (D. Mass. Apr. 27, 2018). Relator has made no such specific allegations here.

[4] Even as to Diplomat Pharmacy—Relator's only proffered "'real world' benchmark"—Relator never identifies how much Diplomat receives for the services it provides, alleging only its overall net "profit margin." Opp. 55–56; SAC ¶¶ 668–73. Nor, for that matter, does Relator explain the basis for his naked assertions that the services Diplomat Pharmacy provides as an independent specialty pharmacy are the same as those provided by PBMs, such that it could provide an appropriate benchmark at all. *See* Opp. 55 (characterizing the PBM Defendants' observation of this difference as "specious" but offering no substantive response).

3. Reporting of Fees to CMS

Lastly, Relator's theory depends on plausibly alleging that the Defendants somehow caused a Part D plan sponsor to fail to properly report to CMS (or, for the handful of defendant Part D plan sponsors, *see* PBM MTD 4 n.4, failed themselves to properly report to CMS) any service fees that exceeded FMV. There is nothing inappropriate (let alone illegal) about PBMs receiving service fees in excess of FMV as long as the fees are properly reported to CMS in plan sponsors' Direct and Indirect Remuneration ("DIR") reporting. *See* PBM MTD 15. Relator concedes this point, as he must. Opp. 15. Nevertheless, Relator did not plead (and his Opposition does not identify) any particularized allegations about any reporting deficiency by any Part D plan sponsor. Instead, his Opposition relies upon an online CMS database that lists the number of prescriptions reimbursed under Medicare Part D for each of the drugs in question. *See* Opp. 45 (citing CMS Medicare Part D Drug Spending Dashboard & Data ("CMS Dashboard"), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html) (last modified May 23, 2018). Relator claims that the information contained in the CMS Dashboard "exceeds the Rule 9(b) requirements pertaining to all other Part D submissions for payment, including [DIR] reports, annual bid submissions and the data required for Catastrophic reconciliation." *Id.* at 50.

Relator's contention is simply not true; indeed, it is inexplicable. The CMS database does not contain any information at all about DIR reporting. CMS explains on the very website to which Relator cites that "[t]he Part D spending metrics do not reflect any manufacturers' rebates or other price concessions as CMS is prohibited from publicly disclosing such information." CMS Dashboard. Relator offers nothing else. His claims about false reporting are all based on pure, uninformed speculation about what may or may not have been reported to CMS. These sorts of "hypotheses," which are "not supported by particularized allegations of fact," are plainly

insufficient under Rule 9(b). *United States ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 26–27 (2d Cir. 2016).

C. Relator's Anti-Kickback Statute and Catastrophic Coverage Theories Are Insufficiently Pled and Should be Dismissed for the Same Reasons.

In addition to alleging that all the PBM Defendants received service fees in excess of FMV and uniformly failed to (or caused failures to) report the excess amount in DIR Reports, Relator asserts two additional theories of liability against the PBM Defendants. The first alleges that the service fees the PBM Defendants received were actually kickbacks from the Manufacturer Defendants, paid in exchange for favorable formulary placement of their drugs, that violated the Anti-Kickback Statute ("AKS"). The second theory alleges that the Manufacturer Defendants routinely waived the PBM Defendants' or their affiliates' obligations to make catastrophic coverage payments and that those concessions were not properly reported to the government.

As with Relator's service-fee theory, neither of these theories passes muster under Rules 9(b) and 12(b)(6). For example, Relator's failure to plead particular service fees paid by any Manufacturer Defendant to any PBM Defendant means that he has not identified with particularity any purported remuneration at all. Nor has Relator plausibly and specifically pleaded any details regarding any supposed preferred formulary placement given by any of the PBM Defendants to any of the Manufacturer Defendants' drugs in question—a necessary component of his AKS claim. *See* 42 U.S.C. § 1320a-7b(b)(1) (making it a crime to "knowingly and willfully solicit[] or receive[] any remuneration . . . *in return for*" specified conduct) (emphasis added).[5] Furthermore, Relator fails to plausibly allege the *mens rea* required to support an AKS allegation. He offers only

[5] Relator insists that the PBM Defendants' statement that it is "at least equally plausible that any service fees were paid in exchange for legitimate services provided by PBMs" amounts to an admission that his own theory is plausible. Opp. 35 (quoting PBM MTD 21) (emphasis omitted). Quite to the contrary, the PBM Defendants' point was that payments by manufacturers to PBMs are not inherently fraudulent, and therefore Relator must plead with particularity the specific *unlawful* benefits that the supposedly excessive service fees procured. Relator fails to do that.

conclusory assertions that the supposed kickback violations were committed in a "knowing," "intentional," and "willful" fashion, Opp. 57, providing none of the "facts that give rise to a *strong* inference of fraudulent intent" that the applicable pleading standards demand here, *United States ex rel. Grubea v. Rosicki, Rosicki & Assocs., P.C.*, 318 F. Supp. 3d 680, 694 (S.D.N.Y. 2018) (internal quotation marks omitted); *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. v. RCJ Constr. Servs. Corp.*, No. 14-cv-432, 2018 WL 1178034, at *3 (E.D.N.Y. Jan. 19, 2018).

Similarly, in support of his catastrophic-coverage theory, Relator does not identify *any* debt of *any* PBM Defendant (or its plan sponsor affiliate) that was forgiven by *any* Manufacturer Defendant and then not properly reported to CMS. Instead, Relator again offers nothing more than pure speculation because—having no insider, first-hand knowledge—he does not know whether and how catastrophic coverage information has been reported to CMS. *See* Opp. 50–51 (conceding that pleading any further detail "is not possible" for him "without access to Defendant and/or CMS data," the details of which "are undisclosed beyond CMS and the Defendants themselves").

II. THE PUBLIC DISCLOSURE BAR ALSO REQUIRES DISMISSAL OF RELATOR'S CLAIMS

Nothing in the Relator's Opposition spares the SAC from the dismissal required under the FCA's public disclosure bar. Nowhere does Relator rebut the two central flaws in his case that trigger that bar: (1) factual allegations and inferences of fraud nearly identical to Relator's allegations were publicly disclosed before Relator filed this lawsuit; and (2) Relator is not an original source of those allegations.

A. Relator Concedes that His Allegations and Inferences of Fraud Are Drawn Directly from Public Sources.

Relator continues to acknowledge in the Opposition—as he did in the SAC—that the essential elements of his claims were public long before he filed this case. He even appends to his

Opposition additional material that confirms and underscores the public information and inferences on which he has based his claims.

To start, Relator's "initial report" provided to the Government in the fall of 2013 admitted that "much of the supporting data" underlying his claims was "in the public domain" in the form of "OIG reports, SEC filings, industry reports, etc." ECF No. 271-3 ("Initial Report"), at 93; *see* Opp. 25. A March 2011 OIG report regarding "contractual relationships between sponsors and PBMs" in Medicare Part D, *see* PBM MTD Ex. H ("OIG Report"), at 3, in Relator's own words, "highlight[ed] major concerns that may both reduce the accuracy/reliability of the reported data and lead to increased drug costs for the Medicare Part D program and its beneficiaries," Initial Report, ECF No. 271-3, at 65; *see also* PBM MTD 25–27 (discussing overlap between SAC and OIG Report). Indeed, Relator concedes that the OIG Report was the genesis of his claims: "Borzilleri himself did not uncover the fraudulent 'service fee' scheme until 4-6 months after initially reviewing [the] OIG report." Opp. 22; *see also* SAC ¶¶ 227–30, 764–69 (pleading allegations based on OIG Report); Initial Report, ECF No. 271-3, at 64–65 (cataloging information Relator obtained from OIG Report).

What is more, Relator admits that another "of the key public disclosures that *put [him] on the trail* to the scheme was a brief article in the January-February 2013 issue of Specialty Pharmacy Times." Opp. 22 (citing SAC ¶¶ 386–87) (emphasis added); *see* PBM MTD 28 (discussing article's disclosure of essential elements of Relator's claims). Relator also concedes that his allegations were openly discussed at an October 2013 conference regarding "Fair Market Value Of Bona Fide Service Fees," two years before he initiated this *qui tam*. Opp. 26; Initial Report, ECF No. 271-3, at 82. Records of that conference, which Relator cites and refers to repeatedly in his SAC and his Initial Report, *see* SAC ¶¶ 452–89; Initial Report, ECF No. 271-3, at 98–105,

confirm that key elements of Relator's allegations were publicly disclosed both at the event itself, which was open to anyone who wished to register, and in the written compendium, which could be obtained online by anyone willing to pay the fee for a copy, *see, e.g.*, ECF 271-2 ("Compendium"), at 10, 32, 35, 36, 85, 187;[6] PBM MTD 28 & Exs. T, U. Information from the conference was "the determining factor in Dr. Borzilleri's decision to file the initial *qui tam* action in RI less than three months later." Opp. 26.

Despite these concessions, Relator now contends that these sources are too "general" to bar his suit.[7] *Id.* at 22–24. But, the appropriate analysis compares the public disclosures to the actual allegations *made*, and Relator here offers no more than his own generalized inferences that merely echo the concerns about *potential* fraud that appeared first in the March 2011 OIG Report and other public sources. *See* PBM MTD 6–7, 25–28. The SAC adds no greater specificity or detail about any material alleged fact.

B. Relator Misapplies the Public Disclosure Bar Test.

On the law, Relator fares no better. Relator appears to contend that his *exact* allegations must have been publicly disclosed for the bar to apply. *See, e.g.*, Opp. 28–29. But, so long as public disclosures aired "'the essential elements'" and "'crux of the alleged fraud,'" the bar forecloses a relator's claims. *United States ex rel. Ping Chen v. EMSL Analytical, Inc.*, 966 F.

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[6] The Compendium specifically distinguished "legitimate fees for service" from "actual or constructive price concessions *characterized* . . . as 'service fees' or 'administrative fees,'" and warned that prosecutors "will not hesitate to look beyond the 'four corners' of a service agreement to determine the true nature of the fees." Compendium, ECF No. 271-2, at 10, 36 (emphasis added). It also noted the "percent of WAC" or "percent-of-sales" service fee arrangements that are at the heart of Relator's theory. *Id.* at 32, 187. As Relator admitted in his Initial Report, the purported "practice of structuring manufacturer/PBM contracts based upon 'per cent of manufacturer product revenues'" that is key to Relator's theory was "well-documented" long before Relator crafted this lawsuit. Initial Report, ECF No. 271-3, at 80; *accord* PBM MTD 26–28 (cataloging public disclosures discussing service fees set at a percentage of sale price).

[7] Notably, the Opposition addresses only four of the 11 sources identified in the PBM Defendants' Motion. PBM MTD 25–28. It does not contest that each of those sources, which it admits are "public reports" and "public documents," Opp. 21, is a qualifying source under the public disclosure bar.

Supp. 2d 282, 297 (S.D.N.Y. 2013) (quoting *United States ex rel. Monaghan v. N.Y.C. Dep't of Housing*, No. 09-cv-6547, 2012 WL 4017338, at *5 (S.D.N.Y. Sept. 10, 2012)). Relatedly, the focus of the public disclosure bar is not a subjective inquiry into when and how Relator *himself* began to suspect potential fraud, *see* Opp. 61, but rather the objective question whether public information was sufficient to "'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 Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 654 (D.C. Cir. 1994)). These tests are easily met here. *See* PBM MTD 33–39.

Unable to avoid the reality that he cobbled together his complaint from public disclosures, Relator argues that his "investigation" and "intensive research," coupled with his "experience and common sense," allowed him to "recognize[] the fraudulent practices," Opp. 10, 12, 23; in other words, that his "unique expertise, training and motivation" allowed him to "*detect*[] the underlying fraud" from patently public sources, Initial Report, ECF No. 271-3, at 93 (emphasis added). He argues that he gathered public information and "overla[id] numerous other central factors" like "massive price increases" for the Manufacturer Defendants' drugs (which were public) and "numerous design and operational factors related to Medicare Part D" (also public). Opp. 23. But even if Relator were somehow expert in Medicare Part D,[8] "combining publicly available information with specialized expertise is not sufficient to overcome the first step of the public disclosure bar." *United States ex rel. JDJ & Assocs. LLP v. Natixis*, No. 15-cv-5427, 2017 WL 4357797, at *11 (S.D.N.Y. Sept. 29, 2017). Allegations based even in part on public information

[8] Quite the opposite is true here. By his own admissions, Relator had never heard of "bona fide services fees" until July 2013—years after they became a mainstay of Medicare Part D regulation, *see* PBM MTD 5–6—and had "minimal prior knowledge" of how "fair market value" impacts Medicare Part D, Initial Report, ECF No. 271-3, at 90.

are prohibited. *United States ex rel. Kreindler & Kreindler v United Techs. Corp.*, 985 F.2d 1148, 1158 (2d Cir. 1993).

C. Relator Is Not an Original Source.

Claims based on publicly disclosed information can be salvaged only where the Relator is an "original source." But Relator clearly is not. He and his prior counsel have candidly admitted, multiple times, that he is a "non-insider," Opp. 30; *accord* Initial Report, ECF No. 271-3, at 1, 98; RI Am. Compl., ECF 271-4, at 32, with no first-hand knowledge of or access to actual contracts or submissions to CMS that are at the heart of his claims, *see, e.g.*, Initial Report, ECF No. 271-3, at 1 ("I am fully aware that I do not have direct access to potentially fraudulent 'market-based/per cent of revenue' contracts . . . ."); Emails from Paul Barone to U.S. Attys (Nov. 14 & 17, 2013), ECF No. 271, at 113, 114. As the U.S. Motion states, "[u]nlike the whistleblowers contemplated by Congress, Relator is not a current or former employee of any defendant or even one of their suppliers, customers, or competitors," U.S. MTD 3 n.3, and lacks "insider or programmatic knowledge concerning his allegations," *id.* at 4. Relator's assertion that he nevertheless qualifies as an "original source" again rests on errors of fact and law.[9]

For example, Relator's claim to original-source status relies heavily on his attendance at an October 2013 conference, at which he *listened* to what *actual* industry insiders publicly presented to all conference attendees. *See, e.g.*, SAC ¶¶ 459–89. Relator calls this "first-hand-witness commentary" and claims it gave him "direct and independent" knowledge underlying his allegations, Opp. 24, 26, but there is nothing first-hand about it, and it does not render Relator an

[9] To the extent Relator shared his claims with the Government before filing a complaint, that is necessary, but not sufficient (as Relator seems to suggest, *see* Opp. 25) to qualify as an original source. *See* 31 U.S.C. § 3730(e)(4)(B) (defining "original source" as an individual "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") (emphasis added).

original source. *See* 31 U.S.C. § 3730(e)(4)(B); *United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins.*, 944 F.2d 1149, 1160 (3d Cir. 1991) ("[A] relator who would not have learned of the information absent public disclosure did not have 'independent' information within the statutory definition of 'original source.'") (citation omitted).

Additionally, just as applying "expertise" to analyze public information is insufficient at the first step of the public disclosure test, it likewise does not render a relator an "original source" in the second step. *JDJ*, 2017 WL 4357797, at *11; *accord United States ex rel. Alcohol Found., Inc. v. Kalmanovitz Charitable Found., Inc.*, 186 F. Supp. 2d 458, 461–64 & n.4 (S.D.N.Y. 2002) (distinguishing a "perceptive third-party" with a unique understanding of "time, statistics, science, politics, and the law" from an "archetypal whistle-blower" with "firsthand knowledge of the wrong and its perpetrators"), *aff'd*, 53 F. App'x 153 (2d Cir. 2002). Therefore, even if Relator's supposed "expertise" enabled him to compile and analyze information published by others—like OIG, conference participants, and drug pricing resources—he still would not qualify as an "original source."

This Court should dismiss the SAC because the public disclosure bar precludes it.

III. THE FIRST-TO-FILE RULE ALSO REQUIRES DISMISSAL OF RELATOR'S CLAIMS

The PBM Defendants' Motion identified and advanced a third basis for dismissal of Relator's SAC. When Relator filed this suit, his own near-identical *qui tam* action was pending in the United States District Court for the District of Rhode Island. *See* PBM MTD 35–37; *accord* U.S. MTD 3 ("virtually identical theories of liability"), 17 ("two duplicative *qui tam* cases"). Those irrefutable facts are enough to dismiss this suit under the FCA's first-to-file bar. *See, e.g.*, *United States ex rel. Wood v. Allergan, Inc.*, 899 F.3d 163, 169 (2d Cir. 2018).

Nothing in Relator's Opposition changes that fact. He attempts to skirt the first-to-file bar by relying on what amounts to an artificial distinction between his Rhode Island case and this one: Multiple sclerosis drugs targeted in the Rhode Island complaint are swapped out for rheumatoid arthritis, diabetes, and cancer drugs in the SAC. *See* Opp. 59–62. The Opposition contends that the Rhode Island case concerns only the "specialty" drug market, while this case concerns "traditional" drugs. *Id.* But Relator overstates both the degree of any distinction his complaints draw between "specialty" and "traditional" drugs and the relevance of any such distinction to the fraud theories he pleads.

To begin with, according to Relator himself, only nine of the fourteen drugs targeted in the SAC are "traditional" drugs at all; the other five are "specialty drugs" of the type Relator claims were targeted in his Rhode Island complaint. Opp. 26. Relator's correspondence with the Government ahead of filing his *qui tam* complaints and the allegations in his Rhode Island complaint give away his strategy: He believes that "collusive practices between manufacturers and PBMs are . . . a very broad, far-reaching phenomenon," but he nevertheless focused on multiple sclerosis ("MS") drugs in his first-filed complaint because they are the "most straightforward to prove." Email from Borzilleri to U.S. Attys (Oct. 25, 2013), ECF No. 271, at 109–10; *see also, e.g.*, RI Am. Compl. ¶¶ 10, 285.[10] As the United States wrote in its motion to dismiss Relator's claims, "there is no rational reason . . . for Relator to proceed with two duplicative, overlapping litigations" "[a]part from the hope that the two cases will afford Relator the proverbial 'two bites at the proverbial apple' in pursuit of his claims." U.S. MTD 17. Relator's

[10] Notably, in order to demonstrate that he voluntarily provided the Government with information underlying his allegations before filing *this* case (for purposes of the "original source" exception to the public disclosure bar), Relator relies upon and attaches the *2013* disclosure of his "initial report" on *specialty drug markets and multiple sclerosis drugs*. *See* Opp. 25; Initial Report, ECF No. 271-3, at 1–8. Relator himself thus admits that his two cases are the same.

effort to break his one theory of widespread Medicare Part D fraud into severable parts is transparent litigation and reward-maximization strategy. It does not exempt him from the first-to-file bar.

In any event, whether the alleged service fees "scheme" operated via "specialty" or "traditional" drugs—or affected MS drug markets versus other drug markets—has no relevance to the touchstone of the first-to-file analysis: Whether Relator's first-filed Rhode Island action gave the government sufficient notice "to initiate an investigation into allegedly fraudulent practices." *United States ex rel. Heineman-Guta v. Guidant Corp.*, 718 F.3d 28, 36–37 (1st Cir. 2013). The Rhode Island complaint contained the essential factual allegations necessary to prompt the government to investigate, which it did.[11] *See, e.g.*, U.S. MTD 4, 5, 16.

Finally, it should go without saying that Relator is not entitled to an evidentiary hearing regarding the first-to-file bar. By requesting one, Relator effectively concedes—as he must—that the SAC does not plead sufficient facts to overcome the first-to-file bar. Opp. 1, 58, 62. There is no amount of additional evidence that could change the only facts relevant to the first-to-file analysis here: Relator filed a complaint in Rhode Island in January 2014, and nearly 21 months later, he asserted materially identical allegations of a fraudulent service-fees scheme in this Court. His suit is therefore barred by 31 U.S.C. § 3730(b)(5), and it should be dismissed.

IV. THE UNITED STATES' MOTION TO DISMISS IS WELL-FOUNDED AND PROVIDES AN INDEPENDENT, ADDITIONAL BASIS FOR DISMISSAL

Finally, the PBM Defendants note their agreement with the United States' separate motion to dismiss under § 3730(c)(2)(A) of the FCA. The PBM Defendants concur with the reasoning of

[11] The Government's motion to dismiss the Rhode Island complaint, in particular, indicates that those first-filed allegations led to a "wide-ranging and extensive inquiry," including "review[ing] and analyz[ing] tens of thousands of responsive documents touching on all aspects of Part D fee negotiation, structure, handling, and reporting." U.S. Mot. to Dismiss 15–16, *United States ex rel. Borzilleri v. Bayer Healthcare Pharms, Inc.*, No. 1:14-cv-00031 (D.R.I. filed Dec. 21, 2018).

the United States under the *Swift* line of cases that dismissal of a *qui tam* action under § 3730(c)(2)(A) is a matter wholly committed to the Executive Branch's "unfettered" discretion. *See* U.S. MTD 4–7; *Swift v. United States*, 318 F.3d 250, 252 (D.C. Cir. 2003). In this case, even under an alternative standard, the exercise of that discretion is well justified, for the reasons discussed by the United States. *See, e.g.*, U.S. MTD 3–5, 18 (unwarranted and duplicative expenditure of government resources, "absence of any reasonable likelihood of significant monetary recovery" for the United States, Relator's outsider status and personal short-selling motivations). Accordingly, the U.S. Motion should also be granted.

CONCLUSION

For the foregoing reasons, and others advanced by the United States and the Manufacturer Defendants in their motions to dismiss, the SAC should be dismissed with prejudice.

Dated: January 4, 2019

Respectfully submitted,
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CERTIFICATE OF SERVICE

I, Sarah L. O'Connor, do hereby certify that on January 4, 2019, I electronically filed the foregoing "Pharmacy Benefit Manager Defendants' Reply in Support of Motion to Dismiss" with the Clerk of Court using the Court's electronic filing system, which will send notification of such filing to all CM/ECF counsel of record for all parties.

Dated: January 4, 2019

/s/ Sarah L. O'Connor
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