UNITED STATES DISTRICT COURT
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 MANUFACTURER DEFENDANTS' JOINT MOTION TO DISMISS RELATOR BORZILLERI'S SECOND AMENDED COMPLAINT

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INTRODUCTION

The *qui tam* provision of the federal False Claims Act (FCA) is intended to incentivize whistleblowing insiders to bring genuinely valuable information to the attention of the United States. It is not intended to encourage generalized speculation of alleged wrongdoing to advance the short-selling goals of opportunist individuals looking for personal gain. Relator John Borzilleri falls squarely in the latter camp. He is a (now former) health care investment fund manager who admits that he is accusing the thirteen defendant companies of fraud on the Medicare Part D program based on absolutely no personal knowledge of anything that any of them have done in connection with this federal drug prescription program. Instead, his 922-paragraph Second Amended Complaint (SAC or N.Y. SAC) spins a meandering and speculative conspiracy theory based on his purported analysis of public sources and conversations with individuals unconnected to any of the companies he has named as defendants.

This suit is subject to dismissal for many reasons. First, before Borzilleri filed this suit, he filed another *qui tam* complaint in the District of Rhode Island offering a substantively identical Medicare Part D fraud theory, which was pending at the time he filed this suit (and remains pending). As a result, this suit is precluded by the FCA's first-to-file bar. *U.S. ex rel. Wood v. Allergan, Inc.*, 899 F.3d 163, 167 (2d Cir. 2018) ("The command is simple: as long as a first-filed complaint remains pending, no related complaint may be filed." (citation omitted)). Second, the SAC is deficiently pled in its entirety. Among other things, the SAC does not come remotely close to pleading fraud with particularity as required by Rule 9(b). It hypothesizes that the "Manufacturer Defendants" paid service fees to the "Pharmacy Benefit Manager (PBM)

Defendants"[1] that were criminal kickbacks, were not properly reported by Medicare Part D plan sponsors to Medicare, and caused false claims. But Borzilleri admits he lacks any knowledge of the existence or terms of any contract he says included a service-fee provision, has no knowledge of how any service fees were reported by PBMs to the plan sponsors or by the plan sponsors to Medicare, and has no knowledge of any false claims. Such generalized speculation is the antithesis of pleading fraud with particularity. Third, because Borzilleri is not an insider, he derives all of his allegations from the public domain. His allegations amount to nothing more than the notion that undisclosed, excessive service fees between manufacturers and PBMs can lead to an inference of fraud—a notion that the SAC confirms had been publicly disclosed in various qualifying sources before he filed suit, including (among other places) in a report that the Office of the Inspector General (OIG) for the Department of Health and Human Services published entitled "Concerns with Rebates in Medicare Part D." The FCA's public-disclosure bar precludes precisely this type of *qui tam* claim, unless a relator qualifies as an original source. Borzilleri plainly does not.

The SAC should be dismissed in its entirety and without leave to amend. Borzilleri has already repeatedly amended his complaint and has no way to cure basic pleading deficiencies that result from either (1) his admitted lack of actual knowledge of any conduct by any Defendant or (2) the public-disclosure bar. The Manufacturer Defendants incorporate by reference the arguments made in the PBM Defendants' motion to dismiss.

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[1] Relator Borzilleri refers to AbbVie Inc., Amgen Inc., Bristol-Myers Squibb Company, Eli Lilly and Company, Novartis Pharmaceuticals Corporation, Pfizer, Inc., and sanofi-aventis U.S. LLC collectively as the "Manufacturer Defendants," and he refers to Aetna, Inc., Cigna Corporation, CVS Health Corporation, Express Scripts Holding Company, Humana, Inc., and UnitedHealth Group, Inc. collectively as the "Pharmacy Benefit Manager (PBM) Defendants." SAC ¶ 1.

BACKGROUND

Borzilleri filed this *qui tam* action under seal on October 6, 2015. Dkt. 1. After investigating the allegations, the federal government, all state governments, and the District of Columbia declined to intervene, and the complaint was unsealed on April 13, 2018. Dkt. 20, 141. Borzilleri filed a First Amended Complaint on July 4, 2018, Dkt. 58, and he filed the SAC on August 3, 2018. Dkt. 148.

Borzilleri describes himself as a "professional healthcare investment fund manager." SAC ¶ 1. Defendants are pharmaceutical manufacturers, pharmacy benefit managers (PBMs), and private health insurers. While employed at the investment firm Shepherd Kaplan Krochuk, LLC, Borzilleri came to believe that rising drug prices were the result of "a straightforward price collusion scheme between certain pharmaceutical companies" and PBMs. SAC ¶ 11. In an effort to capitalize on his hypothesis, Borzilleri filed two separate FCA lawsuits against pharmaceutical manufacturers and PBMs and then began short-selling the stock of the companies that he had sued. Complaint, *John R. Borzilleri, MD, v. Shepherd Kaplan Krochuk, LLC*, No. 18-cv-04654-RJS (S.D.N.Y. May 25, 2018), Dkt. 1, ¶¶ 24, 29.[2]

A. Borzilleri's Allegations[3]

1. Borzilleri's First *Qui Tam* Lawsuit

In January 2014, Borzilleri filed a *qui tam* complaint in the District of Rhode Island against pharmaceutical manufacturers, PBMs, and health insurers. On May 1, 2014, Borzilleri

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[2] In considering a motion to dismiss, the Court may consider materials referenced in the complaint and matters of public record. *See, e.g.*, *Pani v. Empire Blue Cross Blue Shield*, 152 F.3d 67, 75 (2d Cir. 1998). "[M]atters of public record" that may be considered include "pleadings in another action." *Rahman v. Schriro*, 22 F. Supp. 3d 305, 311 (S.D.N.Y. 2014) citation omitted); *see also In re RadPro SecurPass Scanner Cases*, No. 13-cv-6095-CS, 2014 WL 4054310, at *4 (S.D.N.Y. Aug. 13, 2014).

[3] Borzilleri's well-pleaded factual allegations are assumed to be true solely for purposes of this motion.

filed a first amended complaint in that action, which was the operative complaint pending when Borzilleri filed this lawsuit. *See* Exhibit A, First Amended Complaint, *U.S. ex rel. John R. Borzilleri, M.D. v. Bayer AG, et al.*, No. 14-cv-00031-WES-LDA (D.R.I. May 1, 2014), Dkt. 6 (R.I. FAC). The R.I. FAC was unsealed on April 5, 2018, after the United States declined to intervene. *See* Order, *id.*, Dkt. 36, 37. On August 17, 2018, Borzilleri filed a second amended complaint in the Rhode Island action. *See* Exhibit B, Second Amended Complaint, *id.*, Dkt. 95 (R.I. SAC). The crux of Borzilleri's Rhode Island complaint—just like his complaint in this case—is the contention that pharmaceutical manufacturers paid excessive service fees to PBMs that amounted to criminal kickbacks and were not properly reported by Part D plan sponsors to the Centers for Medicare & Medicaid Services (CMS). *Id.* ¶¶ 14-15, 29, 31, 152-153. The Rhode Island case remains pending.

2. Borzilleri's Second *Qui Tam* Lawsuit

On October 6, 2015, while the United States was still investigating his Rhode Island complaint, Borzilleri filed this action. Dkt. 1. Defendants include eight companies that are also defendants in his Rhode Island suit (Pfizer, Novartis, Express Scripts, CVS, Aetna, UnitedHealth Group, Humana, and Cigna) and five additional companies (AbbVie, Amgen, Bristol-Myers Squibb, Eli Lilly, and sanofi-aventis U.S. LLC). SAC ¶ 1.

The allegations in the N.Y. SAC are nearly identical to those in the Rhode Island action. In fact, hundreds of paragraphs in the two operative complaints are materially identical to one another, the product of copying-and-pasting and only minor editing to reflect different parties or products.[4] In both suits, Borzilleri alleges:

- The *same* purported "kickbacks" and price collusion scheme (manufacturers' payment to PBMs of service fees in excess of fair market value to enable drug price increases);

[4] *Compare generally* R.I. SAC *with* N.Y. SAC.

- through the *same* means ("secretive" Medicare Part D service fee contracts);
- over the *same* period (2006 to present);
- resulting in the *same* false claims (false reports to CMS and false certifications); and
- in violation of the *same* laws (the FCA, the Anti-Kickback Statute, and state false-claims laws).

Compare id. at ¶¶ 28, 169, 170, 806-921 *with* R.I. SAC at ¶¶ 29, 152, 153, 691-806.

The SAC's factual allegations are based overwhelmingly upon publicly available documents and data. Borzilleri relies, for instance, on press releases (¶ 219); SEC filings (¶¶ 220-22, 283, 605, 668-671, 780-804); publicly disclosed PBM contracts (¶¶ 193, 691-700, 704-713); reports and other publications from the OIG (¶¶ 36, 156, 227-228, 340, 344-345, 645, 676-680, 761, 763-765); court filings (¶¶ 90, 301-304, 329-331); congressional documents (¶¶ 407, 755); and widely accessible reports and articles (¶¶ 67, 99-101, 177-213, 498, 616, 658). Borzilleri also describes communications allegedly made at an October 2013 compliance conference. *See id.* at ¶¶ 445-489.

Indeed, as Borzilleri acknowledged in response to a recent suit filed by his now-former employer, "the DOJ indicated that Dr. Borzilleri's investigation and [the] Qui Tam actions were not based upon any 'insider information,' " but rather on "Dr. Borzilleri's extensive proprietary research, based upon public information." Exhibit C, Answer and Counterclaim, *Shepherd Kaplan Krochuk, LLC v. John R. Borzilleri*, No. 18-1418, ¶ 32 (Mass. Super. Ct. May 31, 2018).

Borzilleri's reliance on public information has resulted in a *qui tam* lawsuit that lacks *any* specifics regarding any Defendant's supposed misconduct. For example, Borzilleri argues that the Manufacturer Defendants paid "straightforward 'kickbacks' " to the PBM Defendants. SAC ¶ 169(1)-(2) (emphasis omitted). But he concedes that he does not know the timing or amount of any payment(s) by a Manufacturer Defendant to any PBM Defendant, on what terms any such

payments were made, or even whether any Manufacturer Defendant had a contract that included a service-fee term with any PBM Defendant: "Of note, the individual 'service fee' contracts between the Manufacturer and PBM Defendants remain a closely guarded secret, obtainable by the non-insider Relator only via discovery." *Id.* at ¶ 180 (emphasis omitted); *see also id.* at ¶ 218 (admitting that he lacks information regarding "financial terms and transactions" between pharmaceutical manufacturers and PBMs). Nor does the SAC contain any details regarding any allegedly false report submitted by any Part D plan sponsor to Medicare regarding service-fee payments to PBMs by any Manufacturer Defendant. *See generally* SAC.

B. The Government's Declination and Borzilleri's Short-Selling

On March 8, 2018, the federal government, the named states, and the District of Columbia all declined to intervene in the Rhode Island action. D.R.I. Dkt. 36, 37. Five days later, this Court issued an order stating that the federal government, the named states, and the District of Columbia declined to intervene in this action. Dkt. 19. Borzilleri's complaint in Rhode Island was unsealed on April 5, 2018, and his complaint before this Court was unsealed on April 13, 2018. D.R.I. Dkt. 37; S.D.N.Y. Dkt. 19.

Knowing the unsealing was coming, Borzilleri "significantly increased" his "short positions in the securities of the defendants." Exhibit D, Complaint, *Shepherd Kaplan Krochuk, LLC v. John R. Borzilleri*, No. 18-1418, ¶¶ 35, 52 (Mass. Super. Ct. May 8, 2018); *see also* Answer and Counterclaim, *Shepherd Kaplan Krochuk, LLC v. John R. Borzilleri*, No. 18-1418, ¶ 35. Borzilleri's employer noticed those "unusually large short positions" and "restricted [his] Fund from trading the two largest positions, both of which were securities of defendants" in one or both of the complaints Borzilleri had filed. Complaint, *Shepherd Kaplan Krochuk, LLC v. John R. Borzilleri*, at ¶ 36. In fact, "by April 17, 2018, the seven largest short positions in the Fund were against the securities of the defendants" named in one or both of Borzilleri's

complaints. *Id.* at ¶ 37. On that same day, Borzilleri issued a press release to numerous media outlets and financial institutions, describing his allegations and attaching the two complaints. *Id.* at ¶ 38. After an internal investigation by his employer, Borzilleri was terminated for "aggressive trading during the period in which he knew that information about the [lawsuits] would soon be made available to the public." *Id.* at ¶ 52.

REGULATORY FRAMEWORK

A. The Medicare Part D Program

Medicare is a federal government health insurance program operated by CMS for the elderly and those with certain disabilities. There are four parts to the Medicare program: Parts A through D. 42 U.S.C. § 1395 *et seq*. The SAC concerns only the Medicare Part D program.

Medicare Part D is a prescription drug benefit program that was fully implemented in 2006. Over 40 million Medicare beneficiaries today receive coverage for prescription drugs through a Part D plan. *See* Kaiser Family Foundation, Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing (May 17, 2018).[5] Part D plans are operated by Part D "sponsors," private health insurers that contract with CMS to offer outpatient drug benefits to Medicare beneficiaries. *See* 42 U.S.C. § 1395w-111(b). Part D plan sponsors negotiate drug prices with pharmaceutical manufacturers, establish formularies, and otherwise manage Part D plans, sometimes using the services of PBMs. *See* 42 C.F.R. Part 423.

PBMs may also perform services for drug manufacturers and receive payment for doing so. For instance, as Borzilleri acknowledges, PBMs can be "directly compensated by drug manufacturers via designated 'bona fide service fees[.]' " SAC ¶¶ 13, 155. The Part D regulations define bona fide service fees (BFSFs) as "fees paid by a manufacturer to the entity

[5] Available at http://files.kff.org/attachment/Issue-Brief-Medicare-Part-D-in-2018-The-Latest-on%20Enrollment-Premiums-and-Cost-Sharing.

that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer." 42 C.F.R. § 423.501. The service should be one that the manufacturer would otherwise perform or contract for and that fee must not be "passed on" to the PBM's clients. *Id.*

Under the Part D program, plan sponsors report direct and indirect remuneration (DIR) to CMS, which reduces CMS's payments to plan sponsors. *See* 42 C.F.R. § 423.308. CMS defines DIR as "including discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers." *Id.* BFSFs, however, are excluded from DIR. 42 C.F.R. § 423.514(d)(4) (stating that DIR is to "exclud[e] bona fide services fees").

Part D plan sponsors and PBMs have reporting obligations under Part D. For example, Part D plan sponsors report DIR directly to CMS. *See, e.g.*, Exhibit E, CMS Memo from Cheri Rice to All Part D Plan Sponsors, *Final Medicare Part D DIR Reporting Requirements for 2016* at 1 (June 23, 2017). Similarly, PBMs must provide information to plan sponsors so that plan sponsors can report DIR. 42 C.F.R. § 423.514(d) ("[e]ach entity that provides pharmacy benefits management services" must provide certain information to Part D sponsors); *see also* SAC ¶ 285. After the Part D program was launched, BFSFs were also required to be reported by Part D plan sponsors to CMS. *See, e.g.*, CMS Memo from Cheri Rice, *supra*, at 28-29 (directing plan sponsors to "[i]nclude in this column" of the Summary DIR Report the portions of all fees that meet the definition for "bona fide service fees"). Manufacturers have no reporting obligations for DIR or BFSFs under Part D. *See id.*; *see also* 42 C.F.R. § 423.514.[6]

[6] Borzilleri is legally incorrect in asserting that "service fees" exceeding fair market value must be reported "by the Drug Manufacturer to the plan sponsor in Medicare Part D." SAC ¶ 30; *see also* ¶ 169(5).

The Part D program does not prohibit service fees that exceed fair market value; it only requires that plan sponsors report any amount that exceeds fair market value as DIR. *See, e.g.*, CMS Memo from Cheri Rice, *supra*, at 11, 16, 21. Borzilleri acknowledges that CMS permits payments for service fees under Part D that exceed fair market value. SAC ¶¶ 291, 640.

B. The Federal Anti-Kickback Statute (AKS)

The AKS prohibits the knowing and willful payment, receipt, solicitation, or offer of "remuneration" to induce the purchase or recommendation of "any good, facility, service, or item 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). Congress, however, specifically protected a variety of arrangements under the AKS. For instance, "discounts or other reductions in price," including rebates, are protected under a statutory exception. *Id.* § 1320a-7b(b)(3)(A).

Separately, Congress delegated authority to OIG to create additional safe harbors for various arrangements that might otherwise constitute "remuneration" under the AKS. *Id.* § 1320a-7b(b)(3)(E). One safe harbor created by the OIG protects payments made to Group Purchasing Organizations (GPOs). The OIG has stated, in longstanding guidance, that payments from manufacturers to PBMs can be protected under the GPO safe harbor. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,736 (May 5, 2003) (GPO "rebates and other payments" are afforded "[p]rotection" under the AKS by "structuring such arrangements to fit in the GPO safe harbor at 42 CFR 1001.952(j)."). When this safe harbor applies, percentage-based fees paid by a vendor, such as a pharmaceutical manufacturer, to a GPO are protected. 42 C.F.R. § 1001.952(j)(1). Other safe harbors exist in addition to the GPO safe harbor, and they may be applicable to various PBM-manufacturer relationships. Further, an arrangement need not comply with a safe harbor to be permitted under

the AKS. OIG, *Federal Anti-Kickback Law and Regulatory Safe Harbors, Fact Sheet* (Nov. 1999).[7]

ARGUMENT

I. THE FIRST-TO-FILE BAR MANDATES DISMISSAL OF THIS ACTION.

This case should be dismissed because it mirrors an FCA suit that was pending in the District of Rhode Island when Borzilleri filed the present action. Under the FCA's first-to-file bar, "[w]hen a person brings an action under [the FCA], *no person* other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5) (emphasis added). As the Second Circuit held recently, this bar means that "as long as a first-filed complaint remains pending, no related complaint may be filed." *Wood*, 899 F.3d at 167 (quoting *U.S. ex rel. Batiste v. SLM Corp.*, 659 F.3d 1204, 1210 (D.C. Cir. 2011)). The command is "exception-free," applying even if the same relator brought both actions. *See U.S. ex rel. Kelly v. Novartis Pharm. Corp.*, 827 F.3d 5, 11-12 (1st Cir. 2016) (collecting cases).

The first-to-file rule "furthers the FCA's goal of avoiding piecemeal and duplicative litigation that does not advance the [G]overnment's investigation of alleged fraud." *Id.* at 11; *see also U.S. ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 233-34 (3d Cir. 1998) ("[D]uplicative claims do not help reduce fraud or return funds to the federal fisc, since once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds."). Thus, as the Second Circuit has stated, "[i]f the first-filed complaint ensures that the Government would be equipped to investigate the fraud alleged in the later-filed complaint," then the first-to-file bar applies and the second suit must be dismissed. *Wood*, 899 F.3d at 169 (citation omitted). This Court put it even more succinctly:

[7] Available at https://oig.hhs.gov/fraud/docs/safeharborregulations/safefs.htm.

"notice to the Government is key." *U.S. ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 792 (S.D.N.Y. 2017), *aff'd in part, rev'd in part on other grounds*, 889 F.3d 163 (2d Cir. 2018).

Here, Borzilleri's original complaint, filed on October 6, 2015, duplicated the *qui tam* lawsuit that Borzilleri had filed in Rhode Island nearly two years earlier. *See U.S. ex rel. Borzilleri v. Bayer Healthcare Pharm., Inc.*, No. 14-00031 (D.R.I., filed under seal Jan. 16, 2014). The Rhode Island case—in which the Government also declined to intervene—was "pending" on the day Borzilleri filed this action (and remains pending today). Therefore, his New York suit is barred so long as the two suits are "related." *See* 31 U.S.C. § 3730(b)(5); *Wood*, 899 F.3d at 172 ("[A] claim is barred by the first-to-file bar if at the time the lawsuit was *brought* a related action was pending." (emphasis in original)).

Borzilleri's Rhode Island and New York complaints are clearly "related." To be related for purposes of the first-to-file bar, two suits need not be precisely the same. Rather, two actions are related when "the claims incorporate 'the same material elements of fraud,' " even if the later-filed "allegations [also] incorporate additional or somewhat different facts or information." *Wood*, 899 F.3d at 169 (citation omitted). Applying this test requires nothing more than "a side-by-side comparison" of the two complaints. *Wood*, 246 F. Supp. 3d at 790 (citing *In re Natural Gas Royalties*, 566 F.3d 956, 964 (10th Cir. 2009)); *see also U.S ex rel. Hanks v. U.S. Oncology Specialty, LLP*, No. 08-3096, 2018 WL 4409832, at *19 (E.D.N.Y. Sept. 17, 2018) ("To determine relatedness, the Court compares Relator's original pleading to the pleadings in actions that were pending at the time this action was commenced.").

The overlap between Borzilleri's original New York complaint and the Rhode Island FAC, which was pending when he filed his New York suit, is striking. Both complaints alleged the *same fraud*: "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 [systemic] collusive [price-inflation] scheme in the Medicare Part D program." R.I. FAC ¶ 10; N.Y. Compl. ¶ 2 (alterations appear in N.Y. Compl.). Both complaints alleged the Manufacturer Defendants compensated the PBM Defendants with fraudulent BSFSs based upon "percent of revenue" service contracts. R.I. FAC ¶ 26; N.Y. Compl. ¶ 7. Both complaints alleged the PBM Defendants accepted these BFSFs as "kickbacks" in exchange for favorable formulary placement. R.I. FAC ¶ 167(1); N.Y. Compl. ¶ 10. And both complaints alleged the purported scheme facilitated massive price inflation benefitting the Manufacturer Defendants and PBM Defendants alike. R.I. FAC ¶ 26; N.Y. Compl. ¶¶ 25, 60. Finally, both complaints alleged this "scheme" resulted in the PBM Defendants submitting a "myriad of false claims" to the Government in violation of the FCA and Anti-Kickback Statute. R.I. FAC ¶ 95; NY Compl. ¶¶ 450-51. In short, the two actions "incorporate the same material elements of fraud," and are thus "related" under the FCA. *Wood*, 869 F.3d at 169.

The operative complaints in both actions further confirm Borzilleri has alleged the same material elements of fraud in the two *qui tam* cases. Indeed, the operative Rhode Island and New York complaints frequently use verbatim language, with more than 600 paragraphs essentially copied from the former and pasted into the latter. *Compare* R.I. SAC ¶¶ 15, 29, 81 (alleging payment by pharmaceutical manufacturers of "kickbacks" to the same PBMs in the form of "service fees" that are "often linked to massive drug prices" with "no legitimate 'services' provided by the PBM Defendants and their specialty pharmacy subsidiaries" and that this fraud involved "the Manufacturer and PBM Defendants enter[ing] into an intentional, secretive and fraudulent price inflation scheme, based upon 'service fee' contracts, in gross violation of the [FCA] and the Anti-Kickback Statute (AKS)") *with* N.Y. SAC ¶¶ 14, 28, 79 (same); *compare*

also R.I. SAC ¶¶ 7, 20, 27, 88, 198-99, 205, 302, 443 *with* N.Y. SAC ¶¶ 7, 19, 26, 86, 220-21, 227, 284, 445 (asserting virtually verbatim allegations in both complaints).

Aside from their venues and filing dates, the two cases differ in only two basic respects: they focus on different drugs, and each includes some additional defendants. But neither of these differences can save this case from dismissal under the first-to-file bar.

First, it does not matter that the Rhode Island suit "focuses" on multiple sclerosis ("MS") medications, *see* R.I. FAC ¶ 10, whereas this New York suit mainly focuses on "the next three largest Part D spending categories"—"anti-tumor necrosis factor (TNF) drugs (for rheumatoid arthritis, etc.), chronic myeloid leukemia (CML) oral cancer drugs and diabetes therapies," *see* N.Y. Compl. ¶ 39. Because the two suits allege the same fraudulent scheme, the Government would be "equipped to investigate the fraud alleged in" this action based on the Rhode Island action. *Wood*, 899 F.3d at 169.

This Court's and the Second Circuit's opinions in *Wood* are controlling on this score. In *Wood*, the relator alleged Allergan paid "kickbacks" in the form of "surgical care kits" to induce physicians to prescribe three Allergan drugs to treat cataract patients. *Wood*, 246 F. Supp. 3d at 792. When the *Wood* relator filed his complaint, there was an already-pending *qui tam* action that alleged a similar scheme by Allergan—but that scheme involved only a single Allergan drug used to treat conjunctivitis. *Id*. at 788, 792. The *Wood* relator claimed his complaint's "additional drugs" precluded a first-to-file dismissal because the prior action was not "related." *Id*. at 792. This Court rightly disagreed—finding the second action's different drugs to be "of no moment"—because the two complaints otherwise "were based on the same essential facts and involved the same elements of fraud." *Id*. at 790, 792. The Second Circuit affirmed this Court's ruling, finding both complaints alleged "very similar kickback schemes" even though different

drugs were involved. *See Wood*, 899 F.3d at 169 (holding the first-to-file bar applied because both cases "allege a scheme where Allergan provided free cataract surgery recovery kits to induce increased use of Allergan products").

This action fails for the same reason. Borzilleri's Rhode Island and New York complaints may focus on different drugs, but both actions allege the same scheme with the same elements: (1) "kickbacks" in the form of "service fees" exceeding FMV; (2) paid to an identical list of PBMs and payors, and paid by two of the same manufacturers; (3) to advance a "fraudulent price inflation scheme"; (4) causing the submission of false claims under Medicare Part D. And though the Rhode Island action focuses on MS medications, there Borzilleri *explicitly alleged* that the same "fraudulent practice is occurring *in other drug therapeutic categories* in Medicare Part D as well, including treatments for *cancer, diabetes and inflammatory conditions (rheumatoid arthritis, psoriasis, etc.).*" R.I. FAC ¶ 10 (emphasis added); *see also id.* at ¶ 285 (alleging "anticompetitive behavior in other specialty drug therapeutic categories, including . . . rheumatoid arthritis, diabetes and cancer").

These "other drug therapeutic categories" identified in Rhode Island are the focus of the New York action. N.Y. Compl. ¶ 39. In other words, Borzilleri's Rhode Island complaint notified the Government that it should investigate the very "scheme" Borzilleri subsequently made the focus of his New York *qui tam* lawsuit. Indeed, the Rhode Island FAC references repeatedly the drugs at issue in the New York case. *See, e.g.*, *id.* Exhibit 26 (listing drugs and therapeutic categories targeted in second-filed action), Exhibit 28 (identifying Enbrel and Gleevec); Exhibit 34 (identifying Enbrel, Humira, and Gleevec), Exhibit 49 (discussing products manufactured by Novartis, BMS, and Pfizer), Exhibit 50 (listing drugs in therapeutic categories targeted in second-filed action), Exhibit 56 (discussing Enbrel, Humira, Gleevec, Sprycel,

Simponi, Tasigna, Cimzia, among others). There can thus be no question the first-filed Rhode Island action equipped the Government to investigate the fraud later alleged in Borzilleri's New York *qui tam* action. *Wood*, 899 F.3d at 169.

Second, for similar reasons, the addition of new defendants to this case cannot save the action from dismissal under the first-to-file bar. Eight of this suit's thirteen Defendants—all six PBM Defendants and two of the Manufacturer Defendants (Novartis and Pfizer)—are named as defendants in the Rhode Island action. The remaining five Manufacturer Defendants are named as defendants in this action only. Under the first-to-file bar, however, "the fact that the later action names different or additional defendants is not dispositive as long as the two complaints identify the same general fraudulent scheme." *U.S. ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 503, 517 (6th Cir. 2009). Thus, courts applying the first-to-file bar—including the first court to apply the Second Circuit's decision in *Wood*—find regularly that two actions are related, despite different defendants, so long as the two complaints allege "the same material elements of fraud." *See Hanks*, 2018 WL 4409832, at *19 (applying *Wood* and holding it is "irrelevant to the first-to-file analysis" that an earlier-filed action named "only one" of the defendants named in a later-filed action); *U.S. ex rel. Denis v. Medco Health Sols., Inc.*, No. 11-684-RGA, 2017 WL 63006, at *10 (D. Del. Jan. 5, 2017) ("[c]ourts will find that two actions are related, despite different defendants," when the first-filed complaint equipped the government to discover the "fraud alleged in the second-filed complaint, including the identity of the new defendants"); *U.S. ex rel. Szymoniak v. ACE Secs. Corp.*, No. 13-cv-464, 2014 WL 1910876, at *5 (D.S.C. May 12, 2014) (dismissing second-filed suit naming sixteen defendants not named in earlier action because of first-filed suit's "significant overlap and allegations of industry-wide fraud," which made the government "aware of the essential or material facts of the scheme" and "put the government on

notice to investigate the fraudulent scheme alleged" in the second suit); *U.S. ex rel. Bane v. Life Care Diagnostics*, No. 06-cv-467, 2008 WL 4853599, at *7 (M.D. Fla. Nov. 10, 2008) (dismissing second-filed suit against defendant identified in first-filed suit's complaint as having "engaged in false or fraudulent Medicare billing" though not named as a defendant in the first suit); *U.S. ex rel. Wilson v. Emergency Med. Assocs. of Ill., Inc.*, No. 01 C 4558, 2000 WL 34026709, at *2 (N.D. Ill. Sept. 24, 2000) (dismissing second-filed suit that "name[d] additional parties involved in the alleged billing scheme" where "claims arise out of the same underlying facts" alleged in first-filed suit).

This standard is easily met here. The Rhode Island action explicitly alleged an industry-wide scheme in which fraud was ongoing with MS treatments and in "drug therapeutic categories" raised in this action. R.I. FAC ¶ 10. And the Rhode Island action even described the drugs and expressly identified the manufacturers named in this action. *Id.* at ¶¶ 10, 209, 232-36 (describing conference allegedly offering "definitive confirmation of the scheme" attended by, among others, Amgen, AbbVie, BMS, Pfizer, and Sanofi), 272-73 (describing founding of the scheme and identifying, among others, defendants BMS and Eli Lilly), 285 (alleging "uncompetitive behavior" in "treatments for . . . rheumatoid arthritis, diabetes and cancer" and specifically implicating BMS, Novartis, and Pfizer), and Exhibits 26 (identifying Amgen, AbbVie, Novartis, and BMS), 28 (identifying Amgen and Novartis), 34 (identifying Amgen, AbbVie, and Novartis), 49 (identifying Novartis, BMS, and Pfizer). The products at issue here are, according to Borzilleri, the top spending drugs in Medicare Part D in the "other drug therapeutic categories" that he identified in Rhode Island. NY Compl. ¶ 39; N.Y. SAC ¶ 375.

For all of these reasons, the present action is "related" to the earlier-filed and still-pending Rhode Island action and, under the FCA's first-to-file bar, Borzilleri's New York

lawsuit was "incurably flawed from the moment he filed it." *Wood*, 899 F.3d at 171 (quoting *U.S. ex rel. Shea v. Cellco P'ship*, 863 F.3d 923, 930 (D.C. Cir. 2017)). Accordingly, the FCA "require[s], in express terms, the dismissal of [Borzilleri's] action." *Id.* (quoting *State Farm Fire & Cas. Co. v. U.S. ex rel. Rigsby*, 137 S. Ct. 436, 442-43 (2016)).

Finally, Borzilleri seeks recovery in the New York action under the FCA analogues of numerous States and the District of Columbia, just as he did in the Rhode Island action. *Compare* N.Y. Compl. Counts 5-34 *with* R.I. FAC Counts 5-34. These Counts fail here for the same reasons as his federal causes of action, because each State has its own first-to-file provision materially identical to the federal first-to-file bar.[8]

II. THE SAC IS DEFICIENTLY PLED UNDER RULES 9(b) AND 12(b)(6).

The SAC also is subject to dismissal for an assortment of pleading deficiencies. An FCA complaint must satisfy both Rule 9(b)'s heightened pleading standard and Rule 12(b)(6)'s plausibility pleading standard. To meet the plausibility standard, a complaint's well-pled factual content must "allow[ ] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Claims that do not cross the line "from conceivable to plausible" must be dismissed. *Id.* To satisfy Rule 9(b)'s heightened pleading standard, a complaint must "(1) specify the statements that the plaintiff

[8] Cal. Gov't Code § 12652(c)(10); Colo. Rev. Stat. § 25.5-4-306(2)(e); Conn. Gen. Stat. § 4-277(d); D.C. Code § 2-381.03(b)(6); Del. Code Ann. tit. 6, § 1203(b)(5); Fla. Stat. § 68.083(7); Ga. Code § 49-4-168.2(c)(6); Haw. Rev. Stat. § 661-25(e); 740 Ill. Comp. Stat. § 175/4(b)(5); Ind. Code § 5-11-5.5-4(g); Iowa Code § 685.3(2)(e); La. Stat. Ann. § 46:439.2(A)(3); Md. Code Ann., Gen. Provis. § 8-104(a)(8); Mass. Gen. Laws ch. 12, § 5C(6); Mich. Comp. Laws § 400.610a(4); Minn. Stat. § 15C.05(b); Mont. Code Ann. § 17-8-406(7); N.H. Rev. Stat. Ann. § 167:61-c(II)(b); Nev. Rev. Stat. § 357.080(2); N.J. Stat. Ann. § 2A:32C-5(i); N.M. Stat. Ann. § 44-9-5(E); N.Y. State Fin. Law § 190(4); N.C. Gen. Stat. § 1-608(4); Okla. Stat. tit. 63, § 5053.2(5); 9 R.I. Gen. Laws § 9-1.1-4(b)(5); Tenn. Code Ann. § 71-5-183(b)(5); Tex. Hum. Res. Code Ann. § 36.106; Va. Code Ann. § 8.01-216.5(E); Wash. Rev. Code § 74.66.050(5); Wis. Stat. § 20.931(5)(e) (repealed July 13, 2015).

contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *U.S. ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 25 (2d Cir. 2016) (internal quotation marks omitted). "In other words, Rule 9(b) requires that a plaintiff set forth the who, what, when, where and how of the alleged fraud." *U.S. ex rel. Polansky v. Pfizer, Inc.*, No. 04-CV-704 (ERK), 2009 WL 1456582, at *4 (E.D.N.Y. May 22, 2009) (internal quotation marks omitted).

Rule 9(b)'s heightened pleading standard applies both to allegations about the underlying fraud scheme and to allegations that false claims were submitted to CMS. *U.S. ex rel. Chorches for Bankr. Estate of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 83 (2d Cir. 2017). A relator can satisfy this standard by alleging personal knowledge of specific false claims or by making "plausible allegations creating a strong inference that specific false claims were submitted to the government" and "pleading that the particulars of those claims were peculiarly within the opposing party's knowledge." *Id.* at 86. But a relator cannot satisfy Rule 9(b) by "bas[ing] claims of fraud on speculation and conclusory allegations." *Id.* (internal quotation marks omitted); *see also Ladas*, 824 F.3d at 26-27 ("hypotheses," "conclusory statements," and assertions "not supported by particularized allegations of fact" did not satisfy Rule 9(b)); *U.S. ex rel. Tessler v. City of New York*, 712 F. App'x 27, 30 (2d Cir. 2017) (affirming dismissal where relator's complaint "alleges only 'hypotheses' and conclusory allegations").

A. Borzilleri's Allegations Regarding A "Service Fee" Scheme Fail To Plead Fraud With Particularity.

Borzilleri alleges a scheme in which the Manufacturer Defendants contractually agreed to pay a percentage of their drugs' list price as "service fees" to the PBM Defendants. SAC ¶ 26. He claims that at least a portion of the service fees are not BFSFs within the meaning of Part D because as the drugs' prices increased over time, the percentage-based service fees exceeded the

fair market value of any services being provided by the PBM. *See generally* SAC ¶¶ 34-46. Plan sponsors must report to CMS any portion of service fees paid by manufacturers to PBMs that exceed fair market value, *see supra* 8-9, which, according to Borzilleri, did not occur. SAC ¶ 30. His theory is that Medicare Part D plan sponsors' misreporting of service fees affected the amount that CMS paid plan sponsors, making plan sponsors' requests to CMS for payment "false claims" within the meaning of the FCA.

Borzilleri's service-fee FCA theory does not satisfy the standard articulated in *Chorches*. Because Borzilleri has no "personal knowledge" of anything in the SAC, let alone any "specific claims," he must rely on the second prong of *Chorches*. That requires pleading both "plausible allegations creating a strong inference that specific false claims were submitted to the government" and "plead[ing] that the particulars of those claims were peculiarly within the opposing party's knowledge." 865 F.3d at 86. But he cannot satisfy that prong either. His generalized allegations—which are conjecture based on information in the public domain—do not plausibly implicate any Manufacturer Defendant in fraudulent conduct, are often contradicted or unsupported by the sources he cites, and do not create a strong inference that specific false claims were submitted to CMS. Moreover, he has not pled that the particulars of any claims he says are false are "peculiarly within" any Manufacturer Defendant's knowledge, which is unsurprising given that manufacturers submit neither claims nor DIR reports.

1. Borzilleri pleads no details of any fraudulent service fee paid by any Manufacturer Defendant or any fraudulent claim.

Borzilleri does not identify the amount of any service fee paid by any Manufacturer Defendant to any PBM, or the terms of any contract by which any such payment was made. The SAC does not specify whether any PBM reported the unidentified payment (or any portion of the payment) to the plan sponsor, or whether the plan sponsor then reported the amount to CMS in a

DIR report. And it does not allege any details about any claims for payment from CMS that were affected by any misstated DIR reporting. Without these missing details, there is no plausible basis to conclude—let alone find a strong inference—that any Manufacturer Defendant paid fraudulent service fees that caused the submission of any false claims.

The SAC pleads a daisy chain of hypotheses, and nothing more. Because the prices of certain drugs have increased over time, Borzilleri believes that the Manufacturer Defendants *must have* entered into secret contracts with PBMs to pay service fees that exceed fair market value for any services, which *must have* led to above-fair-market-value service fees, which a PBM *must not have* reported as a price concession to the plan sponsor, which the plan sponsor *must not have* reported as a price concession in its DIR reports. But that is all speculation. He does not claim to know (1) how any such contract was negotiated, (2) the scope, methodology, or amount of any service-fee term, (3) whether the contract required that service fees be treated as price concessions, (4) when any contract took effect, or (5) how any service fees changed over time. He admits that he is guessing at every turn. *See* SAC ¶ 180 ("the individual 'service fee' contracts between the Manufacturer and the PBM Defendants remain a closely guarded secret") (emphasis omitted); *see also id.* at ¶¶ 241, 306.[9]

Because the SAC lacks any of these details, it does not plead with particularity that any Manufacturer Defendant paid any PBM a service fee that should have been, but was not,

[9] Borzilleri also makes passing reference to the service fees being criminal kickbacks paid to the PBMs in exchange for "formulary access" and the PBMs' agreement to forego "standard cost-savings practices that would lead to far lower Defendant drug prices." SAC ¶¶ 79, 169(2). He offers nothing beyond a couple speculative suggestions, and he never identifies any supposed payment for formulary access by any Manufacturer Defendant to any PBM or any circumstances that indicate that the payment was intended as an inducement for formulary access or to avoid cost-saving measures. A generalized assertion that the Manufacturer Defendants paid unlawful kickbacks for formulary access falls woefully short of Rule 9(b). *Polansky*, 2009 WL 1456582, at *4 ("Rule 9(b) requires that a plaintiff set forth the who, what, when, where and how of the alleged fraud.") (citation omitted).

reported in part or whole as a price concession by plan sponsors. *See U.S. ex rel. Mooney v. Americare, Inc.*, No. 06-CV-1806 FB VVP, 2013 WL 1346022, at *4 (E.D.N.Y. Apr. 3, 2013) (FCA claim failed where it did not identify "specific payers or recipients" of alleged kickbacks and vaguely referred to participants in alleged scheme without "identify[ing] what specific roles they played or what false claims they submitted"). Borzilleri admits that whether a manufacturer pays a service fee to a PBM for a given drug—and if so, whether the fee is a percentage of the list price or something else—"depend[s] upon specific contractual terms" of contracts that he has never seen and is speculating exist. SAC ¶¶ 242-43; *see also id.* at ¶ 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"). Borzilleri knows nothing about the Manufacturer Defendants' actual contracts with PBMs.

Nor does he know anything about any plan sponsor's DIR reporting. The SAC never alleges with particularity (or even plausibility) that any plan sponsor improperly characterized a service fee in its DIR reports. Borzilleri does not claim to know who prepared or submitted any DIR report, what service-fee price concessions were or should have been included in any report, how any reported amount was calculated, why any calculation was improper, or whether any Manufacturer Defendant had any knowledge of what DIR was reported. These are gaping holes in his theory. *See id.* at ¶ 30. As the SAC acknowledges, manufacturers can lawfully pay PBMs service fees that exceed fair market value; the amount that exceeds fair market value is simply reported to CMS as DIR by the plan sponsor and used by CMS in determining a Part D plan's drug costs. *See, e.g., id.* at ¶ 290; *see also* CMS Memo from Cheri Rice, *supra*, at 6 ("Administrative fees charged to manufacturers must be reported as DIR only to the extent that they exceed fair market value or if they do not qualify as bona fide service fees."). The OIG

report that Borzilleri cites (SAC ¶ 227) makes this same basic point: only service fees that qualify as BFSFs need not be reported. *See* OIG, *Concerns with Rebates in the Medicare Part D Program*, OEI-02-08-0050 at 4 & n.16 (Mar. 2011) (2011 OIG Report).[10] And the OIG report specifically notes that some plan sponsors report service fees as DIR. *Id.* at 19, 21.

Knowing nothing about any DIR reporting, Borzilleri unsurprisingly offers no details of any false claims for payment by a plan sponsor. Instead, he just asserts that there has been "staggering" harm to the public fisc and offers his guess, without any factual support, that "30%" of the sales of the Manufacturer Defendant's products is "attributable to the Part D program." SAC ¶¶ 32, 92.

Borzilleri believes that he can use discovery to fill in all these holes: to obtain contracts from the Defendants, to analyze financial transactions between the parties, to determine the propriety of DIR reporting by plan sponsors, and to find false claims. *E.g.*, *id.* at ¶¶ 122, 218, 433, 720. He is wrong. As the Second Circuit has long emphasized, Rule 9(b) requires a plaintiff to have a particularized basis to allege fraud *before* filing suit. *See Madonna v. United States*, 878 F.2d 62, 66 (2d Cir. 1989) ("One of the purposes of Rule 9(b) is to discourage the filing of complaints as a pretext for discovery of unknown wrongs." (internal quotation marks omitted)). Borzilleri, however, can offer nothing but his conjecture that a contract *might* exist between some Manufacturer Defendant and some PBM Defendant, that under this hypothetical contract some service fee *may* have been paid, that the hypothetical service fee *may* have exceeded the fair market value for the services provided, that the hypothetical amount over fair market value *may* not have been reported to CMS as DIR, and that false claims *may* exist. That is a far cry from the particularity necessary to satisfy Rule 9(b). *Ladas*, 824 F.3d at 26-27;

[10] Available at https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf.

Tessler, 712 F. App'x at 30.

2. Nothing alleged in the SAC overcomes Borzilleri's lack of knowledge of any fraudulent service fee paid by any Manufacturer Defendant.

Given his admitted lack of knowledge of any actual service-fee payment made by any Manufacturer Defendant and any DIR report submitted by any plan sponsor, Borzilleri spends the bulk of the SAC on two subjects: (1) allegations about the price and usage of drugs, total sales figures, and whether competitor products are available; and (2) Borzilleri's basis for his speculation that service-fee fraud is occurring. He then offers a group indictment of the Manufacturer Defendants and the PBM Defendants. None of this pleads fraud with particularity.

a. The SAC's few allegations about individual Manufacturer Defendants relay pricing, sales, and usage data, but do not allege fraud.

The SAC's allegations that relate to the individual Manufacturer Defendants are small in number and narrow in scope. For each of the fourteen drugs at issue, Borzilleri alleges (at length) that the drug's list price, revenues, and profits have increased over time. For some of the drugs, he alleges that usage has gone down over time and constructs charts depicting how (according to him) the total dollar value of sales for those drugs would have been lower without price increases. For others, he alleges that usage has gone up over time. Finally, for some of the drugs, he makes allegations about other available drugs in the same drug class and market share.

These allegations have one thing in common: they say nothing about any supposedly fraudulent service fee paid by any Manufacturer Defendant or any allegedly false claims submitted to Part D. They thus do not help Borzilleri satisfy Rule 9(b).

b. The SAC's "sources" contradict its allegations, do not ascribe conduct to any Manufacturer Defendant, or both.

Nor can Borzilleri meet Rule 9(b)'s requirements by virtue of the "sources" underlying his allegations. None of these sources comes close to pleading with particularity any fraudulent

service fee paid by any Manufacturer Defendant or any resulting false claim for any drug.

For starters, the SAC repeatedly claims that an "incriminating" (¶¶ 67, 178) report published by PhRMA "discloses" that drug manufacturers pay PBMs a "standard," "typical," or "average" service fee of 8% of a "specialty" drug's list price and 4% of a "traditional" drug's list price. SAC ¶¶ 67, 70, 95, 109, 179, 182-83, 190, 271, 389. Far from being "incriminating," this report (attached as Exhibit F) directly contradicts Borzilleri's position that it "disclosed average contract terms for 'service fees.' " *Id.* at ¶ 179 (emphasis omitted). The report describes complexities in the drug distribution and payment system and emphasizes that "*[b]ecause payment terms are determined through confidential, private negotiations, the terms of individual contracts are highly variable*[.]" PhRMA Report at 2 (emphasis added); *see also id.* at 1, 9. While the report offers "illustrative examples" depicting what three patients might pay for a drug under different cost-sharing mechanisms (copayment, deductible, and coinsurance), the report says nothing about standard, typical, or average levels of service fees in Part D contracts. *Id.* at 10-15. And the report certainly does not mention any conduct by any Manufacturer Defendant. The report thus contradicts Borzilleri's claim that it provides a basis to infer a standard service fee across manufacturers and contracts. "If a document relied on in the complaint contradicts allegations in the complaint, the document, not the allegations, control, and the court need not accept the allegations in the complaint as true." *TufAmerica, Inc. v. Diamond*, 968 F. Supp. 2d 588, 592 (S.D.N.Y. 2013); *see also Roth v. Jennings*, 489 F.3d 499, 511 (2d Cir. 2007) ("the contents of the document are controlling where a plaintiff has alleged that the document contains, or does not contain, certain statements"); *Equinox Gallery Ltd. v. Dorfman*, 306 F. Supp. 3d 560, 576 (S.D.N.Y. 2018) (similar); *Poindexter v. EMI Record Grp. Inc.*, No. 11 CIV. 559 LTS JLC, 2012 WL 1027639, at *2 (S.D.N.Y. Mar. 27, 2012) (similar). Because the

PhRMA report contradicts the SAC's characterization of it, those allegations cannot help Borzilleri survive dismissal.[11]

Borzilleri relies on a second document that he describes as "definitively incriminat[ing] both Defendant parties in the 'service fee' scheme." SAC ¶ 199. This document, a report prepared for the Pharmaceutical Care Management Association (PCMA) and attached as Exhibit G, also does not help him establish an inference of fraudulent service fees paid by any Manufacturer Defendant. The document is limited to discussing rebates and price increases; it contains no discussion—none—of service fees, much less any fraudulent service fees. It therefore provides no support for an allegation that any Manufacturer Defendant violated the FCA through service-fee payments.

The remaining sources of "information" on which Borzilleri's speculative theory is based are just as unhelpful to him. He claims to rely on consultants who he alleges told him "that they had never seen or reviewed a single 'service fee' contract between a PBM and a drug manufacturer." SAC ¶ 192. As a result, those consultants plainly have not seen or reviewed any service-fee contract that Borzilleri theorizes might exist for the drugs at issue. Similarly, Borzilleri's alleged discussion with the CEO of a company *not named as a defendant* (*id.* at ¶¶ 448-49) does nothing to make plausible Borzilleri's speculative theory that each Manufacturer Defendant paid kickbacks in the form of service fees or caused false claims. Nor does his description of a conference in which there was general discussion about service fees and various fair market valuation methodologies (*id.* at ¶¶ 452-89) provide an indication that any manufacturer generally, or any Manufacturer Defendant specifically, was paying Part D service

[11] All of the SAC's allegations that purport to identify a specific service-fee amount for a drug are calculated by Borzilleri multiplying the drug's publicly available list price by his made-up "standard" 4 and 8 percent service fee. *E.g.*, SAC ¶¶ 250, 259. Thus none of those allegations help Borzilleri either.

fees that were improperly reported in a plan sponsor's DIR reports. Certainly nothing about this conference indicates any Manufacturer Defendant participated in a price collusion scheme designed to cheat Medicare. And finally, the handful of contracts between PBMs and employers providing employees insurance that the SAC references (*id.* at ¶¶ 689-713) also provide no information from which the Court could infer that any Manufacturer Defendant paid fraudulent service fees. That leaves Borzilleri with just his own self-serving speculation and conclusions.

c. Group pleading does not satisfy Rule 9(b).

Lacking specific facts and relying on "sources" that contradict or are silent on any Manufacturer Defendant's conduct, the SAC attempts to rely on group pleading. Many of the SAC's allegations refer only to the "Manufacturer Defendants"—seven separate companies—and "PBM Defendants"—six separate companies. Using those terms, the SAC then makes the sweeping allegation that drug manufacturers and PBMs have defrauded the government through percent-of-list-price service fees that are not reported as price concessions on DIR reports. *E.g.*, SAC ¶ 35 ("The fraudulent Manufacturer Defendant 'service fee' payments to the PBM Defendants are standardly calculated via secretive 'percent of revenue' contracts[.]"). Such group pleading fails to satisfy Rule 9(b)'s heightened pleading standard. As this Court recently held, a complaint that "lumps all Defendants together" and identifies "no specific statements" and "no specific speakers" is "plainly insufficient to satisfy Rule 9(b)'s heightened pleading requirements." *City of Perry, Iowa v. Procter & Gamble Co.*, 188 F. Supp. 3d 276, 290 (S.D.N.Y. 2016); *see also, e.g.*, *U.S. ex rel. Grubea v. Rosicki, Rosicki & Assocs., P.C.*, 318 F. Supp. 3d 680, 696 (S.D.N.Y. 2018) (complaint insufficient under Rule 9(b) "where it alleges 'nothing at all' with respect to how each individual defendant 'did or did not perform' its obligations " (citation omitted)); *Lankau v. Luxoft Holding, Inc.*, 266 F. Supp. 3d 666, 674

(S.D.N.Y. 2017) ("Rule 9(b) prohibits 'lump[ing]' separate defendants together in vague and collective fraud allegations" and requires "inform[ing] each defendant of the nature of his alleged participation in the fraud' " (citation omitted)).

Each Manufacturer Defendant is entitled to know—specifically—the PBM(s) with which it is being accused of committing service-fee fraud, during what time period, and with what supposedly improper service-fee terms. Courts have repeatedly made clear that fraud claims against multiple defendants must separately set forth each defendant's allegedly fraudulent acts. *See, e.g.*, *Aronov v. Mersini*, No. 14-CV-7998 PKC, 2015 WL 1780164, at *4 (S.D.N.Y. Apr. 20, 2015); *United States v. N.Y. Soc. 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); *Bruno v. Zimmer, Inc.*, No. CV156129LDWAKT, 2017 WL 8793242, at *7 (E.D.N.Y. Aug. 11, 2017). That requirement aligns with Rule 9(b)'s purposes, which are "to provide a defendant with fair notice of a plaintiff's claim, to safeguard a defendant's reputation from improvident charges of wrongdoing, and to protect a defendant against the institution of a strike suit." *Ladas*, 824 F.3d at 25 (internal quotation marks omitted).

The SAC's group pleading contravenes each of these purposes. The SAC generically hypothesizes that Part D plan sponsors *could* have failed to report service fees as price concessions on DIR reports when those amounts should have been reported. It makes no specific allegation that such misreporting occurred or that any of the Manufacturer Defendants knew about and played a role in it. Just the opposite: the SAC repeatedly acknowledges that Borzilleri cannot offer individualized allegations absent discovery. *E.g.*, SAC ¶ 180 (Borzilleri has no knowledge of individual contracts absent discovery), ¶ 296 (Borzilleri needs to obtain and review "all financial transactions between the Manufacturer Defendants and a given PBM Defendant for

a particular drug product, at the corporate level" to make individualized allegations); ¶ 720 (Borzilleri needs discovery to learn what support services, if any, are being provided for any specific drug under any contract). Borzilleri's reliance on group pleading renders the SAC deficient—and subject to dismissal—under Rule 9(b).

3. Borzilleri fails to plead scienter.

The SAC also fails to state an FCA claim because it does not sufficiently plead any Manufacturer Defendant's conduct satisfied the FCA's "knowing" scienter requirement. That requirement is "rigorous," *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, --- U.S. ---, 136 S. Ct. 1989, 2002 (2016), and it is not met here. Even indulging Borzilleri's speculation that a Part D plan sponsor submitted a DIR report that failed to correctly characterize service fees, Borzilleri does not allege any facts demonstrating that any Manufacturer Defendant knew or should have known of such misreporting. Although "Rule 9(b) allows a plaintiff to allege intent 'generally' rather than 'with particularity,' " it is not "a license to base claims of fraud on speculation and conclusory allegations." *Sanchez v. ASA Coll., Inc.*, No. 14-CV-5006 JMF, 2015 WL 3540836, at *7 (S.D.N.Y. June 5, 2015) (citations omitted). A relator still must plead facts plausibly demonstrating the scienter element of an FCA violation. Because the SAC fails to do so, dismissal is warranted. *See Grubea*, 318 F. Supp. 3d at 694-95 (dismissing FCA claims against certain defendants for failure to plead scienter where relator had no information about whether other parties actually passed charges on to the government, and if they did, whether they did so recklessly).

B. Borzilleri's Remaining Theories Are Deficiently Pled.

1. No FCA conspiracy is plausibly pled.

Borzilleri also attempts to plead an FCA conspiracy. Like other FCA liability theories, "[c]onspiracy claims under the FCA must be pleaded with particularity under Rule 9(b)." *N.Y.*

Soc. for the Relief of the Ruptured & Crippled, 2014 WL 3905742, at *25. The SAC flunks this requirement because it offers no particularized allegations of a conspiracy to defraud the government. *Id.* Even under Rule 12(b)(6), the conspiracy claim fails because Borzilleri has not plausibly alleged facts showing an unlawful agreement between any Manufacturer Defendant and any PBM Defendant or any overt act taken pursuant to that agreement. *See U.S. ex rel. Scharff v. Camelot Counseling*, No. 13-cv-3791 (PKC), 2016 WL 5416494, at *9 (S.D.N.Y. Sept. 28, 2016); *U.S. ex rel. Sterling v. Health Ins. Plan of Greater N.Y., Inc.*, No. 06-cv-1141 (PAC), 2008 WL 4449448, at *4 (S.D.N.Y. Sept. 30, 2008).

Borzilleri instead vaguely claims "collusion" exists and offers the entirely conclusory statement that Defendants conspired "to defraud the United States by inducing the United States to pay and/or approve false and fraudulent claims" and "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. The SAC never details any Defendant's entry into an agreement to violate the FCA—*when* the agreement occurred, *who* was involved, *how* it originated, and *what* the details of it were—or what overt acts in furtherance of the agreement followed. *See U.S. ex rel. Capella v. Norden Systems, Inc.*, No. 94 Civ. 2063, 2000 WL 1336487, at *11 (D. Conn. Aug. 24, 2000) (dismissing complaint that "merely alludes to an agreement between Defendants and does not specify . . . what act was committed in furtherance of the conspiracy"). As a result, his FCA conspiracy claim should be dismissed. *See Sterling*, 2008 WL 4449448, at *4 (general allegation of FCA conspiracy is "the type of conclusory allegation that Rule 9(b) was intended to prevent"); *N.Y. Soc. for the Relief of the Ruptured & Crippled*, 2014 WL 3905742, at *25 (FCA conspiracy claim fails where complaint "does not identify the purported roles of the three defendants" and

offers only a "generalized allegation that they entered 'into one or more conspiracies' "); *Morgan ex rel. U.S. v. Sci. Applications Int'l Corp.*, No. 07 CV 4612, 2008 WL 2566747, at *6 (S.D.N.Y. June 26, 2008) (dismissing FCA conspiracy claim).

2. The SAC lacks facts showing that any Manufacturer Defendant waived catastrophic cost-sharing.

Borzilleri accuses drug manufacturers of "routinely 'forgiving' " a cost-sharing obligation that is triggered for Part D plan sponsors when a participant's drug costs exceed a threshold amount. SAC ¶ 33, *see also, e.g., id.* at ¶¶ 347, 399. Borzilleri concludes that because drug prices have gone up over the past decade, the Manufacturer Defendants must be forgiving this cost-sharing obligation "to further the 'service fee' pricing scheme." *Id.* at ¶ 352.

Borzilleri pleads no details of any Manufacturer Defendant waiving any cost-sharing obligation of any Part D plan sponsor. He appears to theorize that there is the "potential" for abuse because sometimes a PBM Defendant is also a plan sponsor (*id.* at ¶¶ 353, 401), but this theory relies entirely on improper group pleading. *See supra* at 26-28. And his unsubstantiated conjecture that there can be no other explanation for PBMs having avoided "havoc" from increased catastrophic cost-sharing obligations, SAC ¶ 416, is insufficient by leaps and bounds to plausibly plead a strong inference of specific false claims. *See De Jesus v. Sears, Roebuck & Co., Inc.*, 87 F.3d 65, 70 (2d Cir. 1996) (allegations "devoid of any specific facts or circumstances" and that consist "of conclusory allegations unsupported by factual assertions" cannot survive a motion to dismiss) (citation and emphasis omitted). Finally, even if Borzilleri's allegations did not fall woefully short of satisfying Rule 9(b), his cost-sharing-waiver theory would still fail because he does not come close to alleging how a waiver of a plan's cost-sharing obligations ties into a Part D claim for payment and could render it false.

3. To the extent Borzilleri is asserting a false-certification theory against the Manufacturer Defendants, it is deficiently pled.

Borzilleri vaguely alludes to the Manufacturer Defendants being liable because of an "express certification requirement[ ]." SAC ¶ 169(8) (emphasis omitted). Borzilleri provides no additional details, and any such theory should be dismissed. " 'Express' legal falsity generally arises where 'a government program requires participants to submit forms explicitly stating that they have complied with certain statutes,' " *Wood*, 246 F. Supp. 3d at 810 (internal citations omitted), and "the defendant explicitly misstates compliance" with those statutes. *N.Y. Soc. for the Relief of the Ruptured & Crippled*, 2014 WL 3905742, at *17. Borzilleri has not pointed to any express certification that the Manufacturer Defendants made to the government relating to service fees or data submission and has not specified any document or submission supposedly containing a misstatement. *See United States v. TEVA Pharm. USA, Inc.*, No. 13 CIV. 3702 (CM), 2016 WL 750720, at *27 (S.D.N.Y. Feb. 22, 2016) ("conclusory allegations" do not state a claim premised on express certification; a relator "must identify the express certification").

4. The SAC's "reverse false claims" theory lacks a factual predicate.

Count 3 asserts a claim under the FCA's "reverse false claims" provision, 31 U.S.C. § 3729(a)(7) (now 31 U.S.C. § 3729(a)(1)(G)). Liability under this provision "must be premised on a 'false statement[ ] designed to conceal, reduce, or avoid an obligation to pay money or property to the Government.' " *Wood*, 246 F. Supp. 3d at 826 (citing *Wood ex rel. U.S. v. Applied Research Assocs., Inc.*, 328 F. App'x 744, 748 (2d Cir. 2009)). Borzilleri fails to plead at all—let alone with particularity—"any financial obligation that the [Manufacturer Defendants] owed to the government" and "any false records or statements used to decrease such an obligation." *Wood*, 328 F. App'x at 748. Count 3 is therefore not pled plausibly or with particularity. *Id.*; *see also Haas v. Gutierrez*, No. 07-CV-3623 (GBD), 2008 WL 2566634, at *5

(S.D.N.Y. June 26, 2008).

C. Borzilleri Lacks Standing To Pursue Claims For Unjust Enrichment And Common Law Fraud.

Borzilleri asserts claims for unjust enrichment and common law fraud in Counts 33 and 34. SAC ¶¶ 916, 921. He lacks standing to bring those claims. "While the FCA gives a relator the right to bring an action for violation of the FCA, it 'does not give relators the right to assert common law claims on behalf of the United States.' " *U.S. ex rel. Phipps v. Comprehensive Cmty. Dev. Corp.*, 152 F. Supp. 2d 443, 452 (S.D.N.Y. 2001) (internal citations omitted) (dismissing relator's unjust-enrichment and common-law-fraud claims); *see also Conn. Action Now, Inc. v. Roberts Plating Co.*, 457 F.2d 81, 84 (2d Cir. 1972) ("[T]here is no common law right to maintain a *qui tam* action; authority must always be found in legislation."); *Morgan*, 2008 WL 2566747, at *3 ("the Congressional grant of private standing to sue in FCA cases does not extend to common law causes of action"). As a result, those claims should be dismissed.

D. Borzilleri's State-Law "Reverse False Claim" Counts Fail To State A Claim.

Borzilleri also asserts claims (Counts 5-32) under the "reverse false claims" provision of 28 state FCA analogues. Those provisions, like the federal provision discussed above, prohibit knowingly concealing, avoiding, or decreasing an obligation to pay money to the state. *E.g.*, SAC ¶ 832 (California), ¶ 836 (Colorado), ¶ 839 (Connecticut). But the SAC does not plead that any Manufacturer Defendant *had* any obligation to pay any money to any State in the first place—let alone that the Manufacturer Defendant concealed, avoided, or decreased that obligation. These claims fail on that basis alone.

Borzilleri's theory seems to be that each State overpaid the federal government to fund some portion of the federal government's Part D spending on individuals from the State who are "dual eligible[s]." *Id.* at ¶ 166. These so-called "clawback payments" by States, Borzilleri

speculates, were higher than they would have been if Defendants had not engaged in service-fee fraud. *E.g.*, *id.* at ¶ 832. Even if Borzilleri had pled some other provision of state law besides the "reverse" false claims provisions in Counts 5-32, his clawback-payment theory would fail because the SAC does not plead that any Manufacturer Defendant actually engaged in any service-fee fraud. That too requires dismissal of Counts 5-32.[12]

III. THE PUBLIC-DISCLOSURE BAR MANDATES DISMISSAL OF THE FCA CLAIMS.

The SAC is subject to dismissal for yet another reason: it is barred by the FCA's public-disclosure bar. 31 U.S.C. § 3730(e)(4). That bar precludes "parasitic lawsuits" by those who allege fraud based on publicly available information. *U.S. ex rel. Doe v. John Doe Corp.*, 960 F.2d 318, 319 (2d Cir. 1992).[13] It applies when (1) a relator's allegations are "substantially similar" to prior public disclosures, and (2) the relator is not an "original source." *U.S. ex rel. JDJ & Assocs. LLP v. Natixis*, No. 15-cv-5427 (PKC), 2017 WL 4357797, at *5 (S.D.N.Y. Sept. 29, 2017). The bar is "broad" and "applies to claims based *in any part* upon" public disclosures. *Patriarca*, 295 F. Supp. 3d at 196 (internal quotation marks omitted).

Remarkably, Borzilleri *admits* that his allegations are based entirely on a mosaic of

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[12] Alternatively, the Court can dismiss the federal FCA claims and decline to retain supplemental jurisdiction over Borzilleri's state-law claims. *See, e.g., Ruotolo v. Fannie Mae*, 933 F. Supp. 2d 512, 527 (S.D.N.Y. 2013).

[13] The public-disclosure bar was jurisdictional, *see Graham Cty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 285 (2010), until Congress amended it as part of the Affordable Care Act of 2010 ("ACA"). *See* Pub. L. No. 111-148, § 10104(j)(2), 124 Stat. 119, 901-02 (Mar. 23, 2010). Because the ACA amendment was not retroactive, it does not apply to pre-ACA conduct. *See, e.g., U.S. ex rel. Patriarca v. Siemens Healthcare Diagnostics, Inc.*, 295 F. Supp. 3d 186, 195 (E.D.N.Y. 2018). As a result, this Court should apply the jurisdictional version for conduct that allegedly occurred before March 23, 2010, and the non-jurisdictional version for conduct after that date. *See id.* In addition, Borzilleri has the burden of establishing jurisdiction as to the pre-ACA claims. *See Morrison v. Nat'l Australia Bank Ltd.*, 547 F.3d 167, 170 (2d Cir. 2008), *aff'd*, 561 U.S. 247 (2010). Under both versions of the bar, however, the result is the same—dismissal under Rule 12(b)(1) for pre-ACA claims and dismissal under Rule 12(b)(6) for post-ACA claims.

public disclosures, and the disclosures themselves include the elements from which he infers fraud.[14] Far from being an insider or "original source," Borzilleri is a quintessential "opportunistic plaintiff[ ] who ha[s] no significant information to contribute." *Graham Cty.*, 559 U.S. at 294 (citation omitted, internal quotation marks omitted). He is a former investment fund manager who, with no affiliation to any Defendant, filed this action in an attempt to drive Defendants' stock prices down and improve his short positions. *See supra* at 6-7. As such, the FCA's public-disclosure bar requires dismissal of the SAC.

A. Borzilleri's Allegations Are Substantially Similar To Prior Public Disclosures.

A relator's allegations are substantially similar to prior public disclosures where, as here, the "essential elements" of the purported fraudulent transaction were publicly disclosed. *U.S. ex rel. Kirk v. Schindler Elevator Corp.*, 437 F. App'x 13, 17 (2d Cir. 2011). This includes instances where a relator like Borzilleri alleges that he "infer[s]" a fraudulent transaction from facts revealed in public disclosures. *U.S. ex rel. Lissack v. Sakura Glob. Capital Markets, Inc.*, No. 95 Civ. 1363 (BSJ), 2003 WL 21998968, *10 (S.D.N.Y. Aug. 21, 2003), *aff'd* 377 F.3d 145 (2d Cir. 2004). In other words:

> [I]f X + Y = Z, Z represents the *allegation* of fraud and X and Y represent its essential elements. In order to disclose the fraudulent *transaction* publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, *i.e.*, the conclusion that fraud has been committed.

Id. (alteration in original, internal quotation marks omitted). In these circumstances, the public-

[14] Because Borzilleri admits that he based his allegations entirely on qualifying public disclosures, the Court need not look beyond the SAC to dismiss. *See, e.g.*, *Iqbal*, 556 U.S. at 678 ("[A] complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." (internal quotation marks omitted)); *Carter v. HealthPort Techs., LLC*, 822 F.3d 47, 56-57 (2d Cir. 2016) (noting that a defendant can make a "facial" or a "fact-based" challenge to the Court's jurisdiction under Rule 12(b)(1), and that a facial challenge is "based solely on the" pleading). Even if Borzilleri had not admitted this, however, the disclosures themselves, of which the Court should take judicial notice, reveal that the complaint is based on qualifying public disclosures, also requiring dismissal.

disclosure bar applies even if the relator "decod[ed] . . . publicly available complex or technical information," *Patriarca*, 295 F. Supp. 3d at 197, or "spen[t] hundreds of hours compiling facts into a 'mosaic,' " *JDJ & Assocs.*, 2017 WL 4357797, at *6 (citation omitted).

The SAC itself confirms that Borzilleri did not uncover the alleged fraudulent scheme through insider information, but instead is inferring it from his review of federal regulations and administrative reports, SEC filings, and published drug-pricing and sales data that existed before he filed suit.

First, Borzilleri alleges that the Manufacturer Defendants must have paid inflated service fees to the PBM Defendants because various federal administrative reports[15] reveal that PBMs earned high profits, despite retaining minimal rebates and allegedly facing high catastrophic cost-sharing exposure. Specifically, based on public sources, Borzilleri alleges:

- PBMs retained minimal rebates for drugs reimbursed by Part D, which were less than rebates for drugs reimbursed by Medicaid, *see* SAC ¶¶ 227-31, 761-68 (citing 2011 OIG Report, *supra*); HHS-OIG, OEI-03-13-00650, *Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin* (2015)); *id.* at ¶¶ 234, 258, 759, 771-78 (citing U.S. Gov't Accountability Office, GAO-10-242, *Spending, Beneficiary Cost Sharing, and Cost-Containing Efforts for High-Cost Drug Eligible for a Specialty Tier* (2010));
- PBMs had high catastrophic cost-sharing exposure that should have negated profits, absent a fee scheme, *id.* at ¶¶ 395-444 (citing *Medicare Payment Advisory Comm'n, Report to the Congress: Medicare and the Health Care Delivery System* (June 2015));
- PBM Medco generated significant profits from service fees and relied less on rebates for profits, *id.* at ¶¶ 779-805 (citing Medco Health, Annual Reports (SEC Forms 10-K) (2003-2011)); and
- Profits of Defendant Express Scripts nearly tripled between 2013 and 2017, *id.* at ¶¶ 115-

[15] An OIG report is a "paradigmatic example" of a qualifying public source. *U.S. ex rel. Davis v. Prince*, 753 F. Supp. 2d 569, 591 (E.D. Va. 2011). SEC filings also qualify as public disclosures under 31 U.S.C. § 3730(e)(4)(A). *See, e.g.*, *U.S. ex rel. Jones v. Collegiate Funding Servs., Inc.*, 469 F. App'x 244, 257 (4th Cir. 2012); *U.S. ex rel. Ryan v. Endo Pharm., Inc.*, 27 F. Supp. 3d 615, 628 n.16 (E.D. Pa. 2014), *aff'd sub nom. U.S. ex rel. Dhillon v. Endo Pharm.*, 617 F. App'x 208 (3d Cir. 2015).

20 (citing unidentified "SEC-reported financial statements of Express Scripts").[16]

Second, Borzilleri alleges that these service fees could not have been fair market value or BFSFs because SEC filings reveal that a non-defendant pharmacy received more modest service fees, and one PBM Defendant spent little on performing actual services. For example, Borzilleri alleges that:

- "SEC filings . . . of Diplomat Pharmacy, Inc., verify 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.* at ¶¶ 668-73 (citing Diplomat Pharmacy, Inc., Registration Statement (SEC Form S-1) (July 3, 2014)); and
- Expenditures of Defendant Express Scripts allocated to "Selling, General and Administrative" in 2013-2017 "sharply declin[ed]," *id.* at ¶¶ 115-20 (citing unidentified "SEC-reported financial statements of Express Scripts").[17]

Third, Borzilleri alleges that the fees must have been kickbacks in exchange for favorable formulary placement, in violation of the AKS, because various federal administrative reports and published drug pricing and sales data[18] reveal that the Manufacturer Defendants' drug prices and sales have risen despite the availability of cheaper alternative drugs. *See, e.g.*, *id.* at ¶¶ 7-12, 21, 82-83, 123, 759, 770, 799, Exs. 1-11, 15-20 (citing "public" CMS data; and drug pricing and sales data published by Truven Health Analytics Inc., *Red Book*, IMS Health, PhRMA, and

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[16] Borzilleri also alleges that two industry news publications released after he filed this action, but before he filed the SAC, "publicly corroborated" his suspicions of inflated service fees. *See* SAC ¶¶ 67, 95-96, 99-101, 109, 182-85, 198-213 (citing PhRMA and PCMA reports). To the extent the SAC makes new allegations based on inferences he is drawing from those publications, those new allegations are equally barred by the public-disclosure bar.

[17] Borzilleri also alleges that participants in a public conference, presented by an independent organization, opined that percent-of-revenue-based fees could raise fraud risks. SAC ¶¶ 128, 445-47, 452-89.

[18] Data published by CMS qualifies as a public disclosure under 31 U.S.C. § 3730(e)(4)(A). *See, e.g., U.S. ex rel. Conrad v. Abbott Labs., Inc.*, No. CIV. A. 02-11738-RWZ, 2013 WL 682740, *5 (D. Mass. Feb. 25, 2013). The same holds for drug-pricing data published in nongovernmental sources. *See U.S. ex rel. Lager v. CSL Behring, L.L.C.*, 855 F.3d 935, 945-46 (8th Cir. 2017) (*Red Book* data is a public disclosure), *aff'd*, 855 F.3d 935 (8th Cir. 2017); *U.S. ex rel. Osheroff v. Humana Inc.*, 776 F.3d 805, 813 (11th Cir. 2015) (holding that "publicly available websites . . . intended to disseminate information . . . qualify as news media").

company reports). The alleged fraudulent scheme, Borzilleri concludes, is "the only viable explanation." *Id.* at ¶ 123.

Fourth, Borzilleri alleges that the Manufacturer Defendants must have caused the submission of false claims because federal regulations condition Part D participation on certain submissions, which must have been false due to unreported inflated service fees and AKS violations. *See id.* at ¶¶ 30, 88, 151-53, 168, 297-300 (citing 42 C.F.R. § 423.505).

In addition, even if the SAC did not confirm that Borzilleri's allegations rely entirely on public disclosures, the disclosures themselves confirm this as detailed in the PBM/Payor brief. For instance, the SAC lifts concerns directly from the 2011 OIG Report that found, among other things, that "[s]elected sponsors reported that their PBMs collected fees from drug manufacturers that were not always passed on to the Part D program," that the "fees were structured like rebates in that they were generally based on a fixed percentage of WAC [the drug's list price]," that in some cases "the sponsors did not report the fees to CMS and therefore they were not passed on to the program" because "the PBMs considered these fees to be bona fide services fees, which CMS does not consider price concessions if they are at fair market value," and that "[b]ecause sponsors may not always be able to verify whether these fees should be considered rebates or bona fide service fees, they may be inaccurately reporting this information to CMS." 2011 OIG Report, *supra*, at 18-19. The SAC simply recasts these concerns as unsubstantiated fraud allegations. The Court should take judicial notice of this report, and the other disclosures cited in the PBM/Payor brief, and dismiss on this ground too.

These disclosures are more than sufficient to trigger the public-disclosure bar. Numerous courts have recognized that a prior disclosure does not need to identify a specific defendant to be a sufficient disclosure. *See, e.g.*, *In re Natural Gas Royalties*, 562 F.3d 1032, 1043 (10th Cir.

2009); *United States v. Alcan Elec. & Eng'g, Inc.*, 197 F.3d 1014, 1018-19 (9th Cir. 1999); *United States ex rel. Fine v. Sandia Corp.*, 70 F.3d 568, 569-72 (10th Cir. 1995). The import of those decisions seems particularly applicable when, as here, the relator offers no allegations specific to any Defendants either. Moreover, the government could easily identify from DIR reports all Part D plan sponsors that use the services of a PBM which has entered into a service-fee contract with a manufacturer.

In sum, because Borzilleri "infer[red]" the alleged fraudulent scheme ("Z") entirely from qualifying public disclosures ("X + Y"), and the disclosures themselves confirm this, the public-disclosure bar precludes his FCA claims unless he is an "original source"—which he is not. *Lissack*, 2003 WL 21998968, at *10.

B. Borzilleri Is Not An "Original Source."

Borzilleri is not an "original source" under either the pre-ACA or post-ACA versions of the bar because he admits that he derived all of his alleged information from public disclosures. *See U.S. ex. rel. Keshner v. Immediate Home Care, Inc.*, No. 06-CV-01067 (FB) (VPP), 2016 WL 3545699, at *3 (E.D.N.Y. June 24, 2016) (relator's "self-serving, conclusory assertion that he is an 'original source' will not save his complaint") (citation omitted).

Under the pre-ACA version of the bar, the FCA defined an "original source" as an "individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action." 31 U.S.C. § 3730(e)(4)(B) (2006). Under the post-ACA version, an "original source" is an individual who either (1) "prior to a public disclosure . . . voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based," or (2) "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." 31 U.S.C. § 3730(e)(4)(B) (2012).

Borzilleri fails to qualify as an "original source" under the pre-ACA public-disclosure bar because the core information he alleges derives exclusively from third-party disclosures, and he does not allege having "knowledge obtained from actually viewing source documents, or firsthand observation of the fraudulent activity." *Ping Chen ex rel. U.S. v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282, 300 (S.D.N.Y. 2013) (internal quotation marks omitted); *see also U.S. ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1159 (2d Cir. 1993) ("Nor does the fact that [relator's] background knowledge enabled it to understand the significance of the information acquired . . . make its knowledge independent of the publicly disclosed information."); *U.S. ex rel. Alcohol Found., Inc. v. Kalmanovitz Charitable Found., Inc.*, 186 F. Supp. 2d 458, 463 (S.D.N.Y. 2002) (relator not an "original source" despite spending hours compiling a " 'mosaic' of information that shows a fraud . . . that an average member of the public could neither understand . . . nor perceive"), *aff'd*, 53 F. App'x 153, 154 (2d Cir. 2002).

Borzilleri also fails to qualify as an "original source" under the post-ACA public-disclosure bar. He neither disclosed his alleged information to the government prior to its public disclosure, nor has "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions." 31 U.S.C. § 3730(e)(4)(B) (2012); *see U.S. ex rel. Coyne v. Amgen Inc.*, 229 F. Supp. 3d 159, 172-73 (E.D.N.Y. 2017) (information must "add some new value" and be "qualitatively different," rather than a mere "outgrowth of publicly disclosed information" (internal quotation marks omitted)), *report and recommendation adopted*, 243 F. Supp. 3d 295 (E.D.N.Y. 2017), *aff'd* 717 F. App'x 26 (2d Cir. 2017). His suit is based entirely on preexisting, publicly disclosed information, and he contributes no inside or valuable

information.[19]

CONCLUSION

For the foregoing reasons, and those in the Motion to Dismiss filed by the PBM Defendants, Borzilleri's SAC should be dismissed. The dismissal should be without prejudice if it is based on the first-to-file bar or for lack of jurisdiction, and with prejudice on all other grounds.[20]

October 1, 2018

Respectfully submitted,

[counsel listed on next page]

[19] Because the Court lacks jurisdiction over the pre-ACA FCA claims, the Court also lacks jurisdiction over all of the pre-ACA state-law claims. 31 U.S.C. § 3732(b). In addition, for substantially the same reasons that the FCA's public-disclosure bar precludes the FCA claims in this case, various state public-disclosure bars preclude the state-law claims. *See* Cal. Gov't Code § 12652(d)(3)(A); Colo. Rev. Stat. § 25.5-4-306(5)(c); Conn. Gen. Stat. § 4-282(b); 6 Del. Code Ann. tit. 6, § 1206(b); D.C. Code § 2-381.03(c-1)(1); Fla. Stat. § 68.087(3); Ga. Code Ann. § 23-3-122(j)(3); Haw. Rev. Stat. Ann. § 661-31(b); 740 Ill. Comp. Stat. 175/4(e)(4)(A); Ind. Code § 5-11-5.5-7(f); Iowa Code § 685.3(5)(c); La. Stat. Ann. § 439.1(D); Mass. Gen. Laws. ch. 12 § 5G(c); Mich. Comp. Laws. § 400.610a(13); Minn. Stat. § 15C.05(f); Mont. Code Ann. § 17-8-403(6)(a); Nev. Rev. Stat. Ann. § 357.100; N.J. Stat. Ann. § 2A:32C-9(c); N.M. Stat. Ann. § 27-14-10(C); N.Y. State Fin. Law § 9(b); N.C. Gen. Stat. § 1-611(e); Okla. Stat. § 5053.5(B); R.I. Gen. Laws § 9-1.1-4(e)(4)(A); Tenn. Code Ann. § 4-18-104(d)(3); Tex. Code Ann. § 36.113(b); Va. Code Ann. § 8.02-218.8; Wash. Rev. Code § 74.66.080(2).

[20] As discussed, *supra* at 6-7¸ Borzilleri is a former investment fund manager who has never been employed by any of the Defendants and, as such, has no "insider" information from which to amend his complaint; he has presumably exhausted the information he could mine from public sources since he filed suit three years ago and amended his complaint for a second time in August 2018. For that reason, amendment would be futile and any dismissal other than under the first-to-file bar or for lack of jurisdiction should be with prejudice. *See Cuoco v. Moritsugu*, 222 F.3d 99, 112 (2d Cir. 2000); *U.S. ex rel. Tessler v. City of New York*, No. 14-CV-6455, 2016 WL 7335654, at *5 (S.D.N.Y. Dec. 16, 2016), *aff'd*, 712 F. App'x 27 (2d Cir. 2017).

ABBVIE INC.
By its Attorneys,

/s/ Joan McPhee
Joan McPhee
Ropes & Gray LLP
1211 Avenue of the Americas
New York, NY 10036-6230
Tel: 212.596.9443
Fax: 617.951.7050
Email: Joan.McPhee@ropesgray.com

Laura G. Hoey (*pro hac vice*)
Ropes & Gray LLP
191 North Wacker Drive
Chicago, IL 60606
Tel: 312.845.1318
Fax: 617.951.7050
Email: Laura.Hoey@ropesgray.com

Aaron M. Katz (*pro hac vice*)
Ropes & Gray LLP
800 Boylston Street
Boston, MA 02110
Tel: 617.951.7117
Fax: 617 951.7050
Email: Aaron.Katz@ropesgray.com

AMGEN INC.
By Its Attorneys,

/s/ David S. Rosenbloom
David S. Rosenbloom (*pro hac vice*)
McDermott Will & Emery LLP
444 West Lake Street
Suite 4000
Chicago, Illinois 60606-0029
Tel: 312.984.7759
Fax: 312.984.7700
Email: DRosenbloom@mwe.com

Dana M. McSherry (*pro hac vice*)
McDermott Will & Emery LLP
28 State Street
Boston, Massachusetts 02109-1775
Tel: 617.535.4600
Fax: 617.535.3800
Email: DMcsherry@mwe.com

Michael R. Huttenlocher
McDermott Will & Emery LLP
340 Madison Avenue
New York, New York 10173-1922
Tel: 212.547.5482
Fax: 212.547.5444
Email: MHuttenlocher@mwe.com

BRISTOL-MYERS SQUIBB CO.
By Its Attorneys,

/s/ Mitchell J. Lazris
Mitchell J. Lazris (*pro hac vice*)
Jessica L. Ellsworth (*pro hac vice*)
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, D.C. 20004
Tel: (202)637-5863
Fax: (202)637-5910
Email: mitch.lazris@hoganlovells.com
jessica.ellsworth@hoganlovells.com

Michael E. DeLarco
Hogan Lovells US LLP
875 Third Ave.
New York, NY 10022
Tel: (212) 918-3265
Fax: (212) 918-3100
Email: michael.delarco@hoganlovells.com

ELI LILLY AND COMPANY
By Its Attorneys

/s/ Benjamin J. Razi
Benjamin J. Razi (*pro hac vice*)
Covington & Burling LLP
One City Center
850 Tenth Street, NW
Washington, D.C. 20001
Tel: 202.662.5463
Fax: 202.778.5463
Email: brazi@cov.com

William A. Sarraille (*pro hac vice to be submitted*)
Sidley Austin LLP
1501 K Street, NW
Washington, D.C. 20005
Tel: 202.736.8195
Fax: 202.736.8711
Email: wsarraille@sidley.com

NOVARTIS PHARMACEUTICALS CORP.
By Its Attorneys,

/s/ Glenn C. Colton
Arent Fox LLP
1301 Avenue of the Americas, 42nd Floor
New York, New York 10019
Tel.: (212) 484-3900
Fax: (212) 484-3990
Email: glenn.colton@arentfox.com

D. Jacques Smith *(pro hac pending)*
Randall A. Brater *(pro hac pending)*
Michael Dearington *(admission pending)*
Arent Fox LLP
1717 K Street, NW
Washington, DC 20006-5344
Tel.: (202) 857-6000
Fax: (202) 857-6395
Email: jacques.smith@arentfox.com
randall.brater@arentfox.com
michael.dearington@arentfox.com

PFIZER INC.
By Its Attorneys,

/s/ Michael A. Rogoff
Michael A. Rogoff
Paula R. Ramer
Arnold & Porter Kaye Scholer LLP
250 W. 55th St.
New York, NY 10019
Tel: 212.836.7684
Fax: 212.836.6615
Email: michael.rogoff@arnoldporter.com
paula.ramer@arnoldporter.com

Andrew James Hoffman, II (*pro hac vice*)
DLA Piper LLP
2000 Avenue of The Stars, Suite 400
Los Angeles, CA 90067
Tel: 310.595.3010
Fax: 310.595.3310
Email: andrew.hoffman@dlapiper.com

SANOFI-AVENTIS U.S. LLC
By Its Attorneys,

/s/ Rajeev Muttreja
Rajeev Muttreja
Jones Day
250 Vesey Street
New York, NY 10281-1047
Tel: 212.326.3939
Fax: 212.755.7306
Email: rmuttreja@jonesday.com

Heather M. O'Shea (*pro hac vice*)
Jones Day
77 West Wacker Drive, Suite 3500
Chicago, IL 60601-1692
Tel: 312.782.3939
Fax: 312.782.8585
Email: hoshea@jonesday.com