UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

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

Plaintiffs,

v.

BAYER HEALTHCARE PHARMACEUTICALS, INC., *et al.*,

Defendants.

C.A. No. 1:14-cv-00031-WES-LDA

ORAL ARGUMENT REQUESTED
ESTIMATED TIME OF TWO HOURS

MANUFACTURER DEFENDANTS' JOINT MOTION
TO DISMISS THE SECOND AMENDED COMPLAINT

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Defendants Bayer Healthcare Pharmaceuticals, Inc., Biogen Inc., EMD Serono, Inc., Novartis Pharmaceuticals Corporation, Pfizer Inc., Teva Neuroscience, Inc. and Teva Pharmaceuticals USA, Inc. (collectively the "Manufacturer Defendants") hereby move pursuant to Federal Rules of Civil Procedure 8(a), 9(b), 12(b)(1), and 12(b)(6) and 31 U.S.C. § 3730(e)(4) to dismiss Relator John Borzilleri, M.D.'s Second Amended Complaint (Dkt. 95) with prejudice as to all Manufacturer Defendants. In support of this Joint Motion, the Manufacturer Defendants rely upon the legal arguments set forth herein and the accompanying exhibits attached hereto. Pursuant to Local Rule 7(c), the Manufacturer Defendants respectfully request a hearing on their Joint Motion and estimate that the hearing will last no more than one hour.

PRELIMINARY STATEMENT

In this *qui tam* action, Relator John Borzilleri, M.D.—an opportunistic short seller and corporate outsider—sets forth an unsupported hypothesis conjured entirely from public information. Borzilleri alleges a "secret" agreement between seven "Manufacturer Defendants" that manufacture multiple sclerosis (MS) drugs approved by the U.S. Food and Drug Administration and seven "Pharmacy Benefit Manager (PBM) Defendants" that provide services in connection with the Medicare Part D prescription drug benefit program.[1] Based entirely on conjecture, Borzilleri's Second Amended Complaint (SAC) alleges that the Manufacturer Defendants paid the PBM Defendants service fees in excess of fair market value. Borzilleri speculates that these service fees were not properly reported to the Centers for Medicare & Medicaid Services (CMS) by Medicare Part D plan sponsors, that they also were kickbacks to PBM Defendants, and that plan sponsors submitted false claims to CMS as a result.

[1] Borzilleri refers to Aetna, Inc., Cigna Corporation, CVS Health Corporation, Express Scripts Holding Company, Humana, Inc., and UnitedHealth Group, Inc. as the "PBM Defendants." SAC ¶ 1.

Although Borzilleri has amended his complaint three times, his 808-paragraph SAC offers no factual support for his theories and fails to plead plausibly the violations he asserts, as required by Fed. R. Civ. P. 8(a). The SAC also falls far short of pleading fraud with the particularity required by Fed. R. Civ. P. 9(b). It does not plead any particularized facts about any alleged contract between a Manufacturer Defendant and a PBM Defendant, any service fee paid under such a contract, or any basis for concluding that any such service fee (even if paid) exceeded fair market value. The SAC is also devoid of facts that might connect any hypothetical excess service fee to an actual claim submitted by a Medicare Part D sponsor, such as details of how a particular alleged above fair market value service fee was misreported by a PBM Defendant to a Medicare Part D plan sponsor, or by a plan sponsor to CMS. Indeed, Borzilleri does not plead any facts demonstrating that any false claims actually were submitted. Rather, Borzilleri admits that his theory is based on "estimates," "assumptions," and "conclusions" drawn from publicly available data about drug pricing and service fees, which he hopes will be validated through discovery. Rule 9(b), however, requires Borzilleri to plead facts, not theories, and precludes the type of unfounded fishing expedition Borzilleri seeks to undertake here.

The SAC's lack of factual support is not surprising. Borzilleri is not a Manufacturer or PBM Defendant insider with personal knowledge of any Defendant's operations; instead, he is an opportunistic former health care investment fund manager who admits his SAC (like his largely duplicative second lawsuit filed in the U.S. District Court for the Southern District of New York against many of the same Defendants here (*see infra* Section B.2) is based entirely on public information he compiled in an effort to profit from large short positions that he took in the Defendants' stock. Borzilleri's attempt to manipulate the *qui tam* provision of the False Claims Act (FCA) for personal gain not only is antithetical to the provision's intent, but also runs afoul

of the FCA's "public disclosure" bar. As the SAC confirms, Borzilleri's primary allegation—that service fees paid by drug manufacturers to PBMs might be excessive or misreported—was publicly disclosed in qualifying sources (including sources cited in the SAC) before Borzilleri filed suit. Because Borzilleri cannot qualify as an original source of his allegations, his SAC is foreclosed as a matter of law.

For each of these reasons, as well as those set forth in the PBM Defendants' Motion to Dismiss, the SAC should be dismissed with prejudice. After more than *four* years and *four* attempts to plead a viable FCA claim against the Defendants, Borzilleri is unable to cure the SAC's basic pleading deficiencies because, as he admits, he lacks actual knowledge of any conduct by any Defendant. The Court should not grant him leave to amend again.

BACKGROUND

[2]

Borzilleri filed this *qui tam* suit under seal in January 2014 and a First Amended Complaint on May 1, 2014. Dkt. 6. Following a lengthy investigation, the Department of Justice, all 29 named states, and the District of Columbia declined to intervene in this action, and the First Amended Complaint was unsealed on April 4, 2018. Dkts. 36, 37. Borzilleri then filed the SAC on July 6, 2018 against thirteen Manufacturer and PBM Defendants. Dkt. 57. Borzilleri re-filed the Second Amended Complaint on August 17, 2018, correcting the misjoinder of three parties and making other changes to the allegations. Dkts. 69, 95. The crux of

[2] In considering a motion to dismiss, the Court may consider facts incorporated by reference in the SAC, matters of public record and those susceptible of judicial notice. *See Lister v. Bank of Am., N.A.*, 790 F.3d 20, 23 (1st Cir. 2015); *see also In re Colonial Mortgage Bankers Corp.*, 324 F.3d 12, 15 (1st Cir. 2003). In particular, the Court may consider any document "'integral to or explicitly relied upon in a complaint, even if that document is not annexed to the complaint.'" *Rederford v. U.S. Airways, Inc.*, 586 F. Supp. 2d 47, 50 (D.R.I. 2008) (Smith, J.), aff'd sub nom. *Rederford v. U.S. Airways, Inc.*, 589 F.3d 30 (1st Cir. 2009) (citations omitted). Copies of such documents are cited herein as "Ex. __" and submitted herewith.

Borzilleri's complaint is his contention that the Manufacturer Defendants paid service fees to PBMs in excess of fair market value in violation of the Federal Anti-Kickback Statute (AKS), and which Medicare Part D plan sponsors did not properly report to CMS. *See* SAC ¶¶ 27, 29, 81, 88–89, 107, 152–53.

A. Regulatory Framework

1. The Medicare Part D Program

Medicare is a federal government health insurance program for the elderly and those with certain disabilities. The Department of Health and Human Services (HHS) operates Medicare through CMS. 42 U.S.C. § 1395 *et seq.* There are four parts to the Medicare program, Parts A through D. *Id.* The SAC concerns only the Medicare Part D program.

Medicare Part D is a voluntary prescription drug benefit program established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Pub. L. No. 108-173, 117 Stat. 2066 (2003). Part D plans are operated by plan sponsors, which are private health insurers that contract with CMS to offer health plans with outpatient drug benefits to Medicare beneficiaries. *See* 42 U.S.C. § 1395w-111(b). After contracting with CMS, plan sponsors negotiate drug prices with pharmaceutical manufacturers, establish formularies, and apply utilization management tools, sometimes using the services of PBMs. *See generally* 42 C.F.R. § 423.514. CMS pays plan sponsors in part based on their costs for reimbursing drug claims for their Part D enrollees. Plan sponsors report these costs to CMS in annual cost estimates they submit over the course of a year. *See* 42 C.F.R. § 423.265.

CMS needs to know about discounts that plan sponsors receive from drug manufacturers that may offset costs incurred by the plan sponsors. SAC ¶ 30. As a result, Part D plan sponsors are required to report direct and indirect remuneration (DIR) to CMS, to capture the discounts they receive from manufacturers. 42 C.F.R. § 423.308; Ex. A, CMS Memo to All Part D Plan

Sponsors, *Final Medicare Part D DIR Reporting Requirements for 2016*, at 1 (June 23, 2017) (the "CMS 2016 Reporting Memo"). DIR includes "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 to some or all purchasers." *Id*. DIR ultimately reduces CMS's payments to plan sponsors by offsetting their costs. *See* Ex. B, CMS Memo to All Part D Plan Sponsors, *Final Medicare Part D DIR Reporting Requirements for 2009 Payment Reconciliation*, at 9 (June 10, 2010).

Under the Part D program, PBMs may perform services for drug manufacturers, and receive bona fide service fees (BFSFs) in exchange. BFSFs are defined as "fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer." *See* 42 C.F.R. § 423.501. Borzilleri repeatedly admits that drug manufacturers may pay BFSFs to PBMs for a "wide array" of support services, such as "rebate administration, inventory management, drug shipping/delivery, reimbursement/financial assistance, patient educations/clinical programs, drug adherence programs, phone support, data reports, etc." SAC. ¶¶ 35, 138. As Borzilleri further acknowledges, BFSFs are a recognized part of the Part D Program. *Id.* ¶¶ 14, 138.

Plan sponsors also may receive BFSFs and must report them to CMS. *See, e.g.*, Ex. A, CMS 2016 Reporting Memo 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"). Notably, CMS excludes BFSFs from the definition of DIR, and BFSFs are not treated as discounts by CMS if they are consistent with fair market value.[3] 42 C.F.R. § 423.514(d)(4)

[3] CMS has repeatedly confirmed that manufacturers are to be given flexibility in determining the fair market value of BFSFs. *See, e.g.*, Medicaid Program; Prescription Drugs, 72 Fed. Reg. 39,142, 39,191 (July 17, 2007) (withdrawn Nov. 2010) (explaining that "in the

(stating that DIR is to "exclude[e] bona fide service fees"); 42 C.F.R. § 423.501. BFSFs that exceed fair market value, however, should be reported as DIR. *See* Ex. A, CMS 2016 Reporting Memo at 29.

So that plan sponsors can accurately report DIR to CMS, PBMs are obligated to provide certain information to plan sponsors. 42 C.F.R. § 423.514 (explaining that "[e]ach entity that provides pharmacy benefits management services must provide to Part D sponsors" information about rebates, discounts and price concessions). Critically, however, ***manufacturers have no reporting obligations*** for DIR or BFSFs under Part D. *See generally* Ex. A, CMS 2016 Reporting Memo (discussing only plan sponsor obligations to report direct and indirect remuneration to Medicare Part D); *see also* SAC ¶ 244 (citing 42 C.F.R. § 423.514 and referencing reporting requirements that are applicable only to "[e]ach entity that provides *pharmacy benefits management services*" (emphasis added)). Thus, Borzilleri is simply wrong when he alleges, without support, that "service fees" purportedly in excess of fair market value should be reported "by the Drug Manufacturer to the plan sponsor in Medicare Part D." SAC ¶ 31; *see also id.* ¶ 152(5).

2. <u>The Federal Anti-Kickback Statute</u>

The Federal AKS prohibits the knowing and willful payment, receipt, or solicitation 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

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absence of specific guidance, manufacturers may make "reasonable assumptions consistent with the statute, regulations and general business practices"); Medicaid Program; Covered Outpatient Drugs, 77 Fed. Reg. 5318 (February 2, 2012) ("[d]ue to the rapidly changing market in which new types of arrangements arise, we believe that manufacturers should appropriately determine fair market value."); Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5170, 5179 (Feb. 1, 2016) ("Given the continually changing pharmaceutical marketplace, we will continue to allow manufacturers the flexibility to determine the fair market value of a service when evaluating whether the service fee is bona fide or not.").

U.S.C. § 1320a-7b(b)(1) (B), (2)(B). Because the AKS potentially sweeps in a wide swath of legitimate conduct, the AKS protects a variety of arrangements through statutory exceptions. For example, discounts and rebates are protected under a statutory exception. 42 U.S.C. § 1320a-7b(b)(3)(A). Separately, Congress delegated authority to HHS's Office of Inspector General (OIG) to create regulatory safe harbors that likewise protect various arrangements under the AKS. 42 U.S.C. § 1320a-7b(b)(3)(E).[4]

B. Factual Background

1. Borzilleri's Allegations

Borzilleri describes himself as a professional healthcare "investment fund manager." SAC ¶ 116. While employed at the investment firm of Shepherd Kaplan Krochuk, LLC (SKK), Borzilleri managed and was the largest investor in a health care hedge fund with a short-side focus. Borzilleri came to believe that rising pharmaceutical drug prices were caused by "a straightforward price collusion scheme" between certain pharmaceutical companies and PBMs. SAC ¶ 12.

Borzilleri alleges that large price increases for drugs used to treat multiple sclerosis are primarily caused by contracts between the Manufacturer Defendants and PBMs that provided for excessive service fees. SAC ¶¶ 7, 15, 27. He speculates that service fees paid by Manufacturer Defendants to PBM Defendants are suspect because they purportedly are based upon a

[4] Although Borzilleri asserts, without support, that BFSFs paid by Manufacturer Defendants are not protected by any statutory exception or regulatory safe harbor, SAC ¶¶ 263, 560-574, various safe harbors may apply depending upon the facts. In particular, one safe harbor protects payments made to Group Purchasing Organizations (GPOs) and explicitly protects percentage-based fees paid by a vendor, such as a pharmaceutical manufacturer, to a GPO. 42 C.F.R. § 1001.952(j)(1). OIG specifically has stated that payments from manufacturers to PBMs can be protected by complying with the GPO safe harbor. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,736 (May 5, 2003) (GPO "rebates or 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)").

percentage of the drugs' list prices, which he asserts facilitated price inflation, benefitting both the Manufacturer and PBM Defendants. *Id.* ¶ 36. He alleges that, as drug prices increased over time, so too did the service fees, to the point where they exceeded the fair market value of the services provided by the PBMs. *Id.* ¶¶ 35–40. Borzilleri claims that the "service fees in excess of [fair market value] should be reported by the Drug Manufacturer to the plan sponsor in Medicare Part D," but were not, and also asserts that they constituted illegal kickbacks. *Id.* ¶ 31. Borzilleri also alleges that the Manufacturer Defendants routinely forgave a cost-sharing obligation that is triggered for Part D plan sponsors when a drug cost exceeds a threshold amount, *id.* ¶¶ 34, 305–310, in order to "advance the now pervasive 'service fee' pricing scheme." *Id.* ¶ 424. Borzilleri, however, does not plead any allegations regarding a specific contract between any manufacturer and any PBM, any specific BFSF provision, or any reports submitted by any Part D plan sponsors that purportedly mischaracterized any BFSF.

Putting aside that these allegations fail to identify any specific contract, service fee, or false claim involving any of the Manufacturer Defendants, Borzilleri's allegations are also based entirely on publicly available documents and information and raw speculation. Borzilleri relies, for instance, on press releases (SAC ¶¶ 182, 197); congressional documents (*id.* ¶¶ 409, 640); SEC filings (*id.* ¶¶ 80, 99–105, 492, 554, 556, 666-674, 677–690); publicly disclosed PBM contracts (*id.* ¶¶ 112(d), 176, 509–593); reports and other publications from OIG (*id.* ¶¶ 205, 302, 548, 649); court filings (¶¶ 92, 259–262, 287–289); and other publicly available reports, articles, and disclosures (*id.* ¶¶ 68, 70–72, 76, 97, 161–165, 167–173, 181, 189, 409, 498, 638). Borzilleri also heavily relies on alleged statements purportedly made during an October 2013 compliance conference that was open to the public. *See id.* ¶¶ 450-478. Indeed, as Borzilleri acknowledged in connection with a recent suit his former employer SKK filed against him, "the

DOJ indicated that Dr. Borzilleri's investigation and [the] Qui Tam actions were not based upon 'insider information,'" but rather on "Dr. Borzilleri's extensive proprietary research, based upon public information." *See* Ex. C, Answer & Counterclaims, *Shepherd Kaplan Krochuk, LLC v. John R. Borzilleri*, No. 18-1418-BLS1, ¶ 32 (Mass. Super. Ct. May 26, 2018).

2. Borzilleri's Second Qui Tam Lawsuit

While DOJ was still investigating the allegations in this action—and in a poorly disguised effort to forum shop—Borzilleri filed a second, nearly identical *qui tam* action in the Southern District of New York (SDNY). *See* Ex. D, Second Amended Complaint, *Borzilleri v. Abbvie, Inc.*, 15-cv-7881-JMF (S.D.N.Y. Apr. 13, 2018) (the "SDNY SAC"). The action, filed on October 6, 2015, named eight of the same defendants named in this case, as well as five additional manufacturers who are not defendants here. *Id.* Hundreds of paragraphs in the two operative complaints are materially identical to one another, the product of simplistic cutting-and-pasting and only minor editing to reflect different parties and products. *Compare, e.g.*, SAC ¶¶ 3-7, 11-47, 51-68, 81-96, 98-112, *with* Ex. D, SDNY SAC ¶¶ 3–7, 10–46, 50-67, 79–94, 114–28. In fact, the SAC in this case asserts facts that are wholly irrelevant to this case and applicable only to Defendants or drugs named in the SDNY case. *See, e.g.*, SAC ¶¶ 661–662.

On March 13, 2018, just five days after the government declined to intervene in this case, the Department of Justice, all of the named states, and the District of Columbia declined to intervene in the SDNY action. *See Borzilleri*, 15-cv-7881-JMF (S.D.N.Y.), Dkt. 19. The Complaint in that case was unsealed on April 13, 2018. *Id.* On October 1, 2018, the SDNY Defendants filed two joint motions to dismiss the SDNY SAC, which are now pending. *Borzilleri*, 15-cv-7881-JMF (S.D.N.Y.), Dkts. 258, 259.

3. Borzilleri's Short Selling

Armed with the knowledge that his two complaints would soon be unsealed, Borzilleri undertook a scheme of his own that ultimately resulted in his termination. After the government declined to intervene in either of Borzilleri's actions, but before the two *qui tam* complaints were unsealed, Borzilleri significantly increased the short positions of his hedge fund against the securities of the defendants in the two *qui tam* lawsuits. Ex. E, Complaint, *Shepherd Kaplan Krochuk, LLC v. John R. Borzilleri*, No. 18-1418-BLS1, ¶ 32, 35 (Mass. Super. Ct. May 8, 2018). In fact, "[b]y 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.* ¶ 37.

Upon the complaints being unsealed, Borzilleri sent the complaints to major media and financial institutions, along with a press release, which Borzilleri admits, "make substantially negative allegations about the defendants in those actions." *See* Ex. E, ¶¶ 38–40 (SKK Complaint); Ex. C, ¶¶ 38–40 (Answer & Counterclaims). Once SKK became aware of Borzilleri's press release and his conduct, the firm investigated Borzilleri's conduct and terminated him for "aggressive trading during the period in which he knew that information about the [lawsuits] would soon be made available to the public," and ultimately filed a lawsuit against him on May 9, 2018. *Id.* ¶ 52. Borzilleri's blatant attempt to capitalize from his *qui tam* complaints is further evidence of his opportunistic motives.

ARGUMENT

I. THE SAC IS DEFICIENTLY PLED UNDER RULES 9(b) AND 8(a)

The SAC 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 8(a)'s plausibility pleading standard; those that fail to do so are subject to dismissal under Rule 12(b)(6). To satisfy Rule 9(b)'s particularity requirement, a False Claims Act complaint must set forth the "who,

what, when, where, and how" of the alleged fraud. *United States ex rel. Ge v. Takeda Pharm. Co., Ltd.*, 737 F.3d 116, 123 (1st Cir. 2013) (citation omitted). "The FCA penalizes those who present, or cause to be presented, 'false or fraudulent claim[s] for payment or approval' to the federal government." *Hagerty ex rel. United States v. Cyberonics, Inc.*, 844 F.3d 26, 31 (1st Cir. 2016) (quoting 31 U.S.C. § 3729(a)(1)). Thus, fraud alleged under the FCA must contain two components pled with particularity in accordance with Rule 9(b): "the defendant must submit or cause the submission of a claim for payment to the government, and the claim for payment must itself be false or fraudulent." *Id.* The heightened pleading standard therefore applies both to the underlying fraudulent scheme and to allegations that a defendant submitted or caused the submission of a false claim.

Recognizing that the FCA at times attracts "parasitic" relators, the First Circuit has oft explained:

> [A] relator must provide details that identify particular false claims for payment that were submitted to the government. In a case such as this, details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices are the types of information that may help a relator to state his or her claims with particularity.

Ge, 737 F.3d at 123 (quoting *United States ex rel. Karvelas v. Melrose–Wakefield Hosp.*, 360 F.3d 220, 232–233 (1st Cir. 2004), *abrogated on other grounds by Allison Engine Co. Inc. v. United States ex rel. Sanders*, 553 U.S. 662 (2008)). While this information does not "constitute a checklist," a relator must include at least some of it to satisfy Rule 9(b). *Ge*, 737 F.3d at 123.

Critically, a relator may not merely "rais[e] facts that suggest fraud was possible," but instead must provide evidence beyond possibility. *United States ex. rel. Kelly v. Novartis Pharm. Corp.*, 827 F.3d 5, 13 (1st Cir. 2016). Similarly, allegations that fraud "could have"

taken place fail under Rule 9(b). *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 6–7 (1st Cir. 2016). Furthermore, "[c]onclusory allegations and references to 'plans and schemes' are not sufficient" to satisfy Rule 9(b). *Kelly*, 827 F.3d at 13; *see also United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 45 (1st Cir. 2009) ("Conclusory allegations . . . are not sufficient to satisfy Rule 9(b)."") (alteration in original) (internal quotations omitted). In short, arguments that proceed from insinuation or surmise instead of facts fail under Rule 9(b). *Hagerty*, 844 F.3d at 33.

To adequately plead a false claim in an action where "the defendant is alleged to have induced third parties to file false claims with the government," a relator must, at a minimum, provide "'factual or statistical evidence to strengthen the inference of fraud beyond possibility,'" if he or she is unable to provide "'details as to each false claim.'" *Ge*, 737 F.3d at 123–24. In such cases, the First Circuit has made clear that where relators offer only "aggregate expenditure data" for the drug at issue without "identify[ing] specific entities who submitted claims . . . much less times, amounts, and circumstances," their claim falls far short. *Ge*, 737 F.3d at 124. And "[m]erely alleging that a scheme was wide-ranging—and, therefore, that a fraudulent claim was presumably submitted—will not suffice" either. *Kelly*, 827 F.3d at 13–14.

In addition to Rule 9(b)'s rigorous pleading standards, an FCA complaint must satisfy Rule 8(a)'s plausibility standard. In considering a motion to dismiss, "a court must accept all factual allegations in the complaint as true," but the Court need not accept as true conclusory allegations, and "a formulaic recitation of the elements of a cause of action will not do." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Accordingly, 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." *Id.* The Court must dismiss claims that do not cross the line "from conceivable to plausible." *Id.* at 680.

A. The SAC's Allegations Regarding A "Service Fee" Scheme Do Not Satisfy Rule 9(b) Or 8(a)

1. The SAC Fails To Plead A Fraudulent Service Fee Scheme Plausibly And 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 ¶ 15, 27. 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 id.* ¶¶ 35–47. He asserts that Part D plan sponsors failed to properly report service fees exceeding fair market value to CMS. *Id.* ¶ 31. 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.

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* properly reported to the plan sponsor, which the plan sponsor *must not have* properly reported to CMS. But, strikingly, Borzilleri does not allege the amount of any service fee paid by any Manufacturer Defendant, nor the details of any contract between any PBM and any Manufacturer Defendant, nor how PBMs reported these service fees to a plan sponsor, nor how that plan sponsor ultimately reported these fees to the government. He readily admits that he lacks all of these details. *See, e.g.*, SAC ¶ 162 ("the individual 'service fee' contracts between

the Manufacturer and the PBM Defendants remain a closely guarded secret") (emphasis omitted); *see also id.* ¶¶ 223, 265; *id.* ¶ 197 (same); *id.* ¶ 434 (noting need to rely on discovery for information concerning reporting). Without such details, the SAC is devoid of facts that could move Borzilleri's allegations from the realm of the possible to the plausible, *Iqbal*, 556 U.S. at 679, let alone provide the particularity required by Rule 9(b).

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 is only speculating exist. SAC ¶¶ 225-226; *see also id.* ¶ 537 ("[W]e anticipate a thorough investigation of these fraud allegations must include a review of all economic transfers between the Manufacturer and PBM Defendant, starting with their contractual agreements."). Borzilleri clearly has never seen the contracts about which he spends nearly 200 pages postulating. He knows nothing about their terms and has not read even one. Not surprisingly, then, the SAC omits any allegation regarding any actual contract between any Manufacturer Defendant and any PBM Defendant. The SAC also fails to plead any facts suggesting that any hypothetical service fees paid by any Manufacturer Defendant exceeded fair market value. The SAC certainly does not plead that any Manufacturer Defendant paid any PBM a service fee that was not properly reported to a plan sponsor or CMS. The SAC thus fails to plead—even plausibly, let alone with particularity—the fraudulent scheme Borzilleri alleges.

Lacking any specific details that might make his allegations plausible, Borzilleri relies on speculation. *See, e.g.*, SAC ¶ 363 ("Without the pricing scheme, we ***estimate*** that overall combined US sales for the 7 Defendant MS drugs would have remained flat in the $2.5 billion range between 2005 and 2017. We ***assumed*** a US launch prices of $30,000 patient/year for

Gilenya and Tecfidera, far higher than the $17-19,000 range in Europe") (emphasis added); *see also* SAC ¶¶ 364–395. While building assumptions onto hypotheticals onto guesswork, Borzilleri's SAC "ignores the fact that it is the fraud itself which must be pled with particularity." *Gagne*, 565 F.3d at 47; *see also United States ex rel. Cavallino Consulting, LLC v. Smith & Nephew, Inc.*, No. 17-CV-11517-IT, 2018 WL 3966301, at *2 (D. Mass. Aug. 17, 2018) (holding that under the First Circuit "fraud itself must be pled with particularity, and the complaint must connect the fraud alleged to an effort to get false claims paid or approved by the government, including some details on the alleged fraudulent submissions to the government"). Here, Borzilleri simply hypothesizes that a fraudulent scheme occurred and that the Manufacturer Defendants would have benefited from his speculative fraud. This does not suffice to plead a fraudulent scheme under Rule 8(a) or Rule 9(b).

2. The SAC Fails To Plead Any False Claims Plausibly And With Particularity

Even if the SAC pleaded plausibly and with particularity that the Manufacturer Defendants paid PBMs service fees in excess of fair market value that should have been reported as discounts by a Part D plan sponsor, Borzilleri would still need to plead facts sufficient to suggest that such fees actually were improperly reported to Medicare and that false claims resulted. As the First Circuit has explained, "the defendant's presentation of false or fraudulent claims to the government is a central element of every False Claims Act case. A health care provider's violation of government regulations or engagement in private fraudulent schemes does not impose liability under the FCA unless the provider submits false or fraudulent claims to the government for payment based on these wrongful activities." *Karvelas*, 360 F.3d at 232; *see id.* at 225 ("[T]he statute attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment. Evidence of an actual false claim

is the *sine qua non* of a False Claims Act violation." (citation and internal quotation marks omitted)).[5] Simply put, the SAC fails because it is devoid of ***any*** factual allegations that might tie any purported service fees paid by a Manufacturer Defendant to any hypothetical claims submitted by a Part D plan sponsor or that create an inference that such claims were submitted.

The SAC fails to specifically identify a single false claim, and does not even plausibly plead that any false claims were submitted. The SAC contains no facts whatsoever regarding the information purportedly provided by any PBM to any plan sponsor, and certainly never alleges with particularity that any plan sponsor improperly characterized a service fee in its reports to CMS. Borzilleri does not claim to know *who* prepared or submitted any DIR report, *what* service fees 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 was reported. *See id.* ¶ 31. These are gaping holes in his theory, and are fatal to the SAC. *See D'Agostino,* 845 F.3d at 10.

In *D'Agostino,* the First Circuit held that to plead the submission of a false claim with particularity, a relator generally needs to provide "examples of actual false claims submitted to the government." *Id.* "By doing so, the relator conveys that if the facts alleged are true, the filing of a false claim is not merely a possibility, but rather, necessarily occurred." *Id.* While the First Circuit has recognized a limited exception to this rule in cases in which a defendant is alleged to have caused a third party to submit a false claim, such cases must still be supported by "factual or statistical evidence to strengthen the inference of fraud beyond possibility." *Id.* (internal quotation marks omitted); *see also Ge,* 737 F.3d at 124. The SAC fails to satisfy this

[5] For that reason, "Rule 9(b)'s particularity requirement applies with full force" to alleged false claims asserted under sections 31 U.S.C. §§ 3729(a)(1) and (a)(2), (*see* SAC ¶¶ 693-694, 709-715). *Ge,* 737 F.3d at 129 n.5; *Karvelas*, 360 F.3d at 232; *Gagne,* 565 F.3d at 46.

limited exception. It offers only generalized data regarding the pharmaceutical industry, none of which provides a basis for inferring that the Manufacturer Defendants induced plan sponsors to submit false claims. *See, e.g.*, SAC ¶ 3 (asserting that pharmaceutical spending consumes 17% of the U.S. economy); ¶ 9 (asserting that list prices for four of the drugs at issue in this case have increased from 2005 to 2018 while prescriptions and usage have plummeted 40–70%). To the contrary, the data the SAC cites is precisely the type of generalized statistics that the First Circuit has repeatedly found insufficient to support an inference of fraud. *See Ge*, 737 F.3d at 124 (dismissing claim where plaintiff provided "aggregate expenditure data for one of the four subject drugs, with no effort to identify specific entities who submitted claims or government program payers, much less times, amounts, and circumstances."); *Lawton ex rel. United States v. Takeda Pharm. Co., Ltd.*, 842 F.3d 125, 132 (1st Cir. 2016) (holding that allegations regarding the percentage of off-label sales and the amounts of Medicare and Medicaid funds spent on the drug at issue were insufficient to create an inference of fraud). As further demonstrated below, nothing in the SAC provides either the statistics or the facts necessary to establish the strong inference of submission of a false claim by a third party. *See Kelly*, 827 F.3d at 14; *Ge*, 737 F.3d at 124.

(a) The SAC's Few Allegations About Individual Manufacturer Defendants Are Insufficient And Group Pleading Does Not Satisfy Rule 9(b)

The SAC's allegations that relate to the individual Manufacturer Defendants are small in number, narrow in scope, and, at best, weave a conclusory theory based on general information about the distribution of pharmaceuticals. Borzilleri offers purported data about the list prices, revenues and profits of the Manufacturer Defendants' drugs, asserts that there has been "staggering" harm to the public fisc, and guesses, without any factual support, that "30%" of the

sales of the Manufacturer Defendants' products is "attributable to the Part D program." SAC ¶ 94. None of this suffices to plead either a fraudulent scheme or a false claim.

For each of the products at issue, Borzilleri alleges (at length) that the drug's list price, revenues, and profits have increased over time. *See, e.g.*, *id.* ¶¶ 227–234; 301-396. He alleges that usage has decreased 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. *See, e.g.*, *id.* ¶¶ 301–396. Finally, for some of the drugs, he makes allegations about other available drugs in the same drug class and market share. *See, e.g.*, *id.* ¶¶ 313, 321, 327. 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 Medicare Part D. Rather, Borzilleri's allegations regarding the Manufacturer Defendants' drugs amount to mere speculation about a market that Borzilleri admits is complex and influenced by numerous factors. They certainly do not plead a fraudulent scheme with particularity or provide any inference to suggest any false claims were submitted to the government. They therefore do not meet the requirements of either Rule 8(a) or Rule 9(b).

Lacking specific facts about any Manufacturer Defendants' conduct, the SAC relies on impermissible group pleading. Many of the SAC's allegations refer only to the "Manufacturer Defendants"—seven separate companies— and "PBM Defendants"—six separate companies. *See*, *e.g.*, SAC ¶¶ 27, 29, 32, 34, 36, 38, 41, 48, 49, 68, 72, 73, 79–81, 85, 89, 96, 123, 152–153, 157–159, 164, 243, 249, 268, 290, 308–310, 313, 386, 388, 392, 394, 431, 435, 525, 538, 558, 623. 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 appropriately to plan sponsors or CMS. *E.g.*, *id.* ¶ 36 ("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 has previously explained, "it is well established that '[w]here multiple defendants are involved, each person's role in the alleged fraud must be particularized in order to satisfy Rule 9(b).'" *W. Reserve Life Assur. Co. of Ohio v. Caramadre*, 847 F. Supp. 2d 329, 343 (D.R.I. 2012) (Smith, J.) (citations omitted) (collecting cases). A plaintiff may not allege wholesale fraud on the part of multiple defendants absent "particularized allegations of each [d]efendant's role." *Id.*; *see also Rick v. Profit Mgmt. Assocs., Inc.*, 241 F. Supp. 3d 215, 224 (D. Mass. 2017) (dismissing fraud claim against multiple defendants because the plaintiff failed to allege with particularity the specific role of each in the alleged fraud). Indeed, the purpose of Rule 9(b)'s particularity requirement "is to 'give notice to defendants of the plaintiffs' claim, to protect defendants whose reputation may be harmed by meritless claims of fraud, to discourage 'strike suits,' and to prevent the filing of suits that simply hope to uncover relevant information during discovery.'" *Karvelas*, 360 F.3d at 226 (quoting *Doyle v. Hasbro, Inc.*, 103 F.3d 186, 194 (1st Cir. 1996)).

The SAC's group pleading contravenes each of these purposes. The SAC repeatedly acknowledges that Borzilleri cannot offer individualized allegations absent discovery. *E.g.*, SAC ¶ 162 (Borzilleri has no knowledge of individual contracts absent discovery), ¶ 196 (noting financial terms and transactions will be key part of discovery in case.) And 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. Further, each Manufacturer Defendant is entitled to know— specifically—

what plan sponsor ultimately submitted an allegedly false claim, when the plan sponsor submitted the claim, and how the Manufacturer Defendants knew the plan sponsor would submit the claim. Courts have repeatedly made clear that fraud claims against multiple defendants must separately set forth each defendant's allegedly fraudulent acts to advise each defendant of the nature of the allegations against it. *See, e.g.*, *Ezell v. Lexington Ins. Co.*, No. 17-10007-NMG, 2018 WL 4654706, at *5 (D. Mass. Sept. 27, 2018) (granting motion to dismiss against various insurance companies because "where there are multiple defendants, the specific role of each must be alleged"); *Rick*, 241 F. Supp. 3d at 224. As a result, Borzilleri's reliance on group pleading renders the SAC deficient—and subject to dismissal—under Rule 9(b).

(b) The SAC's "Sources" Contradict Its Allegations, Do Not Ascribe Conduct To Any Manufacturing 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.[6]

To the contrary, the SAC is replete with citations to sources that contradict Borzilleri's allegations. For example, the SAC claims that an "incriminating" 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. SAC ¶¶ 68, 161–172 (citing "PhRMA Report" attached as Ex. F). Curiously, Borzilleri then compares this 8% "average" to estimates he made in earlier filings with the Court, apparently trying to draw an inference based on his own faulty assumptions. SAC ¶¶ 68, 97, 163, 165–178, 174. Far from being "incriminating," the PhRMA

[6] Equally importantly, as these sources were previously publicly disclosed, Borzilleri's reliance upon them precludes his SAC under the FCA's public disclosure bar. *See infra* Section II.

report directly contradicts Borzilleri's position that it "disclosed average contract terms for 'service fees.'" *Id.* ¶ 163 (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, and cannot help Borzilleri survive dismissal.[7]

Borzilleri relies on a second document that he describes as "definitively incriminat[ing] both Defendant parties in the 'service fee' scheme." SAC ¶ 179. This document, a report prepared for the Pharmaceutical Care Management Association (PCMA) also does not help him establish an inference of fraudulent service fees paid by any Manufacturer Defendant. *See* Ex. G. 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

[7] As this Court has summarized: "when the complaint adverts to specific written instruments but does not attach them, the court may credit the actual terms of the instruments and reject the plaintiff's inconsistent conclusory characterization of them in granting a motion to dismiss." *Pimental v. Wells Fargo Bank, N.A.*, C.A. No. 14-494S, 2015 WL 5243325, at *4 (D.R.I. Sept. 4, 2015), report and recommendation adopted, 2016 WL 70016 (D.R.I. Jan. 6, 2016); *see also Newman v. Lehman Bros. Holdings Inc.*, 901 F.3d 19, 27 (1st Cir. 2018) (noting that a plaintiff may plead himself out of court through documents referenced in complaint because when a written instrument contradicts the allegations of the complaint, the instrument trumps the complaint).

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 fare no better. 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 ¶ 175. 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.* ¶¶ 446–47) 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 an industry conference—which was open to anyone interested in attending—at which there was general discussion about service fees and various fair market valuation methodologies (*id.* ¶¶ 450–87) provide an indication that any manufacturer generally, or any Manufacturer Defendant specifically, paid Part D service fees that were improperly reported. Certainly nothing about this conference indicates that any Manufacturer Defendant participated in a price collusion scheme designed to cheat Medicare.

Finally, the handful of contracts between PBMs and employers providing employees insurance referenced in the SAC (*id.* ¶¶ 575–99) also provide no information from which the Court could infer that any Manufacturer Defendant paid fraudulent service fees. The contracts between payers and PBMs say nothing about the Manufacturer Defendants other than that service fee arrangements may exist. *Id.* ¶¶ 581, 595. These payer contracts do not identify the amount of the service fees, the details of any service fee paid, or the submission of any claim to

the government. That leaves Borzilleri with just his own self-serving speculation and conclusions.

(c) Borzilleri Cannot Rely Upon Discovery To Generate The Facts Missing From His SAC

Borzilleri believes that he can use discovery to fill in the following 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.* ¶¶ 105, 162, 196, 197, 349, 434. He is wrong. The First Circuit emphasizes that courts do not permit relators to use discovery to meet the requirements of Rule 9(b), recognizing "a concern that a qui tam plaintiff, who has suffered no injury in fact, may be particularly likely to file suit as a pretext to uncover unknown wrongs." *Karvelas*, 360 F.3d at 231 ("[W]e hold that a qui tam relator may not present general allegations in lieu of the details of actual false claims in hopes that such details will emerge through subsequent discovery."); *see also Cavallino Consulting*, 2018 WL 3966301, at *3 (dismissing qui tam action under Rule 9(b) and noting that a "qui tam relator may not present general allegations in lieu of the details of actual false claims in the hope that such details will emerge through subsequent discovery"); *Driscoll v. Simsbury Assocs., Inc.*, No. 17-CV-12373-ADB, 2018 WL 2139223, at *4 (D. Mass. May 9, 2018) (dismissing FCA claims under Rule 9(b) because a "[p]laintiff may not present general allegations and seek to amend the complaint after discovery, but rather, she is required to plead her claims with particularity at the outset").

Precisely because of this concern that *qui tam* plaintiffs will file lawsuits without particularized allegations to gain access to discovery fishing expeditions, an FCA relator cannot plead generally as Borzilleri has done here. The breadth of the discovery Borzilleri proclaims would be necessary exemplifies the danger of allowing a relator to spin a fantastic tale of

wrongdoing in hopes of propounding discovery. *See* SAC ¶ 537 (asserting that Borzilleri's theory about service fees requires examination of "all economic transfers between the Manufacturer and PBM Defendants"). Such an outcome would run counter to Rule 9(b). Borzilleri 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 appropriately reported to CMS, and that false claims may exist. That is a far cry from the particularity necessary to satisfy Rule 9(b). *See D'Agostino*, 845 F.3d at 10; *Gagne*, 565 F.3d at 47.

(d) Borzilleri's False Certification Theory Does Not Plead A False Claim Plausibly And With Particularity

As an apparent alternative theory, Borzilleri half-heartedly alleges the Manufacturer Defendants violated the FCA based on the "express certification" theory of liability. An express certification claim may arise when the party making the claim for payment expressly represents compliance with a statute or regulation, *U.S. ex rel. Bierman v. Orthofix Int'l, N.V.*, 113 F. Supp. 3d 414, 420 (D. Mass. 2015), and compliance is material to the Government's decision to pay. *See United States ex rel. Escobar v. Universal Health Servs. Inc.*, 842 F.3d 103, 109 (1st Cir. 2016). Borzilleri, however, fails to plead any actual express certification. In one brief sentence, Borzilleri alleges that Manufacturer Defendants are liable because of a supposed express certification requirement. SAC ¶ 152(8). But that is the only reference in the SAC to an express certification requirement for Manufacturer Defendants, and Borzilleri provides no other detail. Indeed, the only support that Borzilleri provides regarding an express certification requirement generally are citations to 42 C.F.R. § 423.505, which imposes certification requirements on only

Part D plan sponsors and subcontractors of Part D plan sponsors, ***not drug manufacturers***. *See, e.g., id.* ¶¶ 135–36, 151, 153, 257–58. An FCA case based on the express false certification theory rises or falls on the existence of actual certifications. *United States ex rel. Gelbman v. City of New York*, No. 14-CV-771 (VSB), 2018 WL 4761575, at *7 (S.D.N.Y. Sept. 30, 2018) (dismissing claim based on express certification theory because relator failed to plead an actual certification that was either signed or caused to be signed by the defendant). Yet, Borzilleri fails to allege any express certification requirement for Manufacturer Defendants or an actual express certification that Manufacturer Defendants made to the Government that relates to service fees or any other conduct alleged in the SAC. Accordingly, to the extent Borzilleri's FCA claims are predicated on an express certification theory, those claims fail under Rules 8(a) and 9(b) as well.

B. The SAC's Catastrophic Cost-Sharing Theory Does Not Satisfy Rule 9(b) or 8(a)

Borzilleri also speculates that Manufacturer Defendants engaged in "cost-sharing fraud" by "fraudulently excusing" a cost-sharing obligation that exists for Part D plan sponsors when a participant's drug costs exceed a certain threshold amount. SAC ¶¶ 423–33. Borzilleri theorizes that because drug prices have increased in recent years, Defendants must have entered into a "secretive fraudulent financial arrangement" to avoid "unforeseen 'cost sharing' exposure." *Id.* ¶ 423. Borzilleri's speculative discussion about supposed "cost-sharing fraud" lacks any specific facts sufficient to satisfy Rule 9(b)'s pleading requirements.

First, this theory inappropriately relies entirely on group pleading, referring to Defendants (both Manufacturer and PBM) collectively. (*See supra* Section I.A.2(a).)

Second, Borzilleri's discussion regarding the alleged cost-sharing scheme is rife with speculation, conjecture, and assumptions. For example, he speculates that "[t]he only way the PBM Defendants could avoid tremendous dislocation" from increased cost-sharing obligations is

through a fraudulent scheme. SAC ¶ 423. Borzilleri further hypothesizes, "[*i*]*f* the Manufacturer Defendants are commonly 'forgiving' the PBM Defendants from their Part D catastrophic exposure, these amounts should be properly reported as discounts . . . to CMS, serving to lower program 'negotiated' drug prices." *Id.* ¶ 431 (emphasis added). Such baseless allegations cannot plausibly state a claim because they are mere conjecture. *Twombly*, 550 U.S. at 555 (2007). And they certainly are insufficient to plead an inference of fraud beyond possibility as required under Rule 9(b) because it is "not enough simply to 'raise facts that suggest fraud was possible.'" *Kelly*, 827 F.3d at 13 (quoting *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007)). Accordingly, all claims related to alleged "cost-sharing fraud" should be dismissed.

C. The SAC's Kickback Theory Fails To Satisfy Rule 9(b) And 8(a)

In addition to alleging that service fees purportedly paid by Manufacturer Defendants to PBMs exceeded fair market value and should have been reported by plan sponsors as discounts, Borzilleri characterizes those service fees as kickbacks to PBMs in exchange for "formulary access" and their alleged agreement to forego "standard PBM cost-savings practices that would lead to far lower Defendant drug prices." SAC ¶¶ 80, 81, 152(2), 709–15. Yet he identifies no payments made by any Manufacturer Defendant to any PBM, let alone any facts or circumstances to indicate any such payment was intended as an inducement for formulary access or to avoid cost-saving measures. Generalized assertions that the Manufacturer Defendants paid unlawful kickbacks for formulary access fall woefully short of what Rule 9(b) requires. *Ge*, 737 F.3d at 123 (a complaint must set forth the "who, what, when, where, and how" of the alleged fraud).

Indeed, Borzilleri's kickback theory amounts to "no more than conclusions, [which] are not entitled to the assumption of truth" and do not even suffice under Rule 8(a). *Iqbal*, 556 U.S. at 679. Borzilleri appears to hypothesize kickbacks predicated on the difference between the

service fees actually paid and the presumably lower fair market value of the underlying services. SAC ¶¶ 81, 153(2). The SAC, however, identifies neither the service fees actually paid nor the fair market value of the services. As such, Borzilleri's kickback theory is not even superficially plausible.

D. The SAC Fails To Adequately Allege Scienter

To establish liability under the FCA, Borzilleri must prove that the Manufacturer Defendants, as entities that do not submit claims to the Government, "knowingly" caused the submission of false claims. An entity acts "knowingly" if it "(i) had actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (ii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1). The FCA's scienter requirements are "stringent." *See Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S.Ct. 1989, 2002 (2016). The SAC, which contains no specific, plausible allegations regarding Manufacturer Defendants' knowledge, falls far short of meeting this requirement.[8]

Although Rule 9(b) allows a plaintiff to allege intent "generally" rather than "with particularity," conclusory allegations and speculation are insufficient to plead scienter. *See Greenstone v. Cambex Corp.*, 975 F.2d 22, 25 (1st Cir. 1992) ("The courts have uniformly held inadequate a complaint's general averment of the defendant's 'knowledge' of material falsity, unless the complaint *also* sets forth specific facts that make it reasonable to believe that defendant knew that a statement was materially false or misleading." (emphasis in the original) (citation omitted), *superseded by statute on other grounds*; *see also U.S. ex rel. Pilecki-Simko v.*

[8] In addition, to the extent that the SAC attempts to assert an FCA claim predicated upon an AKS violation, it must plead that the Manufacturer Defendants "knowingly and willfully" paid excessive service fees in exchange for formulary access or PBM acquiescence to price increases. 42 U.S.C. § 1320a-7b(b). The SAC also fails to meet this requirement.

Chubb Inst., 443 F. App'x 754, 761 (3d Cir. 2011) (affirming dismissal of FCA claims where plaintiff failed to allege facts such as how the defendant companies "documented, or were aware or informed of the [alleged] violations, that would support a plausible claim that they knowingly submitted false claims").

Borzilleri fails to allege the Manufacturer Defendants' knowledge of any step of Borzilleri's attenuated hypothetical scheme, let alone any knowledge of "obvious risks" that false claims were being submitted. The SAC does not allege with any specificity that Manufacturer Defendants knew or should have known that any fees paid to PBM Defendants were fraudulent. Moreover, even if Borzilleri's speculation regarding the alleged fraudulent scheme is correct and Part D plan sponsors submitted inaccurate reports, the SAC does not include any allegations that the Manufacturer Defendants knew or should have known anything about the reports submitted by Part D plan sponsors, let alone whether they mischaracterized service fees. *See United States ex rel. Modglin v. DJO Glob. Inc.*, 114 F. Supp. 3d 993, 1024 (C.D. Cal. 2015), aff'd sub nom. *United States v. DJO Glob., Inc.*, 678 F. App'x 594 (9th Cir. 2017) (finding that scienter was not adequately alleged and dismissing FCA complaint where relator alleged no facts giving rise to a reasonable inference that medical device manufacturers were on notice of alleged false claims). Instead, Borzilleri relies solely on his own hypotheses and conjecture to allege implausibly that Defendants "knew or should have known" about various aspects of an alleged scheme to submit false claims. *See, e.g.*, SAC ¶¶ 43, 152. In short, the SAC is devoid of facts regarding Manufacturer Defendants' knowledge of any alleged scheme. For this additional reason, Borzilleri's FCA claims should be dismissed.

E. The SAC's Other Federal FCA Claims Fail

1. The SAC Fails To State An FCA Conspiracy Claim Plausibly And With Particularity

Borzilleri also attempts to plead an FCA conspiracy. Like other FCA liability theories, conspiracy under the FCA must be pled with particularity. *Gagne*, 565 F.3d at 45. For all of the reasons discussed above, the SAC fails to plead an underlying FCA violation with the requisite particularity; it therefore cannot state a claim for a conspiracy to violate the FCA. *See United States ex rel. Hagerty v. Cyberonics, Inc.*, 95 F. Supp. 3d 240, 269 (D. Mass. 2015) ("Because the complaint does not state allegations of fraud under the FCA with the particularity required by Rule 9(b), the conspiracy claim under the FCA must fall as well."). The SAC also must be dismissed because it offers no particularized allegations of a conspiracy to defraud the government. *Id.*

The SAC's conspiracy claim fails because Borzilleri has not even 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 United States ex rel. Estate of Cunningham v. Millennium Labs. of California*, No. 09-12209-RWZ, 2014 WL 309374, at *2 (D. Mass. Jan. 27, 2014) (holding relator's complaint failed to allege agreement and actions in furtherance of agreement and therefore should be dismissed). 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 ¶ 700. 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. This does not suffice. *See United States ex rel. Gagne v. City of*

Worcester, No. 06-40241-FDS, 2008 WL 2510143, at *5 (D. Mass. June 20, 2008) (dismissing conspiracy and other FCA claims where complaint was "rife with abstract, repetitive, and somewhat incoherent allegations of conspiracy and administrative wrongdoing"). Count Two of the SAC therefore must be dismissed.

2. The SAC Fails To State A Reverse False Claim Plausibly And With Particularity

Count Three of the SAC alleges that the Manufacturer Defendants violated 31 U.S.C.§ 3729(a)(7) (now 31 U.S.C. § 3729(a)(1)(G)), which provides a cause of action where the defendant has made what is commonly known as a "reverse false claim." Whereas a traditional false claim action involves a false or fraudulent statement made to the Government to support a claim for money *from* the Government, a typical reverse false claim action involves a defendant knowingly making a false statement to avoid a payment *to* the Government when payment is otherwise due. *Id.* Here, Borzilleri alleges the "Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States Government." SAC ¶ 705. An "obligation" is an established duty, whether fixed or not, arising from . . . the retention of any overpayment." 31 U.S.C. § 3729(b)(3); *United States ex rel. Martino-Fleming v. S. Bay Mental Health Ctr., Inc.*, No. 15-13065-PBS, 2018 WL 4539684, at *6 (D. Mass. Sept. 21, 2018). There "is no liability for obligations to pay that are merely potential or contingent." *Id.*

Count Three is misplaced because there is nothing "reverse" about the conduct alleged in the SAC. Instead, it is redundant of Borzilleri's traditional FCA claims under Count One. Borzilleri cannot simply recast his claims under §§ 3729(a)(1) and (a)(2) as "reverse" false claims under § (a)(7). *See S. Bay Mental Health Ctr., Inc.*, 2018 WL 4539684, at *6 (dismissing reverse false claims count because, in part, "FCA liability [cannot] be premised solely on the

same conduct that gives rise to traditional presentment or false-statement claims"). Thus, Borzilleri's reverse false claim should be dismissed.

But even if this were a reverse false claims action, Borzilleri's claim still fails because the SAC includes no allegation, let alone one pleaded with particularity, regarding any Manufacturer Defendant's obligation to pay the government money, or any false record or statement used to avoid such an obligation. Borzilleri also fails (1) to specify the parameters of the obligation, such as what triggers the duty to repay, what sort of repayment it requires, and the amounts owed, and (2) to allege that Defendants undertook some action to avoid repaying that obligation. *See id.* (dismissing reverse FCA claim because, in part, "[r]elator had not adequately explained how any of the other defendants had an 'established' – as opposed to a potential or contingent – 'obligation' to repay funds to the government"); *see also, e.g.*, *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 473 (6th Cir. 2011) (dismissing reverse false claim because relator failed to identify "any concrete obligation owed to the government by" defendant); *Wood ex rel. United States v. Applied Research Assocs., Inc.*, 328 F. App'x 744, 748 (2d Cir. 2009) (affirming dismissal of reverse false claim because the complaint did not allege any financial obligation that contractor defendants owed to the government). Further, Borzilleri has failed to allege any details that might suggest any Manufacturer Defendant's involvement in a Part D plan sponsor's failure to pay any allegedly owed amounts. For example, the SAC is devoid of allegations regarding any action undertaken by Manufacturer Defendants to cause any alleged failure by Part D plan sponsors to repay any allegedly owed payments, or any allegations regarding any "false record or statement" used in such an effort. This, too, requires dismissal of the claim. Because Borzilleri's conclusory allegations fail to plead a "reverse false" claim plausibly or particularly, Count Three should be dismissed.

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

Borzilleri's common law claims for unjust enrichment (Count Thirty-Three) and common law fraud (Count Thirty-Four) should be dismissed because Borzilleri lacks standing to assert them. Borzilleri brings these claims to recover damages to the Government. *See, e.g.*, SAC ¶ 696. While the FCA permits private citizens to bring a civil action for a violation of the FCA on behalf of the Government, the FCA does not give relators the right to assert common law claims on behalf of the Government. *See United States ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 149 (D. Mass. 2000). Courts have consistently held that a *qui tam* relator lacks standing under the FCA to assert common law claims, including payment, on behalf of the Government. *See id.* ("[T]he Relator lacks standing to bring any common law claims on behalf of the United States."); *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 01-12257-PBS, 2007 WL 4287572, at *5 (D. Mass. Dec. 6, 2007) ("Ven–A–Care, as a relator, cannot separately assert claims for fraud or unjust enrichment on behalf of the government."). Because Borzilleri lacks standing to assert Counts Thirty-Three and Thirty-Four of the SAC, these counts must be dismissed with prejudice.

G. The State FCA Counts Fail To State A Claim

In addition to his federal claims, Borzilleri asserts reverse false claims under the false claims act statutes of 27 states and the District of Columbia.[9] *See* SAC ¶¶ 716–99. His theory appears to be that Manufacturer Defendants, via the alleged service-fee scheme, caused states to

[9] Relator initially named 29 states and the District of Columbia. However, Borzilleri removed claims under the false claims act statutes of New Hampshire and Maryland in the SAC. With respect to Maryland, the Maryland False Health Claims Act provides that "[i]f the State does not elect to intervene and proceed with the action . . . before unsealing the complaint, the court shall dismiss the action [as to the Maryland claims]." Md. Code Ann., Health Gen, § 2-604 (a)(7).

overpay the federal government because states pay the federal government to fund a portion of its Part D spending on certain state beneficiaries.

Where, as here, a relator does not include allegations about how a state law analogue differs from the FCA, the state laws "may be construed consistently with the [FCA]." *Hagerty*, 95 F. Supp. 3d at 270 (citation omitted). Thus, Borzilleri's state law claims should be dismissed for the same reasons as the federal claims. *See United States ex rel. Ge v. Takeda Pharma. Co.*, Nos. 10-11043-FDS, 11-10343, 2012 WL 5398564, at *6 (D. Mass. Nov. 1, 2012) (dismissing state law claims where complaint did not differentiate state claims from the dismissed FCA claims). This is not a reverse false claims case and, even if it was, Borzilleri has failed to state a claim, as he has not alleged any Manufacturer Defendant had any obligation to pay any state government or that any Manufacturer Defendant undertook some action to avoid repaying that obligation. These claims also fail for an additional reason. Borzilleri's reverse false claims theory is predicated on the Manufacturer Defendants actually having engaged in service-fee fraud. But because, as discussed above, Borzilleri has failed to plead adequately any service-fee fraud, Borzilleri's reverse false claims theory has no foundation on which to stand.

Moreover, Borzilleri's state law claims fail to satisfy Rule 9(b) independent of the federal FCA claims' deficiencies. *See, e.g.*, *Rost*, 507 F.3d at 734 n.8 ("The heightened pleading standard of Rule 9(b) generally applies to state law fraud claims brought in federal court."). Borzilleri must include state-specific allegations for each state law claim. *See, e.g.*, *Ge*, 2012 WL 5398564, at *6 (dismissal of the state law FCA claims is appropriate "because the complaints fail to plead with specificity the details of any claims for payment made to any of the states"); *see also United States ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 357 (D. Mass. 2011) (relator "must allege some specificity with respect to each asserted state").

Borzilleri's state law claims do not satisfy these requirements. They do not add any substantive allegations to the federal claims, which themselves do not comply with Rule 9(b) for the reasons stated in Section I.A. Indeed, they contain no state-specific information about any state claims, aside from generalized allegations in the counts themselves. Instead, the SAC's state FCA claims are comprised entirely of legal conclusions that state statutes were violated, and thus they should be dismissed.

II. 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. *United States ex rel. Poteet v. Bahler Med., Inc.*, 619 F.3d 104, 107 (1st Cir. 2010). It applies when (1) a relator's allegations are "substantially similar" to prior public disclosures, and (2) the relator is not an "original source." *United States ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201, 205, 211 (1st Cir. 2016). The bar is "broad" and applies to claims "based *even partly* upon public disclosures." *United States ex rel. Poteet v. Lenke*, 604 F. Supp. 2d 313, 317 (D. Mass. 2009) (internal quotation marks omitted) (emphasis added).

Remarkably, Borzilleri *admits* that his allegations are based entirely on a mosaic of public disclosures, and the disclosures themselves include the elements from which he infers fraud.[10] Far from being an insider or "original source," Borzilleri is a quintessential

[10] 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)); *Torres-Negron v. J & N Records, LLC*, 504 F.3d 151, 162 (1st Cir. 2007) (noting that a defendant can make a "facial" or a "factual" challenge to the Court's jurisdiction under Rule 12(b)(1), and that "[f]acial attacks on a complaint require the court merely to look and see if the plaintiff has sufficiently alleged a

"'opportunistic plaintiff[ ] who ha[s] no significant information to contribute of [his] own.'" *Graham Cty. Soil & Water Conservation Dist. v. United States. ex rel. Wilson*, 559 U.S. 280, 294 (2010) (citation omitted). He is a former investment fund manager who, with no affiliation with any Defendant, filed this action in an attempt to drive Defendants' stock prices down and improve his short positions. (*See supra* Section Background B.3.) As such, the FCA's public-disclosure bar requires dismissal of the SAC.

A. The SAC Should Be Dismissed Under Both The Pre- And Post-ACA Public-Disclosure Bars

Given the span of alleged conduct, two versions of the public-disclosure bar preclude Borzilleri's allegations in this case. Before the Affordable Care Act (ACA) took effect on March 23, 2010,[11] the public disclosure bar stated that "[n]o court shall have jurisdiction over [a False Claims Act *qui tam* action] based upon the public disclosure of allegations or transactions" from a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media unless "the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4)(A) (2009).[12] Following the ACA, the public-disclosure bar now provides in pertinent part that "[t]he court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim

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basis of subject matter jurisdiction" (internal quotation marks omitted)). 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.

[11] Patient Protection & Affordable Care Act, Pub. L. No. 111-148, § 10104(j)(2), 124 Stat. 119, 901–02 (2010) (codified at 31 U.S.C. § 3730(e)(4)(A) (2012)).

[12] Under this pre-ACA version, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information. *Id.*

were publicly disclosed [in certain enumerated sources] unless . . . the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4)(A).

The ACA made three primary changes to the public-disclosure bar. *First*, it removed the language that deprived a court of subject-matter jurisdiction over a case based on public disclosures.[13] *Second*, it altered the list of enumerated sources.[14] *Compare* 31 U.S.C. § 3730(e)(4)(A) *with id.* § 3730(e)(4)(A) (2009). *Third*, as discussed in Section II.C. below, it changed the definition of "original source." Because the ACA amendment was not retroactive, it does not apply to the SAC's alleged pre-ACA conduct. *See, e.g.*, *Graham Cty.*, 559 U.S. at 283 n.1; *United States ex rel. Poteet v. Bahler Med., Inc.*, 619 F.3d 104, 107 n.2 (1st Cir. 2010); *accord United States ex rel. Patriarca v. Siemens Health Care Diagnostics, Inc.*, 295 F. Supp. 3d 186, 195 (E.D.N.Y. 2018). Therefore, this Court should apply the pre-ACA version for conduct

[13] Although the First Circuit has not expressly determined whether the ACA rendered the public disclosure bar non-jurisdictional, *Winkelman*, 827 F.3d at 205, 211, courts in this district and elsewhere have concluded that it is no longer jurisdictional. *See United States ex rel. Winkelman v. CVS Caremark Corp.*, 118 F. Supp. 3d 412, 420 (D. Mass. 2015), aff'd, 827 F.3d 201 (1st Cir. 2016) (post-ACA public disclosure bar requires dismissal under Rule 12(b)(6); *but see United States ex rel. D'Agostino v. EV3, Inc.*, No. 10-11822-RGS, 2014 WL 4926369, at *5 (D. Mass. Sept. 30, 2014) *rev'd on other grounds*, *United States ex rel. D'Agostino v. EV3, Inc.*, 802 F.3d 188, 195 (1st Cir. 2015) (treating amended public disclosure bar as jurisdictional). In any event, the analysis remains the same: the Court can consider under Rule 12(b)(6) the same matters of public record and facts susceptible to judicial notice that it could consider under Rule 12(b)(1). (*See supra* Background n.2.)

[14] Following the ACA's amendments, the enumerated sources now include (i) a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) news media. 31 U.S.C. § 3730(e)(4)(A). The ACA's amendments to the enumerated sources do not alter the analysis here, as Borzilleri's claims are derived exclusively from public disclosures in sources that qualify under either version of the statute.

that allegedly occurred before March 23, 2010, and the post-ACA version for conduct after that date. *See Patriarca*, 295 F. Supp. 3d at 196.[15]

Under either version of the public disclosure bar, however, the Court must perform the same two-step analysis and determine: (1) whether the allegations in the complaint are "substantially similar"[16] to the allegations contained in prior "public disclosures," and, if so, (2) whether the suit may nonetheless go forward because the relator is an "original source" of the information on which he bases his allegations. Borzilleri's SAC is foreclosed under both versions of the statute. His purported inference of fraud—pre- and post-ACA—is based *entirely* on qualifying public disclosures, and he is not an "original source" under either definition. The public-disclosure bar requires his SAC to be dismissed.

B. 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. *Winkelman*, 827 F.3d at 208. This includes instances where a relator like Borzilleri alleges that he "infer[s]" a fraudulent transaction from facts revealed in public disclosures. *United States ex*

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[15] Consequently, the Court should decide whether it has subject-matter jurisdiction over the pre-ACA claims before reaching the Manufacturing Defendants' other arguments as to why those claims must be dismissed. *See, e.g.*, *Steel Co. v. Citizens for A Better Env't.*, 523 U.S. 83, 94 (1998); *Northeast Erectors Ass'n of the BTEA v. Sec'y of Labor, Occupational Safety & Health Admin.*, 62 F.3d 37, 39 (1st Cir. 1995). In addition, Borzilleri has the burden of establishing jurisdiction as to the pre-ACA claims. *Poteet*, 619 F.3d at 109 (holding that the relator, "as the proponent of federal jurisdiction, bears the burden of proving its existence by a preponderance of the evidence.")

[16] Although the pre-ACA version requires dismissal of actions that were "based on" qualifying public disclosures, and the post-ACA version requires dismissal of actions that are "substantially similar" to allegations in qualifying public disclosures, that change merely codified how the First Circuit had interpreted the pre-ACA version and thus the analysis remains the same. *Winkelman*, 827 F.3d 206, 208 (*citing United States ex rel. Ondis v. City of Woonsocket*, 587 F.3d 49, 57 (1st Cir. 2009)).

rel. Conrad v. Abbott Labs., Inc., No. 02-11738-RWZ, 2013 WL 682740, at *4 (D. Mass. Feb. 25, 2013). "[T]he public disclosure bar contains no requirement that a public disclosure use magic words or specifically label disclosed conduct as fraudulent." *Winkelman*, 827 F.3d at 209 (citing *United States ex rel. Findley v. FPC-Boron Emps.' Club*, 105 F.3d 675, 688 (D.C. Cir. 1997), *overruled on other grounds*, *Rockwell Int'l Corp. v. United States*, 549 U.S. 547 (2007) ("A relator's ability to recognize the legal consequences of a publicly disclosed fraudulent transaction does not alter the fact that the material elements of the violation already have been publicly disclosed.")). Rather, a public disclosure occurs when the relevant disclosure:

> present[s] either a direct allegation of fraud, or else both a misrepresented state of facts and a true state of facts such that the recipient may infer fraud. The misrepresented facts and the true facts may also appear in several separate disclosures that combine to create an inference of fraud.

Conrad, 2013 WL 682740, at *3 (internal citation omitted). In these circumstances, the public-disclosure bar applies even if the relator's "expertise makes h[im] the first to understand the alleged fraud." *Id*. at *4. That "a person studying all of these sources would likely need substantial expertise in the field" to understand the alleged fraud is immaterial because "the only question is whether the material facts exposing the alleged fraud are already in the public domain, not whether they are difficult to recognize." *Id*.; *see also Winkelman*, 827 F.3d at 209.

The SAC is barred for two independent reasons: (1) Borzilleri admits in his allegations that he relies on public disclosures to establish the alleged fraudulent scheme; and (2) the essential elements of Borzilleri's allegations are disclosed in pre-complaint public sources.

1. A Facial Review Of The SAC Demonstrates Borzilleri Relied On Qualifying Public Disclosures

The SAC on its face confirms that Borzilleri did not uncover the alleged fraudulent scheme through insider information, but instead is inferring it from his review of public sources—federal regulations and administrative reports, SEC filings, and published drug-pricing

and sales data—that existed before he filed suit. Indeed, the SAC specifically cites to public disclosures to support the allegations of fraud. If Borzilleri's allegations are taken as true, then the essential elements of his purported fraud theory necessarily derive from public disclosures.

First, Borzilleri alleges that the Manufacturer Defendants must have paid inflated service fees to the PBM Defendants because various federal administrative reports[17] reveal that PBMs earned high profits, despite retaining minimal rebates and allegedly facing high catastrophic cost-sharing exposure. 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 ¶¶ 205–209, 646–657 (citing 2011 OIG Report, Ex. H); U.S. Dept. of Health & Human Services-OIG, OEI-03-13-00650, *Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin* (2015)); *id.* ¶¶ 212, 644, 656–663 (citing U.S. Gov't Accountability Office, GAO-10-242, *Spending, Beneficiary Cost Sharing, and Cost-Containment Efforts for High-Cost Drugs Eligible for a Specialty Tier* (2010));

- PBMs had high catastrophic cost-sharing exposure that should have negated profits, absent a fee scheme, *id.* ¶¶ 397–442 (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.* ¶¶ 664–690 (citing Medco Health, Annual Reports (SEC Forms 10-K) (2003-2011)); and

- Profits of Defendant Express Scripts nearly tripled between 2013 and 2017, *id.* ¶¶ 99–104 (citing unidentified "SEC-reported financial statements of Express Scripts").[18]

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[17] An OIG report is a "paradigmatic example" of a qualifying public source. *United States ex rel. J. Cooper & Assocs., Inc. v. Bernard Hodes Grp., Inc.*, 422 F. Supp. 2d 225, 235 (D.D.C. 2006) (dismissing relator's FCA complaint because allegations were disclosed in an OIG report, among other sources); *United States ex rel. Waris v. Staff Builders, Inc.*, No. CIV. A. 96-1969, 1999 WL 788766, at *4 (E.D. Pa. Oct. 4, 1999) (explaining that "the Inspector General's audit report is a paradigmatic example of an 'administrative audit,' which is rendered a public disclosure by the plain wording" of the bar). SEC filings also qualify as public disclosures under 31 U.S.C. § 3730(e)(4)(A). *See United States ex rel. Jones v. Collegiate Funding Servs., Inc.*, 469 F. App'x 244, 257 (4th Cir. 2012).

[18] 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 ¶¶ 68, 72, 76, 97–98, 164–166, 168, 178–191 (citing PhRMA and PCMA

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.* ¶¶ 554–559 (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.* ¶¶ 99–104 (citing unidentified "SEC-reported financial statements of Express Scripts").

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[19] reveal that the Manufacturer Defendants' drug prices and sales have risen despite the availability of cheaper alternative drugs. *See, e.g.*, *id.* ¶¶ 7–13, 22, 84-85, 107, 644, 655, 656, 685 and Exs. 1–12 incorporated therein (citing "public" CMS data; and drug pricing and sales data published by Truven Health Analytics Inc., *Red Book*, IMS Health, PhRMA, and company reports). The alleged fraudulent scheme, Borzilleri concludes, is "the only viable explanation." *Id.* ¶ 107.

Thus, even according to Borzilleri himself, the essential elements of his allegations are taken from public disclosures. As such, the SAC should be dismissed.

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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.

[19] Data published by CMS qualifies as a public disclosure under 31 U.S.C. § 3730(e)(4)(A). *See, e.g.*, *Conrad*, 2013 WL 682740 at *5. The same holds for drug-pricing data published in nongovernmental sources. *See United States v. CSL Behring, L.L.C.*, 855 F.3d 935, 945-46 (8th Cir. 2017) (affirming dismissal under public disclosure bar and determining that *Red Book* data is a public disclosure); *United States 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").

2. A Factual Review Of The SAC Further Confirms Borzilleri's Reliance On Public Disclosures

Not only do Borzilleri's allegations affirmatively state his reliance on public disclosures, but the "essential elements" of the alleged scheme in fact appear in public disclosures. *Ondis*, 587 F.3d at 54. Borzilleri alleges that the Manufacturer and PBM Defendants have entered into secretive contracts that provide for the payment of service fees to PBMs that exceed fair market value. SAC ¶¶ 27–29. Moreover, Borzilleri claims Defendants are intentionally not reporting the payments in excess of fair market value in order to increase drug prices and maximize profits. *Id.* ¶ 31. These allegations are disclosed in several different public sources, many of which were published by the government itself. Therefore, there can be no doubt that "the government has received fair notice, prior to the suit." *Winkelman*, 827 F.3d at 208.

Indeed, a March 2011 report of the U.S. Department of Health and Human Services Office of Inspector General entitled, "Concerns with Rebates in the Medicare Part D Program" (2011 OIG Report) "requires hardly an inferential step to connect the allegedly true and allegedly misrepresented facts." *Winkelman*, 827 F.3d at 209; *see generally*, 2011 OIG Report, Ex. H. The 2011 OIG Report examined administrative fees received by PBMs and found that, among other things:

- "Selected sponsors reported that their PBMs collected fees from drug manufacturers that were not always passed on to the Part D program," 2011 OIG Report, Ex. H, at 18; SAC ¶ 47;
- The "fees were structured like rebates in that they were generally based on a fixed percentage of WAC [the drug's list price]," 2011 OIG Report, Ex. H, at 18-19; SAC ¶¶ 36–37, 210;
- 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," 2011 OIG Report, Ex. H, at 19; SAC ¶¶ 31, 152(5)–(6); and

- "Because 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, Ex. H, at 19; SAC ¶¶ 176–177.

The government was thus acutely aware of the potential for fraud like that alleged by Borzilleri. This disclosure alone is sufficient to bar Borzilleri's claims.

Likewise, several additional sources—including sources not referenced in the SAC that the Court may take judicial notice of—disclose the essential elements of Borzilleri's alleged fraudulent scheme. The following chart outlines Borzilleri's core allegations and the corresponding public disclosures.

"Essential Element" of Borzilleri's Allegations	**Relevant Public Disclosure**[20]
Manufacturer rebates are not the primary source of PBM profits. SAC ¶¶ 70–72, 77, 165, 169, 205-206, 222.	January 2010 GAO Report: "All seven of the plan sponsors we surveyed reported that they were unable to obtain price concessions from manufacturers on 8 of the 20 specialty tier-eligible drugs in our sample between 2006 and 2008. For most of the remaining 12 drugs in our sample, plan sponsors who were able to negotiate price concessions reported that they were only able to obtain price concessions that averaged 10 percent or less, when weighted by utilization, between 2006 and 2008."[21]
Drug prices continue to rise, despite the availability of cheaper drugs. SAC ¶¶ 7, 10, 32, 312–396.	January 2010 GAO Report: "GAO reports that, on average, negotiated prices of the sample specialty tier drugs increased by 36 percent between CY 2006 and CY 2009. We would like to note that price increases are not unique to specialty tier drugs. An internal CMS analysis revealed a more than 30 percent increase in the price indices of brand name drugs (both

[20] "The general rule is that a disclosure is 'public' if it is generally available to the public." *Poteet*, 619 F.3d at 110. DOJ press releases and articles published in BusinessWire and various healthcare industry and academic publications constitute "news media." *See Nowak*, 806 F. Supp. 2d at 330 ("industry or national news media" qualify as sources of public disclosures); *see also Winkelman*, 827 F.3d at 209 (AG press release and news articles reporting on the Change to Win report were sources of public disclosures). CBO, GAO, and OIG reports qualify as administrative "report[s], . . . audit[s], or investigation[s]." 31 U.S.C. § 3730(e)(4)(A)(ii).

[21] Ex. I, January 2010 GAO Report to the Chairman, Subcommittee on Health, Committee on Ways and Means, House of Representatives, Medicare Part D: Spending, Beneficiary Cost Sharing, and Cost-Containment Efforts for High Cost Drugs Eligible for a Specialty Tier (the "January 2010 GAO Report") at 22.

	specialty and non-specialty tier drugs) between January 2006 and October 2009."[22]
PBM fees are not always passed on to the Part D program. SAC ¶¶ 28–31, 38, 60, 274.	2010-2011 OIG Semiannual Report: "Our review also revealed that some sponsors reported large differences in rebates across their plans and received manufacturer rebates when they encouraged beneficiaries to use certain drugs. Some sponsors had complex contractual relationships with their third-party pharmacy benefit managers that sometimes lacked transparency, and some reported that their pharmacy benefit managers collected fees from drug manufacturers that were not always passed on to the Part D program."[23]
Defendants must be paying high, percentage-based fees that are above fair market value in return for favorable formulary treatment. SAC ¶¶ 81–86, 152(2), 153(3), 195–196, 223–224, 239, 244–45, 287-290, 520–523.	2005 Medicare Prescription Drug Benefit Rule: "In the preamble to the proposed rule, we said that to the extent the administrative fees paid to Part D plans (or their subcontractors, such as PBMs) are above the fair market value of the services rendered, this differential will be considered a price concession. . . .[A]s fiduciaries of the Medicare trust fund, we have a responsibility to ensure that price concessions are not masked as administrative fees."[24] January 2007 CBO Report: "Manufacturers also make other types of payments to PBMs in addition to rebate payments. For example, manufacturers commonly pay a fee to PBMs for the service of administering formularies. Such fees are frequently equal to about 3 percent of wholesale list prices."[25] 2012 Medicaid Program Proposed Rule: "We continue to be concerned that [bona fide service fees] could be used as a vehicle to provide discounts, as opposed to fees at 'fair market value' for bona fide services. Thus, to avoid potential fraud concerns, we are retaining our definition, but have chosen not to define 'fair market value' at this time."[26]

[22] Ex. I, January 2010 GAO Report at 36.

[23] Ex. J, October 1, 2010-March 31, 2011, OIG Semiannual Report to the Congress (the "2010-2011 OIG Semiannual Report") at I-16.

[24] Ex. K, Medicare Prescription Drug Benefit Rule, 70 Fed. Reg. 4194, 4308-4309 (January 28, 2005) (the "2005 Medicare Prescription Drug Benefit Rule").

[25] Ex. L, January 2007, Congressional Budget Office (CBO), Prescription Drug Pricing in the Private Sector (the "January 2007 CBO Report") at 12.

[26] Ex. M, Medicaid Program; Covered Outpatient Drugs, 77 Fed. Reg. 5318-01 (Proposed Rule) (February 2, 2012) (the "2012 Medicaid Program Proposed Rule").

	2013 Specialty Pharmacy Times: "Bona Fide Service Fees (BFSFs) is one of the most important industry terms today, with a dramatic impact across pharmaceutical manufacturers, . . . specialty pharmacy and specialty distributors, and GPOs, as well as CMS and oversight agencies such as the [OIG] and [DOJ]. . . . If the government pays more than it thinks it should for pharmaceutical products under these programs, it can apply the False Claims Act, which is legal action [sic] related to the pharmaceutical manufacturer submitting incorrect data which causes the government to pay more than it should. . . . [T]he treatment of fees impacts all of the statutory pricing. . . ."[27] Spring 2013 OIG Semiannual Report: Disclosing OIG review of three plan sponsors' BFSFs.[28]

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).

In sum, because Borzilleri "infer[red]" the alleged fraudulent scheme entirely from qualifying public disclosures, and the disclosures themselves confirm this, the public-disclosure bar precludes his FCA claims unless he is an "original source"—which he is not. *Conrad*, 2013 WL 682740, at *3.

C. Borzilleri Is Not An "Original Source"

Borzilleri is not an "original source" under either the pre-ACA or post-ACA versions of the public disclosure bar. Under the pre-ACA version of the bar, the FCA defined an "original

[27] Ex. N, January-February 2013, Specialty Pharmacy Times, *Why We Care About Bona Fide Service Fees* (the "2013 Specialty Pharmacy Times"), at 1–2.

[28] Ex. O, April 2013-September 2013, OIG's Semiannual Report to Congress (the "Spring 2013 OIG Semiannual Report"), at 95-96 (App'x B).

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) 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." 31 U.S.C. § 3730(e)(4)(B) (2012).

Borzilleri fails to qualify as an "original source" under the pre-ACA version of the public-disclosure bar because the core information he alleges derives exclusively from third-party disclosures, and he does not allege having "something more than secondhand information or collateral research and investigations." *United States ex rel. Banigan v. PharMerica, Inc.*, No. 07-12153-RWZ, 2018 WL 2012684, at *2 (D. Mass. Apr. 30, 2018) (dismissing FCA action where relator was aware of alleged scheme through his job experience) (internal quotation marks omitted); *see also Ondis*, 587 F.3d at 59 ("If a relator merely uses his or her unique expertise or training to conclude that the material elements already in the public domain constitute a false claim, then a *qui tam* action cannot proceed." (internal quotation marks omitted)). Borzilleri is far from an insider with direct and independent knowledge. Rather, he was a "professional healthcare industry investment analyst"—his job was to analyze public disclosures and identify profitable health care investments for his clients. His "knowledge was simply a compilation of publicly disclosed information," and "based on research into public records, review of publicly disclosed materials, or some combination of these techniques," and therefore does not constitute direct and independent knowledge. *Ondis*, 587 F.3d at 59.

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 Winkelman*, 827 F.3d at 211 ("[T]he relators' allegedly new information [must be] sufficiently significant or essential so as to fall into the narrow category of information that materially adds to what has already been revealed through public disclosures."). His suit is based entirely on preexisting, publicly disclosed information, and he contributes no inside or valuable information.[29]

Accordingly, as demonstrated by Borzilleri's own admissions in the SAC and a review of the public disclosures themselves, Borzilleri's allegations have already been disclosed in statutorily enumerated sources. The information in the public domain is substantially similar to the allegations in the SAC, and Borzilleri is not an "original source" of the disclosures. Therefore, the public-disclosure bar applies, and the SAC should be dismissed.

III. THE SAC SHOULD BE DISMISSED WITH PREJUDICE

Borzilleri's claims should be dismissed with prejudice. A district court may refuse leave to amend where there is, among other factors, "repeated failure to cure deficiencies" or "futility

[29] 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.H. Rev. Stat. § 167:61-e(III); 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. § 8.01-218.8; Wash. Rev. Code § 74.66.080(2).

of amendment." *Gagne*, 565 F.3d at 48. Here, Borzilleri filed his action in January 2014 and had nearly *five years* to develop a viable FCA claim against the Manufacturing Defendants. He has failed to do so, despite a multi-year government investigation (in which the government declined to intervene) and *four* attempts at his complaint. *See* Dkt. Nos. 1, 6, 57, 95. Justice does not require granting Borzilleri leave to amend to "try to get it right" in what would be his fifth complaint in this action. *Gagne*, 565 F.3d at 48 (affirming denial of relators' request to amend for the fourth time "based on relators' repeated failure to cure the deficiencies in their pleadings" in three prior complaints).

Moreover, it is clear that granting Borzilleri leave to further amend would be futile. In Borzilleri's action pending in the Southern District of New York based upon a nearly-identical complaint, he was explicitly given leave to amend his complaint in response to the defendants' motions to dismiss—and advised that no further amendments would be permitted. *Borzilleri*, No. 15-cv-7881-JMF (S.D.N.Y.), Dkt. 265. Borzilleri failed to amend his complaint in the SDNY case, confirming that he cannot cure his complaints' numerous pleading deficiencies. His inability to do so is not surprising given his status as a short-selling corporate outsider, who does not—and cannot—rely on anything other than publicly available information. After four prior attempts, Borzilleri remains unable to cure the SAC's basic pleading deficiencies, and any prospective amendment would be futile. Accordingly, the SAC should be dismissed in its entirety, with prejudice.

CONCLUSION

WHEREFORE, for the foregoing reasons, and those set forth in the Joint Motion to Dismiss filed by the PBM Defendants, Borzilleri's SAC should be dismissed with prejudice pursuant to Fed. R. Civ. P. 8(a), 9(b), 12(b)(1), and 12(b)(6) and 31 U.S.C. § 3730(e)(4).

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CERTIFICATE OF SERVICE

I hereby certify that I filed the within Motion through the ECF system on the 19th of November, 2018, and that notice will be sent electronically to the counsel who are registered participants identified on the Mailing Information for Case No. 14-cv-31.

/s/ Patricia K. Rocha