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

REPLY IN SUPPORT OF MANUFACTURER DEFENDANTS' JOINT MOTION TO DISMISS THE SECOND AMENDED COMPLAINT

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PRELIMINARY STATEMENT

The Manufacturer Defendants[1] file this Reply to address the shortcomings in Borzilleri's Opposition to the Defendants' Motion to Dismiss Relator's Second Amended Complaint. (ECF No. 176, the "Opposition"). Notwithstanding Borzilleri's attempt to bolster his deficient claims with new, improperly added allegations,[2] he still fails to (i) plausibly plead the essential elements of an FCA claim, let alone with particularity, or (ii) demonstrate how the SAC could survive the FCA's public disclosure bar.

Borzilleri's Opposition largely repackages the SAC's unsupported theory that a hypothetical collusive scheme between the Manufacturer Defendants and the PBM Defendants —involving allegedly excessive service fees that purportedly were improperly reported to the government or intended as kickbacks—is the only possible explanation for increasing drug prices over the past decade. Borzilleri also incorrectly asserts that the Manufacturer Defendants have not understood the thrust of his allegations. The Opposition fails, however, to address the SAC's utter lack of allegations regarding the facts, circumstances, or details of any Manufacturer-PBM contract, service-fee payment, or any fraudulent claim (the very essence of Borzilleri's alleged scheme)—all of which are necessary to satisfy the requirements of Federal Rules of Civil Procedure 12(b)(6) and 9(b).

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[1] In this brief, all abbreviations have the same meaning assigned to them in the Manufacturer Defendants' Joint Motion to Dismiss the Second Amended Complaint, ECF No. 157 (the "Manufacturer Defendants' Motion") cited herein as "Mfr. Mot."

[2] Borzilleri improperly attached 15 new exhibits to his Opposition. ECF No. 176, Exs. 1-7; ECF Nos. 176-1 to 176-8 (the "Separate Exhibits"). None of these emails, media articles, and Borzilleri-created documents were attached to the SAC. Because Borzilleri has not sought to amend his complaint to include these materials, these new extrinsic materials are not properly before the Court. *See Freeman v. Town of Hudson*, 714 F.3d 29, 35-36 (1st Cir. 2013).

This is unsurprising given that Borzilleri, an admitted "non-insider," has never seen any of the contracts he alleges gave rise to fraudulent claims and has no knowledge about whether the contracts actually call for service-fee payments, the amount or purpose of any alleged service-fee payments, or how those payments were reported to Medicare Part D plan sponsors or to CMS. *See* ECF No. 176, Opp at 13. Unable to plead these crucial facts, Borzilleri insists, without support, that he "sees no significant deficiencies in his understanding of the mechanics of the scheme or the validity of his specific allegations" and is "confident of confirming his allegations expeditiously in discovery"—seemingly ignoring that this is precisely the type of fishing expedition Rule 9(b) exists to prevent. *Id.* at 31, 33. Borzilleri also attempts to obscure the insufficiency of his allegations by suggesting the Defendants' motions are "devoid of any significant 'factual' information beyond what has already been provided," as if this somehow validates his claims. *Id.* at 8-9. Borzilleri fundamentally misunderstands the motion-to-dismiss standard. He also improperly introduces new facts and exhibits via his Opposition, none of which appear in his operative SAC. A motion to dismiss is not the time for a defendant to prove that a complaint's factual allegations are wrong, nor may Borzilleri amend his SAC through his Opposition. The Manufacturer Defendants' Motion demonstrates that the SAC's conclusory allegations fail to state a plausible claim for relief and fail to plead fraud with the requisite particularity; Borzilleri's Opposition cannot, and does not, remedy these deficiencies.

Moreover, Borzilleri's Opposition does not dispute that the SAC's allegations are derived from public disclosures nor does it demonstrate that he can overcome the public disclosure bar by qualifying as an original source. Borzilleri continues to rely exclusively on public sources and concedes that he is not a corporate insider, instead claiming that his "close observation" of

the healthcare industry and professional experience qualify him as an original source. *See, e.g.*, *id.* at 3, 4-5, 7, 27. This argument finds no support in case law or the FCA itself.

Finally, after the Defendants filed their motions to dismiss, the United States filed a motion to dismiss, and briefing on that motion is complete. ECF No. 166 ("U.S. Mot."). The Manufacturer Defendants believe the government's meritorious arguments provide an independent basis for dismissing this case in its entirety. *See* U.S. Mot. at 1 n.2 (noting "this action is also brought on behalf of twenty-seven states and the District of Columbia" each of which "consent[s] to dismissal of this action, without prejudice as to the states").

For each of these reasons, the SAC should be dismissed with prejudice.

ARGUMENT

I. The Opposition Does Not Refute That Borzilleri's "Service Fee" Fraud Theory Is Deficiently Pled Under Rules 9(b) And 12(b)(6)

The Manufacturer Defendants' Motion explained why Borzilleri's allegations regarding a "service fee" scheme failed to plead fraud with particularity as required under Rule 9(b). In particular, it established that Borzilleri:

- pled no facts, circumstances, or details of any service fee paid by any Manufacturer Defendant, any contract involving a service fee, or any fraudulent claim resulting from a service fee (Mfr. Mot. at 13-15);
- pled no facts, circumstances, or details regarding any fraudulent scheme entered into by any Manufacturer Defendant with any PBM concerning service fees (Mfr. Mot. at 13-15);
- failed to identify a single false claim that allegedly was caused to be submitted as a result of any conduct by any Manufacturer Defendant (Mfr. Mot. at 15-17);
- offered no allegations specific to any Manufacturer Defendant other than publicly available information about pricing, sales, and usage of individual drugs (Mfr. Mot. at 17-18);
- relied solely on group pleading and lacked a factual basis for his fraud allegations as to any individual Manufacturer Defendant (Mfr. Mot. at 17-20);

- made allegations about "sources" that did not ascribe conduct to any Manufacturer Defendant and were contradicted by the materials themselves (Mfr. Mot. at 20-23); and
- pled no facts, circumstances, or details showing that any Manufacturer Defendant had knowledge of what any plan sponsor included in any Direct and Indirect Remuneration report ("DIR") (Mfr. Mot. at 27-28).[3]

Despite its bluster, labels, and conclusions, Borzilleri's Opposition confirms that the Court should dismiss the SAC. For all of its length and hyperbole, the Opposition still fails to identify any particularized allegations in the SAC that are sufficient to state a claim under the FCA. Instead, the Opposition continues to proclaim that hypotheses may replace particularized allegations under Rule 9(b), and argues for a more lenient standard against which to measure the SAC's allegations. Borzilleri misapprehends the case law upon which he sporadically relies and continues to tout generalized, group allegations that are insufficient to state a claim under the FCA.

A. The SAC Fails To Adequately Plead A Fraudulent Service Fee Scheme

In response to the Manufacturer Defendants' argument that the SAC does not plausibly plead the amount of any service fee paid at any time by any Manufacturer Defendant to any PBM in connection with any drug, or the terms of any contract by which any such payment was made, Borzilleri concedes that he has no knowledge of any of the "product-specific 'service fee' contracts" that he theorizes exist. Opp. at 32. In response to the Manufacturer Defendants' argument that Borzilleri cannot plausibly allege what any PBM reported to a plan sponsor about any unidentified service fee, or what any plan sponsor reported to CMS in any of its DIR reports, Borzilleri's only answer is that he could use discovery to learn those facts. *Id*. at 31-33. In

[3] The Government's Motion to Dismiss and Reply in Further Support of Government's Motion to Dismiss further highlight the factual shortcomings of Borzilleri's SAC. *See* U.S Mot. at 4; Government Reply in Further Support of Motion to Dismiss, ECF No. 177 ("U.S. Reply Br."), at 3 n.1.

response to the Manufacturer Defendants' argument that the SAC offers nothing but a daisy chain of hypotheses and speculation concerning both service-fee contracts and DIR reporting, Borzilleri merely repeats his conjecture that the Defendants' alleged scheme "is the only viable explanation" for "virtually all instances of 'inexplicable' massive US brand drug price inflation over the past decade-plus," *id.* at 9, and that the DIR reporting for the drugs at issue must be fraudulent.

In light of the litany of Borzilleri's factual failings, Rule 9(b) is tailor-made for this suit. Its particularity requirement ensures that a plaintiff comes to court with more than a speculation-laden complaint before subjecting a defendant to the reputational and financial costs of defending against a fraud action. *See, e.g., United States ex rel. Karvelas v. Melrose–Wakefield Hosp.*, 360 F.3d 220, 226 (1st Cir. 2004) (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"), *abrogated on other grounds by Allison Engine Co., Inc. v. United States ex rel. Sanders*, 553 U.S. 662 (2008). To state a claim under Rule 9(b), a complaint must allege with particularity that each defendant submitted or caused to be submitted a claim for payment to the government that the defendant knew was false. *See Hagerty ex rel. United States v. Cyberonics, Inc.*, 844 F.3d 26, 31 (1st Cir. 2016).[4] As such, to survive dismissal as to any individual Manufacturer Defendant, Borzilleri must plead specific details sufficient to plausibly show the existence of a fraudulent scheme, and each Manufacturer Defendant's involvement in the knowing submission of a false claim. *Id.*

[4] Borzilleri incorrectly argues that Second Circuit precedent is "binding" on this Court. Opp. at 36. The Manufacturer Defendants' Motion articulated the proper legal framework under First Circuit precedent. Mfr. Mot. at 10-13.

Borzilleri admits that he cannot meet this standard. *See* Opp. at 31-33 (discussing Borzilleri's need for discovery to learn about service fee contracts that serve as major component of his SAC). His SAC fails to identify any details of any alleged contract between a Manufacturer Defendant and a PBM Defendant, any basis to infer that any alleged service fees were above FMV or were intended as an inducement, or any facts establishing that any service fees (even if above FMV) were not properly reported to a plan sponsor or to CMS. The SAC thus fails to even plausibly plead a fraudulent scheme, let alone do so with particularity.

B. The SAC Fails To Adequately Plead Any False Claims

Under the applicable First Circuit precedent, Borzilleri must "provide details that identify particular false claims for payment that were submitted to the government." *United States ex rel. Ge v. Takeda Pharm. Co., Ltd.*, 737 F.3d 116, 123 (1st Cir. 2013). Such details may include "the dates of the claims, the content of the forms or bills submitted, their identification numbers, [and] the amount of money charged to the government." *Id.* (citation omitted). Alternatively, where a relator alleges that a defendant induced a third party to submit a false claim, he must provide '"factual or statistical evidence to strengthen the inference of fraud beyond possibility,'" even if he is unable to provide '"details as to each false claim.'" *Id.* at 124 (citation omitted).

Borzilleri, unable to meet either of these standards, attempts to lessen his burden under Rule 9(b) by focusing on out-of-Circuit precedent to argue that he need not provide examples of every instance of fraudulent conduct implicated by the SAC. Opp. at 40. As a factual matter, Borzilleri ignores that he does not identify even a single instance of fraudulent conduct in the entire SAC, let alone any evidence of actual false claims. As a legal matter, Borzilleri overlooks that the First Circuit has made clear that where, as here, a relator offers only "aggregate expenditure data" for the drugs at issue without "identify[ing] specific entities who submitted claims . . . much less times, amounts, and circumstances," his claims fall far short of satisfying

the pleading requirements. *Ge*, 737 F.3d at 124. Borzilleri attempts to argue that he satisfies Rule 9(b)'s particularity standard by citing data from a publicly available CMS database that he just discovered, which he asserts shows that Medicare paid prescription drug claims for the drugs at issue. Opp. at 50-58. But, of course, the fact that Medicare may have paid claims for the Manufacturer Defendants' drugs is of no consequence unless Borzilleri can plead with particularity—or at least provide factual or statistical evidence to establish—that those claims were false. Borzilleri cannot do so as the SAC lacks any details about any circumstances underlying even a single one of the purported claims for the drugs at issue—such as who submitted the claims, when they were submitted, and whether they involved any allegedly excessive service fees—let alone facts showing that any of those claims were false. Borzilleri's conclusory, aggregate allegations are precisely what the First Circuit deemed insufficient in *Ge* and do not suffice to plead an FCA claim.[5]

C. The SAC Improperly Relies Upon Group Pleading

Although Borzilleri attempts to argue that the SAC's sweeping group allegations regarding the Manufacturer Defendants are sufficient, the very case on which Borzilleri relies to support his group pleading approach makes clear that group pleading is inadequate. Opp. at 61-62 (citing *United States ex rel. Swoben v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1181-82 (9th Cir. 2016)). In *Swoben*, the Ninth Circuit differentiated those defendants for whom the relator merely offered "broad allegations" lacking "a strong factual basis" from those for whom more was pled, and held that dismissal was appropriate for each defendant where no strong

[5] Borzilleri also argues for a lower burden based on a Second Circuit case that expressly recognizes that First and Second Circuit law differ. Opp. at 41; *United States ex rel. Chorches for Bankr. Estate of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 92 (2d Cir. 2017) (noting that the First Circuit has its own strict standard, but had not been called upon to decide the particular issue then before the Second Circuit).

factual basis linking the company to a fraud scheme existed. *Id.* The court underscored that the factual allegations against each defendant must be separately addressed to determine whether sufficiently pled allegations subject that individual defendant to continued litigation. *Id*. Here, the SAC contains no individualized allegations for any Manufacturer Defendant. *See* Mfr. Mot. at 17-21; *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) (holding that "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)'").[6]

II. The Opposition Does Not Refute The Deficiencies Of Borzilleri's Other Theories

A. Borzilleri's Catastrophic Cost-Sharing Claims Lack A Factual Basis As To Any Manufacturer Defendant

The SAC fails to plead any facts about any instance in which any Manufacturer Defendant "forgave" a cost-sharing obligation for Part D plan sponsors. Mfr. Mot. at 25-26. While Borzilleri's Opposition continues to highlight this theory, he does not dispute his pleading shortcoming and implicitly acknowledges that he has no particularized information to support his theory. Instead, he claims that the PBM Defendants—not the Manufacturer Defendants—submit "PDE reports" to CMS that he assumes contain incorrectly calculated drug costs, thus leading to "false claims." Opp. at 61. Tellingly, he does not actually cite to any of the allegedly fraudulent PDE reports, and did not attach any to the SAC. Nor does he provide any details of any such

[6] Borzilleri also relies on *City of Perry, Iowa v. Procter & Gamble Co.*, 188 F. Supp. 3d 276 (S.D.N.Y. 2016), to purportedly support his claim that group pleading is not fatal. While *City of Perry* suggested that group pleading may suffice under Rule 8, it ultimately held that a complaint that "lumps all Defendants together" and "identifies no specific statements" and "no specific speakers" is "plainly insufficient to satisfy Rule 9(b)'s heightened pleading requirements." *Id.* at 290.

reports, but only asserts that they might exist. *Id.* These general allegations are pure speculation, and thus any claims based on Borzilleri's catastrophic cost-sharing theory should be dismissed.

B. Borzilleri's References To The Anti-Kickback Statute Are Unhelpful To Him

Borzilleri accuses the Manufacturer Defendants of choosing to "minimize factual challenge[s] to the kickback allegations" contained in his SAC because—according to Borzilleri—those allegations are "straightforward and egregious." *Id.* at 12, 35. This statement overlooks that, at the motion-to-dismiss stage, the Manufacturer Defendants are not permitted to make factual challenges to Borzilleri's conclusory allegations. It also ignores (or misunderstands) the fact that the bulk of the Manufacturer Defendants' Motion sets forth arguments demonstrating that Borzilleri has not identified the facts that would be necessary to plead a criminal kickback scheme with particularity. In particular, as noted in the Manufacturer Defendants' Motion, the SAC fails to plead facts to show that any Manufacturer Defendant actually paid any above-FMV service fee to any PBM Defendant, which is the foundation for Borzilleri's purported kickback theory. Mfr. Mot. at 14-15, 23-27. Borzilleri simply reiterates his belief that the Manufacturer Defendants paid above-FMV service fees and asserts that these must have been intended as kickbacks. But he has not pled any facts to establish that any above-FMV fees were paid, let alone that any such fees were intended as an inducement.

To the extent his Opposition claims that his kickback theory relates to formulary access, the Manufacturer Defendants' Motion explains that a few generalized assertions coupled with a few speculative suggestions fall woefully short of Rule 9(b)'s pleading standard. *Id*. at 26-27. Borzilleri's Opposition suggests nothing to the contrary. As the authority Borzilleri relies on to support his Anti-Kickback Statute claim recognizes, a relator bringing a claim under the FCA cannot "circumscribe" Rule 9(b) by alleging a scheme and then concluding that false claims must have been submitted. *United States ex rel. Kester v. Novartis Pharm. Corp.*, 23 F. Supp. 3d 242,

253 (S.D.N.Y. 2014).[7] Indeed, *Kester* confirms that a relator must plead a fraudulent scheme and the submission of false claims "with a high degree of particularity." *Id.* at 255. Borzilleri has done neither and recasting his fraudulent reporting theory as a kickback theory does not alter the reality that he has not pled any facts regarding the alleged service fees that underpin either theory.

C. Borzilleri Does Not Plead An FCA Conspiracy

The Manufacturer Defendants' Motion explained that general and conclusory allegations of "collusion" do not amount to a sufficiently pled FCA conspiracy claim. Mfr. Mot. at 29-30 (citing numerous cases). Borzilleri's Opposition recognizes that this liability theory requires both an agreement to get a false claim paid and overt acts in furtherance of that agreement. Opp. at 72. But then he simply offers his unfounded allegation that Defendants collectively and individually entered into contracts involving service fees based on list prices. *Id.* at 72-73. That does not amount to pleading any element of an FCA conspiracy claim—let alone all of the elements. *See United States ex rel. Gagne v. City of Worcester*, Civ. A. 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").

D. Borzilleri's False Certification, Reverse False Claims, Unjust Enrichment, Common Law Fraud, And State-Law Theories All Fail To State A Claim

Borzilleri's Opposition does not dispute that he has not pled any factual basis for a false certification theory. *See* Mfr. Mot. at 24-25. Indeed, Borzilleri admits that he "incorrectly stated that the Manufacturers must also 'expressly certify' compliance with the FCA and the AKS, as a

[7] *Kester* also confirms that one of the purposes of Rule 9(b)'s particularity requirement is to discourage complaints that serve as a pretext to conduct discovery, like the SAC here. 23 F. Supp. 3d at 252.

precondition to payment in Medicare Part D." Opp. at 38. As to the Manufacturer Defendants' arguments regarding Borzilleri's reverse false claims, unjust enrichment, common law fraud, and state-law theories, Borzilleri's Opposition provides no response whatsoever. Accordingly, all of those claims fail not only for the reasons set forth in Manufacturer Defendants' Motion, but also because Borzilleri has conceded them. *Mahoney v. Found. Med., Inc.*, 342 F. Supp. 3d 206, 217 (D. Mass. 2018) (deeming a claim waived where opposition to defendants' motion to dismiss failed to respond to defendants' argument that the claim should be dismissed); *see also Collins v. Marina–Martinez*, 894 F.2d 474, 481 n.9 (1st Cir. 1990) ("It is settled beyond peradventure that issues mentioned in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived.").

III. The SAC Fails To Adequately Allege Scienter

As explained in the Manufacturer Defendants' Motion, Borzilleri has failed to plead any specific, plausible allegations regarding 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. *See* Mfr. Mot. at 27-28; *see also 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."), *superseded by statute on other grounds as stated in N. Am. Catholic Ed. Programming Found., Inc. v. Cardinale*, 567 F.3d 8, 13 (1st Cir. 2009). To plead that the Manufacturer Defendants had the knowledge required to violate the FCA, Borzilleri relies solely on his own hypotheses and conjecture to allege implausibly that each Manufacturer Defendant "knew or should have known" about various aspects of an alleged scheme to submit false claims. *See, e.g.*, SAC ¶¶ 43, 152. But the allegations Borzilleri points to

in his Opposition for support—such as that unnamed "executives" from unspecified "Defendants" attended a conference in October 2013—do nothing to address his pleading deficiencies and further demonstrate that those allegations are based solely on conjecture. Opp. at 72. Thus, Borzilleri's FCA claims also should be dismissed because he fails to plead scienter.

IV. The Opposition Confirms That The Public Disclosure Bar Mandates Dismissal Of Borzilleri's Claims

The Manufacturer Defendants' Motion demonstrated that Borzilleri bases his allegations entirely on qualifying public disclosures and that, because he is not an "original source," this case should be dismissed under the FCA's public disclosure bar. *See* Mfr. Mot. 34-46. Borzilleri's Opposition all but concedes these points, and his arguments as to why the bar should not apply are not only unavailing but, in fact, confirm that dismissal is required.

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

In his Opposition, Borzilleri admits that all of his factual allegations derive from public disclosures identified in the SAC. In particular, he repeatedly admits that he is a "non-insider," Opp. at 3, 13, 21, 27, and his pre-filing disclosure to the government under 31 U.S.C. § 3730(b)(2) (which he improperly attaches as an exhibit to his Opposition) admitted that "much of the supporting data disclosed in [his] report is in the public domain," including "drug prices, Part D regulations, OIG reports, SEC filings, industry reports, etc." Opp., Separate Ex. 5 at 93; *see also* U.S. Reply Br. at 3 n.1 (noting that Borzilleri offers only "suppositions derived from public sources"). While Borzilleri strains to articulate why the public disclosure bar should not apply despite these admissions, each of his arguments is meritless.

First, Borzilleri erroneously argues that the bar does not apply because no single disclosure specifically accused the Manufacturer Defendants of fraud. Opp. at 18-23. But "the public disclosure bar contains no requirement that a public disclosure use magic words or

specifically label disclosed conduct as fraudulent." *United States ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201, 209 (1st Cir. 2016). Rather, the bar requires merely that the "essential elements" of the fraudulent scheme were disclosed, including where "the listener or reader may infer fraud" from "a misrepresented state of facts and a true state of facts" drawn from "different sources" that are "combined." *Id.* at 208. As the Manufacturer Defendants' Motion demonstrates, all of the "essential elements" of Borzilleri's alleged fraudulent scheme were publicly disclosed. *See* Mfr. Mot. 37-44 (collecting public disclosures cited in the SAC that allegedly evince a catastrophic-cost sharing kickback and false-reporting scheme). Borzilleri has done precisely what *Winkleman* makes clear is insufficient and will trigger the bar: inferred a purported fraudulent scheme from a combination of publicly disclosed facts. *See Winkelman*, 827 F.3d at 209; Mfr. Mot. 39-40.[8]

Second, Borzilleri erroneously argues that the bar does not apply because there have been few public mentions of *his complaint* in the news media or public filings. Opp. at 24. This assertion is irrelevant. The bar is concerned only with whether the allegations are substantially similar to *prior* public disclosures—not whether there have been disclosures about the complaint itself. *See* 31 U.S.C. § 3730(e)(4)(A).

[8] Applying the test in *Winkelman*, Borzilleri allegedly inferred a fraudulent scheme from public disclosures of "a misrepresented state of facts and a true state of facts," by alleging that: (1) the PBM Defendants certified to CMS that they complied with the AKS and that all service fees were BFSF (i.e., the alleged "misrepresented state of facts"), *see* SAC ¶¶ 135-36, 151, 244, 258 (alleging that the PBM Defendants must have made these certifications to CMS because they are publicly disclosed conditions of Part D participation); and (2) in reality, contrary to the certifications, the PBM Defendants did *not* comply with AKS because they accepted service fees as kickbacks from the Manufacturer Defendants, and the service fees were *not* BFSF because they exceeded fair market value (i.e., the alleged "true state of facts"), *see* Mfr. Mot. 37-44 (collecting public disclosures cited in the SAC that allegedly evince a kickback and false-reporting scheme). *See Winkelman*, 827 F.3d at 209.

Third, Borzilleri contends that the bar does not apply because, even if the essential elements of the scheme were publicly disclosed before he filed suit, "the OIG apparently was not acutely concerned" about a possible service-fee fraud and Borzilleri had not seen "any government inquiry/investigation of BFSFs." Opp. at 21. This assertion, too, is irrelevant. Even assuming that these dubious characterizations were true, Borzilleri admits that the "ultimate inquiry" is not whether or how the government reacted to the public disclosures, but rather whether the disclosures provided "fair notice" to the government about the "potential . . . fraud." *See id.* (quoting *Winkelman*, 827 F.3d at 208-09). Borzilleri's claim that the various public disclosures identified in the SAC permitted him to infer fraud plainly demonstrates that the government had "fair notice" sufficient to trigger the bar.[9] These disclosures therefore bar his claims.[10]

Thus, for all of these reasons, and for the reasons stated in the Manufacturer Defendants' opening brief, the bar squarely applies here because *all* of Borzilleri's allegations derive from prior public disclosures.

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[9] Indeed, if Borzilleri, an industry outsider who has no "programmatic knowledge," U.S. Mot. 3 & n.3, can purportedly infer the alleged fraud from various public disclosures, so too can the government, with its numerous industry experts and unparalleled programmatic knowledge. *See United States ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 327 (D. Mass 2011) ("[O]nce the materials necessary to ground an inference of fraud are generally available to the public, . . . there is nothing to prevent the government from detecting it." (internal quotation marks omitted)).

[10] Borzilleri also makes a handful of meritless arguments that appear to be directed only at the PBM Defendants' brief. (ECF No. 163-1 cited herein as "PBM Mem."). For instance, he argues that the Court should ignore certain disclosures in the PBM Defendants' brief that predate Medicare Part D, Opp. at 18, and that a conference he attended in October 2013 was not sufficiently public to constitute a public disclosure even though it was open to anyone who paid a fee and its materials were available online, *id.* at 21-22. But the bar precludes his claims even without considering these disclosures, *see* Mfr. Mot. at 37-44, and, in any event, these sources do qualify as public disclosures, *see* PBM Mem. at 29-32.

B. Borzilleri Is Not An "Original Source"

Borzilleri admits that he is a "non-insider." Opp. at 3, 13, 21, 27; *see also* U.S. Mot. 3 & n.3 (criticizing Borzilleri's "lack of insider or programmatic knowledge" concerning his allegations). This admission confirms that this is just the type of "parasitic" suit by an "opportunistic plaintiff who [has] no significant information to contribute of [his] own" that the bar is meant to curtail. *Graham Cty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 294 (2010). Despite this dipositive admission, Borzilleri nonetheless insists that he is an "original source," but his arguments are unpersuasive and premised on a fundamental misunderstanding of the original-source exception.

1. Pre-ACA Original-Source Exception

Under the pre-ACA version of the bar, Borzilleri erroneously claims that he is an original source because a public conference he attended in October 2013 provided him with "direct and independent knowledge" of the alleged fraudulent scheme. Opp. at 25-27 (quoting 31 U.S.C. § 3730(e)(4)(B) (2006)). His knowledge is "direct and independent," he asserts, because he obtained it "first-hand" from the conference presenters. *Id.* This argument falls flat.

Borzilleri's knowledge of the alleged fraud is not "direct" because it is not "marked by absence of an intervening agency, instrumentality, or influence: immediate." *United States ex rel. Ondis v. City of Woonsocket*, 587 F.3d 49, 59 (1st Cir. 2009). Far "from actually viewing source documents, or first hand observation of the [alleged] fraudulent activity," *Ping Chen ex rel. United States v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282, 300 (S.D.N.Y. 2013) (citation omitted), Borzilleri claims that he obtained his knowledge from conference presenters who were unaffiliated with the Defendants and who also lacked direct knowledge of the alleged fraud. *See* SAC Ex. 15 (alleged presenter list). Even if a presenter had shared "direct" knowledge of the alleged fraud, Borzilleri's knowledge would still be second-hand. *See, e.g., United States ex rel.*

Barth v. Ridgedale Elec., Inc., 44 F.3d 699, 703 (8th Cir. 1995) ("[A] person who obtains secondhand information from an individual who has direct knowledge of the alleged fraud does not himself possess direct knowledge and therefore is not an original source under the Act."). And his knowledge would still be based on the presenter's public disclosures at the conference. *See United States ex rel. Estate of Cunningham v. Millennium Labs. of Cal. Inc.*, 713 F.3d 662, 673 (1st Cir. 2013) ("Knowledge is not direct if it is based on . . . review of publicly disclosed materials." (internal quotation marks omitted)); *accord Ondis*, 587 F.3d at 59. Thus, Borzilleri had no "direct" knowledge of the alleged fraud and cannot be an original source under the pre-ACA version of the bar.[11]

Borzilleri's knowledge of the alleged fraud is also not "independent" because he gained it exclusively from a series of public disclosures, *see* Mfr. Mot. 37-44, including the October 2013 public conference he highlights. *See Ondis*, 587 F.3d at 59 ("Virtually by definition, a relator whose knowledge is dependent upon the public disclosure of allegedly fraudulent transactions cannot be said to have independent knowledge of the fraud."). This is not surprising since he is an outsider as to the defendants and the pharmaceutical industry as a whole. Thus, Borzilleri had no "independent" knowledge of the alleged fraud, providing yet another reason why he cannot be an original source under the pre-ACA version of the bar.

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[11] Borzilleri also argues that he should be afforded original-source status because he does not consider himself a "disinterested outsider" and was instead a "close observer" of the pharmaceutical markets and of the "Defendants and their business practices," which helped him "generate a wide array of direct and independent knowledge." Opp. at 27-28. But he fails to identify this "direct and independent knowledge," and, in any event, it is well settled that a relator is not an original source merely because he "use[d] his or her unique expertise or training to conclude that the material elements already in the public domain constitute a false claim." *Ondis*, 587 F.3d at 59; *accord Cunningham*, 713 F.3d at 673; *see also In re Pharm. Indus. Average Wholesale Price Litig.*, Civ. A. No. 01-12257-PBS, 2010 WL 1375298, at *2-3 (D. Mass. Mar. 25, 2010) ("Direct and independent knowledge must be something more than secondhand information or collateral research and investigations.").

2. Post-ACA Original-Source Exception

Under the post-ACA version of the bar, Borzilleri also fails to satisfy the original-source exception because his knowledge of the alleged fraud is neither "independent of" nor "materially add[s] to" the publicly disclosed information. 31 U.S.C. § 3730(e)(4)(B) (2012).[12]

Borzilleri argues that his knowledge of the alleged fraud was "independent of" prior public disclosures because he obtained it at the October 2013 conference and through various SEC filings for Medco and Diplomat. Opp. at 29. This argument is erroneous. Contrary to his assertion, his knowledge is based *entirely* on public disclosures, which are featured prominently throughout his SAC. *See* Mfr. Mot. 37-44; *see also Ondis*, 587 F.3d at 59 (knowledge dependent on public disclosures is not "independent"). These include the Medco and Diplomat SEC filings, which are themselves public disclosures. Mfr. Mot. 37-44. And they include the public conference Borzilleri attended, *see* PBM Mem. 31, which Borzilleri himself claims only "verified" the alleged fraud, which he had already purportedly inferred from prior public disclosures, SAC ¶¶ 444, 458. Thus, his knowledge is not "independent of" prior public disclosures, and he cannot be an original source under the post-ACA version of the bar.

Even less convincing, Borzilleri argues that his knowledge of the alleged fraud from the public conference and the Medco and Diplomat SEC filings "materially added to" the prior public disclosures. Opp. at 28-29. As an initial matter, his knowledge could not have added to information in the public domain, because it was *based* on information in the public domain, *i.e.*, drawn from SEC filings and a public conference. More important, he fails to identify any "new information" that he learned from these public sources that is "sufficiently significant or essential

[12] Borzilleri does not contend that he is an original source on the alternative ground that he disclosed his alleged information to the government prior to the public disclosures, consistent with § 3730(e)(4)(B)(i). That exception does not apply here.

so as to fall into the narrow category of information that materially adds to what has already been revealed through public disclosures." *Winkelman*, 827 F.3d at 211. He claims that the conference "provided definitive evidence of scienter" and an "array" of potential witnesses, but these vague and conclusory assertions do not "materially add[]" to the prior public disclosures, and they are implausible since none of the presenters was affiliated with a defendant or involved with the alleged fraud. *See* SAC Ex. 15 (alleged presenter list).[13] Thus, Borzilleri's knowledge of the alleged fraud did not "materially add to" information already in the public domain, and he cannot be an original source under the post-ACA version of the bar.

In sum, Borzilleri acknowledges that he inferred the alleged fraudulent scheme entirely from public disclosures and he does not qualify as an "original source." Therefore, this Court must dismiss his FCA claims, *see* Mfr. Mot. 34-46, as well as his analogous state-law claims, *id.* at 46 n.29.

CONCLUSION

For the foregoing reasons, those in the Manufacturer Defendants' opening brief, and those in the PBM Defendants' and government's motions to dismiss, Borzilleri's SAC should be dismissed with prejudice as to Borzilleri.

[13] In fact, Borzilleri even admitted in his pre-filing disclosure to the government that he had already developed his fraud theory before attending the conference, and that the information he learned there was merely "consistent" with his preexisting theory. Opp., Separate Ex. 5 at 1. This is why, after the conference, he "deemed it unnecessary to edit [his] extensive report which was completed prior to the event." *Id.*

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Certificate of Service

I hereby certify that on March 21, 2019, I served *via the Electronic Court Filing System (ECF)* a true copy of the within pleading on counsel of record. The document has been filed electronically and it is available for viewing and downloading from the ECF system.

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