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

DEFENDANT BIOGEN INC.'S SUPPLEMENTAL REPLY BRIEF IN FURTHER SUPPORT OF THE MANUFACTURER DEFENDANTS' JOINT MOTION TO DISMISS

DATED: March 21, 2019

BIOGEN INC.

By Its Attorneys,

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PRELIMINARY STATEMENT[1]

Biogen's Supplemental Brief submitted in support of the Manufacturer Defendants' Joint Motion to Dismiss the Second Amended Complaint demonstrated that neither the SAC's group pleading allegations against the Manufacturer Defendants, nor its handful of allegations specifically relating to Biogen and its multiple sclerosis medications, suffice to plead a False Claims Act violation against Biogen under the standards set forth in Federal Rules of Civil Procedure 9(b) and 8(a).[2] Borzilleri's Opposition to Biogen's Supplemental Brief makes no meaningful attempt to rebut Biogen's arguments or to identify any facts in the SAC that might meet these standards. Instead, Borzilleri argues that his claims against Biogen should not be dismissed because, according to him, the only conceivable explanation for increases in the price of Biogen's multiple sclerosis drugs over the past decade is Biogen's alleged participation in an industry-wide, collusive scheme to pay excessive service fees to pharmacy benefit managers. Contrary to Borzilleri's assertions, supposition and conjecture do not suffice to plead a FCA claim. Rather, to avoid dismissal, the SAC must plead particularized ***facts*** plausibly alleging that Biogen caused the submission of false claims. The SAC fails to do so, and Borzilleri's Opposition does not—and cannot—cure these deficiencies. The SAC should be dismissed with prejudice as to Biogen.

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[1] Defendant Biogen Inc. joins in the Reply In Support Of The Joint Motion To Dismiss The Second Amended Complaint (SAC) submitted on behalf of the Manufacturer Defendants, and incorporates by reference the arguments made therein. (ECF No. 179.) Biogen submits this Supplemental Reply to address Relator John Borzilleri's Opposition to Biogen's Supplemental Brief in Support Of The Joint Motion To Dismiss (ECF No. 178) (the "Opposition").

[2] Unless otherwise noted, defined terms used in this Supplemental Reply have the meanings set forth in Biogen's Supplemental Brief (cited herein as "Supp. Br.") and the Manufacturer Defendants' Joint Motion to Dismiss.

ARGUMENT

1. The Opposition Acknowledges That The SAC Fails To Plausibly Allege Particular Fraudulent Conduct By Biogen

Biogen's Supplemental Brief demonstrated that the SAC's sparse allegations about Biogen do not allege plausibly, let alone with particularity, a single instance where (1) Biogen paid a service fee to a PBM that exceeded fair market value; (2) the service fee was either improperly reported or intended as a kickback; or (3) a false claim was submitted as a result. (Supp. Br. 3-7.)[3] In response, the Opposition cites a list of purportedly "plausible and specific allegations against Biogen." (*See* Opp. 3-4 ¶¶ a-m.) This list simply rehashes the SAC's non-specific, industry-wide allegations about increasing drug prices and PBM profits in the face of supposedly declining drug usage and reduced PBM rebates. None of the cited allegations contain any particularized facts connecting Biogen to any fraudulent service fee payment or to the submission of a false claim.

To the contrary, the Opposition concedes that Borzilleri has no knowledge of any of these critical facts, asserting that "he cannot be expected to provide 'service' and 'fee' specificity to the Court when the evidence indicates the Defendants themselves are not doing so." (Opp. 5-6.) Unfortunately for Borzilleri, specific facts about the alleged fraudulent scheme underlying his claim against Biogen are precisely what Rule 9(b) requires.[4] *United States ex rel. Karvelas v.*

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[3] The Opposition erroneously asserts that "Biogen has only provided arguments fueled with conjecture, without any factual support." (Opp. 5; *see also* Opp. 6.) As the Court certainly appreciates, Borzilleri has the burden to plead particularized facts that plausibly allege fraudulent conduct on the part of Biogen, and in moving to dismiss Borzilleri's complaint, Biogen must take well-pled facts as true. Borzilleri's attempt to shift these burdens further illustrates the SAC's fundamental pleading deficiencies.

[4] Although the Opposition notes that "Biogen makes no arguments related to public disclosure of Relator's allegations" and "focuses its arguments on the Rule 8(a) and Rule 9(b) standards for plausibility and particularity" (Opp. 2), it ignores that Biogen joined in the Manufacturer Defendants' Joint Motion and incorporated by reference the arguments made

Melrose–Wakefield Hosp., 360 F.3d 220, 231 (1st Cir. 2004) (holding 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"), *abrogated on other grounds, Allison Engine Co., Inc. v. United States ex rel. Sanders*, 553 U.S. 662 (2008). By Borzilleri's own admission, the SAC does not contain such facts; it therefore must be dismissed.[5]

2. The Opposition Ignores Biogen's Arguments Regarding The SAC's Numerous Deficiencies

The Opposition entirely ignores many of the arguments in Biogen's Supplemental Brief that identify the SAC's specific pleading deficiencies as to Biogen. (*See* Supp. Br. at 6-7.) For example, the Supplemental Brief demonstrated that the SAC's purported sources of "wide-ranging" and "overwhelming" evidence of alleged "service fee" fraud do not mention Biogen or in any way connect Biogen or its drugs to any fraudulent conduct. (*Id.* at 6.) The Supplemental Brief also demonstrated that the SAC fails to state a claim against Biogen relating to alleged "catastrophic cost-sharing" because it does not allege a single fact demonstrating that Biogen actually "forgave" any catastrophic cost-sharing obligation on the part of a Part D sponsor, let alone that doing so caused the submission of a false claim. (*Id.* at 6-7.) By failing to address these arguments, the Opposition concedes them. *See McMann v. Selene Finance LP for*

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therein, including that the public disclosure bar provides an independent basis to dismiss the SAC against all the Defendants. (Supp. Br. at 1.)

[5] The Opposition also argues that this "case warrants a flexible approach pertaining to Rule 9(b) for Biogen and all the Defendants because the 'facts are peculiarly within the opposing party's knowledge.'" (Opp. at 6 (citing *United States ex rel. Chorches for The Bankr. Estate of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71 (2d Cir. 2017)).) But the Opposition's reliance on this Second Circuit authority is misplaced: under First Circuit law, where a relator claims he is unable to plead particular details of a false claim, he is still required to allege "'factual or statistical evidence to strengthen the inference of fraud beyond possibility.'" *United States ex. rel. Kelly v. Novartis Pharm. Corp.*, 827 F.3d 5, 13 (1st Cir. 2016) (citations omitted). Borzilleri does not come close to doing so here.

Wilmington Savings, 332 F. Supp. 3d 481, 485 (D. Mass 2018) (finding that plaintiffs conceded claim where they failed to address defendants' argument in their opposition to motion to dismiss).[6] These concessions provide an additional basis for dismissing the SAC.

3. New Material Cited In The Opposition Should Not Be Considered

In a last-ditch, unavailing effort to shore up his claim against Biogen, Borzilleri seeks to (1) resuscitate allegations from the First Amended Complaint ("FAC") he filed more than five years ago (*see* Opp. 3-4 citing FAC ¶¶ 76-78, 145 and Exs. 18, 19, 26, 27), and (2) introduce entirely new allegations and exhibits to his Opposition that are not found or alleged anywhere in the SAC. (*See* Opp. 1-4, Exs. 1-4.) These allegations and exhibits should be disregarded in their entirety.

Allegations in Borzilleri's FAC that do not appear in his operative SAC are superseded and may not be considered on a motion to dismiss the operative SAC. *See Pona v. Weeden*, No. 16-612 WES, 2018 WL 1417725, at *4 (D.R.I. Mar. 21, 2018) (Smith, J.) (adopting Report and Recommendation to dismiss amended complaint and disregarding facts alleged in superseded complaint because "[i]n performing a Fed. R. Civ. P. 12(b)(6) post-amendment inquiry, the court's analysis must focus only on the facts alleged in the amended complaint"); *see also Connectu LLC v. Zuckerberg*, 522 F.3d 82, 91 (1st Cir. 2008) (reasoning that a superseded, earlier complaint "is a dead letter and 'no longer performs any function in the case'" (citation omitted)). Nor may Borzilleri use his Opposition to assert new allegations and introduce new exhibits that are not in his operative SAC. *See Emrit v. Universal Music Grp., Inc.*, No. CA 13-181-ML, 2013 WL 3730423, at *1 n.3 (D.R.I. July 12, 2013) (granting motion to dismiss and

[6] *See also 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).

reasoning that the "[c]ourt need not consider new factual allegations set forth in Plaintiff's opposition memorandum"); *Gustavsen v. Alcon Labs., Inc.*, 272 F. Supp. 3d 241, 252 n.2 (D. Mass. 2017) (granting motion to dismiss and disregarding exhibits attached to plaintiffs' opposition because "[t]hey may not be considered in deciding the motion to dismiss"), *aff'd*, 903 F.3d 1 (1st Cir. 2018).

Moreover, even if Borzilleri's improperly cited allegations and exhibits were considered—which they should not be—they do not cure the SAC's abject failure to plead a FCA violation against Biogen. First, the Opposition cites to Biogen's publicly reported 2018 sales figures and asserts that the price increases they reflect would not have been possible absent the hypothetical scheme Borzilleri alleges. But, as set forth in Biogen's Supplemental Brief, even if Biogen's prices have increased over time, this does not mean that fraud has occurred, and Borzilleri offers no facts to suggest that it has. Second, Borzilleri cites aggregate 2012-2016 Avonex, Tecfidera, and Plegridy claims expenditure data published by the Centers for Medicare and Medicaid Services, and asserts in conclusory fashion that this data establishes that claims for Biogen's products were submitted to CMS. (Opp. at 4; *see also* ECF No. 176-6.) But, of course, evidence that CMS paid claims for Biogen's drug is of no consequence absent any facts establishing the alleged falsity of those claims, and the SAC is completely devoid of such facts. At most, the CMS expenditure data provides precisely the type of aggregative spending data that the First Circuit has found insufficient in the absence of details of specific claims. *See United States ex rel. Ge v. Takeda Pharm. Co.*, 737 F.3d 116, 124 (1st Cir. 2013) (affirming dismissal of FCA claim where relator alleged "aggregate expenditure data" for a drug, but made "no effort to identify specific entities who submitted claims or government program payers, much less times, amounts, and circumstances").

Third, the Opposition devotes four pages to selectively quoting news media and purported public commentary about increased multiple sclerosis drug prices in the United States in hopes that it will substantiate Borzilleri's unsupported hypothesis. (*See* Opp. 7-10.) But bald assertions that "something somewhere is just not right" are wholly insufficient to allege a FCA violation. *See United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, No. 2:99-CV-00086, 2007 WL 2713913, at *4 (D. Utah Sept. 12, 2007) (dismissing FCA claim with prejudice where relator "postulat[ed] doomsday scenarios" but failed to articulate "a legal theory that explains why any particular claim is false in any relevant sense").

Like the relator in *Sikkenga*, Borzilleri "has had every opportunity to identify a single false claim or to find a provision in a statute, regulation, or contract that would support h[is] generalized allegations of falsity" but has "failed to do so." *Id.* at *6. The SAC should therefore be dismissed with prejudice as to Biogen.

CONCLUSION

For the foregoing reasons, and the reasons stated in Biogen's Supplemental Brief, as well as the Joint Motion papers, Borzilleri's SAC should be dismissed against Biogen (and the other Manufacturer Defendants) with prejudice.

DATED: March 21, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 21, 2019 the foregoing document, Defendant Biogen Inc.'s Supplemental Reply Brief In Further Support Of The Manufacturer Defendants' Joint Motion To Dismiss, was filed through the Rhode Island ECF system and will be sent electronically to counsel who are registered participants identified on the Notice of Electronic Filing and mailed to parties who are not registered participants of the ECF system.

Dated: March 21, 2019

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