

operations, complying with applicable FDA regulations, applying for and receiving NYSDOH and New Jersey Clinical Laboratory Improvement Services (“NJCLIS”) approval of Defendant’s Sentinel Prostate Test, and helping Defendant’s Sentinel Prostate Test gain acceptance into the FDA’s “Breakthrough Devices Program.”

Defendant did not provide Plaintiff with the data needed to prepare the relevant applications. In response to Plaintiff’s data requests, Defendant told Plaintiff that, “we will show it to you shortly” or “it will be shared within the next few days / weeks.” In or around August 2020, without Plaintiff’s assistance, knowledge or review, Defendant submitted its “Breakthrough Devices Program” application for FDA approval. Around the same time, Plaintiff began to suspect that the actual data did not match the data Defendant had included in its FDA application and would include in its subsequent NYSDOH application.

In or around November 2020, Defendant’s Sentinel Prostate Test was accepted into the FDA’s “Breakthrough Devices Program.” Plaintiff worried that this acceptance would require further submissions to the FDA and worried about the accuracy of those submissions. On around November 16, 2020, although Defendant still had not shown Plaintiff the relevant data, Defendant applied for NYSDOH approval of its Sentinel Prostate Test without Plaintiff’s knowledge. On November 17, 2020, when Plaintiff first reviewed the NYSDOH application, Plaintiff observed that the test performance characteristics were different from those submitted to the FDA. The same day, Plaintiff raised concerns with Defendant’s CEO, which led to Defendant’s retracting its NYSDOH application on November 18, 2020.

Plaintiff continued to investigate the data in Defendant’s FDA application. On around December 13, 2020, Plaintiff met with Defendant’s Chief Administrative Officer and Defendant’s Chief Strategy Officer to raise concerns regarding the FDA application. Plaintiff

was concerned that, without intervention, Defendant would submit flawed applications to the FDA, NYSDOH and/or NJCLIS that exaggerated the Sentinel Prostate Test's effectiveness, which could lead to the test's approval. On around December 17, 2020, Plaintiff emailed Defendant's Chief Legal Officer a list of concerns about data in the FDA and NYSDOH applications. Defendant's Chief Legal Officer responded by thanking Plaintiff for raising these issues and reassured him that it would be unlawful for Defendant to retaliate against him for doing so or terminate his employment.

A few days later, on around December 22, 2020, Plaintiff raised the same concerns regarding the FDA and NYSDOH applications to Defendant's Chief Scientific Officer and Defendant's CEO, as well as issues related to quality management, quality assurance and quality control regulatory violations. In response, Plaintiff was told to stop raising these issues. Two weeks later, on January 7, 2021, Defendant terminated Plaintiff's employment.

II. STANDARD

On a motion to dismiss, a court accepts as true all well-pleaded factual allegations and draws all reasonable inferences in favor of the non-moving party but does not consider "conclusory allegations or legal conclusions couched as factual allegations." *Dixon v. von Blanckensee*, 994 F.3d 95, 101 (2d Cir. 2021) (internal quotation marks omitted). To withstand a motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Kaplan v. Lebanese Canadian Bank, SAL*, 999 F.3d 842, 854 (2d Cir. 2021) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678; accord *Dane v. UnitedHealthcare Ins. Co.*, 974 F.3d 183, 189 (2d Cir. 2020). It is not enough for a plaintiff to allege facts that are consistent with liability; the

complaint must “nudge[] [plaintiff’s] claims across the line from conceivable to plausible.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007) (first alteration in original); *accord Bensch v. Est. of Umar*, 2 F.4th 70, 80 (2d Cir. 2021). To survive dismissal, “plaintiffs must provide the grounds upon which [their] claim rests through factual allegations sufficient to raise a right to relief above the speculative level.” *Rich v. Fox News Network, LLC*, 939 F.3d 112, 121 (2d Cir. 2019) (alteration in original) (internal quotation marks omitted).

Allegations of a false claim for payment under the FCA sound in fraud and are subject to the particularity requirement of Federal Rule of Civil Procedure 9(b). *See Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 195 n.6 (2016) (“False Claims Act plaintiffs must also plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b) by, for instance, pleading facts to support allegations of materiality.”). The heightened pleading standard of Rule 9(b) requires a party pleading fraud to “state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.” Fed. R. Civ. P. 9(b). The adequacy of particularized allegations under Rule 9(b) is “case- and context-specific.” *United States ex rel. Chorchos v. Am. Med. Response, Inc.*, 865 F.3d 71, 81 (2d Cir. 2017) (internal quotation marks omitted); *accord Variblend Dual Dispensing Sys. LLC v Crystal Intl. (Grp.) Inc.*, No. 18 Civ. 10758, 2021 WL 1198834, at *4 (S.D.N.Y. Mar. 30, 2021).

III. DISCUSSION

A. FCA and NYFCA

Plaintiff alleges that he was fired in retaliation for raising concerns about the accuracy of data Defendant had submitted to the FDA and NYSDOH in seeking approval of Defendant’s

product. Defendant's motion to dismiss the state and federal retaliation claims is granted because the Complaint does not allege that Plaintiff was seeking to stop a violation of the FCA.

The FCA's anti-retaliation provision provides in relevant part:

[a]ny employee . . . shall be entitled to all relief necessary to make that employee . . . whole, if that employee . . . is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee . . . in furtherance of an action under this section or other efforts to stop 1 or more violations of [the FCA].

31 U.S.C. § 3730(h)(1) (emphasis added). To state a claim for retaliation under the FCA, courts “generally require[] a plaintiff to show that (1) he engaged in activity protected under the statute, (2) the employer was aware of such activity, and (3) the employer took adverse action against him because he engaged in the protected activity.” *Chorches*, 865 F.3d at 95. Because “[t]he NYFCA follows the federal False Claims Act,” New York courts “look toward federal law when interpreting the New York act.” *State ex rel. Seiden v. Utica First Ins.*, 943 N.Y.S.2d 36, 39 (1st Dep’t 2012); accord *Dhaliwal v. Salix Pharms., Ltd.*, 752 F. App’x 99, 100 (2d Cir. 2019) (summary order). The Court’s analysis under the FCA thus applies equally to the NYFCA claim.

The Complaint does not allege any of these elements. The Complaint fails to allege that Plaintiff engaged in protected activity because the Complaint contains no allegation of any claim for payment by Defendant, which is required for an FCA violation. Nor does the Complaint allege that Defendant was aware Plaintiff was engaged in FCA-protected activity, not only because Defendant was not making a claim for payment, but also because any concerns that Plaintiff raised about the FDA and NYSDOH applications represented his core job responsibilities. The Complaint thus also fails to plead the third element, that Defendant fired Plaintiff because Plaintiff engaged in protected activity.

1. Protected Activity

Plaintiff alleges that, prior to his termination, he complained of inaccuracies in Defendant's FDA and NYSDOH applications. However, Plaintiff does not allege that his activity is protected under the FCA by virtue of either "further[ing] an action under [the FCA]" or "other efforts to stop" a false claim for payment submitted by Defendant to either agency. *See* 31 U.S.C. § 3730(h)(1). "[A] misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act." *Escobar*, 579 U.S. at 181. The Complaint's failure to plead a connection between the FDA and NYSDOH applications and a claim for payment necessitates dismissal because the FCA attaches liability to a claim for payment -- not to the underlying fraudulent activity. *See Struck*, 982 F.3d at 59 (affirming dismissal of complaint that did not adequately plead that the alleged misrepresentation was material to the government's decision to make payments under the awarded contracts); *Coyne v. Amgen, Inc.*, 717 F. App'x 26, 28-29 (2d Cir. 2017) (summary order). "While an actual FCA violation is not a prerequisite for a retaliation claim, the plaintiff is required to show a good faith basis, or objectively reasonable basis, for believing that he or she was investigating matters in support of a viable FCA case." *Golub v. Berdon LLP*, No. 19 Civ. 10309, 2021 WL 637974, at *3 (S.D.N.Y. Feb. 17, 2021) (internal quotation marks omitted).

Nothing in the Complaint alleges any actual or anticipated claim for payment by Defendant. The Complaint does not so much as mention the words "claim," "payment" or "funding." In opposition to this motion, Plaintiff argues that the Complaint plausibly alleges a protected activity because Plaintiff reasonably believed that "the failure to get approval would have doomed any chance of receiving additional funding from the FDA" and that the faulty data

“could reasonably be expected to result in ill-gotten gains—first in the form of FDA approval, then as government payment made possible by that approval,” relying on *Josey v. Impulse Dynamics (USA) Inc.*, 371 F. Supp. 3d 603, 609 (D. Ariz. 2019). But it is axiomatic that “a party is not entitled to amend its complaint through statements made in motion papers.”¹ *Soules v. Conn. Dep’t of Emergency Servs. & Pub. Protection*, 882 F.3d 52, 56 (2d Cir. 2018). The Complaint fails to plead that Plaintiff had an objectively reasonable belief that Defendant was acting in violation of the FCA, or that he took action to stop one or more violations of the FCA based on that belief.

2. Notice

Defendant’s motion to dismiss the retaliation claim is granted for the additional reason that, even assuming Plaintiff was engaged in protected activity, there is no evidence that Defendant was aware that he was, and consequently retaliated. To survive dismissal, the Complaint must allege that “[the plaintiff’s] employer was aware” that he was engaged in protected conduct. *Chorches*, 865 F.3d at 95. “[P]laintiffs alleging that performance of their normal job responsibilities constitutes protected activity must overcome the presumption that they are merely acting in accordance with their employment obligations.” *Koshy v. Regeneron Pharmaceuticals, Inc.*, No. 17 Civ. 7781, 2019 WL 6895563, at *7 (S.D.N.Y. Dec. 18, 2019) (internal quotation marks omitted). “An employee who simply engages in behavior wholly

¹ This deficiency is not cured simply by amending the Complaint. Plaintiff’s reliance on *Josey* is misplaced. First, *Josey*, as a federal district court decision is not binding on this Court. Second, Plaintiff’s argument and *Josey* appear to be inconsistent with the Second Circuit’s analysis of the FCA’s materiality requirement, that the misrepresentation be material to the Government’s payment decision, see *United States ex rel. Foreman v. AECOM*, ___ F. 4th ___, No. 20-2756-CV, 2021 WL 5406437, at *13 et seq. (2d Cir. Nov. 19, 2021), and the Supreme Court’s requirement that materiality be pleaded with specificity, *Escobar*, 579 U.S. at 195 n.6.

consistent with his job description will not, without more, provide notice that he is engaging in a protected activity.” *Id.*

The Complaint alleges that, as Defendant’s Director of Commercial Laboratory Operations, Plaintiff was responsible for compliance with applicable FDA regulations, applying for and receiving NYSDOH and NJCLIS approval of Defendant’s Sentinel Prostate Test, and helping the Sentinel Prostate Test gain acceptance into the FDA’s “Breakthrough Devices Program.” Thus, it was Plaintiff’s job to raise concerns about the accuracy of data being submitted to the FDA and NYSDOH in Defendant’s applications. Viewed in this context, Plaintiff’s investigation of the NYSDOH application in mid-November 2020, and Plaintiff’s continued investigation of the data in Defendant’s FDA application through mid-December 2020, would not have alerted Defendant that Plaintiff was doing anything other than what he was hired to do, and in particular, would not have put Defendant on notice that Plaintiff was seeking to prevent a violation of the FCA. The Complaint contains no allegations that Plaintiff sought to go beyond his assigned task and put Defendant on notice that an FCA action was a reasonable possibility. *See Weslowski v. Zugibe*, 626 F. App’x 20, 21 (2d Cir. 2015) (summary order) (“Even assuming that [plaintiff] engaged in protected activity, he did not adequately allege that the County was aware that his refusal to approve the contract at issue was in furtherance of efforts to prevent a violation of the FCA.”); *Ortiz v. Todres & Co. LLP*, No. 15 Civ. 1506, 2019 WL 1207856, at *5 (S.D.N.Y. Mar. 14, 2019).

Plaintiff argues that this “heightened standard” of notice, requiring that plaintiffs “overcome the presumption that they are merely acting in accordance with their employment obligations’ to put their employers on notice” is outdated and did not survive the 2009 amendments to the FCA. Although there is some disagreement among district courts as to

whether a “heightened standard” of notice applies, *see Beckles-Canton v. Lutheran Soc. Servs. of New York, Inc.*, No. 20 Civ. 4379, 2021 WL 3077460, at *6-7 (S.D.N.Y. July 20, 2021) (collecting cases), Plaintiff’s argument falls short because, even under his proposed standard, it is clear that the employer must have notice of the alleged protected activity. *See* 31 U.S.C. § 3730(h)(1). The Complaint fails to allege facts sufficient to show that Plaintiff believed Defendant was violating the FCA, that this belief was reasonable, that Plaintiff took action based on that belief, and that Plaintiff’s actions put Defendant on notice of his efforts to stop one or more violations of the FCA. *See Chorches*, 865 F.3d at 95; *see also Malanga v. New York Univ.*, No. 14 Civ. 9681, 2018 WL 333831, at *3 (S.D.N.Y. Jan. 9, 2018) (“[A] plaintiff must still satisfy each of the related, but distinct elements of an FCA claim. In other words, proving protected conduct is not co-extensive with proving notice.”).

Because the Complaint does not allege Plaintiff engaged in a protected activity nor that Defendant was aware of such activity, the Complaint also does not plead that Defendant retaliated against Plaintiff because he engaged in the protected activity. Accordingly, the FCA and NYFCA claims are dismissed.

B. Leave to Amend

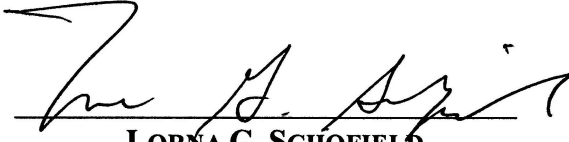
Leave to amend should be freely given “when justice so requires.” Fed. R. Civ. P. 15(a)(2). A court “may deny leave to amend for good reason, including futility, bad faith, undue delay, or undue prejudice to the opposing party.” *Cohen v. Am. Airlines, Inc.*, 13 F.4th 240, 247 (2d Cir. 2021) (internal quotation marks omitted). If Plaintiff has additional facts that Plaintiff believes would cure the deficiencies identified in this Opinion, Plaintiff shall file a letter to the Court seeking leave to replead, explaining how the deficiencies are cured and attaching a

proposed amended complaint marked to show changes from the current Complaint, no later than January 18, 2022.

IV. CONCLUSION

For the foregoing reasons, Defendant's motion to dismiss is granted. Plaintiff may seek leave to replead as set forth above. The Clerk of Court is respectfully directed to close the motion at Docket Number 27.

Dated: December 21, 2021
New York, NY



LORNA G. SCHOFIELD
UNITED STATES DISTRICT JUDGE