

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

EHAB SEFEN, ex rel United States :
 :
 :
 v. : CIVIL ACTION
 : NO. 10-2971
 :
 ANIMAS CORPORATION, ET AL. :

MEMORANDUM

SURRICK, J.

JUNE 13, 2014

Presently before the Court is Defendants Animas Corporation and Johnson & Johnson's Motion to Dismiss. (Defs.' Mot., ECF No. 24.) For the following reasons, Defendants' Motion will be granted.

I. BACKGROUND

A. Procedural History

Defendant Animas Corporation ("Animas") is a wholly-owned subsidiary of Johnson & Johnson with its headquarters located at 200 Lawrence Drive in West Chester, Pennsylvania. (Am. Compl. ¶ 5, ECF No. 6.) Animas manufactures insulin pumps for use by individuals with diabetes. (*Id.*) Defendant Johnson & Johnson is a New Jersey corporation headquartered at One Johnson & Johnson Plaza in New Brunswick, New Jersey. (*Id.*) Johnson & Johnson purchased Animas on February 18, 2006. (*Id.*) Plaintiff Ehab Sefen is a Pennsylvania resident. (*Id.* at ¶ 4.) Plaintiff was hired by Defendant Johnson & Johnson on June 18, 2007 as Senior Quality System Analyst for Animas. (*Id.*)

Plaintiff filed a Complaint, under seal, on June 17, 2010, pursuant to the Federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729, *et seq.* On November 18, 2010, Plaintiff filed an

Amended Complaint under seal, which added a second claim to the Complaint. (Am. Compl.) In his Amended Complaint, Plaintiff alleges that Defendants Johnson & Johnson and Animas continued to sell insulin pumps knowing they were not in compliance with the Food and Drug Administration (“FDA”) regulations while falsely representing that they had corrected deficiencies previously identified by the FDA in a Warning Letter. (*Id.* at ¶ 26.) In addition, Plaintiff alleges that Animas terminated his employment in retaliation for lawful acts performed in furtherance of an FCA action. (*Id.* at ¶¶ 33-34.) Plaintiff sought judgment in the form of compensatory damages, punitive damages, emotional distress, attorney’s fees, interest and costs, and injunctive relief as deemed necessary by the Court. (*Id.* at ¶ 34.)

Service of the Amended Complaint on Defendants was delayed to provide the United States an opportunity to decide whether to intervene in the action. *See* 31 U.S.C. § 3730(b)(2). On January 5, 2012, the United States filed a notice of election to decline intervention. (Notice of Election, ECF No. 13.)¹ On January 17, 2012, the Court entered an order unsealing the Amended Complaint and directing its service upon Defendants. (ECF No. 14.) Thereafter, on February 7, 2012, Plaintiff filed a notice of partial dismissal and stipulation without prejudice, which sought to eliminate his *qui tam* claim and proceed only with his retaliation claim under 31 U.S.C. § 3730(h). (ECF No. 15.) Plaintiff’s request was granted and Count I of the Amended Complaint alleging violation of the FCA was dismissed. (*Id.*)

Upon the dismissal of Count I, the only remaining claim in the Amended Complaint is

¹ If the Government declines to intervene, as it has here, a plaintiff may still pursue claims pursuant to the FCA. 31 U.S.C. § 3730(b)(4)(B); *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 182 (3d Cir. 2001). Although it was entitled to do so, the Government did not move to dismiss the action. 31 U.S.C. § 3730(c)(2)(A).

that Defendants violated Section 3730(h) of the FCA by retaliating against Plaintiff in connection with Defendants' alleged false claims. (Am. Compl. ¶ 34.) Defendants' Motion to Dismiss, filed on June 29, 2012, seeks dismissal of the remainder of Plaintiff's Amended Complaint. (Defs.' Mot. ECF No. 24.) Plaintiff filed a Response to Defendants' Motion to Dismiss on August 15, 2012 (Pl.'s Resp., ECF No. 27), and on August 22, 2012, Defendants filed a Reply (Defs.' Reply, ECF No. 28).

B. Factual History²

Plaintiff was employed by Animas as a Senior Quality System Analyst from June 18, 2007 through March 10, 2008. (Am. Compl. ¶¶ 4, 24.) Plaintiff was responsible for ensuring Animas's electronic records complied with FDA regulations, overseeing the "Patient Complaint System" computer system, and assisting in Computer Systems Validation ("CSV") projects and corrective actions. (*Id.* at ¶ 4.) Plaintiff maintains that until the time of his firing, he received positive feedback from his supervisors regarding his job performance. (*Id.*)

Animas manufactures the OneTouch® Ping™, an insulin pump, which releases small amounts of rapid-acting insulin to keep blood glucose levels steady between meals and during sleep. (*Id.* at ¶¶ 5, 9.) The insulin pumps are medical devices pursuant to Section 201(h) of the Federal Food, Drug, and Cosmetic Act and are regulated by the FDA. 21 U.S.C. § 321(h). On February 24, 2005, Thomas D. Gardine, District Director of the Philadelphia District Office of the FDA, sent a Warning Letter (#5-PHI-03) to Animas. (Warning Letter, Am. Compl. Ex. A; Am.

² In considering Defendants' Motion to Dismiss under Federal Rule of Civil Procedure 12(b)(6), "we accept all factual allegations as true [and] construe the complaint in the light most favorable to the Plaintiff." *DelRio-Mocci v. Connolly Props., Inc.*, 672 F.3d 241, 245 (3d Cir. 2012) (quoting *Warren Gen. Hosp. v. Amgen, Inc.*, 643 F.3d 77, 83 (3d Cir. 2011)).

Compl. ¶ 10.) The Warning Letter stated that “the methods used in, or the facilities or controls used for” the manufacture of certain insulin pumps were “not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.” (Am. Compl. ¶ 11.) Deviations from the CGMP included, but were not limited to, the failure to adequately establish and maintain procedures for implementing corrective and preventive actions (“CAPAs”), to control the manufacture and sale of devices in conformity with specified requirements, and to establish and maintain procedures for rework. (*Id.*) In addition, the Warning Letter advised Animas to “take prompt action to correct these deviations” and warned that “[f]ailure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice.” (Warning Letter.)

According to Plaintiff, the FDA did not inspect Animas related to the insulin pump and waived immediate enforcement of all mandates and conditions cited in the Warning Letter based on Johnson & Johnson’s acquisition of Animas and representations that all deficiencies would be corrected. (Am. Compl. ¶ 10.) In performing his duties as Senior Quality System Analyst, Plaintiff discovered that Animas had not corrected the aforementioned deficiencies as represented and that issues related to Animas’s computer systems were more severe than the FDA had identified in its Warning Letter. (*Id.*)

On August 21, 2007, two months after beginning his employment with Animas, Plaintiff attended a meeting with the Information Technology Manager, Nadine Magic, and Project Manager, Joan Morrissey. (*Id.* at ¶ 14.) In discussing the validation of Animas’s Patient Complaint System, Plaintiff articulated concerns about the appropriateness of the supporting

documentation, which he felt was outdated. (*Id.* at ¶ 15.) Plaintiff objected to certifying that the documentation related to the Patient Complaint System was FDA compliant. (*Id.* at ¶ 16.) Morrissey pressured Plaintiff to use the documents as they had been drafted. (*Id.*) Later that day, Plaintiff met with Donna Pyne, an Animas employee in Quality Assurance and a Computer System Validation Specialist to explain his concerns with regard to the Patient Complaint System documentation. (*Id.*) Plaintiff asked Pyne to join the team handling the documentation. (*Id.*) Plaintiff and Pyne later met with Rita McIntyre, who was also Plaintiff's supervisor, to articulate their concerns. (*Id.* at ¶ 17.)

On September 14, 2007, Plaintiff attended another meeting with Magic, Morrissey, Pyne, and McIntyre. (*Id.* at ¶ 18.) At that meeting, Morrissey changed employees' roles and responsibilities without explanation. (*Id.*) Under the new alignment, Plaintiff's access to information was restricted. (*Id.*) In his new role and with his objections outstanding, Magic and the rest of the management team requested that Plaintiff incorporate and sign off on documents, certifying to their accuracy. (*Id.* at ¶ 19.) Immediately after the September 14, 2007 meeting, Morrissey threatened Plaintiff, stating "let things go or we will get someone else to do your job." (*Id.*) At another meeting, Morrissey told Plaintiff to "let things go, and we will get you back in the clique." (*Id.* at ¶ 20.) Thereafter, Plaintiff had a series of meetings with Human Resources ("HR") employees at which Plaintiff's responsibilities were reduced. (*Id.* at ¶ 21.) At one of those meetings, Magic told Plaintiff that he needed to "scale back his standards since the company is not a very large company like the ones he used to work for in the past, and the company did not have the resources to comply fully with FDA requirements in the same scale that he used to see in his past experience." (*Id.*) At a subsequent meeting, Morrissey told Plaintiff to "let things go or

we will get someone else to do your job.” (*Id.* at ¶ 22.) These developments were inconsistent with the reassurances made to Plaintiff that he had excellent knowledge and that he was “the quality king in the company.” (*Id.*) Morrissey continually asked Plaintiff to trust her and not to worry. (*Id.*) Plaintiff understood that he was being asked to let things go and sign documents with which he did not agree or face the loss of his job. (*Id.*) Meanwhile, Pyne declined to agree with the proposed plan being forced on Plaintiff and instead favored the proposal championed by Plaintiff. (*Id.* at ¶ 23.)

On October 26, 2007, Plaintiff contacted employees in Corporate Quality. (*Id.* at ¶ 24.) Eleven days later, during a meeting with Justine Smith and McIntyre, Plaintiff received a Performance Improvement Plain (“PIP”) from HR. (*Id.*) Plaintiff contends that the PIP contained fabricated allegations, which served as a pretext for retaliation against him. (*Id.*) Plaintiff would later contact the Office of Compliance at the FDA, which followed up with an onsite inspection on February 5, 2008. (*Id.*) One month later, on March 10, 2008, Plaintiff’s employment was terminated. (*Id.*)

II. LEGAL STANDARD

Generally, a party may not raise a defense based on a violation of the statute of limitations by motion. *Robinson v. Johnson*, 313 F.3d 128, 135 (3d Cir. 2002) (“Technically, the Federal Rules of Civil Procedure require that affirmative defenses be pleaded in the answer.”). However, in the Third Circuit, a limitations defense may be raised by motion under Federal Rule 12(b)(6) if “the time alleged in the statement of a claim shows that the cause of action has not been brought within the statute of limitations.” *Id.* (quoting *Hanna v. U.S. Veterans’ Admin. Hosp.*, 514 F.2d 1092, 1094 (3d Cir. 1975)).

Under Federal Rule of Civil Procedure 8(a)(2), “a pleading that states a claim for relief must contain a short and plain statement of the claim showing that the pleader is entitled to relief.” Failure to state a claim upon which relief can be granted is basis for dismissal of the complaint. Fed. R. Civ. P. 12(b)(6). “To survive 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.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A complaint that merely alleges entitlement to relief, without alleging facts that show entitlement, must be dismissed. *See Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir. 2009). This “‘does not impose a probability requirement at the pleading stage,’ but instead ‘simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of’ the necessary elements.” *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008) (quoting *Twombly*, 550 U.S. at 556). “A complaint may not be dismissed because it appears unlikely that the plaintiff can prove those facts or will ultimately prevail on the merits.” *McTernan v. City of York*, 564 F.3d 636, 646 (3d Cir. 2009).

In determining whether dismissal is appropriate, courts use a two-part analysis. *Fowler*, 578 F.3d at 210. First, courts separate the factual and legal elements of the claim and accept all of the complaint’s well-pleaded facts as true. *Id.* at 210-11. Next, courts determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a “‘plausible claim for relief.’” *Id.* at 211 (quoting *Iqbal* 556 U.S. at 679). Given the nature of the two-part analysis, “[d]etermining whether a complaint states a plausible claim is context-specific, requiring the reviewing court to draw on its experience and common sense.” *Iqbal*, 556 U.S. at 663-64 (citing *Twombly*, 550 U.S. at 556).

III. DISCUSSION

A. Timeliness

Defendants contend that Plaintiff's retaliation claim is time-barred. (Defs.' Mot. 4.)

Plaintiff acknowledges that his claim would be time-barred under Pennsylvania law,³ but argues that the retroactive application of the statute of limitations imposed by the Dodd-Frank Wall Street Reform & Consumer Protection Act⁴ ("Dodd-Frank Act") ensures that his claim is timely. (Pl.'s Resp. 17.)

The Dodd-Frank Act, passed on July 21, 2010, amended the FCA. Dodd-Frank Act, Pub. L. 111-230, § 4, Title X, Subtitle G, § 1079A(c), 124 Stat. at 2079. The amended FCA provides that "[a] civil action under [subsection (h)] may not be brought more than 3 years after the date when the retaliation occurred." 31 U.S.C. § 3730(h)(3). Section 4 of the Dodd-Frank Act states: "Except as otherwise specifically provided in this Act or the amendments made by this Act, this Act, and such amendments shall take effect 1 day after the enactment of this Act." Dodd-Frank

³ In *Graham County Soil & Water Conservation District v. Wilson*, 545 U.S. 409, 418 (2005), the Supreme Court held that the six-year statute of limitations in the FCA did not apply to retaliation claims pursuant to Section 3730(h). Instead, courts are to apply the most closely analogous state statute of limitations. *Id.* at 422. The parties agree that the proper borrowing statute and attending limitations period is unresolved in the Third Circuit. In *United States ex rel. Repko v. Guthrie Clinic, P.C., C.A.*, 557 F. Supp. 2d 522, 528-29 (M.D. Pa. 2008), the court relied on Pennsylvania's Whistleblower Law, 43 Pa. Stat. § 1424(a), and applied a 180-day limitations period. Expressly rejecting the application of the 180-day period, the court in *Campion v. Ne. Utilities*, 598 F. Supp. 2d 638, 653 (M.D. Pa. 2009) adopted the residual two-year limitations period prescribed by Pennsylvania's catch-all personal injury statute, 42 Pa. Cons. Stat. Ann. § 5524(7). Under either limitations period, Plaintiff's claim is untimely. Plaintiff's claim accrued, at the latest, on March 10, 2008. (Am. Compl. ¶ 24.) Plaintiff's original Complaint was filed on June 17, 2010. On November 18, 2010, Plaintiff filed an Amended Complaint, which added the retaliation claim. Even if we use the June 17, 2010 filing, which did not include the retaliation claim, Plaintiff's claim would not be timely.

⁴ 12 U.S.C. § 5301 *et seq.*

Act, Pub. L. 111-230 § 4, 124 Stat. at 1390. The amendment to the FCA creating a three-year statute of limitations does not specifically provide an effective date and does not explicitly state that it will apply retroactively. “Retroactive application of a new statute . . . occurs whenever the statute is applied to causes of action already accrued prior to its enactment date.” *Lieberman v. Cambridge Partners, L.L.C.*, 432 F.3d 482, 487-88 (3d Cir. 2005) (citing *Landgraf v. USI Film Prods.*, 511 U.S. 244, 265 (1994)). However, “extending a statute of limitations after the pre-existing period of limitations has expired impermissibly revives a moribund cause of action.” *Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939, 950 (1997) (citing *Chenault v. U.S. Postal Serv.*, 37 F.3d 535, 539 (9th Cir. 1994)).

The Supreme Court has noted that there is a “presumption against retroactive legislation.” *Lieberman*, 432 F.3d at 488 (quoting *Landgraf*, 511 U.S. at 265). In *Landgraf*, the Court created a two part test for determining the applicability of newly prescribed limitations periods. *Landgraf*, 511 U.S. at 280. First, courts are to examine whether Congress has explicitly prescribed the statute’s intended reach. *Id.* If Congress has done so, the issue is resolved. *Id.* If the statute does not reflect Congress’ “express command,” courts are to perform a “retroactive effect” analysis to determine whether retroactively applying the limitations period “would impair rights a party possessed when he acted, increase a party’s liability for past conduct, or impose new duties with respect to transactions already completed.” *Id.*

Addressing the first prong of *Landgraf*, the Third Circuit has determined that where Congress has “expressly provided that the statute in question . . . should not apply retrospectively . . . , we should follow Congress’ express prescription and apply the statute accordingly.” *Mathews v. Kidder, Peabody & Co.*, 161 F.3d 156, 160 (3d Cir. 1998). Here, there is an absence of clear

and unambiguous guidance from Congress regarding retroactivity. We therefore consider the second prong of *Landgraf* to determine the validity of the retroactive application of Section 3730(h)(3). A finding of a “retroactive effect” will lead the court to decline applying the new limitations period retroactively. *Landgraf*, 511 U.S. at 280; *see also Lieberman*, 432 F.3d at 489. This is an issue of first impression in the Third Circuit and has not been resolved by any court of appeals.⁵

Plaintiff claims that there is no retroactive effect by imposing the Dodd-Frank Act’s three-year statute of limitations. We disagree. While we agree with Plaintiff that retroactively applying the Dodd-Frank Act statute of limitations would in no way impair either party’s rights at the time of the underlying conduct, imposing a longer statute of limitations indisputably increases

⁵ When considering the issue, the Fifth Circuit Court of Appeals ultimately chose not to rule on the statutory retroactivity of the Dodd-Frank Act amendment to the FCA’s statute of limitations. *See Riddle v. Dyncorp Int’l Inc.*, 666 F.3d 940, 944 (5th Cir. 2012) (finding that plaintiff’s retaliation claim was timely under the two-year limitations period prescribed by Texas’ personal injury statute thus obviating the need to rule on statutory retroactivity). However, the Fifth Circuit noted that “[w]e may sometimes apply a newly-enacted statute of limitations to a pending case, but not if the effect would be to revive a claim that expired before the statute’s effective date.” *Id.*

In addition, a number of courts have recognized the FCA statute of limitations retroactivity issue but declined to render a decision on its applicability. *See Dyer v. Raytheon Co.*, No. 08-10341, 2011 WL 3294489, at *12 (D. Mass. July 29, 2011); *Saunders v. District of Columbia*, 789 F. Supp. 2d 48, 52 (D.D.C. 2011); *Lindsay v. Tech Coll. Sys. of Ga.*, No. 09-2133, 2011 WL 1157456, at *6 n.6 (N.D. Ga. Mar. 29, 2011); *Gibbs v. United States*, 865 F. Supp. 2d 1127, 1140 n.11 (M.D. Fla. Mar. 31, 2012); *but see Lindsay v. Technical Coll. Sys. of Ga.*, No. 09-2133, 2013 WL 591981, at *4 (N.D. Ga. Feb. 14, 2013) (declining to apply Section 3730(h) retroactively because the plaintiff did not offer a persuasive reason to do so); *United States ex rel. Berglund v. Boeing Co.*, 835 F. Supp. 2d 1020, 1033-34 (D. Or. 2011) (declining to retroactively apply the three-year limitations period in Section 3730(h) in favor of two-year statute of limitations codified in analogous Oregon catch-all law); *Tolman v. Am. Red Cross*, 10-628, 2011 WL 6333700, at *4-5 (D. Idaho Dec. 19, 2011) (retroactively applying Section 3730(h)(3) where limitations period was unsettled and application did not resuscitate a moribund cause of action).

Defendants' liability for past conduct. As the Third Circuit stated in *Lieberman*, "the resurrection of previously time-barred claims 'increase[s] a party's liability' by abolishing a complete defense to suit." *Lieberman*, 432 F.3d at 492 (quoting *In re Enter. Mortg. Acceptance Co., LLC Sec. Litig.*, 391 F.3d 401, 409-10 (2d Cir. 2005)); see also *In re ADC Telecomm., Inc. Sec. Litig.*, 409 F.3d 974, 977 (8th Cir. 2005) (finding retroactive application of statute of limitations period prescribed by Sarbanes-Oxley Act to have a retroactive effect, thus precluding the revival of stale claims).⁶

Plaintiff contends that because the precise statute of limitations for retaliation claims pursuant to the FCA was unsettled at the time Plaintiff filed his Complaint, we should find no retroactive effect in applying the Dodd-Frank Act amended time-frame. (See Pl.'s Resp. 16 ("In fact, on March 12, 2008, when Mr. Sefen was terminated, the statute of limitations was an undecided issue in the Third Circuit. Even in Pennsylvania district courts, no decisions has been handed down, as *Repko* was filed that very day. *Campion* was still over a year away.")) In

⁶ Plaintiff minimizes the importance of *Enterprise Mortgage* and its progeny. (See Pl.'s Resp. 16) ("The problem with Defendants' argument is that they are taken out of context, in cases related to a new cause of action, the Sarbanes-Oxley Act. The Sarbanes-Oxley Act created and codified a new cause of action, previously codified under separate securities fraud statutes.") Plaintiff's argument is unpersuasive. First, the consensus among each court of appeals that resuscitating stale claims creates a retroactive effect is instructive. See *Berman v. Blount Parrish & Co., Inc.*, 525 F.3d 1057, 1058 (11th Cir. 2008) ("Appellants urge that because they filed their complaint within five years of the May 1998 bond purchase, the Sarbanes-Oxley Act's statute of limitations revived their previously expired securities claims. This argument has been *soundly* rejected by every circuit court to consider it.") (emphasis in original). Additionally, we find Plaintiff's argument that Sarbanes-Oxley created a "new causes of action" misleading. In the context of a newly imposed statute of limitations resuscitating a moribund claim, it is axiomatic that the substantive cause of action necessarily must have preexisted. Cf. *Enterprise Mortg.*, 391 F.3d at 403-04 ("In each of these cases, plaintiffs initiated actions for securities fraud prior to the passage of Sarbanes-Oxley. Then, after Sarbanes-Oxley was enacted on July 30, 2002, plaintiffs . . . tr[ie]d to take advantage of Sarbanes-Oxley's extended statute of limitations.").

support of his argument, Plaintiff relies on *Tolman* where a plaintiff brought an FCA retaliation claim in Idaho district court. 2011 WL 6333700, at *4. The *Tolman* court determined that it was unclear which statute of limitations period applied to Tolman’s FCA retaliation claim: 180-days or four-years. *Id.* On the facts of *Tolman*, if the four-year limitations period applied, the case would not be barred. *Id.* Ultimately, the court found that because it was unclear which statute of limitations applied, a retroactive application of the Dodd-Frank Act amended limitations period “would not necessarily ‘revive a moribund cause of action.’” *Id.* In reaching this conclusion, the court noted that the most analogous statute of limitations from which to borrow was the four-year statute of limitations, viz. Idaho Code § 5-224. *Id.*

This case is not like *Tolman*. Plaintiff correctly notes that at the time he filed his FCA retaliation claim, it was unclear what statute of limitations applied. However, unlike in *Tolman*, this factor is not significant because application of either of the relevant Pennsylvania statute of limitations would bar Plaintiff’s claim. Under Pennsylvania law, Plaintiff could avail himself of either the 180-day or the two-year limitations period.⁷ Under either statute, Plaintiff’s claim would be barred because both periods had elapsed by the dates Plaintiff filed his original and amended Complaints. In *Tolman* the facts were different because one possible state limitations period had not elapsed. Therefore, if the longer limitations period applied, the claim would not have been barred and retroactive application of the Dodd-Frank Act amended limitations period

⁷ We agree with Defendants that despite the uncertainty in the Third Circuit when Plaintiff’s claim accrued, the Supreme Court and subsequent case law has provided sufficient guidance with respect to the possible limitations periods to be employed in Pennsylvania. See *Graham*, 545 U.S. at 419 & n.3, 422 (listing Pennsylvania’s 180-day limitation period from its Whistleblower Act, 43 Pa. Cons. Stat. Ann. § 1424(a), as a possible analogous statute for an FCA retaliation limitation period); *Campion*, 598 F. Supp. 2d at 653 (applying two-year limitations period from Pennsylvania’s catch-all personal injury statute).

would not mean reviving a moribund cause of action. Essentially, the action could have survived even without retroactive application of Section 3730(h)(3). The same is not true here. Both state limitations periods had already elapsed when Plaintiff's claim was filed. Thus, retroactive application of Section 3730(h)(3) to this FCA retaliation claim would revive a moribund cause of action, increasing a party's liability for past conduct.

Furthermore, other courts have not applied Section 3730(h)(3) retroactively in circumstances where it was unclear what state statute of limitations should be applied to FCA retaliation claims. *Berglund*, 835 F. Supp. 2d at 1034 (declining to apply Section 3730(h)(3) retroactively and concluding that Oregon's catch-all two-year statute of limitations was applicable to FCA retaliation claims at the time the plaintiff's claim accrued); *see also Riddle*, 666 F.3d at 944 (deciding after the passage of Dodd-Frank that Texas' two-year personal injury statute of limitations applied "at the time [] plaintiff file[d] his complaint").

Because we find that imposing the Dodd-Frank Act statute of limitations increases Defendants' liability for past conduct, "we apply the strong presumption against applying a statute with retroactive effect to pending cases: At this point, only Congress's *clear* intent to apply the statute retrospectively will overcome the presumption." *Mathews*, 161 F.3d at 161 (emphasis in original). Without clear and unambiguous guidance from Congress regarding retroactivity, we are compelled to conclude that Plaintiff cannot claim the benefit of the post-amendment version of Section 3730(h). *See Lytle v. Capital Area Intermediate Unit*, 393 F. App'x 955, 958 (3d Cir. 2010) (finding that plaintiffs could not avail themselves of 2009 amendment to FCA extending standing to contractors or agents as the court could not "find [any]

authority that would give them the benefit of the amended version of § 3730(h)"). Accordingly, Plaintiff's retaliation claim is time barred.

B. Merits of Retaliation Claim

Even if Section 3730(h)(3) were to apply retroactively and Plaintiff's claim were timely, he would have to state a claim for relief pursuant to Federal Rule of Civil Procedure 8(a). This he has failed to do. To establish a claim of retaliation pursuant to the FCA, a plaintiff must establish that he engaged in protected conduct and that he was discriminated against on the basis of engaging in such protected conduct. *Campion*, 598 F. Supp. 2d at 648. In addition, a plaintiff must show that his employer was aware that he was engaged in protected conduct and that the resulting retaliation was, at least in part, motivated by said conduct. *Hutchins*, 253 F.3d at 186. Although the plaintiff need not establish a successful *qui tam* claim, he must allege a sufficient nexus between his conduct and a potential FCA claim. *Campion*, 598 F. Supp. 2d at 648 (citing *Hutchins*, 253 F.3d at 187). In essence, "there [must] be at least a distinct possibility that a viable FCA action could be filed." *Dookeran v. Mercy Hosp. of Pitt.*, 281 F.3d 105, 108 (3d Cir. 2002) (citing cases).

The FCA creates liability for anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." See 31 U.S.C. §§ 3729(a)-(b). The statute defines the term claim as "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property" *Id.* at § 3729(b)(2)(A). While "recovery under the FCA is not dependent upon the government's sustaining monetary damages," *Varljen v. Cleveland Gear*

Co., Inc., 250 F.3d 426, 429 (6th Cir. 2001), the purpose of the act is to protect against fraud “that might result in financial loss to the Government.” *Hutchens*, 253 F.3d at 183 (quoting *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968)); see also *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs, Inc.*, 149 F.3d 227, 230 (3d Cir. 1998) (“The False Claims Act prescribes civil penalties for knowingly submitting fraudulent claims to the federal government. Under the Act, the United States may bring a civil suit to recover funds lost through such transactions.”); *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 304 (3d Cir. 2011) (“The primary purpose of the FCA ‘is to indemnify the government-through its restitutionary penalty provisions-against losses caused by a defendant’s fraud.’”) (quoting *Mikes v. Straus*, 274 F.3d 687, 696 (2d Cir. 2001)); *Rodriguez v. Our Lady of Lourdes Med. Ctr.*, 552 F.3d 297, 304 (3d Cir. 2008) (dismissing suit for failure to state a claim after finding that FCA claims must pertain to pecuniary losses by the federal government or risk converting the statute “into a blunt instrument to enforce compliance with all . . . regulations rather than only those regulations that are a precondition to a payment”) (internal quotations omitted) (abrogated on other grounds by *United States ex rel. Eistenstein v. City of New York*, 556 U.S. 928 (2009)).

To establish a *prima facie* violation of the FCA, plaintiff must prove that: “(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent.” *Wilkins*, 659 F.3d 295, 305 (quoting *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 (3d Cir. 2004)). Integral to the analysis is whether the defendant submitted a false claim for payment that would financially impact the government. In *Hutchins*, the plaintiff,

a former paralegal at Wilentz, Goldman & Spitzer, sued his former employer under the FCA for the submission of inflated legal bills to a United States Bankruptcy Court. 253 F.3d at 179, 182. The Third Circuit held that the submission of false claims to the government for approval would not cause financial loss to the government, as the government merely served as an intermediary. *Id.* at 184. In doing so, the court reasoned that the FCA was meant to redress money taken from the government by fraud and “not [] to impose liability for every false statement made to the government.” *Id.* (citing *Costner v. URS Consultants, Inc.*, 153 F.3d 667, 677 (8th Cir. 1998)). Similarly, in *Campion*, the court found that the plaintiff “fail[ed] to connect his activity to an FCA claim, as there [was] no allegation that he informed his supervisor that he was concerned that the conduct complained of was causing government funds to be lost” *Campion*, 598 F. Supp. 2d at 658.

Here, as in *Hutchins* and *Campion*, Plaintiff alleges that his former employer made false statements to the federal government, but fails to allege any connection to a false claim for payment. Plaintiff argues that his frequent complaints articulated during meetings with team-members and superiors “were related to required certifications of compliance with FDA warnings, on which Animas was required to report.” (Pl.’s Resp. 20.) In addition, in his Response, Plaintiff advances a number of patchwork arguments attempting to establish that

Animas filed false claims.⁸ These recent allegations are insufficient to establish that a potential FCA claim existed.⁹

Moreover, Plaintiff has not established that he was discriminated against because he engaged in protected conduct. Plaintiff cites a number of instances in which he “explained his concern regarding” documentation with regard to FDA compliance. (Am. Compl. ¶ 16.) At base, however, Plaintiff’s allegations primarily relate to perceived mistreatment at work.¹⁰ “‘Mere dissatisfaction with one’s treatment on the job is not, of course enough. Nor is an employee’s investigation of nothing more than his employer’s non-compliance with federal or state regulations.’” *Hutchins*, 253 F.3d at 187-88 (quoting *United States ex rel. Yesudian v. Howard Univ.*, 153 F.3d 731, 740 (D.C. Cir. 1998)).

We also find that Plaintiff did not put his former employer on notice that he intended to file an action under the FCA. In “expressing concern” to team-members and supervisors about Defendants’ documentation and systems, Plaintiff never used terms like “illegal,” “unlawful,” or “*qui tam* action,” and never informed anyone at Animas or Johnson & Johnson that he intended

⁸ For example, Plaintiff argues that “[t]he main focus of the corrective plan was to insure [sic] compliance with the [Current Good Manufacturing Practice], a condition of payment under Federal programs.” (Pl.’s Resp. 24.) Plaintiff also argues that money that should have been spent on filing fees and for compliance was kept from the government. (*Id.* at 25.) Finally, Plaintiff argues that non-FDA compliant products were sold to Medicare-eligible patients. (*Id.*)

⁹ Although Plaintiff does not explicitly articulate that the doctrine applies, a false certification theory of liability is also inapplicable. Under a false certification theory, “an entity is liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds.” *Wilkins*, 659 F.3d at 305. As discussed, Plaintiff, in no way, connects the alleged false certifications of FDA compliance with any payments or receipt of federal funds.

¹⁰ Plaintiff repeatedly references being told to “let things go” and receiving thinly veiled threats about his job security. (Am. Compl. ¶¶ 20-23.)

to contact the Government about false claims. *See Robertson v. Bell Helicopter Textron, Inc.*, 32 F.3d 948, 952 (5th Cir. 1994) (“[Plaintiff] has identified no change in his conduct that might have objectively demonstrated his *qui tam* intentions.”). Furthermore, Plaintiff could not have put Animas on notice that conduct at the company was putting government funds at risk because, as discussed *supra*, there were no government funds at issue.

Accordingly, Plaintiff has failed to state a claim under the FCA for retaliation.

IV. CONCLUSION

Plaintiff’s retaliation claim is untimely. Even if his claim were timely, Plaintiff has failed to properly state a claim for retaliation under the FCA. For these reasons, Defendants’ Motion to Dismiss will be granted.

An appropriate Order follows.

BY THE COURT:



R. BARCLAY SURRICK, J.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

EHAB SEFEN, ex rel United States :
 :
 v. : CIVIL ACTION
 : NO. 10-2971
 :
 ANIMAS CORPORATION, ET AL. :

ORDER

AND NOW, this 13th day of June, 2014, upon consideration of Defendants' Motion to Dismiss (ECF No. 24) and all documents submitted in support thereof and in opposition thereto, it is **ORDERED** that Defendant's Motion to Dismiss is **GRANTED** and Plaintiff's Complaint is **DISMISSED** as to Count II **WITH PREJUDICE**.

IT IS SO ORDERED.

BY THE COURT:



R. BARCLAY SURRECK, J.