UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

)	
MICHELLE HOYTE,)	
)	
Plaintiff,)	
V.)	
)	Civil Action No. 04-1054 (PLF)
AMERICAN NATIONAL RED CROSS,)	
)	
Defendant.)	
)	

OPINION

This case is before the Court on defendant's motion to dismiss plaintiff's complaint for failure to state a claim pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. Upon consideration of defendant's motion, plaintiff's opposition, defendant's reply and the entire record in this case, the Court will grant the motion and dismiss Count Two of the complaint. The Court previously dismissed Count One of the complaint after a hearing and an oral ruling on April 27, 2006.

I. BACKGROUND

A. Factual History

On April 15, 2003, Judge John Garrett Penn approved an Amended Consent

Decree entered into by the American National Red Cross ("ARC") and the United States of

America. Amended Consent Decree of Permanent Injunction ("Amended Consent Decree"),

<u>United States of America v. American Nat'l Red Cross</u>, No. 93-0949 (D.D.C. April 15, 2003);

Amended Complaint ("Am. Compl.") ¶ 11. That case was brought by the government under the

Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., and the Public Health Service

Act, 42 U.S.C. § 201 et seq. Amended Consent Decree at 1. The Amended Consent Decree was entered into for the purpose of "further[ing] [the ARC's] commitment to provide safe blood and enabl[ing] it to focus on blood safety rather than litigation." Id. It delineates, among other things, a series of "Standard Operating Procedures" or "SOPs" and reporting requirements for the handling of blood. See Amended Consent Decree at 9 (defining "SOPs" as "ARC standard operating procedures . . .") (emphasis in original), generally; see also Am. Compl.¶ 11. It also provides for a number of sanctions that the government may impose for ARC's failure to abide by the decree, including fining the ARC. Amended Consent Decree at 36-37, 42, 52-66. see also Am. Compl.¶¶ 11, 79-90. Under the terms of the decree, the Food and Drug Administration ("FDA") is to monitor the defendant's compliance with the Amended Consent Decree and is charged with deciding what sanctions should be imposed if the defendant fails to comply. See Amended Consent Decree at 35-37, 42, 52-66. The Court has no role to play in enforcing the consent decree or imposing sanctions except where ARC appeals an imposition of sanctions by the FDA. Id. at 56-58.

Plaintiff Michelle Hoyte was employed by the defendant from 1997 through 2004, most recently as the Director of Quality Audits. Am. Compl. ¶ 7. Her complaint centers on the alleged mishandling of blood by the ARC. Ms. Hoyte alleges that in or around February 10-12, 2004, while she was conducting an audit of the ARC's "Penn-Jersey" facility located in Philadelphia, Pennsylvania, she discovered that 607 units of blood had been mishandled. Id. ¶¶ 16-18. She alleges that members of both the Penn-Jersey facility's staff and the defendant's Washington D.C. headquarters made the same discovery in December 2003, but failed to take the steps required by defendant's SOPs, FDA regulations or the Amended Consent Decree upon

making the discovery, including failing to report the mishandling to the FDA. <u>Id</u>. ¶¶ 19-23, 30, 43-46. Ms. Hoyte further alleges that defendant's failure to take the required steps was an attempt to avoid possible fines that could have been imposed by the FDA under the Amended Consent Decree for the mishandling of blood. Id. ¶¶ 92-93.

According to Ms. Hoyte, during and after the February 2004 audit, she and her staff urged their supervisors to take appropriate action to report the 607 units of mishandled blood. Am. Compl. ¶¶ 52-58. She states that the defendant continued to take no action on the 607 units of blood, despite her repeated attempts to bring the problem to the attention of her superiors. Id. Ms. Hoyte's complaint alleges that she eventually scheduled a meeting with the Senior Vice President of Quality and Regulatory Affairs, William Cherry, for June 18, 2004, in an attempt to bring this and other issues to his attention. Id. ¶¶ 56, 58. On the day before her scheduled meeting with Mr. Cherry, Ms. Hoyte was terminated by her supervisor. Id. ¶¶ 52, 58.

B. Procedural History

On June 25, 2004, Ms. Hoyte filed this lawsuit pursuant to the False Claims Act ("FCA"), 31 U.S.C. § 3729, et seq., bringing two claims: (1) a qui tam reverse false claim in violation of 31 U.S.C. § 3729(a)(7), as relator; and (2) a wrongful discharge claim under 31 § U.S.C. § 3730(h), as the plaintiff. Pursuant to 31 U.S.C. § 3730(b)(2) of the FCA, the complaint in this case was maintained under seal for 60 days to give the government time to investigate and decide whether to intervene. The government moved for, and received, several extensions of time, pursuant to 31 U.S.C. § 3730(b)(3), to maintain the case under seal, and eventually filed a notice of election declining to intervene on November 7, 2005. The complaint

was then unsealed and served on defendant ARC.

On January 24, 2006, defendant ARC moved to dismiss Count One of the complaint pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure, and Count Two pursuant to Rule 12(b)(6). Thereafter, pursuant to 31 U.S.C. § 3730(c)(2)(A), the United States moved to dismiss the qui tam claim brought in the first count of plaintiff/relator's complaint. See 31 U.S.C. § 3730(c)(2)(A) ("The Government may dismiss the [qui tam] action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion."); see also Swift v. United States, 318 F.3d 250, 252 (D.C. Cir. 2003) (holding that United States has "unfettered right" under 31 U.S.C. § 3730(c)(2)(A) to dismiss a qui tam claim). Plaintiff/relator opposed both the defendant's and the government's motions, requesting a hearing on the government's motion as of right under 31 U.S.C. § 3730(c)(2)(A). After a hearing before the Court on April 27, 2006, the Court in an oral ruling dismissed Count One of plaintiff/relator's complaint pursuant to the United States' motion to dismiss.

II. DISCUSSION

Defendant ARC's motion to dismiss Count One of the complaint pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure is moot, Count One having been dismissed at the request of the United States on April 27, 2006. The Court therefore

[&]quot;'Qui tam'" is an abbreviation of the phrase 'qui tam pro domino rege quam pro si ipso in hac parte sequitur,' which means '[w]ho sues on behalf of the King as well as for himself." <u>United States ex rel. Yesudian v. Howard Univ.</u>, 153 F.3d 731, 736 n.3 (D.C. Cir. 1998) (emphasis in original) (quoting BLACK'S LAW DICTIONARY 1251 (6th ed. 1990)).

considers in this Opinion only defendant's motion to dismiss Count Two, the plaintiff's wrongful discharge claim, brought in her personal capacity.

A. Standard of Review

A motion to dismiss for failure to state a claim may not be granted, unless it appears beyond doubt that the plaintiff can demonstrate no set of facts that supports a claim entitling the plaintiff to relief. See Conley v. Gibson, 355 U.S. 41, 45-46 (1957); Sparrow v. United Air Lines, Inc., 216 F.3d 1111, 1117 (D.C. Cir. 2000). In evaluating the motion to dismiss, the Court must accept the plaintiff's factual allegations in the complaint as true and draw all reasonable inferences in favor of the plaintiff. See Harris v. Ladner, 127 F.3d 1121, 1123 (D.C. Cir. 1997). While the Court must construe the complaint liberally, the Court need not accept the plaintiff's factual inferences if the complaint's factual allegations do not support those inferences, nor must the Court accept the plaintiff's legal conclusions. See National Treasury Employees Union v. United States, 101 F.3d 1423, 1430 (D.C. Cir. 1996); Kowal v. MCI

B. Plaintiff's Wrongful Discharge Claim

Defendant ARC moves to dismiss Count Two of the complaint arguing that plaintiff has failed to state a claim for retaliatory discharge under 31 § U.S.C. § 3730(h) of the FCA because the activity she engaged in is not protected activity under the statute because it could not have led to a viable FCA claim against the defendant. Defendant's Memorandum of Points and Authorities in Support of Defendant's Motion to Dismiss ("Mot. to Dism.") at 21. Defendant further argues that even if plaintiff's complaint stated a viable FCA claim underlying

her retaliation claim, plaintiff has not sufficiently alleged that her actions were in furtherance of such a claim, that the defendant was aware of her actions in furtherance, and that it fired her at least in part because of those actions. <u>Id</u>. at 21-22. The Court agrees with the defendant's first argument, that Ms. Hoyte's complaint does not state a claim for retaliatory discharge under the FCA because her actions were not in furtherance of a matter that could have led to a reasonable FCA case against the ARC.

Section 3730(h) of the FCA states in relevant part:

Any employee who is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment by his or her employer because of lawful acts done by the employee on behalf of the employee or others in furtherance of an action under this section, including investigation for, initiation of testimony for, or assistance in an action filed or to be filed under this section, shall be entitled to all relief necessary to make the employee whole.

31 U.S.C. § 3730(h). An employee bringing a retaliation claim under this provision must demonstrate each of the following two elements to succeed on that claim: (1) that "[s]he engaged in protected activity, that is, 'acts done . . . in furtherance of an [FCA] action under this section'; and (2) that "[s]he was discriminated against 'because of' that activity." <u>United States ex rel. Williams v. Martin-Baker Aircraft Co.</u>, 389 F.3d 1251, 1260 (D.C. Cir. 2004) (quoting <u>United States ex rel. Yesudian v. Howard Univ.</u>, 153 F.3d 731, 736 (D.C. Cir. 1998)). To show that she was engaged in protected activity, <u>i.e.</u>, acts "in furtherance of" an FCA action, the employee does <u>not</u> need to have initiated a <u>qui tam</u> suit at the time of such acts, or even have contemplated initiating such a suit. <u>United States ex rel. Yesudian</u>, 153 F.3d at 739-40, 741; see also Shekoyan v. Sibley Int'l, 409 F.3d 414, 423 (D.C. Cir. 2005). It is enough that the

employee was "investigating matters that 'reasonably could lead' to a viable FCA case." <u>United States ex rel. Williams v. Martin-Baker Aircraft Co.</u>, 389 F.3d at 1260 (quoting <u>United States ex rel. Yesudian</u>, 153 F.3d at at 740 (citation omitted)); <u>see also Shekoyan v. Sibley Int'l</u>, 409 F.3d at 423; <u>Sakote v. District of Columbia</u>, 56 Fed. Appx. 519 (D.C. Cir. 2003).

Ms. Hoyte claims that she was discharged in retaliation for her activity in furtherance of the FCA reverse false claim she brought in Count One of her complaint under 31 U.S.C. § 3729(a)(7).² Specifically, in Count Two of her complaint, she alleges that she engaged in such protected activity that could reasonably have led to a viable FCA case "by repeatedly advising her supervisors that she believed that the American Red Cross had violated the law, SPOs (sic) ["Standard Operating Procedures"], and the Amended Consent Decree by not appropriately addressing the problems associated with the collection of the 607 unsuitable units of blood in Penn-Jersey." See Am. Compl. ¶ 98. The defendant's alleged violation of the law, SOPs, and Amended Consent Decree with relation to the 607 mishandled units of blood form the basis of the claim brought in Count One. See Am. Compl. ¶¶ 72-94.

Defendant argues that the <u>qui tam</u> reverse false claim plaintiff brought under 31 U.S.C. § 3729(a)(7) in Count One of her complaint was never viable, thereby rendering her claim in Count Two meritless. Mot. to Dism. at 21. Specifically, the defendant points to a single word in the relevant statutory language: "obligation." <u>Id</u>. at 2, 7-11, 21-23. A reverse false claim brought under 31 U.S.C. § 3729(a)(7) imposes liability only where one "knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an

Count One, of course, has already been dismissed not on its merits, but rather at the request of the United States, exercising its "unfettered right" to do so. <u>Swift v. United States</u>, 318 F.3d 250, 252 (D.C. Cir. 2003); see 31 U.S.C. § 3730(c)(2)(A).

obligation to pay or transmit money or property to the Government (emphasis added)." A reverse false claim, as opposed to a false claim, is one where "the defendant's action does not result in improper payment by the government to the defendant, but instead results in no payment to the government when a payment is obligated." <u>United States ex rel. Bain v. Georgia Gulf Corp.</u>, 386 F.3d 648, 653 (5th Cir. 2004). The defendant argues that, even were the allegations in Count One of the complaint accepted as true, the ARC's failure to comply with the Amended Consent Decree imposed no "obligation" upon it within the meaning of the statute. The Court agrees.

The term "obligation" is not defined in the FCA. Multiple courts, however, have consistently held that this term means a present, existing debt or liability, owed at the time the alleged false statement is made, and not some future or contingent liability. See, e.g., United States ex rel. Bain v. Georgia Gulf Corp., 386 F.3d at 658 (holding that "reverse false claims act does not extend to the potential or contingent obligations to pay the government fines or penalties which have not been levied or assessed (and as to which no formal proceedings to do so have been instituted)" (emphasis in original)); United States ex rel. American Textile Mfrs. Inst., Inc. v. The Limited, Inc., 190 F.3d 729, 736 (6th Cir. 1999) ("a reverse false claim action cannot proceed without proof that the defendant made a false record or statement at a time that the defendant owed to the government an obligation sufficiently certain to give rise to an action of debt at common law"); United States v. Q Int'l Courier, Inc., 131 F.3d 770, 774 (8th Cir. 1997) ("A potential penalty, on its own, does not create a common-law debt. A debt, and thus an obligation under the meaning of the False Claims Act, must be for a fixed sum that is immediately due."); United States ex rel. Lamers v. City of Green Bay, 998 F.Supp. 971, 997 (E.D. Wis. 1998) ("the FCA's reverse false claims provision has in mind an obligation to pay

which is at least as immediate and recognizable as affirmative claims for payment under the statute"). Furthermore, Congress in enacting Section 3729(a)(7) of the FCA, expressed the view that it was intended to impose liability on those who "make[] a material representation to avoid paying money *owed* the Government," clearly placing the obligation in the past tense. S.Rep. No. 99-345, at 15, 18, reprinted in 1986 U.S.C.C.A.N. at 5280, 5283 (relied upon in United States v. Q Int'l Courier, Inc., 131 F.3d at 773, and United States ex rel. Lamers v. City of Green Bay, 998 F.Supp. at 997)

In this case, the FCA claim underlying Ms. Hoyte's alleged protected activity relies upon the fact that the FDA <u>may</u> impose fines upon the ARC (among other things) for violations of the Amended Consent Decree to create the requisite "obligation." <u>See</u> Am. Compl. ¶ 48, 49, 80-90. Plaintiff states, for instance, that the breach of the Amended Consent Decree created an "obligation" under the FCA by "trigger[ing] a penalty of up to \$10,000 per day per unit of blood," which she then calculates could have reached a maximum amount of \$6,070,000 per day. <u>Id</u>. ¶ 83, 85. She further claims that an obligation was created by a different possible penalty under the Amended Consent Decree that could have reached \$10,000 per day. <u>Id</u>. ¶ 87. Ms. Hoyte calculates the capped amount of permissible penalties for the alleged violations related to the 607 units of blood in the Penn-Jersey to have ben \$19,240,000. <u>Id</u>. ¶ 89; <u>see also</u> Amended Consent Decree at 58.

What Ms. Hoyte's complaint fails to mention, however, is that none of the sanctions she cites – in fact, none of the possible monetary sanctions in the Amended Consent Decree – are automatically imposed on the defendant for its alleged violations of the Amended Consent Decree. The decision whether to impose sanctions rests exclusively with the FDA, and

no obligation will arise until the FDA decides to exercise its authority under the Amended Consent Decree. See, e.g., Amended Consent Decree at 35 ("FDA may assess a penalty of up to \$10,000 per day"); 36 ("FDA may assess a penalty of up to \$10,000 per day"); 42 ("FDA may assess a penalty of up to \$10,000 per day"); 42 ("FDA may assess a penalty of up to \$10,000 per day); 54 ("FDA may assess penalties, and/or . . . take any step that FDA deems necessary . . ."); 56 ("FDA may assess penalty of up to \$10,000 for each violation"); 57 ("If the Court agrees with FDA [on appeal], ARC shall pay the penalty of up to \$10,000 per day" as already determined at discretion of FDA prior to appeal; also "FDA may assess penalty of up to \$10,000 per day from the date of the Court's adverse determination" of ARC's appeal); 61 ("FDA may assess a penalty of up to \$50,000"); 62 ("FDA may assess penalty of up to \$5,000"); 63 ("FDA may assess a penalty of up to \$50,000"); 64 ("FDA may, in addition to any other penalties assessed pursuant to this Order, assess a penalty of up to \$10,000") (emphases added).

Each and every provision of the Amended Consent Decree that permits the imposition of sanctions is subject to the discretion of the FDA, which <u>may</u> seek these particular penalties (up to the maximums cited) or may refrain from doing so. <u>Id</u>. Neither the Amended Consent Decree nor any laws or regulations that the plaintiff can cite impose an obligation on the ARC for its behavior at the time it allegedly mishandled and covered up the mishandling of the 607 units of blood at the Penn-Jersey facility. The Amended Consent Decree merely created the <u>potential</u> for such an obligation or obligations – obligations that are wholly contingent unless and until the FDA chooses to act.

The statute is clear: a reverse false claim exists only where a party seeks to avoid or decrease an "obligation," to pay or transmit money to the government. 31 U.S.C. § 3729(a)(7). It contains no terms modifying it such that it can be interpreted as a future obligation, or potential obligation, or otherwise taken out of its present tense context. There is also no indication that Congress intended for liability to be imposed where an obligation had not yet come into being, or was merely contemplated by the parties. At the time the ARC allegedly covered up its mishandling of the blood, from December 2003 through June 2004, in the later part of which Ms. Hoyte alleges she took actions that led to her discharge, it had no existing obligation to pay the government for any of its alleged misdeeds. Nor does her complaint allege that such an obligation, within the meaning of the statute, existed at the time. Thus, the actions she took that allegedly led to her discharge could not have been protected because there was no viable FCA claim for her to further where there was no extant obligation. 31 U.S.C. § 3730(h); see also United States ex rel. Williams v.Martin-Baker Aircraft Co., 389 F.3d at 1260 (quoting United States ex rel. Yesudian v. Howard Univ., 153 F.3d at 736). The Court therefore must dismiss Count Two of plaintiff's complaint for failure to state a claim upon which relief can be granted.

It may be, as Ms. Hoyte alleges, that the defendant covered up the mishandling of blood at the Penn-Jersey facility, and did so because it was motivated by the desire to avoid FDA sanctions that could follow for its failure to act. The potential sanctions, however, were just that – potential. They were at the discretion of the government to impose or not to impose. In fact, according to Ms. Hoyte herself, despite an investigation into the alleged mishandling of blood at the Penn-Jersey facility, the FDA has to date not imposed any sanctions under the Amended

Consent Decree for the alleged action or inaction by defendant in relation to the 607 units of blood at the facility. See April 27, 2006 Transcript at 13:3-6 (plaintiff's counsel stating that there is "nothing in the record" to indicate the FDA took action under the Amended Consent Decree with respect to the violation alleged in Count One of the complaint). Unfortunately, this fact only tends to underscore the lack of an existing obligation owed by ARC to the government either at the time that the alleged cover-up or retaliatory discharge occurred.

The government has wide discretion in how it chooses to prosecute its claims or, in this case, enforce its rights under the Amended Consent Decree into which it entered. Cf.

Heckler v. Chaney, 470 U.S. 821, 831 (1985) ("an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion"). As previously stated in the Court's April 27, 2006 oral ruling, it is not within this Court's purview to review or reverse the decision of the United States to dismiss the qui tam reverse false claim. Nor is it within this Court's authority – or Judge Penn's – to review or reverse the decision of the FDA not to pursue penalties under the Amended Consent Decree for the defendant's alleged breaches. While Ms. Hoyte may have had the best of intentions in bringing this suit, in view of the language and structure of the Amended Consent Decree, the FCA simply does not provide for a viable reverse false claim against the defendant for its alleged failure to correct the mishandling of blood at the Penn-Jersey facility. It therefore by its terms does not provide Ms. Hoyte with a cause of action for retaliatory discharge under this statute.

III. CONCLUSION

For the foregoing reasons, the Court will grant defendant ARC's motion to dismiss Count Two, the remaining count of the complaint. An Order and Judgment consistent with this Opinion will issue this same day.

SO ORDERED.

DATE: July 14, 2006

PALIL I EDIEDMAN

PAUL L. FRIEDMAN
United States District Judge