U.S. Department of Labor

Office of Administrative Law Judges
800 K Street, NW, Suite 400-N
Washington, DC 20001-8002

(202) 693-7300
(202) 693-7365 (FAX)

Issue Date: 31 August 2007

CASE NOS: 2007 SOX 39 and
2007 SOX 42

***In the Matter of*:**

KATHY J. SYLVESTER

and

THERESA NEUSCHAFER

Complainants,

v.

PAREXEL INTERNATIONAL LLC

Respondent.

Before:
EDWARD TERHUNE MILLER
Administrative Law Judge

DECISION AND ORDER DISMISSING COMPLAINTS

Statement of the Case

This case involves complaints by Theresa Neuschafer and Kathy J. Sylvester filed under the employee protective provisions of § 806 of the Sarbanes-Oxley Act (Corporate and Criminal Fraud Accountability Act of 2002, Public Law 107-204, 18 U.S.C. § 1514A, *et seq.*)(SOX or the Act), and the regulations promulgated thereunder at 29 C.F.R. Part 1980. The applicable statutory provision prohibits any company with a class of securities registered under § 12 of the Securities Exchange Act of 1934, or required to file reports under § 15(d) of that act, or any officer, employee or agent of such company from discharging, harassing, or in any other manner discriminating against an employee with respect to terms and conditions of employment because the employee provided to the employer or Federal Government information relating to alleged violations of 18 U.S.C. § 1341 (mail fraud), § 1343 (wire, radio, TV fraud), § 1344 (bank fraud), or § 1348 (securities fraud), or any rule or regulation of the Securities and Exchange

Commission (see, e.g. 17 C.F.R. Part 210 (2005), Form and Content of the Requirements for Financial Statements), or any provision of Federal law relating to fraud against shareholders.

The Federal mail and wire fraud statutes identified in the Complainants' complaints make it unlawful to use the mails, private parcel services, and various wire, radio, or television transmissions for purposes of planning or executing "any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises…" 18 U.S.C. §§ 1341, 1343. Although these statutes are not by their terms limited to fraudulent activity that directly or indirectly affects investors' interest, the alleged fraudulent conduct alleged in relation to such statutes "must at least be of a type that would be adverse to investors' interests." *See Platone v. FLYi*, ARB Case No. 04-154, ALJ Case No. 2003-SOX-27 (Sept. 29, 2006)(slip at15).[1]

The Complainants allege that they suffered retaliation and unlawful termination by Respondent in response to their allegedly protected disclosures reporting violations by other employees of certain clinical drug testing protocols which they allege constitutes clinical fraud. Respondent has moved to dismiss the complaints pursuant to Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction, or in the alternative pursuant to Rule 12(b)(6), for failure to state a claim upon which relief can be granted.[2] Complainants have filed a consolidated reply. Respondent filed a consolidated reply in support of its motions to dismiss, and a Notice of Supplemental Authority dated August 22, 2007, identifying the recently issued decision in *Portes*, 2007 WL 2363356. The complaints have been consolidated for hearing and decision.

Standards on Respondent's Motions to Dismiss

Complainants bear the burden of proving subject matter jurisdiction over their claims before this tribunal. *See Robinson v. Overseas Military Sales Corp*., 21 F.3d 502, 607 (2d Cir. 1994). They must allege facts establishing that they engaged in protected activity within the definition of the Act. Complainants bear the burden of proof if a challenge is posed to the actual basis for subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1). *See Richmond, Fredericksburg & Potomac R. Co. v. United States*, 945 F.2d 765, 768 (4th Cir. 1991) (citing *Adams v. Bain*, 697 F.2d 1213, 1219 (4th Cir. 1982)).

Respondent has framed two types of motions to dismiss based upon subject matter jurisdiction under Rule 12(b)(1): (1) a facial attack which questions the sufficiency of the pleading, and (2) a factual attack on the pleadings alleging subject matter jurisdiction. *See Hughart v. Raymond James & Ass.*, 2004-SOX-9 (Sec'y Dec. 17, 2004) (citing *Ohio Nat'l Life*

[1] Complainants' reliance on *Reyna v. Conagra Foods*, 2007 WL 1704577, No. 3:04-CV-39 (M.D.Ga.) (June 11, 2007) for the proposition that under § 806 fraud violations under 18 U.S.C. §§ 1341, 1343, 1344, or 1348, do not have to relate to fraud on shareholders is misplaced, because in this respect the case stands alone and in conflict with other authorities such as *Platone*, ARB Case No. 04-154, ALJ Case No. 2003-SOX-27; *Portes v. Wyeth Pharmaceuticals*, 2007 WL 2363356, 06 Civ. 2689 (S.D.N.Y. Aug. 20, 2007); *Fraser v. Fiduciary Trust Co. Int'l*, 417 F. Supp.2d 310, 322 (S.D.N.Y. 2006), among others.

[2] The Rules of Civil Procedure for the District Court of the United States shall be applied in any situation not provided for or controlled by the Rules of Practice and Procedure for Administrative Hearings Before Administrative Law Judges at 29 CFR Part 18, or by any statute, executive order, or regulation. 29 CFR §18.1. There is no provision in 29 CFR Part 18 for a Rule 12(b)(1) motion.

Ins. Co. v. United States, 922 F.2d 320 (6th Cir. 1990)). In the first type of motion, the allegations in the complaint must be taken as true. *See Ohio Nat. Life Ins. Co. v. United States*, 922 F.2d 320 (6th Cir. 1990). *See also Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 161 (2d Cir. 2000); *Witt v. Roadway Express*, 136 F.3d 1424, 1428 (10 Cir. 1998). The complaint is deemed to include any written instrument attached to it as an exhibit or any statements or documents incorporated in it by reference. *See Int'l Audiotext Network, Inc. v. Am. Tel. & Tel. Co.*, 62 F.3d 69, 72 (2d Cir. 1995).

In the second type of factual challenge, commonly called a "speaking motion" no presumptive truthfulness applies to the factual allegations. Rather, if the facts presented generate a factual controversy, this tribunal must weigh the conflicting evidence to arrive at the factual predicate that subject matter jurisdiction exists or does not exist, but has wide discretion to allow affidavits, documents and conduct a limited evidentiary hearing to resolved disputed jurisdictional facts. *See Ohio Nat'l*, 922 F.2d at 325 (internal citations omitted). "[F]actual allegations must be enough to raise a right of relief above the speculative level, on the assumption that all of the allegations in the complaint are true." *See Bell Atlantic Corp. v. Twombly*, 127 S.Ct. 1955, 1965 (2007). In these consolidated cases this tribunal need not proceed beyond the facial attack questioning the sufficiency of the pleading. Thus, determination of jurisdiction in these cases is not linked to a determination of disputed material facts.

Issue

Whether Complainants have alleged facts which establish protected activity within the scope of the Act and jurisdiction over the subject matter in this tribunal as a matter of law.

Findings of Fact

This tribunal assumes the following material facts and allegations by Complainants are true for purposes of resolving Respondent's motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1); *Ohio Nat'l*, 922 F.2d 320:

1. Respondent Parexel International LLC (Parexel or Respondent) is a Limited Liability Company, formed under the laws of Delaware and publicly traded with a class of securities registered under § 12 (15 U.S.C. § 781) and is required to file reports under § 15(d) (15 U.S.C. § 78*o*(d)) of the Securities Exchange Act of 1934. As such, it is a company within the meaning of 18 U.S.C. § 1514A.

2. Respondent operates various research facilities for testing drugs in a clinical setting on behalf of drug manufacturers or other sponsors, including a clinic located with Harbor Hospital in Baltimore, Maryland, (Baltimore Unit) where Complainants worked and where all pertinent actions took place.

3. Complainants were employed by Respondent under circumstances such that they are employees within the applicable definitions under the Act and 29 CFR § 1980.101.

4. Complainant Kathy Jean Sylvester was employed by Respondent from September 2003 until she was discharged on June 15, 2006. She was a shareholder of Respondent while employed by Respondent. She filed a timely discrimination complaint under the Act on September 11, 2006. (2007 SOX 39)

5. Sylvester served as Case Report Forms Department Manager from July 1, 2005, to June 15, 2006. In such capacity she was responsible, among other things, for the accurate reporting of data and related research results from clinical studies conducted by Respondent pursuant to the law and regulations promulgated by the United States Food and Drug Administration ("FDA").

6. A key duty of Sylvester as Case Report Forms Manager was to ensure the reporting of accurate research data and adherence to Good Clinical Practice (GCP) to the FDA, a responsibility regulated by the United States Code of Federal Regulations (CFR).

7. The GCP was produced by the FDA to provide a unified standard for designing, conducting, recording, and reporting trials that involve human subjects, and describes the essential regulatory documents that individually and collectively permit evaluation of the conduct of a clinical study and the quality of the data produced.

8. On or about Thursday, March 16, 2006, Sylvester reported to Elizabeth Jones, Nurse Manager, and Meimpie Fourie, Clinical Research Coordinator/Manager, that Karen Smith, Clinical Research Nurse, and Mary Ann Green, Research Assistant, were reporting false clinical data in violation of the FDA regulated GCP by falsely recording the time points at which Neuro-cognitive testing was performed by clinical subjects at designated times other than when true testing was performed in a Phase I study by Respondent for the drug manufacturer AstraZeneca (March Report). The false entries were witnessed by Ramona Setherley, Clinical Research Nurse. Fourie was Coordinator for the Study. All identified personnel were employees of Respondent. ¶30 Sylvester's report is not alleged to have expressly referred to any fraud on shareholders.

9. On or about May 26, 2006, Sylvester reported to Jones that Smith had fraudulently documented Pharmokinetic (PK) blood sample time points over the prior several weeks. (May Report) Smith placed the PK samples in her pocket, and later scanned the PK samples into Respondent's Clinbase system "at the appropriate time the PK samples should have actually been drawn. The PK samples should have been contemporaneously drawn from the subjects at the time points mandated by the study protocols pursuant to GCP. This fraudulent activity involves three current studies conducted by Parexel including Advanced Magnetics, Proctor & Gamble, and Astra Zeneca (sic)." (¶31) The inaccuracy of the timing and recording of such samples could potentially result in flawed analysis and corrupt and inaccurate data. (¶¶ 31, 32) This report also is not alleged to have expressly referred to any fraud on shareholders.

10. After Sylvester reported Green's conduct, her relations with other employees deteriorated and they retaliated against her. Personnel to whom Sylvester reported such retaliation, including Jones, Lisa Roth, Human Resources Director, and Rachel Garrido, Unit Director, failed or refused to investigate or take remedial action. (¶40, 41, 42)

11. Smith and Green learned of Sylvester's complaint from Jones, who did not take appropriate remedial action. Green reacted adversely against Neuschafer, and Sylvester was blamed, and was issued a disciplinary letter of warning on March 21, 2006, which she interpreted as a preliminary step toward termination for reporting the clinical research fraud, and in retaliation for Sylvester's "reporting the violation of GCP and fraudulent research data by" Smith and Green.

12. At the time of the receipt of this letter Sylvester protested to her management that Respondent was disciplining her in retaliation for revealing the fraudulent clinical practices at Parexel, but her protest was ignored.

13. Sylvester was terminated by Unit Director Rachel Garrido, her supervisor and Senior Director of Business Operations, and Roth on June 15, 2006. Garrido told her that the termination decision was a "corporate decision" and that she was terminated because she was "not a team player." (¶43) Upon her termination Sylvester's computer hard drive was taken from her computer and sent to corporate headquarters in Waltham, Massachusetts, in an allegedly unprecedented action. (¶44)

14. Theresa A. Neuschafer was employed by Respondent as a Clinical Research Nurse (LPN) from August 16, 2004, until she was discharged August 10, 2006. (¶ 4) She filed a timely complaint alleging discrimination under SOX on October 30, 2006 (2007 SOX 42). She was a shareholder of Respondent while employed by Respondent. She was considered by coworkers to be a friend of Sylvester and notoriously unwilling to engage in false reporting or other conduct in violation of GCP (¶¶7, 9)

15. Neuschafer reported to Fourie on Wednesday, March 15, 2006, that two coworkers, Smith and Green, "were reporting false clinical data." Fourie indicated that the fact that the cognitive testing was not being properly recorded at the time it was being done was "no big deal." (¶14) Neuschafer had reviewed four charts of study subjects, discovered that the Neuro-cognitive testing time points were not complete, and questioned Smith and Green, and Ramona Setherly, Research Nurse. Smith responded by grabbing the four charts and falsely filling in the current times in violation of GCP. Sylvester was a witness to some or all of the incident. (¶11) Neuschafer alleges in her complaint that Neuschafer was obligated to make this report to Jones and Fourie pursuant to Respondent's Code of Business Conduct and Ethics, and Respondent did not investigate her report as required by that Code. (¶15) Neuschafer told Sylvester what had occurred. (¶16) Sylvester reported the incident the following day.

16. Neuschafer's report related only the specified misreporting of clinical data by one or two coworkers. Her report is not alleged to have expressly referred to any fraud on shareholders. (¶14)

17. Neuschafer later reported separate additional clinical misconduct to Sylvester, her coworker, who on or about May 26, 2006, reported that misconduct to Jones, who was Neuschafer's supervisor. Neuschafer reported to Sylvester that Smith had fraudulently documented Pharmacokinetic (PK) blood sample time points over the prior several weeks, by placing the PK samples in her pocket after they were drawn and later scanning them into

Respondent's Clinbase system at the times they should have been drawn. The Advanced Magnetics, Proctor & Gamble, and AstraZeneca studies were involved. (¶¶33, 34) Neuschafer does not allege that she herself reported the alleged misconduct of May 26, 2006, to her manager, Jones, or any other supervisor or person authorized to investigate employed by Respondent. There is no allegation that Neuschafer reported the alleged misconduct to anyone other than Sylvester, or that anyone other than Sylvester received a report from Neuschafer regarding improper blood draws or recording thereof by Smith. She does not allege that her report expressly referred to any fraud on shareholders.

18. Respondent issued Neuschafer a written disciplinary letter, and later terminated her employment effective August 10, 2006. Neuschafer was terminated from her employment by Jones, her supervisor, then the Manager of Clinical Operations, on August 10, 2006, allegedly in retaliation for making the March report. Neuschafer alleges she was also disciplined in March because she made the March report, but did not file any complaint until October 2006, which is more than ninety days after the March discipline was imposed. There is no allegation that Sylvester participated in the decision to terminate Neuschafer, but Jones, Neuschafer's supervisor, is alleged to have had knowledge of Neuschafer's report or allegedly protected activity, even though Sylvester is alleged to have made the report regarding Smith to Jones. When Jones terminated Neuschafer on August 10, 2006, she stated that the reason for termination was that Neuschafer's personality did not fit in. Neuschafer was not told of any misconduct or mistakes she made at work that caused her termination. (¶4, 48)

19. Complainants Sylvester and Neuschafer allege that Respondent told, and trained its employees to understand, and that Complainants believed, that false recording of clinical studies data was clinical fraud that could lead to imprisonment; that clinical falsification such as that Complainants reported was a Sarbanes-Oxley violation; that accurate recording of clinical data is covered under a section of the Respondent's Code of Business Conduct and Ethics that discusses the Securities and Exchange Commission; that all employees of Respondent are told that Sarbanes-Oxley covers breaches of controls such as clinical study protocols which could affect Respondent's financial statements, because of the prospect of a wide range of penalties for falsification of data and fraud that might be imposed, and thus shareholders' interests. Complainants allege that they followed Respondent's management statements, memoranda, and training as to what constituted protected activity.

20. Complainants' allegations also include numerous legal conclusions to the effect that the entry of false clinical research data is protected activity under the Act in any event, and that the flow of such false data constitutes imminent mail and wire fraud, actual mail and wire fraud, or both, depending upon whether it was an initial or recurring activity involving release of such data to the FDA, study sponsors, and others. Complainants allege that the recording of false clinical data calls into question the integrity of the results of clinical drug studies; supports an allegation that Respondent is knowingly committing both mail and wire fraud by reporting false study data and results to the FDA, study sponsors, and others; places into question the reputation, integrity, competency, and criminality of the Respondent; and that all such matters would be of interest to, and would involve fraud upon, shareholders.

21. Complainants Sylvester and Neuschafer have made extensive other allegations in their pleadings that pertain to assumptions and predictions regarding the processing and transmission the allegedly false clinical data which they reported, and possibly other false data, and potential omissions or consequences of the entry of such false or inaccurate data such as disclosure, reporting obligations and potential defaults thereof, and possible penalties which might be imposed. Those allegations are conclusory and speculative in nature and do not demonstrate actual personal knowledge, beyond the fact of entry of false clinical data as alleged. Complainants also have alleged various financial consequences of the entry of false clinical data upon Respondent as well as its shareholders which are similarly conclusory and speculative in character.

Conclusions of Law and Discussion

SOX Claims

The complaints are filed pursuant to § 1514A(a)(1) of the Act, which provides in relevant part:

> No company with a class of securities registered under section 12 of the Securities Exchange Act of 1934 (15 U.S.C. 78*l*) or that is required to file reports under section 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78*o*(d)), or any officer, employee, contractor, subcontractor, or agent of such company, may discharge, demote, suspend, threaten, harass, or in any other manner discriminate against an employee in the terms and conditions of employment because of any lawful act done by the employee – (1) to provide information, cause information to be provided, or otherwise assist in an investigation regarding any conduct which the employee reasonably believes constitutes a violation of section 1341, 1343, 1344, or 1348, any rule or regulation of the Securities and Exchange Commission, or any provision of Federal law relating to fraud against shareholders, when the information or assistance is provided to or the investigation is conducted by – (A) a Federal regulatory or law enforcement agency . . . or (C) a person with supervisory authority over the employee (or such other person working for the employer who has the authority to investigate, discover, or terminate misconduct).

18 U.S.C. § 1514A(a)(1).

To establish a whistleblower claim under § 1514A(a)(1), a complainant must prove by a preponderance of the evidence that (1) [she] engaged in a protected activity; (2) the employer knew of the protected activity; (3) [she] suffered from an unfavorable personnel action; and (4) circumstances exist to suggest that the protected activity was a contributing factor to the unfavorable action. *See Portes*, 2007 WL 2363356 (citing *Fraser v. Fiduciary Trust Co. Int'l*, 417 F. Supp.2d 310, 322 (S.D.N.Y. 2006)); *Collins v. Beazer Homes USA, Inc.*, 334 F.Supp. 2d 1365, 1375 (N.D. Ga. 2004). Respondent challenges the claims by motions under Fed. R. Civ. P. 12(b)(1) and 12(b)(6), contending that as a matter of law Complainants cannot show they

engaged in protected activity, and contending that none of Complainant's allegedly protected activities as described in their pleadings or otherwise were sufficiently related to securities fraud or any violation enumerated in § 1514A(a)(1) to support a SOX claim.

The law in this regard is now reasonably well defined. SOX protects employees who report activity that they "reasonably believe[] constitutes a violation" of the enumerated code sections pertaining to mail, wire, and other specified kinds of communications fraud, any SEC rule or regulation, or "any provision of Federal law relating to fraud against shareholders." 18 U.S.C. § 1514A(a)(1). A whistleblower need not cite the specific law or regulation that he believes is being violated in his report or other allegedly protected activity. *See Portes*, 2007 WL 2363356; *Fraser*, 417 F.Supp.2d at 322.

The "context" of the disclosure and "the circumstances giving rise to the communication," if closely related to potential fraud against shareholders, may be sufficient to satisfy the pleading requirements of a SOX whistleblower claim. *Portes*, 2007 WL 2363356; *Fraser*, 417 F.Supp. 2d at 323. But disclosures are protected only when they "implicate the substantive Law protected in Sarbanes-Oxley 'definitively and specifically'" *Portes, supra* at 7; *Fraser*, 417 F.Supp.2d at 322 (citing *Am. Nuclear Res. Inc. v. United States Dep't of Labor*, 134 F.3d 1292, 1295 (6th Cir. 1998)(requiring that protected disclosure under the Energy Reorganization Act "definitively and specifically" relate to safety)).[3] Where a communication is "barren of any allegations of conduct that would alert [a respondent] that [the complainant] believed the company was violating any federal rule or law related to fraud against shareholders," the reporting is not protected by SOX. *Portes*, 2007 WL 2363356; *Fraser*, 417 F.Supp.2d at 322. *See also Livingston v. Wyeth*, 2006 WL 2129794 at *10, No. 1:03CV00919 (M.D.N.C., July 28, 2006) ("To be protected under [SOX], an employee's disclosures must be related to illegal activity that, at its core, involves shareholder fraud."); *Platone*, 2006 WL 3246910 at *8 ("The relevant inquiry is not what [is alleged in the complaint filed with OSHA], but [what was] actually communicated to [the] employer prior to . . . termination.").

In *Livingston*, 2006 WL 2129794, Livingston complained that if Wyeth submitted data to the FDA without disclosing or correcting certain alleged deficiencies, Wyeth could be penalized by the FDA to its detriment, and could be violating some SEC rule or regulation or law relating to fraud against shareholders. The court held that the complaints did not qualify as protected activity under SOX because, "[t]o be protected activity under the Sarbanes-Oxley, an employee's disclosures must be related to illegal activity that, at its core, involves shareholder fraud." Id. at *30. The court also held that a suggestion that management would conceal critical information was entirely speculative in the face of disagreement over training deficiencies, and Livingston could not have held an objectively reasonable belief relating to shareholder fraud when he made his report. But even if it were reasonable to believe that FDA might in the future take some type of enforcement action based on the compliance issue reported, until FDA acted, this would not amount to information sufficiently material to the company's financial picture to form the basis for securities fraud, or to create a substantial likelihood that a reasonable shareholder would consider the information import to a decision to invest. *Id.* at *33 (citing *Minkina v. Affiliated Physician's Group*, 2005 SOX 19 (Sec'y Feb. 22, 2005); *Nixon v. Stewart & Stevenson Services*,

[3] Because of the hitherto relative scarcity of SOX case law authority, authority under analogous whistleblower statutes have been recognized as helpful. *See Collins*, 334 F.Supp.2d at 1374.

Inc., 2005 SOX 1 at 13-14 (Sec'y Feb. 16, 2005); *Harvey v. Safeway, Inc*. 2004 SOX 21 at 31-32 (Sec'y Feb. 11, 2005)). *See also Platone*, 2006 WL 3246910 at *15-16. Thus, whether or not the Complainants' essentially similar reports amount to reports of fraud, they do not qualify as material under the Act to the extent that materiality is in issue with regards to the parade of possible adverse consequences that false data entries might generate as alleged by Complainants.

Protected activity under § 806 of SOX may be deemed to have three essential elements: (1) the report or action must involve a purported violation of a federal law or SEC rule or regulation relating to fraud against shareholders; (2) the complainant's belief about the purported violation must be objectively reasonable; (3) and the complainant must communicate her concern to either her employer, the federal government, or a member of Congress. *See Hughart* 2004 SOX 9 at 47. The first element of this test mandates that the report or action specifically relate to fraud against shareholders. *See Bishop v. PCS Admin.*, 2006 WL 1460032, No. 05 C 5683 (N.D. Ill. May 23, 2006). To fall within the protection of the Act, "the employee's protected communications must relate 'definitively and specifically' to any of the listed categories of fraud or securities violations under 18 U.S.C.A. § 1514A(a)(1)." *Platone*, 2006 WL 3246910. Complainants' reports as described in their pleadings do not do this.

"Fraud" is an integral element of a cause of action under § 806 and incorporates a requisite accusation of intentional deceit that under SOX would pertain to a matter that is material to or that would impact shareholders or investors. *See Tuttle v. Johnson Controls*, 2004 SOX 76 at 3 (Sec'y Jan. 3, 2005); *Grant v. Dominion East Ohio Gas*, 2004 SOX 63 at 40 n. 40 (Sec'y Mar. 10, 2005) (citing *Hopkins v. ATK Tactical Systems*, 2004 SOX 19 (Sec'y May 27, 2004) (discontented employee's request for explanations about projects, accounting, and software without reference to fraud or intention deception of stockholders is not protected activity)); *Brookman v. Levi Strauss & Co.*, 2006 SOX 36 (Sec'y April 27, 2007) (report to SEC charging submission of fraudulent reports to EEOC does not qualify as protected charge of shareholder fraud or securities violations under Act.); *Lerbs v. Buca Di Beppo, Inc*., 2004 SOX 8 (Sec'y June 15, 2004)(queries about classification of questionable entries on general ledger believed to reflect misrepresentation of true financial position to investors insufficiently specific to be protected in the absence of identified particular concerns about illegal behavior).

The alleged fraudulent conduct must "at least be of a type that would be adverse to investors' interests" and meet the standards for materiality under the securities laws such that a reasonable shareholder would consider it important in deciding how to vote. *Platone*, 2006 WL 3246910 at *15-16. Sylvester's complaint on its face does not satisfy these requirements because she alleges only that she reported that certain of Respondent's employees were falsely recording and reporting clinical data in violation of FDA regulations in two different ways on two different occasions, respectively. Neuschafer's complaint on its face does not satisfy these requirements because, in substance, Neuschafer alleges only that she reported to Sylvester that her coworkers were reporting such false clinical data. Thus, neither complaint satisfies the legal requirements for protected activity under SOX, because each complainant alleges at most that she reported that her coworkers were reporting false clinical data contrary to FDA requirements. Any such additional references to FDA regulations or violations thereof do not involve, inherently or otherwise, reference to shareholder fraud or violations of federal criminal statutes related to shareholder fraud or SEC statutory or regulatory requirements.

Complainants' many explanations and conclusory assertions in their complaints which attempt to expand or elaborate the scope of their actual reports of clinical fraud, which they allege comprise protected activity, to establish a connection with shareholder fraud are immaterial as a matter of law. The relevant inquiry is not what Complainants have alleged or argued in their complaints, but what Complainants actually communicated to Respondent prior to their respective terminations as alleged in their pleadings. *Platone*, 2006 WL 3246910 at *17. *See also Lerbs v. Buca Di Beppo*, 2004 SOX 8 at 13 (Sec'y June 15, 2004); *Trodden v. Overnite Transp. Co.*, 2004 SOX 64 at 5 (Sec'y Mar. 29, 2005).[4] Until the allegedly protected a activities are shown to have a sufficiently definitive and specific relationship to any of the listed categories of fraud or securities violations under 18 U.S.C. § 1514A(a)(1), what Complainants might have believed or been told by Respondent regarding any relationship of such false reporting to SOX is irrelevant and immaterial to the legal sufficiency of their complaints under SOX. Complainants' beliefs in such regard would also not be objectively reasonable.

The conclusory allegations reflecting legal conclusions which are not allegations of material fact are not deemed to be controlling. Many of Complainants allegations which would necessarily be assumed to be true for purposes of resolving the Respondent's motions, are immaterial, or are merely conclusory statements lacking requisite factual underpinnings, are speculative, or are conclusory and unsupported legal conclusions. Since they do not establish disputed material facts and related legal conclusions which would defeat Respondent's motions to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), they have been considered and disregarded as unnecessary to determination of Respondent's motion under Rule 12(b)(1).

Complainants' allegations of disclosures to supervisors seek to implicate the substantive law protected in SOX by alleging that Respondent's indoctrination and training of employees and representations to shareholders in effect establish the requisite nexus between the complaints and protected activity under SOX. Complainants allege, in substance, that, by violation of clinical drug testing protocols by the entry of false or inaccurate information, Respondent would face fines and other penalties, and would have engaged in fraudulent conduct that would affect its financial status and reporting and shareholders' interests. Complainants allege that references by Respondent in training and management communications to its employees concerning accuracy of drug trial data reporting as related to SOX provided them with a reasonable belief that the Respondent was obligated to report such violations to the FDA, SEC, and shareholders with potentially adverse effects upon shareholder interests.[5] Thus, Complainants allege such

[4] Respondent points out that Neuschafer did not in her report, or subsequently, allege systemic fraud, that numbers of her coworkers were false reporting clinical data, that the alleged misreporting or fraudulent report was induced or rewarded by manager of Respondent, or that she reported to anyone a belief that her report or reports were not investigated by the study coordinator, as opposed to manager, to whom she delivered her report. She also has not alleged that she reported to anyone that she believed her report was suppressed or covered up despite the nearly five month interval between her alleged protected activity and her alleged retaliatory termination. Any such allegations must be gleaned from her complaint filed long after her allegedly protected report.

[5] Sylvester alleges in her complaint that the accurate reporting of data by her and Respondent to the FDA is critical for the shareholders of Respondent because the FDA and U.S. Code of Federal Regulations require that GCP be followed to ensure the accuracy of the data collected in subject clinical trials. Violation of GCP could constitute a violation of Federal law including the CFR, 18 U.S.C. § 1961 (pattern of racketeering activity under the Racketeering and Influenced Corrupt Organizations Act), 18 U.S.C. 1342 (mail fraud), 18 U.S.C. § 1343 (wire

reports as they made constituted protected activity under SOX. However, the allegations do not demonstrate that their disclosures of false clinical data recorded in violation of drug testing protocols "definitively and specifically" implicate the substantive law of SOX and fraud on shareholders, and thus the employee protection provisions of § 806 of that law.

There is no allegation in the pleadings that Complainants, notwithstanding their alleged beliefs, expressly referred to fraud, shareholders, securities, statements to the SEC, or SOX in their reports of false reporting of clinical data in violation of applicable drug testing protocols made to other employees and supervisors at Respondent. The purported violations might have involved internal and FDA protocols, FDA regulations, and possibly other drug testing guidelines, but not SEC rules or other federal laws related to fraud against shareholders, and thus were not sufficiently related to shareholder fraud to constitute protected activity. *See Portes*, 2007 WL 2363356; *Livingston*, 2006 WL 2129794. Complainants' reports to personnel at Respondent related to alleged violations of regulations or applicable protocols governing the testing of medical drugs or procedures. The circumstances of the disclosures as alleged do not disclose communication to such personnel at Respondent their alleged concern that Respondent was being unfair to its investors, that its lack of compliance with FDA regulations or applicable protocols might have implications for Respondent's reports to investors or the SEC, or that Respondent was engaged in other conduct "that would alert [a respondent] that [the complainant] believed the company was violating any federal rule or law related to fraud against shareholders." *See Portes*, 2007 WL 2363356 (citing *Fraser*, 417 F.Supp.2d at 322); s*ee also Hunter v. Northrop Grumman Synoptics*, 2005 SOX 8 (Sec'y June 28, 2005) ("[r]aising a concern about a violation of an ethics policy is not protected activity.").

Since Complainants were employed in nursing or related capacities, not as investment analysts at a financial services firm, no reasonable inference that they were concerned with shareholder fraud could have been derived from their job responsibilities or the nature of their work. In this context, their disclosures to Respondent are outside the scope of protected reporting under SOX. That they were shareholders at the time of the disclosures, without more, is not shown to have had any appreciable effect upon their concerns with shareholder fraud at the time of the disclosures beyond their self-interest and atypical situation as whistleblowers.

To suggest that Claimants seem to rely upon the old adage that, "for want of a nail the kingdom was lost" in no way belittles the significance of inaccurate assessment and reporting of clinical drug trail data in the larger scheme of things. But concern with responsible conduct of clinical trials and accurate reporting of clinical trial data in such circumstances does not justify relief under SOX for these Complainants. Despite the torrent of secondary and tertiary consequences of the allegedly inaccurate, false, or even fraudulent clinical data generated by one or two coworkers and reported by Complainants, and the alleged failure or refusal of the company managers to investigate and follow up the complaints with corrective action recited in their respective complaints, the material allegations in the complaint do not reasonably extend beyond a complaint that these Complainants were fired for complaining about breach by one or

---

fraud), 18 U.S.C. 1344 (financial institution fraud) or other federal or state law. However, until enforcement action is taken, such allegations are speculative and are deemed insufficiently material to Respondent's financial picture to form a basis for securities fraud or to affect shareholders investment decisions. *See Livingston* at 33.

two coworkers of clinical medical testing protocols. Such complaints about the accuracy and conduct of clinical drug or medical procedure trials do not qualify as protected activity under SOX because they do not have a definitive and specific relation to fraud involving shareholders as required by the Act, *Platone, Portes*, *Livingston,* and other authorities. It follows that Respondent's motion under Rule 12(b)(1) for dismissal of the consolidated complaints for failure of the pleadings on their face to establish subject matter jurisdiction under the Act should be granted.

ORDER

The motions of Respondents to dismiss the complaints of Neuschafer and Sylvester are granted, and the complaints are dismissed.

A

Edward Terhune Miller
Administrative Law Judge