

**IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA**

<b>MARK D. LIVINGSTON,</b>	)	
	)	
<b>Plaintiff,</b>	)	
	)	
<b>v.</b>	)	<b>1:03CV00919</b>
	)	
<b>WYETH INC., BRUCE KAYLOS and</b>	)	
<b>DAVID McCUAIG,</b>	)	
	)	
<b>Defendants.</b>	)	

**MEMORANDUM OPINION AND ORDER**

**Sharp, United States Magistrate Judge**

This matter comes before the Court on the motion for summary judgment filed by Defendants Wyeth Inc., Bruce Kaylos and David McCuaig. (Pleading No. 44.) Plaintiff Mark Livingston has responded in opposition to Defendants' motion, and Defendants have filed a reply. Also before the Court is Plaintiff's motion to strike the affidavits of Defendants' expert witnesses. (Pleading Nos. 55, 56.) The Court heard oral argument on March 7, 2006. The motions are ready for a ruling.

**I. Procedural History**

Plaintiff Mark Livingston filed a Complaint on September 29, 2003 (Pleading No. 1) and a First Amended Complaint on December 15, 2003 (Pleading No. 12, "First Am. Compl."), alleging violation of the employee protection provisions of Section 806 of the

Sarbanes-Oxley Act of 2002, 18 U.S.C. §1514A, and wrongful discharge under North Carolina law. Plaintiff alleges federal question jurisdiction over his federal claims and supplemental jurisdiction over his state law claims. (First. Am. Compl.) Plaintiff seeks reinstatement to his previous position or a comparable position, back pay, front pay, compensatory and punitive damages, restored benefits, attorney's fees and costs, and any other legal or equitable relief to which he may be entitled. *Id.*

After an extensive period of discovery, Defendants have now moved for summary judgment. (Pleading No. 44.) Plaintiff opposes the motion (Pleading No. 53, Pl.'s Mem. in Opp'n to Mot. for Summ. J., & App.) and has filed separate motions seeking to exclude the affidavits of Defendants' two expert witnesses. (Pleading Nos. 55, 56.) The motions, supporting memoranda and appendices are all filed under seal.

## **II. Statement of Facts**

This case arises out of Mark Livingston's employment with and termination from Wyeth, Inc. ("Wyeth"). Wyeth develops and manufactures pharmaceutical, consumer health and animal health products, operates more than two dozen facilities worldwide and is subject to regulation by a number of federal, state, local and foreign government agencies. (Pleading No. 46, App. in Supp. of Def.'s Mot. for Summ. J. ("Defs.' App."), Tab 24 at I-1, I-12, I-16.) At its Sanford, North Carolina facility, Wyeth manufactures components used in the production of PREVNAR®, a vaccine for infants and toddlers. (*Id.*, Tab 4, Deposition of John Bruce Kaylos ("Kaylos Dep.") at 85-86, 96-97; First Am. Comp. ¶ 13.)

Livingston was employed by Wyeth at its supply chain facility in Sanford, North Carolina between August 7, 2000 and December 19, 2002. Bruce Kaylos is, and at all relevant times was, the Managing Director of the Sanford facility and was Livingston's immediate supervisor. (Kaylos Dep. at 7.) David McCuaig served as Director of Human Resources at the Sanford facility from approximately September of 2002 through January 2004. (Defs.' App., Tab 7, Deposition of David McCuaig ("McCuaig Dep.") at 8.)

Wyeth's operations are regulated pursuant to the Federal Food, Drug, and Cosmetic Act ("the Act") and regulations thereunder. *See* 21 U.S.C. §§ 331, 351(a)(2)(B); 21 C.F.R. §§ 210, 211, and 212. The regulations establish a complex scheme that, among other things, requires current good manufacturing practices ("GMPs") by all manufacturers of pharmaceutical vaccine products. *Id.* The FDA may seize impure or adulterated drugs and may seek to enjoin any company practice in violation of the statute. *Id.* The GMP for training requires that each employee engaged in the drug manufacturing process must have the education, training, and experience, or any combination thereof, to enable that person to perform his or her assigned functions. *See* 21 C.F.R. § 211.25. (Pleading No. 53, Pl.'s App., Tab 23.) The regulations do not state exactly what training is required, leaving it to the regulated entity to create and implement training programs, subject to FDA inspection. Wyeth's standard operating procedure for training at the Sanford facility is contained in GMP 4024 Rev. G. (*Id.*, Tab 5, Kaylos Dep. at 200.)

Wyeth hired Livingston in August 2000 to serve as Manager of Training and

Continuous Improvement (“TCI”) at the Sanford, North Carolina facility. As part of his job responsibilities, Livingston was required to ensure that adequate training systems were in place for purposes of complying with federally mandated GMPs.<sup>1</sup> (Pleading No. 12, First Am. Compl. ¶ 13.)

On October 3, 2000, Wyeth entered into a Consent Decree with the FDA following seizures of certain allegedly adulterated product. The seizures were based on FDA inspection reports identifying alleged GMP manufacturing and quality assurance violations at manufacturing sites in Marietta, Pennsylvania and Pearl River, New York. (Pl.’s App. Tab 16.) The Consent Decree did not specifically target the Sanford, North Carolina facility, but it is undisputed that Wyeth was required to retain a consultant to conduct a “division-wide assessment of its quality programs.” Following entry of the Consent Decree, Wyeth sought to address compliance issues in all of its facilities, including the Sanford facility. *Id.* Tab 13; Tab 3. The Consent Decree required Wyeth to respond to the consultant’s report and to submit a timetable for responsive actions. *Id.* Wyeth committed to implementing revised Level II guidance documents relating to training by September 30, 2002. (Def.’s App. Tab 13, Sakers Dep. at 27-30.)

Wyeth retained a consultant as required, who advised the company of certain steps that needed to be taken. Livingston claims that Wyeth advised its officers, managers and

---

<sup>1</sup>Plaintiff and Defendants disagree to some extent over Plaintiff’s precise job responsibilities. However, for purposes of Defendants’ motion for summary judgment, the Court views the facts and the inferences to be drawn therefrom in the light most favorable to the plaintiff non-movant. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

employees that non-compliance with the Consent Decree would impact negatively on shareholder value because Wyeth could face fines of \$15,000 per day for missed commitments. *Id.* ¶ 99; First. Am. Compl. ¶ 24. On May 31, 2001, Wyeth submitted a response to the consultant's report, advising that it would, among other things, revise the quality system guidance documents ("Level II documents") used at Sanford and other facilities. Wyeth provided the FDA with a September 30, 2002 target date for implementing the revisions and verifying compliance. (Livingston Aff. ¶ 14; Tab 4, Kaylos Dep. at 4-5.) Wyeth used an electronic document control system, known as ISOTrain, to track participation in its training programs. (*Id.*, Kaylos Dep. Ex. 4.) Livingston was appointed project team leader of the Sustainable Compliance Initiative ("SCI"), a group set up to ensure site-wide compliance with the GMP training system. (Livingston Aff. ¶¶ 16-19, 23-25.) In this capacity, Livingston directed and oversaw preparations for training system audits at Sanford between January of 2001 and September 2002. *Id.*

The final internal verification before the September 30, 2002 commitment date was to be conducted by Wyeth's Office of Compliance between July 29, 2002 and August 1, 2002. (Pleading No. 53, Pl.'s App. Tab 13, Sakers Dep. at 93-97.) Livingston presents evidence of what he perceived to be serious gaps in the training documentation and training GMPs, including the results of an outside audit by The Quantic Group in 2000 and an internal audit in 2001. (Pleading No. 46 at pp. 12-14 and App. 13, 16, 17 and 23.) In Livingston's view, the state of documented training at the Sanford facility in the summer of

2002 was so abysmal that it mirrored the conditions in Pearl River, New York and in Marietta, Pennsylvania that prompted entry of the Consent Decree. (Pleading No. 46 at 14 and App. 25 at 1.) According to Livingston, as the deadline for the July/August internal audit approached, the ISOTrain report revealed that only sixty percent of all GMP positions at Sanford had training curricula entered into the system. (*Id.* App. 19, 20)

Livingston became convinced that Wyeth would be unable to meet the commitment date. There is record evidence, however, that even if the required training curricula had not been fully developed and implemented by the FDA commitment date, the Sanford site would nevertheless be deemed compliant provided that a satisfactory “legacy plan” was adopted. (Def.’s App. 2, DeFillipo Dep. at 47-48.) A legacy plan is a means of closing compliance gaps after the date for compliance passes. (Pl.’s Dep. at 390-95, 544.) Livingston had drafted legacy plans in the past, including a legacy plan addressing GMP 4024 dated April 29, 2002. *Id.* Livingston does not dispute that he subsequently signed off on the September 30, 2002 verification because a legacy plan was in place by that time. *Id.* Further, he admits that having a legacy plan in place by the end of September 2002 would adequately address any open items related to training. *Id.* at 544.

Livingston relies on several memoranda, including a memorandum dated July 10, 2002, to support his claim that he reasonably believed that Wyeth was about to commit wrongdoing. In the July 10, 2002 memorandum, Livingston formally expressed his concerns about gaps in training that might delay verification. The memorandum was

addressed to Jim Svitanek (site SCI manager), Bruce Kaylos (site manager and Livingston's supervisor), and other members of the Site Quality Control team, including Margaret Savage, Judy Vollmer, and Mary Ellen DiFillipo. *Id.* Vollmer and DiFillipo were affiliated with Wyeth's corporate office. In the memorandum, Livingston opined that the training system at Sanford was deficient, and that the facility would not be able to meet the internal audit verification deadline. (Pleading No. 53, Pl. App. Tab 19.) He further stated that any attempt to verify compliance would be providing "false and misleading information to outside auditors, including the FDA" and that he would not be willing to sign off on the verification of compliance. *Id.*

Because he was on vacation, Kaylos allegedly did not receive Plaintiff's memorandum until on or about July 17, 2002. Kaylos and Livingston met in Kaylos' office on July 24, 2002 to discuss the July 10, 2002 memorandum. According to Livingston, Kaylos threatened to fire Livingston or to alter his job responsibilities at Sanford if he persisted in his criticism of the company's compliance status. (Livingston Aff. ¶ 94.) Kaylos denies threatening Livingston in this manner, but testifies that he reminded Livingston that Livingston bore no responsibility for departments that did not meet their internal training commitments. (Pleading No. 53, App. 4, Kaylos Dep. at 161-162 & Ex. 4.) Kaylos further contends that he attempted to discuss performance issues Livingston had been having since the beginning of 2002, but Livingston would not discuss these issues. (*Id.*; Pleading No. 53, App. Ex. 5.) After the meeting, Kaylos contacted McKnickle in Human

Resources to discuss a personal improvement plan (“PIP”) for Livingston. *Id.*

Wyeth proceeded with its internal verification process between July 29 and August 1, 2002. Marlene Raschiatore from the Wyeth office of Compliance conducted the internal verification of Sanford’s training system and found the system satisfactory, while noting, among other things, that gaps in training documentation would need to be addressed in a legacy plan. (Def.’s App. 12, Raschiatore Dep. at 29-30; Pl.’s App. 22.) Livingston admits that he signed off on Raschiatore’s verification, but claims that he did so only on the limited terms stated by Raschiatore and because he intended to file complaints regarding Kaylos’ conduct with the Compliance and Ethics offices. (Pl.’s App. 1, Livingston Aff. ¶¶ 102-104.) There is no dispute that, in the summer and fall of 2002, Livingston knew what a legacy plan was, and knew that if a legacy plan were in place, any open items in compliance by Wyeth by the FDA commitment date would likely be deemed adequately addressed. (Pl.’s Dep. at 390-95, 544.)

On or about July 29, 2002, Livingston filed a complaint with Wyeth’s Office of Sustainable Compliance (“Office of Compliance”) and Office of Ethics and Business Conduct (Office of Ethics), alleging that Kaylos had ignored Livingston’s criticism of training system compliance, had threatened Livingston with termination, and had indirectly conveyed the message that Sanford was going to conceal facts, data, and information from the internal verification auditor to the extent that it reflected negatively on operations at Sanford. (Pleading No. 46, App. Tab No. 5, Exs. 56 and 57.) The Compliance Office



initiated an investigation of this complaint, which was led by Edward Babiarz. (Def.'s App. 1, Babiarz Dep. at 67-68 & Ex.7.) On or about August 5, 2002, Livingston also met with Wyeth attorney Kenneth O'Brien to discuss Kaylos' conduct. (Pl.'s App. 1, Livingston Aff. at ¶106.) Livingston claims that he told both Babiarz and O'Brien not only of his concerns about gaps in training documentation, but also of "widespread GMP compliance failures at the site and [his] concerns of adulterated release of vaccine." *Id.* ¶ 113. Livingston provides no specific evidence of release or impending release of adulterated vaccine. By the term "adulterated," in this context, Plaintiff apparently means any vaccine that was in fact prepared by a person whose training is not adequately documented.

On or about July 11, 2002, allegedly prior to Kaylos' receipt of the July 10, 2002 memorandum, Kaylos and McKnickle discussed the possibility of placing Livingston on a PIP to address Livingston's performance issues, including: absences from the site, inaccessibility, and abusive conduct toward team members. After Livingston filed his complaint with the Office of Ethics and Business Conduct and the Office of Compliance on July 29, 2002, Wyeth's legal department recommended that Livingston not be placed on the PIP until the office had investigated his internal complaint against Kaylos. On October 9, 2002, after conducting an investigation of Livingston's complaint, the Compliance Office closed the file without finding any violations by Kaylos or others. (Def.'s App. 11, O'Brien Dep. at 33-34; Def.'s App. 3, Grantland Dep. Ex. 7; Def.'s App. 1, Babiarz Dep. at 67-68.)

On September 30, 2002, the Sanford GMP training system received full verification

by the Wyeth Office of Sustainable Compliance. (Def.'s App. 5, Livingston Depo. at 445, 565, 572-75, Exs. 58, 59, 64.) Livingston himself signed the necessary approval documentation verifying that Wyeth met the FDA verification deadline subject to implementation of a legacy plan to address training compliance gaps. *Id.*

After the September 30, 2002 verification and completion of the Compliance Office's investigation, Kaylos and the new Human Resources Director, David McCuaig,<sup>2</sup> placed Livingston on a 90-day PIP on or about October 16, 2002. (Def.'s App. 4, Kaylos Dep. Ex. 1.) The PIP outlined ten separate improvement expectations, including the requirement that, with the investigation closed and the verification accomplished, Livingston must stop making non-constructive comments to internal and external staff or contacts regarding Wyeth's alleged defrauding of the FDA or other departments' non-compliance with training GMPs. (Def.'s App. 4, Ex. 1.) Livingston refused to sign the PIP. *Id.*

The tension between Livingston, Kaylos and McCuaig increased, with Livingston becoming increasingly suspicious that he was about to be terminated. Livingston asserts that on several occasions between October and his termination in December, Human Resources Director McCuaig stalked him at staff meetings and generally led Livingston to believe that he would be terminated in front of his team members. (Pleading No. 53, Pl.'s Brief in Opp. at 24.) On or about December 13, 2002, Livingston and McCuaig had a public

---

<sup>2</sup>In September 2002, Wyeth terminated McNickle and hired David McCuaig as Director of Human Resources for the Sanford facility. (Kaylos Dep. at 63.)

confrontation at an off-site holiday party. McCuaig had not been invited to the party but showed up to wish the group a happy holiday. There was a tense exchange between Livingston and McCuaig in which Livingston told McCuaig to leave the party. (Pl.'s App. 1, Livingston Aff. at ¶¶ 147-152.) Livingston testified on deposition as follows:

I approached Mr. McCuaig, and I asked him, "What are you doing here," and said, "This is a holiday party for the Central Training Team. You're not invited. We have a gift exchange. You have no gift. We have limited food," because of cost-cutting efforts at the plant. I asked Mr. McCuaig, "Why are you bird-dogging me?"

I said, This is why I'm filing a retaliation lawsuit against you, Kaylos and Wyeth. I need you to leave. If you do not leave, I'm going to ask the police escorting holiday traffic downstairs or directing holiday traffic downstairs to escort you out. Please leave. Thank you."

(Pl.'s Dep. at 193.)

On December 16, 2002, Wyeth suspended Livingston pending investigation of the holiday party incident. *Id.* at ¶ 154. Wyeth formally terminated Livingston on December 19, 2002 as a result of his conduct at the holiday party. (Def.'s App. 11, O'Brien Dep. at 130.) To place Livingston's conduct in context, Defendants point to other unprofessional conduct engaged in by Livingston in the past, prior to his expressing concerns about non-compliance with training requirements. In 2001 and 2002, the Human Resources office received complaints from a number of Wyeth employees about abusive and inappropriate language used by Livingston. Among other things, his colleagues and subordinates complained to the Human Resources Director that Livingston was a poor leader, was often unavailable or absent, routinely lost his temper, was argumentative and unstable, had an

inability to relate to his colleagues and regularly abused his subordinates. (Pleading No. 46, Def.'s Br. at pp. 5-7 & Def.'s App. 18, McNickle Aff. & Ex. 2; App. 8, McNickle Dep. at 71-74, 81-82, 138-143; Def.'s App. 2, DeFillipo Dep. at 23-25; Def.'s App. 16, Bowden Aff.) The record suggests, and Livingston does not appear to dispute, that a number of employees complained, resigned and/or asked for transfers as a result of Livingston's conduct. (*Id.* Def.'s App. 8, McNickle Dep. at 138-143.) On May 13, 2002, Wyeth issued Livingston a written warning for use of "foul and abusive language and unprofessional behavior" toward subordinates. (Def.'s App. 5, Livingston Dep. at 277-78, 295, 329-32 & Ex. 11; App. 18, McNickle Aff. ¶ 5.) The written warning stated that "further difficulties in this area will result in further discipline up to and including termination." (*Id.*, Livingston Dep. Ex. 11.) Livingston refused to sign the warning. *Id.* Shortly thereafter, on or about May 15, 2002, Livingston sent identical e-mail apologies to eight Wyeth employees regarding his "inappropriate language," "salty remarks," "intense debating style," and behavior "which may have caused [them] personal pain and discomfort." (Def.'s App. 5, Livingston Dep. at 287-88, 291-95 & Ex. 10.) Defendants also point to evidence that Livingston was inaccessible and was absent from SCI, team meetings and staff meetings more than others. (Def.'s App. 8, McNickle Dep. at 102, 109.)

Livingston does not deny using harsh and/or profane language toward his subordinates during his tenure. He instead argues that the job was inherently stressful and confrontational; that use of profanity was common at the facility; and that, in any event, by

the time he was alerted to his performance issues, he had voiced sufficient criticism of training compliance deficiencies to render any disciplinary action retaliatory in nature. (Pleading No. 53 at 16-18.) Livingston disputes Defendants' contention that he failed to attend critical meetings and has testified in response that he was either not required to be at certain meetings or had work conflicts that prevented him from attending. *Id.* at 18-19. Livingston denies that he behaved inappropriately at the holiday luncheon. *Id.* Livingston claims that he was retaliated against for engaging in protected whistleblowing activity, with the retaliation taking the form of a hostile work environment, the PIP and his ultimate termination. *Id.*

### **III. Motions to Strike Expert Affidavits**

Livingston claims that he made disclosures protected under Sarbanes-Oxley and that his employer retaliated against him because of those disclosures. Defendants have moved for summary judgment dismissing the Sarbanes-Oxley claim and, among their supporting materials, have included the affidavits of two proposed expert witnesses, Daniel Michels and Roberta Karmel. Livingston moves to strike the affidavits as inadmissible. (Pleading Nos. 55, 56.)

Federal Rule of Evidence 702 permits the admission of expert testimony covering "scientific, technical, or other specialized knowledge [which] will assist the trier of fact to understand the evidence or to determine a fact in issue." *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993). Michels has been retained by Defendants as an

expert in the field of FDA regulatory practices and Karmel has been retained by Defendants as an expert in the field of securities law. The affidavits consist primarily of factual summary but also offer opinions on whether it was objectively reasonable for Livingston to believe that the company was about to engage in conduct that represented shareholder fraud.

The Court finds that both Mr. Michels and Ms. Karmel are well qualified in their proffered areas. However, while the summaries of FDA regulatory practices offered by Mr. Michels and securities law offered by Ms. Karmel may be helpful, their application of law to the facts of this case on an ultimate legal question is not. *See generally Adalman v. Baker, Watts & Co.*, 807 F.2d 359, 366 (4<sup>th</sup> Cir. 1986) (trial court properly excluded expert opinion as to whether applicable securities law required particular disclosures). For this reason, the Court grants Plaintiff's motion to strike the expert witness evidence from consideration on Defendants' summary judgment motion.

#### **IV. Motion for Summary Judgment**

##### **A. Summary Judgment and Standard of Review**

The summary judgment standard of review under Rule 56 of the Federal Rules of Civil Procedure is well established. A party is entitled to judgment as a matter of law upon a showing that "there is no genuine issue as to any material fact." Fed. R. Civ. P. 56(c). The material facts are those identified by controlling law as essential elements of claims asserted by the parties. A genuine issue as to such facts exists if the evidence forecast is sufficient for a reasonable trier of fact to find for the nonmoving party. *Anderson v. Liberty Lobby*,

*Inc.*, 477 U.S. 242, 248 (1986). No genuine issue of material fact exists if the nonmoving party fails to make a sufficient showing on an essential element of its case as to which it would have the burden of proof at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). In evaluating a forecast of evidence on summary judgment review, the court must view the facts and inferences reasonably to be drawn from them in the light most favorable to the nonmoving party. *Anderson*, 477 U.S. at 255.

When the moving party has carried its burden, the nonmoving party must come forward with evidence showing more than some “metaphysical doubt” that genuine and material factual issues exist. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986), *cert. denied*, 481 U.S. 1029 (1987). A mere scintilla of evidence is insufficient to circumvent summary judgment. *Anderson*, 477 U.S. at 252. Instead, the nonmoving party must convince the court that, upon the record taken as a whole, a rational trier of fact could find for the nonmoving party. *Id.* at 248-49. Trial is unnecessary if “the facts are undisputed, or if disputed, the dispute is of no consequence to the dispositive question.” *Mitchell v. Data General Corp.*, 12 F.3d 1310, 1315-16 (4th Cir. 1993).

#### B. Sarbanes-Oxley Whistleblower Claims

Plaintiff’s claims under Counts I and II of the First Amended Complaint arise under the Sarbanes-Oxley Act of 2002 (“Sarbanes-Oxley”). Sarbanes-Oxley was enacted on July 30, 2002. Title VIII of Sarbanes-Oxley is designated as the Corporate and Criminal Fraud Accountability Act of 2002. Section 806, codified at 18 U.S.C. § 1514A, is the provision

that provides “whistleblower” protection to employees of publicly traded companies. Pursuant to section 806, an employer may not discriminate against any employee in the terms and conditions of employment because of any lawful act done by the employee to provide information to the employer, a federal agency or Congress concerning violations of 18 U.S.C. §§ 1341 (mail fraud), 1343 (wire fraud), 1344 (bank fraud), or 1348 (securities fraud), or any federal law relating to fraud against shareholders. 18 U.S.C. § 1514A(a)(1).

Under the evidentiary framework of Sarbanes-Oxley, the plaintiff must first make a *prima facie* case by establishing by a preponderance of the evidence that: (1) the employee engaged in protected activity as defined by the Act; (2) the employer was aware of the protected activity; (3) the employee suffered an adverse employment action; and (4) circumstances exist which are sufficient to raise an inference that the protected activity was likely a contributing factor in the unfavorable action. *Collins v. Beazer Homes USA, Inc.*, 334 F. Supp. 2d 1365 (N.D. Ga. 2004). Once an employee has met this burden, he is entitled to relief unless the employer demonstrates by clear and convincing evidence that it would have taken the same unfavorable personnel action in the absence of any protected activity. *Id.*

1. Retroactivity of Sarbanes-Oxley

The Sarbanes-Oxley Act became effective July 30, 2002, after Livingston’s July 10, 2002 memorandum but prior to certain other alleged protected activity. Defendants argue



that the statute has no retroactive application to activity that occurred before its effective date.

The statute does not state that it shall apply retroactively, and courts have acknowledged that in the absence of a retroactivity clause, the statute should not be applied retroactively. *See In re ADC Telecomm., Inc. Sec. Litig.*, 409 F.3d 974, 977 (8<sup>th</sup> Cir. 2005) (refusing to retroactively apply 28 U.S.C. §§ 1658(h) of Sarbanes-Oxley); *see also Martin v. Hadix*, 527 U.S. 343, 352 (1999) (statutes generally presumed non-retroactive). This Court has found no judicial authority addressing whether 18 U.S.C. § 1514A applies retroactively. However, the parties cite several decisions of the Office of Administrative Law Judges from the United States Department of Labor, the entity charged with administrative review of claims under 18 U.S.C. § 1514A and whose opinions, in certain circumstances, represent final decisions under Sarbanes-Oxley. Due to the dearth of federal court decisions addressing the issue, the Court will consider these administrative decisions useful for guidance, although the Court is not bound by them. *Cf. Collins*, 334 F. Supp. 2d at 1375 n.10.

Administrative law judges addressing the retroactivity argument generally have found that Sarbanes-Oxley's whistleblower provision does not apply to conduct that occurred before the date the statute was enacted. *See McIntyre v. Merrill, Lynch, Pierce, Fenner & Smith, Inc.*, 2003-SOX-23 (ALJ Jan. 16, 2004); *Gilmore v. Parametric Technology*, 2003-SOX-1 (ALJ Feb. 6, 2003); *Kunkler v. Global Futures & Forex, Ltd.*, 2003-SOX-6 (ALJ Apr. 24, 2003). However, at least one administrative law judge has found that the Act may

apply where the alleged retaliatory action occurred after the statute's enactment. *Lerbs v. Buca Di Beppo, Inc.*, 2004-SOX-8 (ALJ June 15, 2004).

Livingston claims that he engaged in protected activity through September 2002. There is no question that, although he memorialized his complaints in a July 10, 2002 memorandum and again in a July 29, 2002 complaint before Sarbanes-Oxley was enacted, he persisted in communicating those complaints into the time period after the passage of Sarbanes-Oxley on July 30, 2002. Further, the alleged retaliatory discharge occurred on December 19, 2002, well after enactment of Sarbanes-Oxley. Accordingly, the Court finds that Livingston's Sarbanes-Oxley claim is not barred by the doctrine of non-retroactivity, because protected activity occurred in August and September 2002, after Sarbanes-Oxley was enacted, and the alleged retaliatory discharge occurred in December 2002.

## 2. Protected Activity

Defendants contend that Livingston's claims should be dismissed because the conduct he disclosed could not have constituted a violation of federal laws regulating shareholder fraud and therefore is not "protected activity" within the meaning of section 806 of Sarbanes-Oxley.

Sarbanes- Oxley prohibits covered employers from taking adverse actions (including discharge, demotion, suspension, threats, and harassment) against an employee because of the employee's protected activity. The Act defines protected activity as

- (a) . . . 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 [using Postal Service or interstate commerce for frauds and swindles], 1343 [using interstate commerce, wire, radio or television for frauds], 1344 [bank fraud], or 1348 [securities fraud] . . . or any provision of federal law relating to fraud against shareholders, when the assistance is provided to or the investigation is conducted by (A) a federal regulatory or law enforcement agency; (B) any member of Congress or any committee of Congress; 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 (Supp. 2005). Sarbanes-Oxley was enacted to address corporate fraud on shareholders. One way it does so is by protecting employees who report violations of laws that relate to shareholder fraud. It is clear from the plain language of the statute and its legislative history that fraud is an integral element of a whistleblower cause of action. To be protected, the whistleblower must not only subjectively believe that the reported conduct may constitute fraud on shareholders, there must also be a reasonable, objective basis for suspecting such fraud. *See, e.g.*, S. Rep. No. 107-146, 2002 WL 863249, at \*18-19 (May 6, 2002). The “reasonableness” test used under Sarbanes-Oxley is the same test as that generally used in a variety of legal contexts. *See Cong. Rec. S7418, S7420* (daily ed. July 26, 2002), reprinted at 2002 WL 32054527.

Livingston alleges that his protected activity consisted of his July 10, 2002 memorandum, his July 29, 2002 internal ethics and compliance complaint, his conversations with Babiarez and O’Brien in August 2002, and persistence through September 2002 in his

complaints about training deficiencies and a perceived cover-up of those deficiencies.<sup>3</sup> He claims that he had a reasonably objective basis for believing that if Sanford went forward with compliance verification as scheduled, it would be providing false and misleading information to compliance auditors, including the FDA, thereby potentially subjecting Wyeth to fines and penalties. (First. Am. Compl. ¶¶ 79-80.) According to Livingston, based on the history of FDA compliance issues at Wyeth, the gravity of the Consent Decree (as portrayed by management itself), and management's stubborn refusals to heed his criticisms, it was reasonable for him to believe that Wyeth was "probably violating some SEC 'rule or regulation,' or some 'provision of Federal law relating to fraud against shareholders.'" (Pl.'s Mem. in Opp'n to Summ. J., at 30-31.) In support, he points to: the July 10 and 24 memoranda; his own affidavit testimony regarding his concerns; and documents chronicling the Consent Decree and compliance initiatives, including documents suggesting that, as of June 2002, only 60% of the Sanford employees had documented participation in training.<sup>4</sup>

---

<sup>3</sup>Plaintiff's evidence of a "cover-up" is his own affidavit testimony that when he met with Bruce Kaylos on July 24, 2002, Kaylos told him not to share his assessment with corporate headquarters. In that same affidavit, however, Plaintiff says he directed his July 10 assessment to Kaylos with copies to two persons at corporate headquarters, negating any reasonable perception by Plaintiff of a potential conceal of information from corporate headquarters. (Pl.'s Aff. ¶¶ 82-93.) Moreover, it is undisputed that Plaintiff's assessment was not suppressed in any fashion during the internal audit in late July.

<sup>4</sup>In the Sarbanes-Oxley count of his Complaint, Livingston cites only the July 10, 2002 memorandum as protected activity that *contributed to* the retaliatory conduct. (First Am. Compl. ¶ 82.) In his opposing brief and affidavit, however, he asserts that he feared that the Sanford facility was releasing adulterated product as a result of GMP compliance deficiencies and disclosed this concern to O'Brien and Babiarz in connection with the ethics complaint.

Defendants argue that none of the evidence adduced by Livingston would have provided a reasonable basis for believing that Wyeth was about to commit some form of wrongdoing. Having reviewed the entire record on summary judgment, the Court agrees. To be protected under Sarbanes-Oxley, an employee's disclosures must be related to illegal activity that, at its core, involves shareholder fraud. It may be that the employee need not know precisely what securities law is about to be violated, but there must be some basis for an objectively reasonable belief, considering the employee's experience and knowledge, that the corporation is about to commit wrongdoing. There is nothing in the record – or in Livingston's allegations – indicating that Wyeth made false or misleading statements, or omitted relevant information, in any documents provided to its shareholders. (See First Am. Compl. ¶¶ 49-51.) Disclosures made in 2000 and 2001 regarding the Consent Decree do not relate to the statements of Livingston that he alleges caused his termination. The annual report from 2002, also cited by Livingston in his Complaint, contains information consistent with the compliance efforts signed off on by Livingston and documented in the summary judgment record.

Nor was there an objectively reasonable basis, at the time of the allegedly protected activity, for Livingston to equate the perceived training deficiencies with imminent wrongdoing. On the record before the Court, it is entirely speculative to say that because Defendants disagreed with Livingston's belief that the facility could not meet the September 30, 2002 deadline, this meant that management planned to conceal critical information.

Aside from Livingston's self-serving averments in his Affidavit, on matters of which he does not have personal knowledge or which are contradicted by his deposition testimony, the record is insufficient to support a finding that Defendants appeared to be ready to commit wrongdoing. Livingston admits in his affidavit that "the Consent Decree did not specifically require [training compliance standards] to be implemented by a specific date." (Pl.'s App. 1, ¶ 14.) Although Defendants concede that Wyeth had committed to a September 30, 2002 target for implementing certain training guidelines, Livingston admits that even if compliance concerns persisted on that date, a legacy plan could be created for purposes of avoiding penalties under the Consent Decree. (Pl.'s Dep. at 390, 544.) This concession is fatal to Plaintiff's claims. No reasonable employee in Plaintiff's position could have believed Wyeth was headed toward wrongly concealing training deficiencies. Any such deficiencies, as Livingston well knew, would be deemed by the FDA to be adequately addressed if a legacy plan were adopted by Wyeth to afford it additional time to close any compliance gaps.

Livingston contends that the potential financial impact of non-compliance was so significant that the concerns about training deficiencies should have been communicated to shareholders. Even if it were reasonable to believe that the FDA might, in the future, take some type of enforcement action based on GMP and/or training compliance issues at Sanford, it is not clear that Wyeth would have been obligated to report these alleged violations before the FDA took any action. Information must be sufficiently material to a

company's financial picture before it will form the basis for securities fraud. Under Supreme Court authority, for information to be material, there must be "a substantial likelihood that a reasonable shareholder would consider [the matter] important to his decision to invest." *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976); *see also Basic, Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988). Given the importance of "materiality" under the securities laws, Administrative Law Judges have rejected whistleblower retaliation claims where the information disclosed would not be sufficiently material to shareholders. Livingston's disclosures about issues of potential concern to the FDA, particularly where those concerns could be alleviated for the foreseeable future through legacy plans, are similar to the complaints advanced by the employee in *Minkina v. Affiliated Physician's Group*, 2005-SOX-19 (Dept. of Labor, Feb. 22, 2005) (Pleading No. 46, Def.'s App. 36.) Minkina claimed retaliation for reports she made to OSHA concerning what she believed to be dangerous air quality conditions in her workplace. In finding that her complaints were not protected activity under Sarbanes-Oxley, the Administrative Law Judge stated, "[q]uite simply, while the Complainant may have a valid claim for poor air quality, Sarbanes-Oxley was enacted to address the specific problem of fraud in the realm of publicly traded companies and not the resolution of air quality issues, even if there is a possibility that poor air quality might ultimately result in financial loss." *Id.* at 5-6. *See also Nixon v. Stewart & Stevenson Servs., Inc.*, 2005-SOX-1, at 13-14 (Dept. of Labor, Feb. 6, 2005) (Defs.' App.37) (complaint regarding alleged failure to disclose potential violations of

environmental regulations not material because mere possibility of future legal proceedings too speculative); *Harvey v. Safeway, Inc.*, 2004-SOX-21, at 31-32 (Dept. of Labor, Feb. 11, 2005) (Defs.' App. 32) (complaint of wage irregularities under Fair Labor Standards Act not material and not protected activity).

Finally, the evidence does not support a finding that it was reasonable for Livingston to believe that the Sanford facility was shipping (or would ship) adulterated product. Even assuming that at some point Livingston had a *subjective* belief that gaps in training might increase the chances that adulterated product would be released to the public, that belief was not an *objectively* reasonable one on the evidence adduced. *Cf. Tuttle v. Johnson Controls Battery Division*, 2004-SOX-76 (ALJ Jan. 3, 2005) (granting summary judgment against Complainant where Complainant alleged that he was terminated due to complaints that Respondent had shipped significant numbers of defective batteries, finding that the activities alleged did not involve intentional deceit or result in fraud against shareholders or investors). Moreover, it appears that Plaintiff's allegations about "adulterated product" refer solely to product that is "presumed" adulterated because it was prepared in part by a worker whose training was not fully documented. The Court has already found that there is no evidence to have supported an objective belief in mid-2002 that Wyeth was about to be found in violation of the Consent Decree by reason of training issues at the Sanford facility.



### 3. Causation

Defendants further maintain that even assuming Livingston could show that he engaged in activity protected by Sarbanes-Oxley, his protected activity was not a contributing factor in the decision to discharge him in December 2002. In support, Defendants submit evidence that they contend shows that Livingston had relationship problems with his subordinates, peers and supervisors; was inaccessible; missed meetings; and exhibited insubordinate conduct. According to Defendants, Livingston was terminated for reasons other than his criticism of GMP compliance efforts.

To establish causation, Livingston must be able to demonstrate by a preponderance of the evidence “that protected behavior or conduct was a contributing factor in the unfavorable personnel action alleged in the complaint.” 29 C.F.R. § 1980.109(a). This is not a demanding standard. The allegedly protected conduct need not be the sole factor, but only *a* factor in the unfavorable personnel action. *Collins*, 334 F. Supp.2d at 1379 (citing 49 U.S.C. § 42121(b)(2)(B)(iii); *Marano v. Dep’t of Justice*, 2 F.3d 1137, 1140 (Fed.Cir. 1993)). Temporal proximity between the protected conduct and the unfavorable action has been found to establish causation. *Id.* (citing 29 C.F.R. § 1984.104(b)(2)).

Defendants contend that the passage of time between Livingston’s July 10, 2002 memorandum and his termination on December 19, 2002 precludes a finding of causation based upon temporal proximity. However, there is other evidence of at least some allegedly

hostile conduct following more closely on the heels of Livingston's criticism of compliance efforts.

Defendants may still prevail if they can prove by clear and convincing evidence that the adverse action was motivated by legitimate, non-discriminatory reasons. 29 C.F.R. § 1980.109. Defendants argue that they fired Livingston based solely on his insubordination toward McCuaig at the holiday party. It is undisputed that Livingston not only asked McCuaig, the Director of Human Resources, to leave the holiday party, he threatened to have the police remove McCuaig from the party. There also is undisputed evidence that Livingston had been counseled and reprimanded for professional misconduct well before July 2002. The Court finds as a matter of law that Defendants have established by clear and convincing evidence that a non-discriminatory rationale independently caused Plaintiff's termination. Based on Livingston's own testimony, no reasonable trier of fact could disagree that Livingston would have been discharged for his insubordination at the holiday party, irrespective of his alleged protected activity. Plaintiff, acting in front of subordinate employees, threatened to have a superior official removed from an office party *by police officers* who were nearby. Such an act of insubordination and insolence without question called for and supported Plaintiff's immediate termination, and Plaintiff was in fact suspended immediately and fired within six days on the basis of his actions at the holiday party.

In conclusion, the evidence adduced, viewed in the light most favorable to Plaintiff Livingston, does not support an inference that Livingston had a objectively reasonable belief in August and September 2002 that Wyeth was about to engage in wrongdoing that would impact shareholders. Moreover, even if there were protected activity, Defendants have pointed to clear and convincing evidence that Livingston would have been terminated for insubordination unrelated to the protected activity. Summary judgment will therefore be granted on Counts I and II.

C. Claim for Wrongful Discharge Under North Carolina Law

In Count III of his First Amended Complaint, Livingston asserts a claim for wrongful discharge in violation of North Carolina law. He alleges that although his employment was at will, his discharge violated a public policy of North Carolina because he was discharged for reporting concerns about non-compliance with training GMPs and/or refused to sign off on the company's verification. Defendants move for summary judgment dismissing this claim.

North Carolina recognizes the common law doctrine of employment at will. That is, an employee may be discharged at any time and for any reason at the will of the employer, absent a contract for a definite term. *See Tuttle v. Kernersville Lumber Co.*, 263 N.C. 216 (1964). However, since 1985 North Carolina courts have recognized at least one exception to the employment-at-will doctrine: discharge in violation of public policy. *See Sides v. Duke University*, 74 N.C. App. 331, 328 (1985). In *Sides*, the plaintiff, a nurse anesthetist,

alleged that she refused a doctor's request to administer what she considered a dangerous dose of anesthesia to a patient. *Id.* at 333. The doctor then personally administered the anesthesia and the patient went into cardiac arrest and suffered permanent brain damage. He then sued the doctor and the hospital. Before plaintiff was deposed, several physicians who worked at the hospital and hospital attorneys advised her not to tell all that she knew about what happened and that she would "be in trouble" if she did. *Id.* Rejecting this advice, plaintiff testified truthfully at both the deposition and trial, and the jury returned a large verdict for the patient. *Id.* Three months later, plaintiff was discharged. *Id.* at 334. She sued for wrongful discharge. The trial court dismissed the case for failure to state a claim, but the Court of Appeals recognized a cause of action in circumstances where, as in *Sides*, discharging an employee for refusing to testify untruthfully clearly contravened public policy. *Id.*

The North Carolina Supreme Court first considered the public policy exception in *Coman v. Thomas Mfg. Co.*, 325 N.C. 172, 175 (1989). The plaintiff, a truck driver, alleged that his employer required him to falsify his logs so as to show the company's compliance with federal regulations. *Id.* at 173. He was also instructed that he would have to continue driving for periods of time which violated the regulations if he wanted to maintain his employment. When he refused, he was informed that his pay would be cut in half. *Id.* at 173-74. The Supreme Court held that these facts – which involved falsification of federal records – came "within the reasoning of *Sides* and that the complaint state[d] a cause of

action for wrongful discharge.” *Id.* at 175. The court noted that the North Carolina Administrative Code incorporated the federal regulations and that a North Carolina statute provided for criminal penalties for seeking to evade or defeat such regulations. *Id.* at 176. The court found that the actions of defendant would impair and violate that policy, because they essentially encouraged the plaintiff to violate the public policy. *Id.* at 176.

The *Coman* court did not define what constitutes “public policy” for purposes of a wrongful discharge claim. Indeed, “[t]here is no bright-line test for determining when the termination of an at-will employee violates public policy.” *Teleflex Info. Sys., Inc. v. Arnold*, 132 N.C. App. 689, 691 (1999). The North Carolina Supreme Court has said that

Although it may be tempting to refine the definition of “public policy” in order to formulate a more precise and exact definition, we decline to do so. Any attempt to make the definition more precise would inevitably lead to at least as many questions as answers. True to common law tradition, we allow this still evolving area of the law to mature slowly, deciding each case on the facts before us.

*Amos v. Oakdale Knitting Co.*, 331 N.C.348, 353 & n. 1 (1992) (plaintiffs stated claim by alleging that employer discharged them for refusing to work for less than the statutory minimum wage in violation of North Carolina public policy expressed in the Wage Act, N.C.G.S. § 95-25.3). Since *Amos*, the North Carolina courts, in identifying “public policy,” have looked not only to state statutes but also to the state constitution and state and federal regulations to define “public policy.” *See, e.g., Deerman v. Beverly Cal. Corp.*, 135 N.C. App. 1, 12 (1999) (Board of Nursing regulations); *Lenzer v. Flaherty*, 106 N.C. App. 496, 515 (1992) (the state constitution). “At the very least, public policy is violated when an

employee is fired in contravention of express policy declarations contained in the North Carolina General Statutes.” *Amos*, 331 N.C. at 353. The courts of North Carolina have further noted that the exception is “grounded in considerations of public policy designed either to prohibit status-based discrimination or to insure the integrity of the judicial process or the enforcement of the law.” *Kurtzman v. Applied Analytical Indus., Inc.*, 347 N.C. 329, 333-34 (1997).

According to Livingston, the public policy at issue in this case is the policy against distribution of adulterated drugs, as expressed in the North Carolina Food, Drug and Cosmetic Act, and in the federal Food, Drug and Cosmetic Act. *See* N.C. Gen. Stat. § 106-122 *et seq.* (2003); 21 U.S.C. § 301 *et seq.* (1999 & Supp. 2005). Both of these statutes prohibit the distribution of adulterated drugs and require compliance with good manufacturing practices. *Id.* Livingston contends that he was terminated for internally reporting that Defendant Wyeth was not in compliance with these laws or for refusing to violate these laws.

Defendants contend that there is insufficient record evidence from which a jury could find that they violated the law or that they required Livingston to violate the law. The Court agrees, noting that this case is in a different procedural posture from the vast majority of the cases addressing wrongful discharge claims. The most helpful cases on the issue before this Court, *e.g. Coman, Amos* and *Deerman*, were decided at an earlier stage of the proceedings, when the moving defendant was challenging only the allegations contained in the pleadings.

The posture of this case is summary judgment, and Livingston must be able to forecast sufficient evidence to go to a jury.

Having reviewed the record, the Court finds insufficient evidence to create a triable issue on whether Livingston was discharged for reporting the violation of a law expressing the public policy of North Carolina. At the time Livingston wrote the July 10, 2002 memorandum, Wyeth was about to conduct an internal audit to gauge its readiness for the September 30, 2002 commitment date. Even if there were gaps in compliance at that time, it was entirely speculative, from the evidence adduced, for Livingston to believe that Wyeth planned to misrepresent facts during the September verification or that the company was about to ship adulterated product. Admittedly, there is sharp disagreement – particularly between Kaylos and Livingston – about how Livingston expressed his concerns. That disagreement, however, does not support a finding that Plaintiff believed Wyeth was about to violate the law. Indeed, he admits in his affidavit that “at no time [during his meeting with Kaylos] did I claim that ‘Kaylos and Wyeth were trying to mislead the FDA and those involved with the July 29 verification.’” (Livingston Aff. ¶ 95.) In spite of the picture that Livingston attempts to paint now, the evidence shows that he was *not* telling his supervisors about violations of the law, as he now urges, but rather, consistently with his job duties, was telling them that additional measures were necessary to be ready for verification. This was but one step in the process of complying with the Consent Decree and FDA regulations. The Court does not consider Livingston’s conduct comparable to those cases in which the courts

of North Carolina have found a predicate for a wrongful discharge claim. It is obviously not this Court's intent to discourage employees from voicing concerns about their company's compliance with the law. The Court simply holds that a plaintiff alleging wrongful discharge under the public policy exception must show something more than existence of a public policy and complaints intended to address internal compliance procedures. There must be a forecast of evidence that rests on more than speculation that laws grounded in public policy will be violated at some future date.<sup>5</sup>

Further, there is insufficient evidence to support a finding that Defendants required Livingston to violate the law or risk losing his job. At best, the evidence shows that Livingston was criticized by Kaylos for his internal memorandum. (Livingston Aff. ¶¶ 93, 100, 102.) Livingston signed off on an internal checklist that, according to Livingston, did not attest to compliance. (Livingston Aff. ¶ 122 ("The document I signed on September 30, 2002 focused on completion of these action items as identified by verification auditor Raschiatore. There was no understanding that the Office of Compliance verification

---

<sup>5</sup>Defendants cite *Guy v. Travenol Labs, Inc.*, 812 F.2d 911 (4<sup>th</sup> Cir. 1986) as authority for rejecting Livingston's claim. In *Guy*, the Fourth Circuit rejected a wrongful discharge claim when the employee alleged he had told his employer that others in the company were falsifying records about the quality and quantity of pharmaceuticals the company manufactured, and refused to falsify those records himself. *Id.* at 917. The North Carolina Supreme Court subsequently decided *Coman*, and that decision has been said by some courts to undermine the decision in *Guy*. Indeed, the plaintiffs in *Coman*, *Amos* and *Deerman* all were found to have stated a claim for wrongful discharge where the alleged policy was expressed in federal or state statutes or regulations and the plaintiffs alleged that they were discharged due to their refusal to violate those laws. The Court need not rely on *Guy* to decide the instant motions.



document I signed had anything to do with attesting to the GMP compliance status of the Wyeth Sanford site.”); *see also* Livingston Aff. ¶ 95.) Simply put, Livingston’s own testimony contradicts his argument that he was forced to violate the law or lose his job.

Finally, as discussed hereinabove, Defendants point to evidence that Plaintiff Livingston would have been terminated for reasons independent of his alleged protected activity – his inexcusable insubordination toward the Human Resources Director at the December 2002 holiday party. Defendants having demonstrated that an essential elements of Livingston’s claim for wrongful discharge do not exist, and Livingston having failed to produce evidence to support the claim, Defendants are entitled to summary judgment on the claims under North Carolina law for wrongful discharge (Count III).

### **Conclusion**

For the reasons stated above, **IT IS HEREBY ORDERED** that Plaintiff’s motions to strike Defendants’ experts (Pleading Nos. 55 and 56) are **GRANTED**. **IT IS FURTHER ORDERED** that Defendants’ motion for summary judgment (Pleading No. 44) is **GRANTED** with respect to Plaintiff Livingston’s claims under Sarbanes-Oxley (Counts I and II) and under North Carolina law (Count III) and that those claims are **DISMISSED**

**with prejudice.** The Court having found in favor of Defendants on the substantive claims, Livingston's claim for punitive damages (Count IV) is also **DISMISSED**.

A separate judgment will be entered contemporaneously with this Memorandum Opinion and Order.

/s/ P. Trevor Sharp  
United States Magistrate Judge

Date: July 28, 2006