

PUBLISHED

UNITED STATES COURT OF APPEALS  
FOR THE FOURTH CIRCUIT

MARK LIVINGSTON,  
*Plaintiff-Appellant,*

v.

WYETH, INCORPORATED; BRUCE  
KAYLOS, Wyeth Sanford Managing  
Director; DAVID McCUAIG, Wyeth  
Sanford Human Resource Director,  
*Defendants-Appellees.*

No. 06-1939

UNITED STATES CHAMBER OF  
COMMERCE,  
*Amicus Supporting Appellees.*

Appeal from the United States District Court  
for the Middle District of North Carolina, at Durham.  
Paul Trevor Sharp, Magistrate Judge.  
(1:03-cv-00919-PTS)

Argued: November 1, 2007

Decided: March 24, 2008

Before NIEMEYER and MICHAEL, Circuit Judges, and  
Claude M. HILTON, Senior United States District Judge for the  
Eastern District of Virginia, sitting by designation.

Affirmed by published opinion. Judge Niemeyer wrote the majority  
opinion, in which Judge Hilton joined. Judge Michael wrote a dissent-  
ing opinion.

**COUNSEL**

**ARGUED:** Thad M. Guyer, T. M. GUYER & AYERS & FRIENDS, P.C., Medford, Oregon, for Appellant. Michael Delikat, ORRICK, HERRINGTON & SUTCLIFFE, L.L.P., New York, New York, for Appellees. **ON BRIEF:** Joanne Royce, GOVERNMENT ACCOUNTABILITY PROJECT, Washington, D.C., for Appellant. James H. McQuade, ORRICK, HERRINGTON & SUTCLIFFE, L.L.P., New York, New York; Terry A. Clark, CONSTANGY, BROOKS & SMITH, L.L.C., Winston-Salem, North Carolina, for Appellees. Virginia W. Hoptman, WOMBLE, CARLYLE, SANDRIDGE & RICE, Tysons Corner, Virginia; Charles A. Edwards, Sheri Roberson, WOMBLE, CARLYLE, SANDRIDGE & RICE, Raleigh, North Carolina; Robin S. Conrad, Shane Brennan, NATIONAL CHAMBER LITIGATION CENTER, INC., Washington, D.C., for Amicus Supporting Appellees.

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**OPINION**

NIEMEYER, Circuit Judge:

Relying on the whistleblower protection provisions of the Sarbanes-Oxley Act of 2002, 18 U.S.C. § 1514A, Mark Livingston commenced this action against his employer Wyeth, Inc., a pharmaceutical company, alleging that Wyeth unlawfully discharged him because of his complaints to Wyeth's management about Wyeth's inability to implement on schedule a training program at its Sanford, North Carolina facility, supposing therefore that local employees would likely misrepresent or cover up the deficiencies in progress to internal compliance auditors and to the Food and Drug Administration. The training program was designed to train employees in good manufacturing practices, and its implementation was required by regulations of the Food and Drug Administration. Livingston asserted that in making his complaints, he reasonably believed that Wyeth's potential conduct in misrepresenting or covering up the deficiencies in timely implementation of the program would constitute violations of § 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated under it, and therefore that his conduct was protected under the Sarbanes-Oxley Act.

The district court entered summary judgment against Livingston, concluding that his complaints were not protected activity under the Sarbanes-Oxley Act because Livingston could not reasonably have believed that Wyeth was violating the securities laws. The court also concluded that Wyeth had shown, by clear and convincing evidence, that it had discharged Livingston for insubordination in threatening to have the police remove Wyeth's Director of Human Resources from a company-sponsored holiday party and that Wyeth would have discharged Livingston regardless of whether he had complained about the progress of the training program.

Because we conclude that no objectively reasonable basis existed for Livingston to have believed that Wyeth was violating the securities laws, we affirm.

## I

On Thursday, December 19, 2002, following a brief investigation, Mark Livingston was discharged from his employment with Wyeth as Associate Director of Training and Continuous Improvement at Wyeth's Sanford, North Carolina facility. The parties agree that the precipitating events occurred on the previous Friday, December 13, 2002, when Livingston held a company-funded lunch party for members of the training staff. David McCuaig, the Director of Human Resources at the Sanford facility, came to the party without an invitation from Livingston, allegedly to wish the group a happy holiday. According to Livingston's own testimony, Livingston approached McCuaig as McCuaig came into the room and asked, "What are you doing here? . . . You're not invited. We have a gift exchange. You have no gift. We have limited food." After some more discussion, Livingston then stated, "I need you to leave. I'm asking you to leave. If you do not leave, I'm going to ask the police escorting holiday traffic downstairs . . . to escort you out." Although there is a factual dispute about the manner in which Livingston told McCuaig to leave, it is undisputed that he threatened to have the police remove him. Wyeth suspended Livingston on the following Monday, December 16, 2002, pending investigation, and, following a three-day investigation, it terminated his employment.

Wyeth contends that this incident was the culmination of a long history of abusive and insubordinate conduct by Livingston, about

which he had been warned numerous times previously. Livingston contends, however, that he was fired in retaliation for complaining about the insufficient progress in implementing a training program to teach employees good manufacturing practices, as required by the Food and Drug Administration ("FDA"), and about the potential that Wyeth could misrepresent the progress of the program or cover up its true status, in violation of the securities laws.

Wyeth, Inc., formerly known as American Home Products Corporation, is a publicly traded company that develops pharmaceutical and consumer health products worldwide. Its net revenue in 2001 was approximately \$14.1 billion. Its Sanford, North Carolina facility is one of more than two dozen at which it develops and manufactures products.

From August 2000 to December 2002, Mark Livingston was employed at the Sanford site, first as a manager of Training and Continuous Improvement, and then as Associate Director of Training and Continuous Improvement. He reported to Bruce Kaylos, the managing director of the Sanford site. During the period of his employment, Livingston oversaw audits of training programs at the Sanford facility to monitor their progress. The events which form the basis of Livingston's complaint in this case occurred during July and August 2002.

Wyeth's manufacturing operations are regulated by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et. seq.*, and the FDA regulations promulgated thereunder. Pharmaceutical products, such as the vaccine components produced at the Sanford facility, must be made in accordance with "current good manufacturing practice." 21 C.F.R. § 211.1. In addition to specific mandates, such as requiring workers to wear clean clothing during drug production, *see id.* § 211.28(a), the regulations for good manufacturing practices require that "[e]ach person engaged in the manufacture . . . of a drug product shall have education, training, and experience" sufficient to perform the functions assigned to them. *Id.* § 211.25. The regulations do not specify what training is required, how it should be accomplished, or how it must be documented, but rather leave it to each regulated company to create and implement appropriate procedures, subject to FDA inspection. If a pharmaceutical product is produced in a facility that does not adhere to good manufacturing practices, including training

for good manufacturing practices, the product is legally considered adulterated and is subject to seizure by the FDA. *See* 21 U.S.C. §§ 351(a), 334(a)(1).

Precisely for this reason — a failure to follow good manufacturing practices — the FDA seized allegedly adulterated products at Wyeth's Pearl River, New York and Marietta, Pennsylvania facilities, leading to a Consent Decree in October 2000, directed at those facilities. While the decree did not apply to any other facility, it did require Wyeth to retain an expert consultant to conduct a "division-wide" assessment of its quality control programs at all sites, including the Sanford site, and to respond to the expert's report, providing the FDA with a timetable for its responsive actions. As required, Wyeth did retain a consultant and, in May 2001, advised the FDA that it would revise its training guidance documents, setting September 30, 2002, as the date by which it would implement training changes and verify compliance with the new program. The FDA has never suggested that Wyeth ever violated the October 2000 Consent Decree.

Wyeth's training for good manufacturing practices at the Sanford facility required each manufacturing employee to have a "curriculum" of required training courses and a signed record to document the training. Beginning in 2002, these records were to be loaded into an electronic document control system known as ISOtrain. To transition to the new system, managers needed to be trained on the new system, curricula needed to be drafted, and forms and data for all employees needed to be entered into ISOtrain. As part of his job responsibilities, Livingston was designated to direct and oversee preparations for training system audits at the Sanford site between January 2001 and September 2002, which were to be conducted to monitor progress. For the period through June 2002, Livingston found no problem with the program's progress. He advised management on May 22, 2002, that the Sanford facility remained "on track" for the September 30, 2002, implementation date.

Wyeth's Office of Compliance scheduled the final internal verification of the new training system for July 29, 2002, two months before September 30, 2002, the date committed to the FDA. By July 9, 2002, Livingston became convinced that Wyeth could not meet this internal verification deadline, and he formally expressed his concerns in a July

10, 2002 memorandum to Kaylos and various corporate directors and managers. He stated in the memorandum that several departments of the Sanford site

require additional time to implement the initial components of the Wyeth Site Employee Training System. As well, we will need additional time to verify sustainable operation of a compliant training system in these areas. To indicate otherwise provides false and misleading information to outside auditors, including the FDA.

Kaylos did not receive the memorandum until approximately July 17, 2002, because he was on vacation. But he met with Livingston on July 24 to discuss the memorandum. Livingston states that at the meeting Kaylos threatened to fire him if he persisted in his criticism of the company's compliance status and that Kaylos implied that Livingston should hide or "cover up" noncompliance issues from the Wyeth internal auditor. Livingston also acknowledges, however, that "[a]t no time during this meeting, did I claim that Kaylos and Wyeth were trying to mislead the FDA and those involved with the July 29 [internal] verification" audit.

Wyeth proceeded with the July 29 internal verification audit, and Marlene Raschiatore of the Wyeth Office of Compliance, who conducted the audit, found the system to be satisfactory, noting that gaps in training documentation could be addressed in a "legacy plan." A "legacy plan" is the means of closing compliance gaps after the target date for compliance passes. Livingston, who had drafted legacy plans in the past and was familiar with them, admits that he signed off on Raschiatore's verification, but states that he did so on limited terms because, by then, he intended to file an ethics complaint based on the July 24 meeting with Kaylos.

On or around July 29, 2002, Livingston did file a formal complaint with Wyeth's Office of Compliance, in which he stated that he had informed Kaylos of his belief that the Sanford site was not ready for the planned July 29 internal verification of the training system. As Livingston noted, "I expressed my concern that if we were to conduct the audit and not fully disclose the status of training system implementation at the site, [Wyeth] would be in the unfortunate position of

providing false and misleading information to compliance auditors, including the FDA." He further stated that Kaylos had "mocked and ridiculed" his analysis and that "[t]he underlying message from Mr. Kaylos was clear — we are going to conceal facts, data, and information from the verification auditor that would shine negatively on system implementation or operation at Sanford." The complaint concluded:

Federal law deems it a crime to make any false, fictitious, or fraudulent statement to any government agency, or in making such statement, to conceal any material fact. As I read the Wyeth Code of Conduct, this policy is in place to ensure that information provided to government agencies is truthful, accurate, and complete.

Wyeth's Office of Compliance conducted an investigation into Livingston's complaint, but it found no violations by Kaylos or other Wyeth employees and closed its file on October 9, 2002.

The Sanford facility ultimately met the September 30, 2002 compliance target given to the FDA, and the Sanford site's training system for good manufacturing practices received full verification by the Wyeth Office of Compliance. Livingston does not dispute that he signed the verification checklist certifying that the compliance deadline had been met.

On or around October 16, 2002, well after verification of the new training program was complete, the Human Resources director of the Sanford site, David McCuaig, placed Livingston on a Personal Improvement Plan ("PIP") containing ten expectations. These included the specific requirements that Livingston stop making non-constructive comments, such as saying that the use of "approved and verified training practices is 'defrauding' the FDA," and that he "[r]efrain from making negative and insulting comments regarding the practices of other departments." The PIP stated that "[f]ailure to show immediate, significant and sustained improvement within the next 30 days will result in termination." Livingston refused to sign the PIP.

The October 16 PIP was not the first run-in Livingston had with the Human Resources department. In 2001 and 2002, the Human

Resources office had received numerous complaints from Wyeth employees about Livingston's use of abusive language and inappropriate behavior. In May 2002, Livingston was formally warned for the use of "foul and abusive language and unprofessional behavior" toward subordinates. Livingston does not dispute that a number of employees asked for transfers or resigned as a result of his conduct.

Tension between Livingston and Kaylos and McCuaig continued to grow after the October 16 PIP, with Livingston becoming increasingly suspicious that he was about to be terminated. Livingston states that McCuaig "stalked" him at staff meetings and generally acted in a way that led Livingston to believe that he would be fired in front of his team members.

The situation came to a head on Friday, December 13, 2002, at the off-site Wyeth holiday party, when Livingston excluded McCuaig from the room in front of company employees. Wyeth in turn suspended Livingston the following Monday, December 16, pending investigation of the incident, and formally terminated him on December 19, 2002.

Livingston filed a "whistleblower retaliation" complaint with the Secretary of Labor on January 14, 2003. The Secretary issued preliminary findings against Livingston on June 27, 2003, but did not issue a final decision within 180 days, thus permitting a district court to obtain jurisdiction over the claim. Livingston commenced this action on September 29, 2003, naming Wyeth, Kaylos, and McCuaig as defendants. He alleged that the defendants (hereinafter collectively, "Wyeth") violated 18 U.S.C. § 1514A, by taking adverse employment action against him in retaliation for expressing concerns about training at the Sanford facility, and violated North Carolina common law for wrongful discharge.

After the parties conducted discovery, the district court granted Wyeth's motion for summary judgment, dismissing all counts of the complaint. *Livingston v. Wyeth, Inc.*, No. 1:03CV00919, 2006 WL 2129794 at \*15 (M.D.N.C. July 28, 2006). The court concluded that "[t]here [was] 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 share-



holders." *Id.* at \*10. 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. . . . [T]he record is insufficient to support a finding that [Wyeth] appeared to be ready to commit wrongdoing." *Id.* In addition, the court concluded that any wrongdoing hypothesized by Livingston would, in any event, not have resulted in a "material" loss to Wyeth, requiring the loss to be reported publicly. *Id.* Finally, the court found "as a matter of law that [Wyeth] [had] established by clear and convincing evidence that a non-discriminatory rationale independently caused [Livingston's] termination." *Id.* at \*11. The court observed:

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.

*Id.* Consistent with these conclusions, the court also concluded that essential elements of Livingston's wrongful discharge claim under North Carolina law were lacking. *Id.* at \*12-15.

Livingston appeals the district court's judgment, dated July 28, 2006, challenging each of the reasons given by the district court for granting Wyeth's motion for summary judgment.

## II

We review the district court's grant of summary judgment in favor of Wyeth *de novo*. See *Holland v. Washington Homes, Inc.*, 487 F.3d 208, 213 (4th Cir. 2007).

To address Livingston's claim, the factual essence of his claim must first be articulated.

Livingston rests his claim of retaliation on his complaints about Wyeth's training program at the Sanford facility, principally commu-

nicated through two memoranda dated July 10 and July 29, 2002, but also through related oral conversations. In the July 10 memorandum, Livingston complained to management about "serious deficiencies" in the implementation of the training program for good manufacturing practices, observing that deadlines for completion of the training program were in jeopardy. He said, "We will need additional time to verify sustainable operation of a compliant training system in these areas. To indicate otherwise provides false and misleading information to outside auditors, including the FDA." In the July 29 memorandum, which he submitted as a formal complaint in furtherance of his obligations as Associate Director of Training, he repeated that the Sanford facility "was not ready" for the planned July 29 internal audit to verify the necessary progress of the training program and to ensure that the September 30 deadline would be achieved. He warned that "if we were to conduct the audit and not fully disclose the status of training system implementation at [Sanford], [Wyeth] would be in the unfortunate position of providing false and misleading information to compliance auditors, including the FDA." He added the admonition, "Federal law deems it a crime to make any false, fictitious, or fraudulent statement to any government agency, or in making such statement, to conceal any material fact."

At no time did Livingston complain that Wyeth had in fact made a false statement to any government agency or to stockholders. And, as it turned out, Livingston's fears went unrealized. He signed off on the internal verification audit that took place from July 29 to August 1, and on the implementation of the whole training program, which was completed by September 30, as committed, albeit with an agenda under a "legacy plan" to fill gaps. Nonetheless, in this action Livingston claims that his complaints to management were a contributing factor to his firing on December 19, 2002, and accordingly that Wyeth violated the whistleblowing provisions of the Sarbanes-Oxley Act insofar as it protects employees who make complaints about violations of § 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j, and Rule 10b-5 promulgated under it, 17 C.F.R. § 240.10b-5.

Section 806 of the Sarbanes-Oxley Act of 2002, Pub. L. No. 107-204, 116 Stat. 745, 802-04 (2002), added § 1514A to Title 18 of the United States Code, providing "whistleblower" protection for employees of publicly-traded companies by prohibiting their employers from

retaliating against them for providing information or cooperating in investigations related to violations of specified laws, including 18 U.S.C. § 1348 (prohibiting securities fraud) and Rule 10b-5 of the SEC (prohibiting the same), as well as any other provision of federal law relating to a company's fraud against shareholders. Section 1514A provides, as relevant:

No [publicly-traded company], or any officer [or] employee . . . of such company, may discharge . . . 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* . . . regarding any conduct which the employee *reasonably believes constitutes a violation* of section 1341 [mail fraud], 1343 [wire fraud], 1344 [bank fraud], or 1348 [securities fraud], 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 . . .

\* \* \*

(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) (emphasis added). The burdens of proof for establishing a claim under § 1514A(a) are incorporated from the Whistleblower Protection Program of the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century, Pub. L. No. 106-181, § 519(a), 114 Stat. 61, 145-49 (2000) (codified at 49 U.S.C. § 42121). *See* 18 U.S.C. § 1514A(b)(2)(C) (providing that the retaliation claim under Sarbanes-Oxley "shall be governed by the legal burdens of proof set forth in [49 U.S.C. § 42121(b)]"). Section 42121(b), in turn, provides with respect to the burdens of proof that the plaintiff bears the burden of showing by a preponderance of the evidence that protected activity "was a contributing factor in the unfavorable personnel action alleged in the complaint." 49 U.S.C. § 42121(b)(2)(B). If the plaintiff carries his burden, the employer may nonetheless

defeat the plaintiff's claim for relief by showing "by clear and convincing evidence that the employer would have taken the same unfavorable personnel action in the absence of [the protected activity]." *Id.*

Thus, for Livingston to establish a cause of action under 18 U.S.C. § 1514A, he must show, in the context of this case, by a preponderance of the evidence that (1) he provided information or a complaint to a Wyeth supervisor or to one authorized to investigate and correct misconduct; (2) the information or complaint regarded conduct that he reasonably believed constituted a violation of an enumerated statute or any regulation promulgated by the Securities and Exchange Commission relating to fraud;<sup>1</sup> (3) his employer discharged him or took other unfavorable personnel action against him; and (4) his providing the information or making the complaint was a contributing factor to his discharge or other adverse employment action taken by Wyeth.

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<sup>1</sup>In § 1514A, the language defining the employee's belief of a violation includes a violation of (1) 18 U.S.C. § 1341 (mail fraud); (2) 18 U.S.C. § 1343 (wire fraud); (3) 18 U.S.C. § 1344 (bank fraud); (4) 18 U.S.C. § 1348 (securities fraud); (5) "any rule or regulation of the Securities and Exchange Commission"; or (6) "any provision of Federal law relating to fraud against shareholders." All except the violations described under (5) refer explicitly to a company's *fraud*. We conclude that number (5) also refers to regulations prohibiting fraud. To conclude otherwise would absurdly allow a retaliation suit for an employee's complaints about administrative missteps or inadvertent omissions from filing statements. Moreover, the ambiguity is fully clarified by the context of the whistleblower provision in the Sarbanes-Oxley Act and by the legislative history that indicates that whistleblowing is protected by § 1514A when it relates to "fraud." *See, e.g.*, S. Rep. No. 107-146, at 19 (2002) ("Although current law protects many government employees who act in the public interest by reporting wrongdoing, there is no similar protection for employees of publicly traded companies who blow the whistle *on fraud and protect investors*") (emphasis added); *id.* (noting that whistleblower provision protects employees who report conduct "which they reasonably believe to be *fraudulent*") (emphasis added). In this case, Livingston relies on violations of § 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 under it, both of which prohibit securities fraud.

To "reasonably believe" that company conduct "constitutes a violation" of law, as those terms are used in § 1514A(a)(1), Livingston must show not only that he believed that the conduct constituted a violation, but also that a reasonable person in his position would have believed that the conduct constituted a violation. It would make no sense to allow Livingston to proceed if he himself did not hold the belief required by the statute, and the language of the statute itself requires that the belief be a "reasonable" one. 18 U.S.C. § 1514A(a)(1). Thus, § 1514A requires both a subjective belief and an objectively reasonable belief that the company's conduct constitutes a violation of the relevant law.

Moreover, the statute requires Livingston to have held a reasonable belief about an *existing* violation, inasmuch as the violation requirement is stated in the present tense: a plaintiff's complaint must be "regarding any conduct which [he] reasonably believes constitutes a violation of [the relevant laws]." 18 U.S.C. § 1514A(a)(1) (emphasis added). In an analogous context, we have construed the reasonable belief of a violation to allow for a reasonable belief that the violation not only (1) "has happened" but also (2) "is in progress." *Jordan v. Alternative Resources Corp.*, 458 F.3d 332, 340-41 (4th Cir. 2006) (construing the retaliation provision in Title VII, 42 U.S.C. § 2000e-3(a)), *cert. denied*, 127 S. Ct. 2036 (2007). As we amplified in *Jordan*, "the employee must have an objectively reasonable belief that a violation is actually occurring based on circumstances that the employee observes and reasonably believes." *Id.* at 341. We rejected the claim, however, that a reasonable belief that a violation has occurred or is in progress can include a belief that a violation is about to happen upon some future contingency. *See id.* at 340-41.<sup>2</sup>

Once Livingston establishes his cause of action, Wyeth can nonetheless defeat his claim for relief if it shows, by clear and convincing evidence, that it would have taken the adverse employment action against him even in the absence of his providing the information or making the complaint. *See* 49 U.S.C. § 42121(b)(2)(B)(iv).

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<sup>2</sup>As we noted in *Jordan*, because this analysis for determining whether an employee reasonably believes a law is being violated is an objective one, we resolve the question as a matter of law. *Jordan*, 458 F.3d at 339.

In this case, the district court concluded that Livingston failed to establish element (2) of his cause of action — that his complaint regarded company conduct that he reasonably believed constituted a violation of § 10(b) of the Securities Exchange Act and Rule 10b-5 under it — and that Wyeth would have discharged Livingston even in the absence of Livingston's having provided the information or made a complaint.

Addressing Livingston's failure to establish element (2), we conclude that Livingston failed at several of the suppositional levels assumed by him to satisfy that element in the circumstances of this case. Livingston himself recognizes the speculative multi-step reasoning on which he must rely. As he asserts in his brief on appeal:

All that Livingston needs to show in order for his complaints and disclosure to enjoy protected activity status under Sarbanes-Oxley is a reasonable belief that Wyeth was violating "any rule or regulation" of the SEC, or "any provision of Federal law relating to fraud against shareholders."

Pointing to the July 10 and July 29, 2002 memoranda, he states that "the core" of his complaints about violations of law was that:

Wyeth was intentionally concealing the same type of FDA [good manufacturing practices] violations that resulted in the consent decree [of October 3, 2000, covering two sites in Pennsylvania and New York] and . . . this non-compliance would violate the consent decree and [good manufacturing practices] violations. Concealing consent decree and [good manufacturing practices] compliance violations, after having told the SEC and shareholders in its 2001 and 2002 [annual reports] and 10-Q filings that Wyeth was compliant with [good manufacturing practices] and consent decree requirements constituted a violation or apparent violation of Section 10(b) of the Exchange Act and Rule 10b-5.

In reaching this conclusion, however, Livingston has failed to detail numerous critical steps that he must, but cannot satisfy.

*First*, as of the date of the July 29, 2002 memorandum, and indeed as of anytime, Livingston failed to show that Wyeth misrepresented or concealed anything, and the July 29 memorandum did not complain of any misrepresentation or concealment. It expressed a "concern that *if* we were to conduct the audit and not fully disclose the status of training system implementation at [Sanford], [Wyeth] *would be* in the unfortunate position of providing false and misleading information to compliance auditors, including the FDA." (Emphasis added). Livingston's July 29 memorandum did draw the conclusion that he perceived Kaylos' *implicit* message in their July 24 meeting to be that facts and data *would be* "covered up" from the Wyeth internal auditor and the FDA. Yet, the record is devoid of evidence that any Wyeth employee thereafter manifested even an intent to misrepresent facts or conceal any wrongdoing concerning training documentation. To the contrary, Livingston stated under oath that "[a]t no time during this [July 24] meeting, did I claim that Kaylos and Wyeth were trying to mislead the FDA and those involved with the July 29 verification." Furthermore, he informed the Wyeth investigators who responded to his July 29 ethics complaint that *he did not believe that anyone at the site would intentionally provide false statements*, and a copy of the results of this investigation was actually provided to the Wyeth internal auditor who conducted the July 29 inspection of the Sanford facility, negating any possibility that Livingston's concerns could be "covered up" from the auditor. In addition, in order to anticipate a misrepresentation to the FDA, he would have to assume that the new training documentation system would not actually be implemented by the September 30 commitment date; that Wyeth would fail to develop an acceptable legacy plan to afford it additional time to close any remaining compliance gaps; and that Wyeth would *then* misrepresent or conceal the true status of the program. This chain of speculation is simply too long to support a claim that Wyeth in fact covered up anything and made misrepresentations to the FDA or was in the process of doing so, as is required to support a violation of the securities laws.

*Second*, just as the hypothetical misrepresentations of the program's progress never occurred, so also no violation of the 2000 Consent Decree occurred. That decree, issued with respect to two plants in Pennsylvania and New York, was site-specific and did not cover the Sanford facility. The only way in which activities of the Sanford

site could be implicated by the decree was the decree's requirement that Wyeth "retain an expert consultant to undertake a division-wide assessment" of Wyeth's quality control programs and to submit proposed responsive actions to the FDA, along with a timetable for completing those actions. But Wyeth concededly did those things. It retained an expert, and in response to the expert's evaluation of the Sanford facility's procedures, it committed to implementing a new training program for good manufacturing practices at the Sanford site by September 30, 2002. Thus, during the summer of 2002, when the training system implementation was in progress, there was no objectively reasonable basis from which to conclude that the 2000 Consent Decree had been or was being violated.

*Third*, there is no suggestion in either the July 10 or July 29 memorandum that Wyeth or its employees had or even intended to mislead *shareholders*, as necessary to support a reasonable belief that the securities laws had been or were being violated. The annual reports for 2001 and 2002, indicating that Wyeth was compliant with good manufacturing practices, was never shown to be false or misleading when made, and there is no indication in the record that Wyeth intended to make false or misleading statements about its manufacturing practices in the annual report that would come out in the spring of 2003. In addition, to convert a hypothesized cover-up and misrepresentation with respect to the progress of the training program at the Sanford site into a securities fraud violation would require even larger leaps of speculation than Livingston took in supposing misrepresentations to internal auditors and the FDA. In order to justify his belief that Wyeth committed securities fraud, Livingston would have to have reasonably believed that Wyeth (1) made a material misrepresentation (or omission) (2) with scienter (3) in connection with the purchase or sale of a security (4) on which the seller or purchaser reasonably relied, (5) causing economic loss. See *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 341-42 (2005); *Miller v. Asensio & Co., Inc.*, 364 F.3d 223, 227 (4th Cir. 2004). While Wyeth did state in its public reports for 2001 and 2002 that it was compliant with the 2000 Consent Decree (covering its Pennsylvania and New York sites and not its Sanford, North Carolina site), there is no evidence that that statement was false or misleading. And there was no statement, false or otherwise, about Wyeth's training program implementation at the Sanford site. Indeed, Livingston's own observations indicate that no



finding that Wyeth made a false or misleading statement would be possible, inasmuch as Livingston acknowledged that he never complained that Kaylos and Wyeth were "trying to mislead the FDA and those involved with the July 29 verification" and that he did not believe that anyone at the Sanford site would intentionally provide false statements. Nor was there any actual deficiency in implementing the training program that could be misrepresented or concealed. None of the fears expressed by Livingston in his July 10 and July 29 memoranda about false or misleading statements ever materialized. Thus, even though his claim requires that he have complained about what he believed as a past violation or one in progress, he cannot even point to evidence indicating that Wyeth *intended* to make false or misleading statements in any statement or report to shareholders. The chain of speculation, in light of a record totally devoid of any Wyeth wrongdoing at the Sanford site, is simply too weak on which to hang even a postulated violation of the securities laws. Livingston, therefore, could not have reasonably believed that Wyeth had violated or was violating the securities laws.

*Fourth*, even if Wyeth had made the false statements to compliance auditors and the FDA that Livingston supposed could be made, none would amount to a material statement as necessary to violate § 10(b) of the Securities Exchange Act and Rule 10b-5. For a statement or omission to be actionable under § 10(b) of the Securities Exchange Act and Rule 10b-5, it must concern a *material fact*. The Supreme Court has noted that to fulfill the materiality requirement, "there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available." *Basic, Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988) (internal quotation marks omitted). Thus, for deficiencies in the training program schedule to have had a *material* impact on Wyeth's finances, there must have been some realistic possibility that the FDA would take regulatory action against Wyeth having material financial consequences to a reasonable investor. It is undisputed, however, that the FDA never issued any warning or made any observation regarding Wyeth's training schedule deficiencies at the Sanford site during the period when Livingston made his complaint.

Furthermore, at the time of Livingston's alleged protected activity, Wyeth was developing pharmaceuticals at over two dozen facilities

worldwide and had revenues of over \$14 billion. The Sanford site alone had 27 different "quality elements" defined by its good manufacturing practices manual, of which the training about which Livingston complained was only one element. Livingston has not demonstrated why Wyeth would be obligated to report to investors as "material" any deficiencies in the training documentation procedures at a single site — or why he could "reasonably believe" that they must do so — particularly when the FDA was aware that Wyeth was taking steps to improve that procedure and before the FDA had in any way indicated it would take action, or even threatened such action. *See Acito v. IMCERA Group, Inc.*, 47 F.3d 47, 52-53 (2d Cir. 1995) (noting that failure to disclose negative results of FDA inspections of two plants was not material where defendant operated over 30 plants, the FDA had taken no materially adverse action, and the defendant had committed to correct plant deficiencies).

In sum, not one link in Livingston's imaginary chain of horrors was real or was in the process of becoming real. The only *fact* about which Livingston ever complained was the fact that the training system for good manufacturing practices was off schedule. And based on this one fact, he made a judgment that the program would not likely be ready for verification by internal compliance auditors on July 29 and would not be completed by September 30, 2002. Even this predictive judgment, however, proved to be wrong.

Thus, Livingston has failed to produce evidence that he provided information or made a complaint to Wyeth about conduct which a reasonable employee in his position could have believed at the time constituted a violation of the securities laws. And because we affirm the district court with respect to this element, we need not reach the other conclusions of the district court challenged by Livingston.

### III

Livingston also contends that the district court erred in concluding that he had not established a claim for wrongful discharge under North Carolina common law. On appeal, however, Livingston's entire argument is contained in a single sentence in his opening brief: "Because the district court's findings of fact leading to dismissal of the

federal claim are also the factual basis for dismissing the wrongful discharge claim, the latter dismissal was also in error."

We agree with the district court that Livingston's state law claim is unsupported in the record. He has presented no evidence that he was discharged on December 19, 2002, for refusing to violate the law or that he was fired for reporting the violation of a law expressing the public policy of North Carolina.

The judgment of the district court is accordingly

*AFFIRMED.*

MICHAEL, Circuit Judge, dissenting:

I respectfully dissent from the majority's holding that Mark Livingston can show no set of facts to entitle him to protection under the whistleblower provision of the Sarbanes-Oxley Act of 2002, 18 U.S.C. § 1514A.

The whistleblower protections in § 1514A respond to

a culture, supported by law, that discourage[s] employees from reporting fraudulent behavior not only to the proper authorities . . . but even internally. This "corporate code of silence" not only hampers investigations, but also creates a climate where ongoing wrongdoing can occur with virtual impunity. The consequences of this corporate code of silence for investors in publicly traded companies, in particular, and for the stock market, in general, are serious and adverse, and they must be remedied.

S. Rep. No. 107-146, at 10 (2002). Section 1514A was enacted to provide such a remedy. In short, § 1514A serves to "encourage and protect [employees] who report fraudulent activity that can damage innocent investors in publicly traded companies." *Id.* at 19.

To gain the protection of § 1514A, an employee only has to show that he alerted his publicly traded employer to activity that he reason-

ably believed constituted a violation of an enumerated law, such as the violation of a provision relating to fraud against shareholders. 18 U.S.C. § 1514A. Livingston meets this standard when the facts are read in his favor, as is required at the summary judgment stage. While working at Wyeth, Inc. (Wyeth), a pharmaceutical manufacturer, Livingston formed a reasonable belief that Wyeth was intentionally failing to comply with a consent decree that arose out of regulatory action against Wyeth by the U.S. Food and Drug Administration (FDA). The consent decree compelled compliance with FDA regulations requiring good manufacturing practices aimed at ensuring product safety. When Livingston stated his concerns to his superiors, he was told that he would be fired unless he retracted his statements and stopped all reports of non-compliance at the facility where he worked. He then made an internal complaint to the company's offices that deal with ethics and regulatory compliance, stating that he was concerned about the effect Wyeth's cover-up would have on shareholders. Wyeth then fired him. Because these facts are sufficient to require a trial on Livingston's § 1514A claim, I would reverse the grant of summary judgment to Wyeth. Because the majority affirms the summary judgment by construing the facts in favor of Wyeth (the non-movant), I respectfully dissent.

#### I.

In reviewing the award of summary judgment to Wyeth, the majority has failed to state the facts in the light most favorable to Livingston. See *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986) (stating that "[t]he evidence of the non-movant is to be believed" in summary judgment proceedings). The facts, stated in that light, are as follows.

On October 3, 2000, Wyeth became subject to a consent decree arising out of the FDA's seizure of allegedly adulterated products from two Wyeth facilities. The consent decree was entered in a forfeiture action in which the FDA asserted that the seized products were adulterated under the Food, Drug, and Cosmetic Act, 21 U.S.C. § 351(a)(2)(B), because certain Wyeth facilities had failed to comply with federally mandated good manufacturing practices (GMPs). According to FDA regulations, GMPs require proper training of all persons engaged in manufacturing drugs. 21 C.F.R. § 211.25. The

regulations specify that each employee must be trained in the pertinent GMPs and in the employee's particular job functions. *Id.* § 211.25(a). Training must be "conducted by qualified individuals on a continuing basis." *Id.* This training is essential "to provide assurance that [every] drug product has the safety, identity, strength, quality, and purity that it purports or is represented to possess." *Id.* § 211.25(b).

The consent decree imposed binding requirements on all Wyeth facilities in its drug manufacturing division, including the facility in Sanford, North Carolina. The consent decree ordered Wyeth to hire an independent auditor to conduct a division-wide assessment of the company's quality control and compliance with GMPs. Thereafter, Wyeth was required to submit a plan with a timetable for the correction of deficiencies to the FDA, obtain FDA approval of the plan, and comply with the timetable. The timetable adopted under the consent decree could not be altered without written authorization by the FDA.

In keeping with industry practice of reporting GMP compliance to shareholders, Wyeth represented in its 2001 and 2002 annual reports that it was complying with the consent decree. The 2001 annual report also stated that the company was making an investment of "\$300 million to support our number one operating objective — to make sure that our manufacturing and operations maintain high quality standards." J.A. 323. The statement about this investment also mentioned the consent decree and noted that Wyeth was independently "strengthening sustainable compliance." *Id.*

When the consent decree was entered in October 2000, Livingston was the Manager for Training and Continuous Improvement at the Sanford site. He was responsible for GMP compliance and implementation of the GMP training system. In April 2001 Wyeth (apparently pleased with his work) promoted Livingston to the position of Associate Director of Training and Continuous Improvement. He continued to be responsible for GMP compliance.

In November 2000 the independent auditor (retained pursuant to the consent decree) reported that Sanford was not complying with legally mandated GMP requirements. The auditor listed thirty-five specific deficiencies related to training, including the following: (1)

many employees were manufacturing drugs with no training whatsoever, (2) managers were not trained, (3) the individuals conducting training were not properly trained themselves, and (4) training was not assessed for its effectiveness. In response to the audit report, Wyeth proposed September 30, 2002, to the FDA as the date by which the company would finish implementation and verification of GMP training compliance. The FDA apparently approved this deadline, and there is no evidence that Wyeth ever sought or was granted an extension.

Over the course of the two years leading up to the consent decree deadline for GMP training compliance, Wyeth's Sanford site made little headway on the subject. Wyeth set several internal deadlines (November 2001 was the first) to achieve compliance before the consent decree date, but internal audits showed that the company dismally failed to meet each deadline. Sanford management pushed the November 2001 deadline first to February 2002, then to April, then to July, and finally to the actual September 2002 consent decree date — a date that Wyeth also failed to meet at Sanford. While some of these deadlines were revised, others were "met" through the use of "legacy plans." A "legacy plan" is a term used at Sanford to describe an internal document that provides a time line for remedying noncompliance after a planned compliance date is missed.

Livingston faced stiff resistance from department directors as he attempted to remedy the serious non-compliance with training GMPs identified by the independent auditor and periodic internal audits. This resistance persisted despite Livingston's ongoing (and increasingly urgent) reports of compliance failures.<sup>1</sup> For example, in Novem-

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<sup>1</sup>The majority states that "Livingston found no problem with the [training] program's progress" toward compliance through June 2002. *Ante* at 5. This statement is incorrect. Livingston did prepare slides about compliance for possible use by the Sanford site director during a May 22, 2002, visit by a high-ranking Wyeth executive. While these slides stated that Sanford was "on track" for compliance by September 30, 2002, J.A. 569, Livingston explained that the slides were "optimistically written," J.A. 102. He continued to express his ongoing concerns about the lack of progress in several meetings with site management both before and after the preparation of the slides.

ber 2001 a vaccine development director informed him that she refused to implement the compliance requirements for training in her department. In December 2001, in response to Livingston's report of compliance gaps at a meeting of the Site Quality Council (the group responsible for internally monitoring compliance at Sanford), two members of the council "verbally assaulted" Livingston and refused support for the training plan. J.A. 85. In early March 2002 Livingston reported at a staff meeting that attendance at training for Sanford directors had been abysmal. The directors nevertheless continued to avoid their training obligations. Livingston made similar reports in April and early May 2002, and he was informed by Sanford management that no information regarding Sanford's compliance failures would be shared outside the Sanford site.

As the official FDA compliance date of September 30, 2002, approached, Livingston's reports became more urgent. The district court explained: "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." J.A. 42-43. Convinced that Sanford would be unable to meet the compliance deadline, Livingston requested a meeting with the Site Quality Council. On July 9, 2002, Bruce Kaylos, the Sanford site director, angrily informed him that he would not be allowed to discuss the compliance issue with the council.

After being blocked from meeting with the Site Quality Council about the imminent compliance failure, Livingston shared his evaluation with Kaylos and the council in a memo dated July 10, 2002. He concluded, "I do not support the request for [Sustainable Compliance Initiative] verification or attest to our state of compliance to corporate, site, and regulatory [ ]GMP training requirements." J.A. 709. The following day, July 11, 2002, Kaylos met with human resources to discuss putting Livingston on a "personal improvement plan" (PIP), a Wyeth personnel action threatening termination. Kaylos then left a telephone message for Livingston at his home on July 12 and had his assistant telephone Livingston at work on July 16. Livingston attempted to respond to these messages, but he was not able to speak with Kaylos. Livingston understood the telephone messages of July

12 and 16 to indicate that Kaylos had received the July 10 memo.<sup>2</sup> On July 24, 2002, Kaylos met with Livingston to discuss the memo. According to Kaylos's notes of this meeting, Livingston told him that "the site and I [Kaylos] were trying to mislead FDA and corporate audit groups into believing that training was compliant."<sup>3</sup> J.A. 446. As he had done previously, Kaylos instructed Livingston not to report non-compliance to Wyeth corporate headquarters. Kaylos also threatened to fire or demote Livingston if he continued to report Sanford's failure to comply with training GMPs. That same day, in response to his meeting with Livingston, Kaylos again contacted human resources to discuss the creation of a PIP threatening Livingston's termination.

The final internal audit prior to the FDA compliance date revealed that Sanford continued to violate GMP requirements, and it noted that Wyeth would have to adopt yet another legacy plan to address these problems. Despite the majority's assertion to the contrary, there is no evidence that the auditor verified compliance at this time or that Livingston "signed off on [any] verification." *Ante* at 6.

Around July 29 Livingston submitted a complaint to Wyeth's Office of Ethics and Business Conduct and its Office of Sustainable Compliance (compliance office). Livingston explained that Kaylos had attempted to intimidate him in an effort to prevent his accurate reporting of Sanford's compliance gaps. Livingston concluded,

Federal law deems it a crime to make any false, fictitious, or fraudulent statement to any government agency, or in making such statement, to conceal any material fact. . . . If we succumb to the pressure of the moment, if we avoid our compliance obligations, if we are unwilling to do the right

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<sup>2</sup>The majority writes that "Kaylos did not receive the memorandum until approximately July 17, 2002, because he was on vacation." *Ante* at 6. While this is Kaylos's claim, we are required to view the evidence in the light most favorable to *Livingston*. As I have described, Livingston has produced evidence that permits the inference that Kaylos received Livingston's memo on July 10 and immediately undertook retaliatory action.

<sup>3</sup>The majority states that there were no allegations of fraud at this meeting. *Ante* at 6. Kaylos's own notes contradict this assertion.



thing, or if we purposefully prevent the inner from matching the outer, we fail the ethics test and our Code of Conduct becomes another empty promise for employees, patients, health care providers, regulatory bodies, shareholders, and ourselves.

J.A. 745.

In response to these allegations, Wyeth's compliance office opened an investigation and recommended that the PIP proposed by Kaylos be delayed. An investigator met with Livingston, who explained his concerns about gaps in training documentation and the impending release of adulterated vaccine. The investigator's report found Livingston's training compliance concerns to be "substantiate[d]." J.A. 358. In particular, the investigator found that Sanford supervisors were systematically reporting employees as trained to complete tasks for which they, in fact, lacked training, thus allowing them to manufacture adulterated drugs in violation of 21 C.F.R. § 211.25.

On September 30, 2002, the FDA compliance date, Livingston signed two documents: a verification checklist indicating that certain aspects of the training were complete and yet another legacy plan to address continued training compliance gaps. There is no evidence that Wyeth sought, or that the FDA approved, any extension of the deadline. On October 9 Wyeth's compliance office closed the file on Livingston's complaint without taking any remedial action. Within a week Kaylos and David McCuaig, the human resources director, placed Livingston on a ninety-day PIP. The PIP required, among other things, that Livingston "[i]mmediately end non-constructive comments to internal and external staff and contacts that the establishment and utilization of certain corporately approved and verified training practices is 'defrauding' the FDA." J.A. 814. If Livingston failed to "show immediate, significant and sustained improvement within 30 days," he would be terminated. J.A. 815.

From October through December 2002 Livingston became increasingly concerned that he was about to be terminated, based on repeated actions and comments from McCuaig, his placement on a PIP with little explanation, and a decision by Kaylos to limit his job responsibilities. Livingston and McCuaig both reported to Kaylos and were

equals in the Sanford hierarchy. On December 13, 2002, McCuaig appeared at Livingston's offsite holiday party for his team. McCuaig's appearance was an unusual occurrence because each team had its own holiday party, so McCuaig would have been expected only to attend the human resources party. In fact, McCuaig did not attend any team holiday party other than the one held by Livingston. Using brusque terms, Livingston asked McCuaig to leave, and Livingston was fired five days later.

## II.

Livingston claims that Wyeth terminated him in violation of 18 U.S.C. § 1514A. The statute protects employees of publicly traded companies from retaliation for

provid[ing] information, caus[ing] information to be provided, or otherwise assist[ing] in an investigation regarding any conduct which the employee reasonably believes constitutes a violation of section 1341 [mail fraud], 1343 [wire fraud], 1344 [bank fraud], or 1348 [securities fraud], any rule or regulation of the Securities and Exchange Commission, or any provision of Federal law relating to fraud against shareholders.

18 U.S.C. § 1514A(a)(1). I would refine certain aspects of the majority's interpretation of the statute.

The majority states that a plaintiff's reasonable belief in a violation may not be based on "a belief that a violation is about to happen upon some future contingency." *Ante* at 13 (citing *Jordan v. Alternative Res. Corp.*, 458 F.3d 332, 340-41 (4th Cir. 2006)). While I agree with this statement, it requires some elaboration. The reasonableness standard in § 1514A "is intended to impose the normal reasonable person standard used and interpreted in a wide variety of legal contexts." S. Rep. No. 107-146, at 19 (citing *Passaic Valley Sewerage Comm'rs v. U.S. Dep't of Labor*, 992 F.2d 474, 478 (3d Cir. 1993)). As the majority recognizes, a similar standard is used in Title VII retaliation cases. *See ante* at 13; *see also Allen v. Admin. Review Bd.*, \_\_\_ F.3d \_\_\_, 2008 WL 171588, at \*7 (5th Cir. Jan. 22, 2008). Under Title VII a plaintiff complaining of retaliatory discharge does not have to prove

that he believed a violation had already occurred or was complete. *See Jordan*, 458 F.3d at 340-41 (citing *EEOC v. Navy Fed. Credit Union*, 424 F.3d 397 (4th Cir. 2005)). Instead, he has a claim if he was retaliated against for reporting his reasonable belief that a violation "was taking shape," that "a plan was in motion" to violate the law, or that a violation was "likely to occur." *Id.* at 340-41. In other words, an employee's belief is unreasonable (and unprotected) if it is based entirely on unsupported conjecture about hypothetical future events; his belief must relate to activity that a reasonable person could conclude is *or is about to become* a violation. *Id.* at 341.

Further, in applying the standard requiring the complainant to have an objectively reasonable belief that his employer is engaged in a violation, the majority consistently focuses on whether the violation did, in fact, occur. An actual violation is not required, however. An employee's reasonable belief about a violation is protected even if the belief is mistaken and *an actual violation never occurs*. *Allen*, 2008 WL 171588, at \*6.

Finally, the majority states that "because th[e] analysis for determining whether an employee reasonably believes a law is being violated is an objective one, we resolve the question as a matter of law." *Ante* at 13 n.2 (citing *Jordan*, 458 F.3d at 339). The majority overstates our warrant at the summary judgment stage. *Jordan* simply states that "the issue [of objective reasonableness] *may* be resolved as a matter of law." *Jordan*, 458 F.3d at 339 (emphasis added). The issue of objective reasonableness should be decided as a matter of law only when "[n]o reasonable person could have believed" that the facts amounted to a violation. *Clark County Sch. Dist. v. Breeden*, 532 U.S. 268, 271 (2001) (per curiam). However, if reasonable minds could disagree about whether the employee's belief was objectively reasonable, the issue cannot be decided as a matter of law. *Allen*, 2008 WL 171588, at \*7 (citing *Lipphardt v. Durango Steakhouse of Brandon, Inc.*, 267 F.3d 1183, 1188 (11th Cir. 2001); *Fine v. Ryan Int'l Airlines*, 305 F.3d 746, 752-53 (7th Cir. 2002)).

### III.

Livingston contends that he believed Wyeth was intentionally misleading shareholders about its noncompliance with federal GMP regu-

lations and the consent decree, in violation of § 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and Securities and Exchange Commission Rule 10b-5, 17 C.F.R. § 240.10b-5. To avoid summary judgment on his whistleblower claim asserted under 18 U.S.C. § 1514A, Livingston must proffer evidence that (1) his whistleblower complaints implicated shareholder fraud by Wyeth; (2) he subjectively believed that Wyeth was violating § 10(b) and Rule 10b-5, that a plan was in motion to violate these laws, or that a violation was likely; and (3) his belief was objectively reasonable. *See ante* at 13. For his belief in a § 10(b) and Rule 10b-5 violation to be objectively reasonable, he must show that a person in his position would have believed that Wyeth (1) made "a material misrepresentation (or omission)," (2) with "a wrongful state of mind," (3) in "connection with the purchase or sale of a security," and that (4) a seller or purchaser would have reasonably relied on the representation or omission, (5) with resulting economic loss. *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341-42 (2005) (citations omitted). The majority holds that Livingston has not offered evidence that would create a genuine issue of fact about the elements of his claim. To reach its result, the majority places an improperly high burden on Livingston and fails to recognize fully the strength and breadth of the factual case he has offered.

First, Livingston's whistleblower complaints implicated a violation of § 10(b) and Rule 10b-5. He was not required to specifically cite these provisions. He simply had to "provide information . . . regarding any conduct" that he believed constituted a violation. 18 U.S.C. § 1514A. Livingston satisfied this burden by repeatedly reporting to Wyeth his concern that FDA regulations were certain to be violated, that violations were being covered up, and that, as a result, shareholders were being impacted adversely. As Kaylos's notes of his July 24, 2002, meeting with Livingston reveal, and the October PIP confirms, Livingston informed Kaylos in person that he believed that the Sanford site and Kaylos were involved in fraud on the FDA. Then, in his July 29 complaint to Wyeth's compliance office, Livingston again reported that Sanford was failing to comply with federal GMP requirements and that Kaylos had instructed him to misrepresent the state of Sanford's compliance. Specifically, Livingston reported that Kaylos "attempt[ed] to shame me to retract the analysis and position," imparted the message that "we are going to conceal facts, data, and

information from the verification auditor," and threatened to fire Livingston if he "persisted in raising the awareness level of this issue up the chain-of-command." J.A. 744-45. Livingston was convinced that Kaylos's behavior in the July 24 meeting "violate[d] Wyeth's Code of Conduct," J.A. 744, and explained why in his complaint to the compliance office:

Federal law deems it a crime to make any false, fictitious, or fraudulent statement to any government agency, or in making such statement, to conceal any material fact. As I read the Wyeth Code of Conduct, this policy is in place to ensure that information provided to government agencies is truthful, accurate, and complete.

J.A. 745. Wyeth's Code of Conduct explicitly instructed employees to avoid false reporting to government agencies and to "accurate[ly] and complete[ly] and fairly present" information in its disclosures to shareholders. J.A. 244. Livingston concluded his complaint by asserting that "avoid[ing] our compliance obligations," as Kaylos had suggested, would "fail the ethics test and our Code of Conduct," which would then amount to "another empty promise" for, among others, "shareholders." J.A. 745. In short, Livingston asserted that Wyeth was covering up its noncompliance with GMP requirements and the consent decree, thus failing to keep its commitment to shareholders.

The majority argues that Livingston "did not complain of any misrepresentation or concealment," *ante* at 15, and presumably therefore did not communicate information regarding shareholder fraud. In support of this conclusion, the majority reads the facts in the light most favorable to *Wyeth*, not Livingston as is required. The majority first cites Livingston's use of conditional language in a background paragraph in his July 29 complaint. The conditional language, however, referred to Livingston's earlier July 10 memo to Kaylos, the Site Quality Council, and others, urging full disclosure of problems in the upcoming internal audit of training compliance. *See* J.A. 743 (Livingston stating in his July 29 complaint that in his July 10 memo he "expressed [his] concern that if we were to conduct the audit and not fully disclose the status of training implementation at [Sanford], [Wyeth] would be in the unfortunate position of providing false and misleading information to compliance auditors, including the FDA.").

There is nothing conditional, however, in Livingston's report in his July 29 complaint detailing Kaylos's response to the July 10 memo. Livingston provides an unequivocal report that Kaylos, the site director, threatened retaliation if Livingston refused to join in the plan to cover-up Wyeth's failure to comply with federal law. The majority next concludes that Livingston told investigators that "*he did not believe that anyone at the site would intentionally provide false statements.*" *Ante* at 15. This quote is taken from the investigator's letter, not Livingston. Livingston, in fact, definitively stated under oath that "I *did not* tell [Ed] Babiaz [the investigator] that 'I did not believe anyone would intentionally provide false or misleading statements.'" J.A. 124 (emphasis added). Livingston's affidavit thus directly contradicts the majority's conclusion. The majority also notes that Livingston says in his affidavit that he did not mention fraud in his July 24 meeting with Kaylos. *Ante* at 15. Nevertheless, it is uncontested that Livingston's July 29 complaint informed Wyeth that he had been instructed to misrepresent facts about compliance. In addition, both Kaylos's notes from the July 24 meeting and the October PIP confirm that Livingston was alleging fraud.

Livingston thus meets the first requirement for whistleblower protection because the clear text of his July 29 complaint communicates a concern about fraud on shareholders. Livingston's assertions also provide evidence to satisfy the second and third requirements for protection: he believed Wyeth was committing securities fraud and this belief was objectively reasonable.

In particular, Livingston has provided sufficient evidence to establish that he had a reasonable belief that Wyeth was violating Rule 10b-5. First, Livingston reasonably believed that Wyeth was making (and would continue to make) material misrepresentations or omit material facts in reports to shareholders. Wyeth stated in its 2001 and 2002 annual reports that it was complying with the 2000 consent decree and that GMP compliance was its "highest priorit[y]." J.A. 323. At the time of these representations, Wyeth was not planning to comply with the consent decree, nor was it capable of achieving compliance. Every audit of Sanford's compliance with training GMPs, up to the very last internal audit prior to the FDA compliance date, revealed Sanford's serious failure to comply with federal requirements. Just months prior to the September 30, 2002, deadline, these

failures were "so abysmal that [they] mirrored conditions . . . that prompted the entry of the Consent Decree." J.A. 42-43. At this time, many of Sanford's department directors and staff were receiving *no training at all*, almost half of the site had not even developed training curricula, and most of the training that occurred was deficient. Since 2000 Livingston had watched as Sanford made little effort to correct its deficiencies; he had every reason to believe that it would not — and in fact could not — come into compliance by September 30, 2002. Indeed, Livingston's fears were realized as Sanford failed to reach compliance by this date. Based on his experience at Wyeth, Livingston also believed that Wyeth would misinform shareholders about the company's intention not to comply with the consent decree and GMPs generally. Livingston was correct about this as well: the shareholder reports indicated that Wyeth was complying with GMPs and the consent decree when it was not, and, indeed, had no intention of doing so.

The majority makes several arguments against this aspect of Livingston's claim. Initially, the majority argues that Livingston's concerns about FDA noncompliance were objectively unreasonable because Sanford could not violate the consent decree. According to the majority, the consent decree "did not cover the Sanford facility." *Ante* at 15. This conclusion is directly contradicted by the record. The express terms of the consent decree covered Wyeth's entire drug manufacturing division, of which Sanford was a part. The consent decree ordered Wyeth to (1) hire an independent auditor to conduct "a division-wide assessment" of quality control and GMP compliance, (2) submit a plan (with a timetable) for compliance to FDA, and (3) adhere to the timetable. J.A. 1253. In a company document explaining the decree, Wyeth stated that the decree mandated that "[e]xpert consultants will examine our [quality assurance and compliance] systems at *every facility making product* for the U.S. market; we then *must* take appropriate actions to address any issues they identify in these areas." J.A. 976 (emphasis added). A member of the task force Wyeth created to respond to the consent decree further explained, "Sanford training . . . needed to implement [the GMP] conformance standards" by the September 30, 2002, deadline established in the consent decree timetable. J.A. 965. Thus, Wyeth understood that the consent decree applied to Sanford and mandated that facility's compliance with the September 30, 2002, deadline.

The majority further argues that Wyeth could not violate the consent decree because it could always adopt a legacy plan to correct any compliance gaps still existing on the September 30 deadline. *Ante* at 15. However, as noted above, a legacy plan was an *internal Wyeth procedure*. There was no reason for Livingston to believe that the FDA would accept such a plan, allowing the facility to grant itself extensions to continue to violate federal law. In fact, under the binding terms of the consent decree, Livingston had every reason to believe that the FDA *would not* accept a legacy plan. The consent decree expressly stated that Wyeth could not alter any schedule approved by the FDA without written approval, granted at the discretion of the FDA. Wyeth's internal decision to grant itself an extension through a legacy plan would be an obvious violation of this provision. In fact, despite the majority's contention to the contrary, *ante* at 16, Livingston's evidence shows that *Wyeth did violate the consent decree*; it is undisputed that Sanford adopted a legacy plan to address its failure to comply with GMPs on the FDA compliance date of September 30, 2002. Wyeth did not petition the FDA for an extension, and the FDA did not give it written approval to extend the deadline for compliance. Thus, the consent decree's terms assist in confirming that Livingston's concerns were objectively reasonable because the terms clarify (1) that Wyeth's failure to meet the FDA deadline would be an actual violation of the consent decree (as well as federal law) and (2) that a legacy plan was not a proper means to avoid the company's regulatory obligations.

The majority finally argues that, "[w]hile Wyeth did state in its public reports for 2001 and 2002 that it was compliant with the 2000 Consent Decree (covering its Pennsylvania and New York sites and not its Sanford, North Carolina site), there is no evidence that that statement was false or misleading." *Ante* at 16. Because the majority is mistaken about the reach of the consent decree, this conclusion is unsupported. Any statement by Wyeth that it was complying with the consent decree was false, or at the least misleading, because the company was aware that it would miss the September 30, 2002, deadline for Sanford compliance. Livingston's beliefs that Wyeth was making material misrepresentations or omitting material facts in reports to shareholders were well founded.

Second, Livingston's belief that Wyeth had a "wrongful state of mind" was objectively reasonable for a person in his position. Living-



ston had ample evidence that Sanford was engaged in a cover-up. From the inception of his efforts to bring Sanford into compliance, he was met with hostility and refusals to cooperate from his supervisors and site department directors; as the FDA compliance date approached, this resistance escalated into demands that he mislead corporate management and outside auditors. The department directors never once claimed that Livingston's reports were unfounded; after all, he was backed by the clear results of the audits. But the directors' resistance to training, refusal to report training failures, and refusal to implement GMPs in their own departments were clear indications that they never planned to comply with the consent decree deadline. This resistance and refusal culminated in Livingston's July 24 meeting with Kaylos, the Sanford site director, in which Kaylos threatened to fire Livingston if he persisted in reporting regulatory failures and failed to retract his statements. This threat was eventually formalized in the October PIP. Not only was Livingston subjected to demands that he misrepresent Sanford compliance to authorities, there is independent, direct evidence that an intentional cover-up was underway at the Sanford facility. The investigation of Livingston's internal complaint revealed that Sanford department directors were intentionally documenting untrained employees as having received the necessary training, so that they could continue working in violation of federal regulations. The threats, refusal to cooperate, and actual misrepresentation of the woeful state of training compliance by Sanford department directors is sufficient evidence to support Livingston's belief the Sanford facility was engaging in a fraudulent cover-up of its ongoing violations of federal law. It was objectively reasonable for Livingston, who knew that Wyeth was making intentional misrepresentations to the FDA, to believe that Wyeth was intentionally misleading its shareholders about its compliance with FDA regulations and the consent decree, as evidenced by the actual misrepresentations in the annual reports.

Third, Livingston reasonably believed that Wyeth's misrepresentations in its annual shareholder reports would be material to shareholders and would cause economic loss. Under the consent decree Wyeth was subject to careful, regular reviews by the FDA beyond those conducted in the normal course of business. As a result, the FDA was far more likely to detect and punish any violations by Wyeth, especially violations of the consent decree. Wyeth had explained to its employ-

ees that any failure to meet the consent decree's timetable would cost the company a \$15,000 fine for each day of tardiness, up to a total \$5 million dollars. Wyeth paid the government \$30 million to settle the FDA enforcement action that prompted the consent decree. And the Sanford violations disclosed by Livingston were similar to those underlying the consent decree. Huge settlement costs and fines paid by a company are material to shareholders, and a reasonable shareholder would want to know whether a company is engaged in activity that could trigger such settlements and fines. *See No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. West Holding Corp.*, 320 F.3d 920, 935 (9th Cir. 2003) (airline company's failure to comply with Federal Aviation Administration regulations, which would likely result in a sanction, was material to shareholders). Thus, Wyeth's failure to comply with the consent decree and its ongoing obligations under FDA regulations was material to shareholders.

The majority argues that any false statement made in the annual reports could not have been viewed as material because "the FDA never issued any warning or made any observation regarding Wyeth's training schedule deficiencies at the Sanford site during the period when Livingston made his complaint." *Ante* at 17. The majority erroneously magnifies Livingston's burden. In order to prevail on a § 1514A whistleblower claim, Livingston does not have to prove that Wyeth did, in fact, violate Rule 10b-5. Nor does he have to show a working knowledge of the securities laws. He only has to provide sufficient evidence to show that a person in his position — a manager in charge of complying with federal drug regulations and a binding consent decree — could reasonably believe that Wyeth's reports of compliance constituted a material misrepresentation to shareholders under Rule 10b-5. Livingston had watched as the FDA seized allegedly adulterated products and extracted a massive sum in settlement from Wyeth as a result of the same compliance failures at other facilities as those that he saw at his own; as the manager responsible for compliance, he understood the huge financial impact of the consent decree, was aware of its binding nature, and understood the consequences of failure to meet its deadlines.

In sum, Livingston has produced evidence that his reports implicated shareholder fraud; that Wyeth both planned to violate and actually violated federal laws and regulations; that Wyeth management

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falsely reported compliance (internally and to shareholders) with these same laws; that his direct supervisor threatened him and that he was formally instructed to stop reporting non-compliance; and that Wyeth (and its shareholders) risked substantial financial loss if this cover-up was discovered in the enforcement of the consent decree. Wyeth instructed Livingston to stop his complaints, and after he refused to do so, it fired him. This evidence is sufficient to present an issue of material fact about whether Livingston's complaints were protected under § 1514A. In addition, Wyeth has failed to present clear and convincing evidence that it would have placed Livingston on a PIP and ultimately fired him if he had not made his complaints. As a result, I would conclude that Livingston has presented sufficient evidence to survive summary judgment on his § 1514A claim, and I would remand the case for trial.