UNPUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 11-1498

UNITED STATES OF AMERICA ex rel. DEBRA PARKS,

Plaintiff - Appellant,

and

CALIFORNIA; DELAWARE; FLORIDA; GEORGIA; HAWAII; ILLINOIS; INDIANA; LOUISIANA; MASSACHUSETTS; MICHIGAN; MONTANA; NEVADA; NEW HAMPSHIRE; NEW JERSEY; NEW MEXICO; NEW YORK; OKLAHOMA; RHODE ISLAND; TENNESSEE; TEXAS; VIRGINIA; WISCONSIN; DISTRICT OF COLUMBIA,

Plaintiffs,

v.

ALPHARMA, INCORPORATED; ALPHARMA BRANDED PRODUCTS DIVISION, INCORPORATED; FAULDING LABORATORIES; PUREPAC PHARMACEUTICAL COMPANY,

Defendants – Appellees,

and

SEALED DEFENDANT #5; SEALED DEFENDANT #6; SEALED DEFENDANT #7; SEALED DEFENDANT #8; SEALED DEFENDANT #9; SEALED DEFENDANT #10; SEALED DEFENDANT #11; SEALED DEFENDANT #12; SEALED DEFENDANT #13; SEALED DEFENDANT #14; SEALED DEFENDANT #15,

Defendants.

Appeal from the United States District Court for the District of Maryland, at Baltimore. Richard D. Bennett, District Judge. (1:06-cv-02411-RDB)

Argued: May 17, 2012 Decided: August 14, 2012

Before KING, DUNCAN, and THACKER, Circuit Judges.

Affirmed by unpublished per curiam opinion.

ARGUED: Joseph Saunders Johnston, MORGAN CARLO DOWNS & EVERTON, PA, Hunt Valley, Maryland, for Appellant. Lindsay Buchanan Burke, COVINGTON & BURLING, LLP, Washington, D.C., for Appellees. **ON BRIEF:** Robert C. Morgan, Angus R. Everton, MORGAN CARLO DOWNS & EVERTON, PA, Hunt Valley, Maryland, for Appellant. Thomas S. Williamson, Jr., COVINGTON & BURLING, LLP, Washington, D.C., for Appellees.

Unpublished opinions are not binding precedent in this circuit.

PER CURIAM:

Debra Parks appeals the district court's grant of summary judgment to Alpharma, Inc. ("Alpharma") on her False Claims Act ("FCA") retaliation claim. See 31 U.S.C. § 3730(h). Parks argues that the district court erred in ruling that she failed to make a prima facie case. The district court was correct, however, in deciding that Parks did not make the requisite showing on the second element of the prima facie case: that Alpharma had notice of her alleged protected activities. For this reason, we affirm.

I.

A.

Parks worked as a sales representative for Alpharma, a pharmaceutical company, from spring 2002 until her termination in July 2006. J.A. 23.[1] For a time, Parks was one of Alpharma's most successful employees. She received many awards, including "Sales Representative of the Year," and she was ranked as one of the top sales representatives nationally. Id. at 1943. In February 2006, Parks earned Alpharma's "High Five" award for

[1] Citations to the "J.A." refer to the Joint Appendix filed by the parties in this appeal. Parks's Second Amended Complaint states that she began working for Alpharma in 2001, see J.A. 23, but the district court found that she began in spring 2002, see id. at 178, and Parks does not challenge this finding on appeal.

sales representatives exemplifying five "core values": "bias for action," "creativity," "courage," "integrity," and "teamwork." Id. at 1944.

Parks was tasked primarily with promoting the drug Kadian to physicians in Maryland and Delaware. J.A. 23-24, 352. Alpharma advertised Kadian, a sustained-release morphine product, as a longer-lasting alternative to other pain medications such as Percocet, Vicodin, and OxyContin. Id. at 29. In this regard, Parks's job had many facets, including encouraging physicians to prescribe Kadian and "obtaining formulary status for Kadian[.]" Id. at 358.[2] According to Parks, in an attempt to persuade Medicaid, Medicare, and state-funded health care programs to add Kadian to their list of formularies and to increase sales, Alpharma conducted clinical studies to show the effectiveness, safety, and cost-effectiveness of Kadian. Id. at 1944. Alpharma would then produce the results in the form of presentations and abstracts.

Alpharma conducted many of these studies during Parks's tenure. She claims that she became concerned about the

[2] According to Parks, a drug achieves "formulary status" when it is approved for reimbursement by a government-sponsored or commercial health care program. Formularies, or lists of such approved drugs, are normally approved by committees within a certain program or managed care plan. See J.A. 358-59.

methods by which the studies were conducted and the manner in which the results were presented.

1. SWITCH STUDY

In 2004, Alpharma considered engaging Dr. Michael S. Kaplan, who operated multiple pain clinics in Maryland, to conduct a study to assess the efficacy and pharmacoeconomic (cost-saving) impact of switching patients from other pain medications to Kadian (hereinafter, the "Switch Study"). J.A. 1945. Parks denies in an affidavit having any role in hiring Dr. Kaplan to perform the study, id. at 1945-46, and divulges that she found Dr. Kaplan to be "inappropriate on a personal level," id. at 387.

Nevertheless, Parks worked regularly with Dr. Kaplan, and he prescribed the most Kadian in Parks's sales territory. J.A. 377-78. Indeed, in an e-mail to Dr. Joe Stauffer, Alpharma's Vice President of Global Medical Affairs, Parks wrote that she would be "dead" if Dr. Kaplan "g[o]t angry and stop[ped] writing [prescriptions]" for Kadian. Id. at 956. And in a May 12, 2004 email, Parks sent Dr. Kaplan's curriculum vitae to Dr. Mike Royal, Medical Director and Vice-President of Alpharma Strategic Brand Development, listing several reasons why Dr. Kaplan would be the best person to perform the Switch Study. She concluded, "[h]e is very excited about doing the 'switch' study and wants to start ASAP." Id. at 946. She also

told Dr. Royal that Dr. Kaplan is "truly a doctor we want to keep in our camp," id. at 945-46, and admitted that "it would be impossible for [her], as a sales rep, to replace that sales volume," id. at 393. She agreed that she "wanted to get Kaplan going on the study so it wouldn't adversely affect [her] ability to achieve or exceed [her] quota[.]" Id. at 798. Alpharma ultimately hired Dr. Kaplan to conduct the Switch Study.

2. KAPLAN METHOD

Central to the Switch Study was Dr. Kaplan's personal method of converting patients from other pain medications to Kadian (hereinafter, the "Kaplan Method"). J.A. 1950-51. The Kaplan Method involved adding Kadian to a patient's shorter-acting pain medication, and once Kadian reached a certain level, weaning the patient off of the other drug. Id. at 243. After hiring him to perform the Switch Study, Alpharma asked Dr. Kaplan to train its sales representatives so that they could present the Kaplan Method to other physicians, in an effort to increase the number of Kadian prescriptions. Id. at 201, 1950. He agreed, and the training presentation took place in August 2005. Id. at 1950.

Even though Parks told Dr. Royal that "part of why [Dr. Kaplan] is so successful in convincing doctors to really give Kadian a fair trial is his discussion of conversion," J.A.

496, she nonetheless complained about the Switch Study and the 2005 training for three reasons.

First, Parks did not believe that the other sales representatives fully understood the Kaplan Method. She claims she was "inundated with calls and emails" from sales representatives with questions about it. J.A. 988. In an email to her supervisors, Mike Slesinski and Peter Hill, Parks stated that she was "happy that the talk was met with such enthusiasm" but was "hesitant to give any info on the lecture without talking to management" and could not "handle the huge volume of requests that seems to be building up." Id. at 989. Parks proposed a conference call with the sales representatives to discuss the Kaplan Method because, as she explained in her deposition, she wanted "to clear up the confusion . . . to be able to ensure that the reps did understand the [Kaplan Method] because it was a serious matter and could endanger patient's [sic] safety." Id. at 811. Parks also claims that she complained to Hill about these concerns during field rides with him, but Hill recalls Parks saying only positive things about the Kaplan Method. See id. at 1880.

Second, Parks says that she complained to her superiors that the Kaplan Method encouraged an "off-label" use of the drug. Br. of Appellant 16. An "off-label" use is one that has not been approved by the federal Food and Drug

Administration ("FDA"). See United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 43-44 (D. Mass. 2001). Although physicians may prescribe drugs for off-label usage, federal regulations prohibit drug manufacturers from marketing their drugs for off-label purposes. See id.; 21 U.S.C. §§ 331(a), (d); see also Washington Legal Foundation v. Henney, 202 F.3d 331, 332-33 (D.C. Cir. 2000) (providing background on off-label use and promotion of pharmaceutical drugs).

Parks alleges that she complained to supervisors Slesinski, Hill, and Craig LaFay that representatives were simplifying the Kaplan Method and thus promoting an off-label conversion, but none of them recalls Parks expressing these concerns or ever using the terms "illegal," "fraudulent," or "off-label." J.A. 1903-04, 1880, 1891. Parks admits that she did not put in writing her concerns that Alpharma's marketing practices were off-label or fraudulent, see id. at 819, 821, and never used the terms "illegal" or "fraudulent" in conversation, but rather used the term "off-label," see id. at 789-90.

Finally, Parks says that she voiced concerns about the manner in which the Switch Study and Kaplan Method were presented. She claims that the study revealed that converting patients to Kadian who were also on morphine would result in increased, not reduced, costs. J.A. 1948. An abstract prepared by a third party failed to mention this fact, id. at 274-78, and

Parks says that she expressed her disapproval that Alpharma had decided to "bury" such results, id. at 1948. Parks also says that she spoke with Dr. Stephen Sun, a member of the Alpharma medical affairs division, who told her that the Switch Study was a "failure" and that he did not want the results to be released. Id. Parks claims that she sent an email "to prove" to her supervisor that the pharmacoeconomic results had been buried. Id. at 1949. That email, however, simply states, "This [Abstract] Poster has been presented now. It is my understanding that [a nurse from Dr. Kaplan's office] may present it herself . . . at a District teleconference." Id. at 281.

Aside from her own testimony, Parks presents no other evidence that she expressed her disapproval with Alpharma's handling of the Switch Study abstract, and no reasons why she believed Alpharma was responsible for the alleged "burying," when a third party actually prepared the abstract.

3. COVENTRY PRESENTATION

Parks also says that she complained about a teleconference presentation by Dr. Kaplan to Coventry Health Care in February of 2006. Part of the presentation was meant to promote Kadian as being less prone to diversion (i.e., less prone to be diverted to the black market) than other opioid drugs. J.A. 262. Notably, Parks "arranged for Dr. Kaplan to

speak," and she also provided certain slides for that presentation. Id. at 1884. Nevertheless, Parks claims that because Kadian had not been proven to be less subject to diversion, she felt that marketing it that way would be considered off-label promotion.

When Parks discovered that the presentation would involve a discussion of diversion, she wrote an email to Hill to express these concerns. The email stated,

> Between us, I am not at all comfortable with this approach. If it were me[,] I would not do this. The success with Medicaid in [Maryland] was due to a strong clinical support from my [doctors] and a great detail from Dr. Royal . . . . Nonetheless, I am doing all that I can to help [Matt Anderson, Alpharma's Managed Care Representative, who was responsible for the presentation]."

J.A. 262. Hill responded, "I would agree, I think we need to take a more clinical approach than abuse and diversion." Id. at 1884.[3]

[3] Because Dr. Kaplan was not on Alpharma's list of approved speakers, he could not be paid his $500 honorarium for the Coventry presentation through normal channels. Parks says that her supervisors encouraged her to buy Dr. Kaplan a gift certificate with her company American Express card, but she refused to do so. Eventually, Dr. Kaplan was paid by a check issued by Alpharma. See J.A. 446-58. It is not clear whether Parks desires to use this fact as evidence of an FCA protected activity or retaliatory behavior on the part of Alpharma. Regardless, we do not find it persuasive or relevant to our analysis.

4. DOSE-DUMPING STUDY

The next issue about which Parks says she complained concerned a "dose-dumping" study conducted by Alpharma. In July 2005, the FDA asked a competitor pharmaceutical company to withdraw the pain medication Palladone from the market because a study had shown risks of dose-dumping, which is the premature and exaggerated release of the pain-killing component in a drug caused by alcohol use. J.A. 57, 202-04. The FDA then requested that Alpharma also conduct a dose-dumping study of its own with regard to Kadian. See id. at 57, 1616-18. The study was completed after Parks's July 2006 termination, and the final results indicated that Kadian was not susceptible to dose-dumping risks. See id. at 1618.

In February 2006, however, Parks learned third-hand from a competitor's sales representative that a clinical trial showed risks of dose-dumping in Kadian. Parks relayed the information to Hill, Slesinski, and Alpharma marketing director Eric Vandal. They told her that those rumors were false. See J.A. 772-73, 1547-50, 1955.

Also in February 2006, Parks was told by an Alpharma sales representative that the clinical trials were showing a risk of dose-dumping. J.A. 1955-56. Parks says that she relayed this information to Dr. Sun. She claims that he told her to "stop asking questions" and "mind your own business."

Id. at 774. Dr. Sun has no recollection of this conversation. See id. at 1201-02, 1218-19. Parks also says that she expressed concerns to Ron Warner, Alpharma's Vice-President, that Alpharma was marketing the drug as having no risk when co-ingested with alcohol, when the dose-dumping study was not yet complete. See id. at 1956-57.

5. INTERNET SURVEILLANCE STUDY

Lastly, Parks claims that she complained about an internet surveillance study conducted by Alpharma. The study was conducted to monitor websites frequently used by prescription drug abusers, who share messages about their drug of choice. The results showed that other drugs such as OxyContin and Percocet were mentioned more frequently than Kadian on these sites. J.A. 1019-20.

In June 2006, Dr. Stauffer gave a presentation about the internet surveillance study at a national Alpharma meeting. Parks alleges that she complained about this presentation to LaFay and Dr. Stauffer because she was concerned that sales representatives were using the study to market Kadian as less prone to abuse and diversion, which was not necessarily true.

J.A. 1016-17, 1607, 1957-58. Neither LaFay nor Dr. Stauffer remembers those conversations. See id. at 1034, 1603.[4]

B.

In March 2006, Alpharma's Human Resources Director Regina Donohue began receiving telephone calls from other sales representatives who were complaining about Parks's behavior. They said that Parks was "making inappropriate and disrespectful comments about her supervisors," "inquiring into other employees' salaries and merit increases," and "spreading rumors" about an extramarital affair between Hill and another sales representative. J.A. 1765. In early March 2006, Donohue also learned from Slesinski that Parks was telling others that she was "unhappy" with her 2005 merit increase. Id.

As a result, Donohue conducted an investigation into the complaints about Parks. Donohue interviewed Hill, LaFay, and Slesinski on March 8, 2006, regarding Parks's complaints

[4] Parks presents other allegations in an attempt to show that Alpharma engaged in retaliatory behavior. For example, she claims that Hill made derogatory comments about her physical appearance, mocked her hair color, threatened to fire her unless she attended a meeting in Amelia Island, and urged her to leave her father-in-law's funeral in New Jersey to go on a field ride with him. See J.A. 428-29, 460-61, 1958. Because these allegations were made in support of Parks's claim on the third prong of the prima facie case, we find them to be irrelevant to our analysis here.

about her merit increase.[5] She also conducted telephone interviews with other sales representatives concerning Parks's alleged behavior. Donohue took extensive notes during her investigation, which suggested that several employees complained that Parks had been a negative influence on the sales force because she spread rumors, criticized Alpharma's management, and acted like a "bully." J.A. 1766-67, 1808-15.

Ultimately, on May 5, 2006, Donohue and another human resources manager, George Rose, met with Parks to discuss the complaints. Shortly thereafter, on May 8, 2006, Parks's lawyer faxed a letter to Alpharma, and accused Hill of retaliating against Parks by claiming that she was spreading false rumors about him. In the letter, Parks asked that Alpharma investigate her claim of Hill's alleged retaliation. See J.A. 1873-75. They did so and found no support for her allegations. Id. at 1768-70.

At the conclusion of the investigation into the complaints about Parks, Alpharma legal counsel Elissa Halperin notified Parks that no disciplinary action would be taken against her, but she warned both Parks and her attorney to keep

[5] Notably, however, the evidence shows that Parks did not know about her merit increase until March 16, 2006. Because this discrepancy bears on the third prong of the prima facie case, it is immaterial to our analysis here.

that investigation confidential, and especially not to discuss the results of the investigation with other employees. See J.A. 560-62, 1846. Nonetheless, on June 14, 2006, Hill informed Donohue that Parks was disclosing some details of that investigation to another sales representative. Donohue spoke with this sales representative, who confirmed in a written, signed statement, that Parks had done so. See id. at 1843.

On July 24, 2006, Alpharma terminated Parks. J.A. 661, 1773. According to Alpharma, the company's management decided to terminate Parks's employment as a result of the numerous complaints regarding her insubordinate behavior and as a result of her failure to keep the internal investigation regarding her allegations confidential. Id. at 1682-83, 1772-73, 1846-47.

C.

On September 13, 2006, two months after her termination, Parks filed under seal this qui tam action as a relator. In her Second Amended Complaint, filed June 23, 2008, she alleged that Alpharma paid illegal kickbacks to providers to induce them to prescribe Kadian, in violation of the federal Anti-Kickback Act, 42 U.S.C. §§ 1320a-7b(b), and that it made false representations about Kadian's effectiveness and risks and improperly promoted on-label and off-label uses of the drug, in violation of the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-

97. See J.A. 17-109. Parks averred that, by these practices, Alpharma caused prescriptions to be written based on false pretenses and false claims to be submitted to government-funded health insurance programs for reimbursement. Thus, Parks asserted that Alpharma violated the provisions of the FCA and defrauded federal and state governments out of tens of millions of dollars. See id. at 69; Br. of Appellant 4.

As pertinent here, Parks further alleged that during her four-year tenure with Alpharma, she "questioned the marketing instructions her Alpharma supervisors had given her," "suggested that Alpharma correct them," and "began to gather facts to disclose [Alpharma's] fraud," and was terminated in retaliation for these actions, in violation of the FCA. J.A. 67-68, 103-104; see also Br. of Appellant 3.

The Second Amended Complaint remained under seal while the government investigated the allegations, pursuant to 31 U.S.C. § 3730(b)(2). On March 10, 2010, the Department of Justice and Parks executed a $42.5 million settlement agreement with Alpharma. Parks received over $5 million dollars for her role as a whistleblower, pursuant to 31 U.S.C. § 3730(d). J.A. 727.

As a result of the settlement, all claims against Alpharma were dismissed except Parks's FCA retaliation claim. Alpharma moved for summary judgment on this claim on February

28, 2011, arguing that Parks failed to make a prima facie case. The court granted the motion, see United States ex rel. Parks v. Alpharma, Inc., No. 1:06-cv-02411, 2011 WL 1366491 (D. Md. Apr. 11, 2011),[6] and Parks timely appealed. We possess jurisdiction pursuant to 28 U.S.C. § 1291.

II.

We review the district court's grant of summary judgment de novo, viewing "all facts and reasonable inferences in the light most favorable to . . . the non-moving party" — in this case, Parks. United States ex rel. Owens v. First Kuwaiti Gen. Trading & Contracting Co., 612 F.3d 724, 728 (4th Cir. 2010). Summary judgment is appropriate if "there is no genuine issue as to any material fact" and the movant, Alpharma, is

[6] Parks took other legal actions based on the alleged circumstances of her termination, including filing a criminal complaint accusing Hill of assault and battery because he allegedly "smacked [her] on [her] butt" at a conference, see J.A. 687-88; a defamation action against Hill and another sales representative, see id. at 532; and a wrongful termination suit against Alpharma, see id. at 492, all in state court. The criminal investigation was dropped after several of Parks's co-workers indicated that Parks had asked them to lie and say they had witnessed the alleged actions of Hill. See id. at 1775. The defamation action was voluntarily dismissed by Parks. See id. at 532; Parks v. Armstrong, No. 03C07004974 (Cir. Ct. Baltimore Co.), filed May 2, 2007, dismissed Mar. 13, 2008. The wrongful termination suit was dismissed for failure to state a claim. See Parks v. Alpharma, Inc., 10 A.3d 199 (Md. 2010); aff'd, 25 A.3d 200 (Md. 2011).

"entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).

After reviewing the evidence of an alleged genuine issue of material fact, we must ask "whether a fair-minded jury could return a verdict for the plaintiff on the evidence presented. The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986). Indeed, at the summary judgment stage, the district court has "the affirmative obligation [] to prevent factually unsupported claims and defenses from proceeding to trial." Drewitt v. Pratt, 999 F.2d 774, 778-79 (4th Cir. 1993) (internal quotation marks omitted).

III.

In adopting the FCA, Congress intended "to protect the funds and property of the government." Rainwater v. United States, 356 U.S. 590, 592 (1958). An FCA suit "may be brought against anyone who 'knowingly presents' to the government 'a false or fraudulent claim for payment or approval'" or "'knowingly makes . . . a false record or statement material to a false or fraudulent claim.'" Owens, 612 F.3d at 728 (quoting 31 U.S.C. § 3729(a)(1)).

The FCA contains an enforcement mechanism known as the "qui tam" provision. See 31 U.S.C. § 3730 (b)-(d). A qui tam action is brought by a private party "in the name of the United States." Mann v. Heckler & Koch Defense, Inc., 630 F.3d 338, 343 (4th Cir. 2010). The FCA also contains a whistleblower provision, 31 U.S.C. § 3730(h), which "prevents the harassment, retaliation, or threatening of employees who assist in or bring qui tam actions." Zahodnick v. Int'l Bus. Machs. Corp., 135 F.3d 911, 914 (4th Cir. 1997).

The version of 31 U.S.C. § 3730(h) in effect at the time of the filing of Parks's Second Amended Complaint provided the following:

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

31 U.S.C. § 3730(h) (2006), amended 2009.[7] In order to defeat summary judgment on her FCA retaliation claim, Parks must "establish a genuine issue of fact showing [that] (1) [she] took

[7] The statute was amended in 2009 to add "contractor" and "agent" to "employee" in the list of potential FCA retaliation plaintiffs. That amendment does not impact this appeal.

acts in furtherance of an FCA suit; (2) [Alpharma] knew of those acts; and (3) [Alpharma] treated [her] adversely because of these acts." Owens, 612 F.3d at 735. All three factors must exist in order for Parks to prevail.

Alpharma argues that Parks did not make any of these three required showings. See Br. of Appellee 18-57. The district court held that Parks satisfied the first prong, but not the other two. Because we agree that Parks did not satisfy the second prong – that Alpharma knew that Parks took acts in furtherance of an FCA suit - we affirm on that ground alone.

The second prong of the FCA retaliation test, also known as the "notice" prong, is appropriately viewed from "the employer's perspective" and turns on whether "the employer is aware of the employee's conduct." Mann, 630 F.3d at 344. In that regard, this court has held that the employer must be "on notice that litigation is a reasonable possibility." Eberhardt v. Integrated Design & Constr., Inc., 167 F.3d 861, 868 (4th Cir. 1999).

In Eberhardt, the employee-relator's job description involved internal investigation of fraud against the government. 167 F.3d at 868. This court held that, because of the special nature of his position, Eberhardt could only bring an FCA retaliation action by showing that he "expressly stat[ed] an intention to bring a qui tam suit" or "by any action which a

factfinder reasonably could conclude would put the employer on notice that litigation is a reasonable possibility." Id.

Parks argues that the Eberhardt "notice" standard "is a slightly higher standard than the standard applicable in this case" and "does not apply in this case because [her] job duties at Alpharma never entailed investigating fraud." Br. of Appellant 35. She also argues that because the district court recognized that "internal reporting of allegedly fraudulent or false claims qualifies as activity protected by the whistleblower provisions of the FCA, . . . [it] implicitly found that Mrs. Parks's internal complaints to her superiors at Alpharma were identifiable as disclosures of fraud or falsity," thus satisfying the notice prong. Id. at 35-36 (internal quotation marks omitted). Both arguments lack merit.

First, in Eberhardt, this court explained that the employee-relator must show that his or her actions "let the employer know, regardless of whether the employee's job duties include investigating potential fraud, that litigation is a reasonable possibility." 167 F.3d at 868 (emphasis supplied). Eberhardt may have been held to a higher standard in that particular case, inasmuch as his job duties required that he make certain disclosures of internal fraud and falsity. But the distinction Parks attempts to make is factual, not legal. In applying the Eberhardt standard, we have a duty to make a "fact

specific inquiry" as to Alpharma's knowledge of Parks's activities and view them in the appropriate context. Hutchins v. Wilentz, Goldman & Spitzer, 253 F.3d 176, 189 (3d Cir. 2001). This inquiry does not, however, alter the legal framework described above.

Second, Parks appears to contend that, because the district court concluded that she satisfied the first prong of the FCA retaliation claim, it necessarily should have concluded that she satisfied the notice prong as well. In Mann, although this court stated that "[c]ombining the protected activity and notice elements is a perfectly reasonable approach when both elements are in dispute," it also cautioned against interpreting § 3730(h) "in a manner that would render some of its language meaningless." 630 F.3d at 344 (internal quotation marks omitted). We must, therefore, avoid collapsing the two prongs into the same analysis, and rather, separately address the question of whether Alpharma was on notice that FCA litigation was "a reasonable possibility." Eberhardt, 167 F.3d at 868; see also Hutchins, 253 F.3d at 188 (holding that the notice prong "requires the employee to put his employer on notice of the 'distinct possibility' of False Claims Act litigation"); United States ex rel. McKenzie v. BellSouth Telecomms., Inc., 123 F.3d 935, 944 (6th Cir. 1997) ("An employee must supply sufficient facts from which a reasonable jury could conclude

that the employee was discharged because of activities which gave the employer reason to believe that the employee was contemplating a qui tam action against it." (internal quotation marks omitted)).

Parks fails to satisfy her burden because she does not present sufficient evidence to show that Alpharma was on notice that FCA litigation was a reasonable possibility. She argues that she made "internal complaints that [we]re identifiable as disclosures of fraud or falsity to the employer," which were sufficient to "put [Alpharma] on notice of [her] protected activity." Br. of Appellant 30. According to Parks, these alleged "protected activit[ies]" include,

- "investigat[ing] and question[ing] some of Alpharma's illegal and promotional activities concerning Kadian," id. at 3;
- "complaining to her superiors at Alpharma that the [Kaplan Method] was 'off-label,'" id. at 16;
- "objecting to the proposed off-label [Coventry] presentation [on diversion]," id. at 20;
- "complain[ing] directly to Mr. LaFay about Alpharma's decision to bury the pharmacoeconomic results of the Switch Study," id. at 29;
- "complain[ing] directly to Mr. LaFay about . . . the internet surveillance study," id.; and

- "rais[ing] her concerns regarding the alcohol clinical trials [of the dose-dumping study] with Mr. Warner," id.

Nothing in Parks's proffered evidence, however, shows that anyone at Alpharma would have reasonably believed that she was contemplating or acting in furtherance of an FCA action. Indeed, Parks's complaints were clearly couched in terms of concerns and suggestions, not threats or warnings of FCA litigation. See Zahodnick, 135 F.3d at 914 (affirming summary judgment for the employers where employee "merely informed a supervisor of [a] problem," "never informed anyone that he was pursuing a qui tam action," and provided "no evidence that [the employers] were aware of [employee's] alleged protected activity"); see also Luckey v. Baxter Healthcare Corp., 183 F.3d 730, 733 (7th Cir. 1999) ("An employer is entitled to treat a suggestion for improvement as what it purports to be rather than as a precursor to litigation."); United States ex rel. Yesudian v. Howard Univ., 153 F.3d 731, 743 (D.C. Cir. 1998) ("Merely grumbling to the employer about . . . regulatory violations does not satisfy the requirement – just as it does not constitute protected activity in the first place.").

Furthermore, copious documentary evidence shows that Parks was an employee who was supportive and enthusiastic about promoting Kadian and appeasing Dr. Kaplan. It is clear that it was in Parks's best interest professionally to support and

promote the clinical studies about which she now complains. Even if we view Parks's complaints and objections in a vacuum, however – including her explicit use of the term "off-label" to her supervisors – there is no indication that such internal criticism would have put Alpharma on notice of a False Claims Act lawsuit, as required under Eberhardt and 31 U.S.C. § 3730. The FCA prohibits "false or fraudulent claim[s]" submitted to the government "for payment." See 31 U.S.C. § 3729(a). Here, there is absolutely no evidence that a physician wrote a prescription for Kadian, which was then submitted to the government for reimbursement, based on the Switch Study, Coventry presentation, dose-dumping study, or internet surveillance study. See Hopper v. Solvay Pharms., Inc. 588 F.3d 1318, 1326 (11th Cir. 2009) (affirming dismissal of FCA complaint where it failed to identify "a single physician who wrote a prescription with [] knowledge [that the cost of filling the prescription would be borne by the government]," "a single pharmacist who filled such a prescription," or "a single state healthcare program that submitted a claim for reimbursement to the federal government"); Parke-Davis, 147 F. Supp. 2d at 52 ("[An] alleged FCA violation arises – not from unlawful off-label marketing activity itself – but from the submission of Medicaid claims for uncovered off-label uses induced by Defendant's fraudulent conduct.").

Moreover, Parks failed to adduce any evidence that the off-label promotion would inevitably lead to such false submissions. Indeed, Parks offered no more than speculation, which at summary judgment, is insufficient. See Othentec Ltd. v. Phelan, 526 F.3d 135, 140 (4th Cir. 2008) (observing that non-moving party must come forward with more than "mere speculation or the building of one inference upon another" (internal quotation marks omitted)).

Accordingly, we hold that Parks did not satisfy the notice prong of her FCA retaliation prima facie claim, and we therefore affirm the district court on that ground.

IV.

For the foregoing reasons, the judgment of the district court is

AFFIRMED.