

# United States Court of Appeals For the First Circuit

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No. 16-1805

UNITED STATES ex rel. ALEX BOOKER and EDMUND HEBRON,

Relators, Appellants,

STATE OF CALIFORNIA; STATE OF COLORADO; STATE OF CONNECTICUT;  
STATE OF DELAWARE; STATE OF FLORIDA; STATE OF GEORGIA; STATE OF  
HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF LOUISIANA;  
STATE OF MARYLAND; STATE OF MICHIGAN; STATE OF MINNESOTA; STATE  
OF MONTANA; STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY; STATE  
OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH CAROLINA; STATE  
OF OKLAHOMA; STATE OF RHODE ISLAND; STATE OF TENNESSEE; STATE OF  
TEXAS; STATE OF WISCONSIN; COMMONWEALTH OF MASSACHUSETTS;  
COMMONWEALTH OF VIRGINIA; DISTRICT OF COLUMBIA,

Plaintiffs,

v.

PFIZER, INC.,

Defendant, Appellee.

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APPEAL FROM THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Douglas P. Woodlock, U.S. District Judge]

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Before

Lynch, Stahl, and Barron,  
Circuit Judges.

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Kevin J. Darken, with whom The Barry A. Cohen Legal Team,  
Thomas N. Burnham, and Burnham International Law Office were on  
brief, for appellants.

Kirsten V. Mayer, with whom Brien T. O'Connor, Emily J. Derr,

Nicholas S. Bradley, and Ropes & Gray LLP were on brief, for appellee.

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January 30, 2017

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**LYNCH, Circuit Judge.** On August 31, 2009, the pharmaceutical company Pfizer, Inc. settled various claims that it had violated the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 et seq., with the U.S. Department of Justice ("DOJ"). As part of that settlement, Pfizer entered into a Corporate Integrity Agreement ("CIA") with the U.S. Department of Health and Human Services ("HHS").

Less than a year after that settlement, relators Alex Booker and Edmund Hebron, two former Pfizer sales representatives, brought this qui tam action against Pfizer in federal district court, alleging it was on behalf of the United States, more than two dozen individual states, and the District of Columbia, and asserting that despite the settlement, Pfizer had continued to engage in conduct prohibited by the FCA and state analogues. None of the sovereigns elected to intervene.

Relators filed their original complaint on July 13, 2010 and amended it several times before the district court denied their motion for leave to file a sixth amended complaint. Primarily, they alleged that Pfizer had continued to knowingly induce third parties to file false claims for payment for Pfizer drugs with government programs like Medicaid by (1) marketing the drug Geodon for off-label uses, in violation of sections 331 and 355 of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq.; and (2) paying kickbacks to doctors to compensate them for

prescribing the drugs Geodon and Pristiq, in violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), (g).<sup>1</sup> Relators also alleged that Pfizer had violated the "reverse false claims" provision of the FCA, see 31 U.S.C. § 3729(a)(1)(G), by failing to pay the government money owed it under Pfizer's CIA with HHS. Finally, relators alleged that Pfizer had violated the FCA's anti-retaliation provision, see id. § 3730(h), by terminating Booker's employment on January 6, 2010, purportedly in response to his alleged whistleblowing activities.

All of these claims were resolved against relators, one on a motion to dismiss and the rest on summary judgment. On March 26, 2014, the district court granted Pfizer's motion to dismiss the claim under the reverse false claims provision (the "reverse FCA claim") but allowed relators to proceed to discovery (with limits) on the other claims. See U.S. ex rel. Booker v. Pfizer, Inc. ("Booker I"), 9 F. Supp. 3d 34, 50, 60-61 (D. Mass. 2014). On May 23, 2016, the district court granted Pfizer's motion for summary judgment on the remaining claims. See U.S. ex rel. Booker v. Pfizer, Inc. ("Booker II"), 188 F. Supp. 3d 122, 140 (D. Mass.

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<sup>1</sup> Off-label uses of a drug that are medically "essential" or recognized in certain medical compendia, for which Medicaid does reimburse, see 42 U.S.C. § 1396r-8(a)(3), (g)(1)(B)(i), (k)(6), are not at issue in this case. See U.S. ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 723 n.1 (1st Cir. 2007), abrogated on other grounds by Allison Engine v. U.S. ex rel. Sanders, 553 U.S. 662 (2008).

2016). Relators appeal the dismissal, the grant of summary judgment, and certain of the district court's intervening discovery rulings. We affirm the district court's merits decisions and find no error in its management of discovery.

We rely on the district court's two thorough opinions for a basic recounting of the case. See Booker I, 9 F. Supp. 3d 34; Booker II, 188 F. Supp. 3d 122. We give only that background information needed for this appeal.

## I. ANALYSIS

### A. Appeal from Dismissal of Reverse FCA Claim

#### 1. Appellate Jurisdiction

Pfizer wrongly suggests that we have no jurisdiction to review the district court's March 26, 2014 order dismissing relators' reverse FCA claim due to defects in relators' notice of appeal. See Fed. R. App. P. 3(c)(1)(B) (a "notice of appeal must[] designate the judgment, order, or part thereof being appealed"). Specifically, we reject the contention that there is no jurisdiction because relators' notice of appeal did not explicitly mention the dismissal order. While the notice did specify certain other orders issued by the district court, it also specified the court's May 26, 2016 final judgment disposing of the case, and "it has been uniformly held that a notice of appeal that designates the final judgment encompasses not only that judgment, but also all earlier interlocutory orders that merge in the judgment."

John's Insulation, Inc. v. L. Addison & Assocs., Inc., 156 F.3d 101, 105 (1st Cir. 1998); see also Ocasio-Hernández v. Fortuño-Burset, 777 F.3d 1, 6 n.12 (1st Cir. 2015).

## 2. Merits of Dismissal of Reverse FCA Claim

We affirm the district court's dismissal of relators' reverse FCA claim on de novo review, albeit on grounds different from those relied on by the district court.<sup>2</sup> See Otero v. Commonwealth of P.R. Indus. Comm'n, 441 F.3d 18, 20 (1st Cir. 2006). We take no position on whether the district court's reasoning was correct.

The reverse false claims provision of the FCA imposes liability on anyone who "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay . . . money . . . to the Government." 31 U.S.C. § 3729(a)(1)(G). The term "obligation" is defined by the statute as "an established duty,

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<sup>2</sup> The district court reasoned that relators failed to plead that Pfizer ever had an "obligation" to pay the government because they failed to plead that HHS exercised its right to demand payment under the CIA. Booker I, 9 F. Supp. 3d at 50. Relators insist that an "obligation" to pay the government arises under the CIA as soon as HHS is entitled to demand payment and that they pled that Pfizer had such an obligation by virtue of pleading that Pfizer failed to report a Reportable Event. They note that two district courts have come to this conclusion as to when an "obligation" arises under CIAs materially identical to the one at issue here. See Ruscher v. Omnicare Inc., No. 4:08-CV-3396, 2014 WL 4388726, at \*5-6 (S.D. Tex. Sept. 5, 2014); U.S. ex rel. Boise v. Cephalon, Inc., No. 08-287, 2015 WL 4461793, at \*3-7 (E.D. Pa. July 21, 2015).

whether or not fixed, arising from an express or implied contractual . . . relationship." Id. § 3729(b)(3).

Relators' reverse FCA claim was predicated on Pfizer's alleged breach of its obligations under its August 31, 2009 CIA with HHS. The CIA imposed on Pfizer an ongoing duty to report its "probable" violations of the FCA to HHS. Specifically, the CIA defined as a "Reportable Event," inter alia, "a matter that a reasonable person would consider a probable violation of . . . laws applicable to any FDA requirements relating to the promotion of Government Reimbursed Products." And the CIA provided that "[i]f Pfizer determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) . . . that there is a Reportable Event, Pfizer shall notify [HHS] . . . within 30 days after making the determination."<sup>3</sup> Elsewhere, the CIA stated that Pfizer's failure to meet the "obligations . . . set forth [above] may lead to the imposition of . . . [a] Stipulated Penalty of \$2,500 . . . for each day Pfizer" is in breach. The CIA explained that, if HHS finds "that Pfizer has failed to comply with [the aforementioned] obligations," and if HHS thereafter "determin[es] that Stipulated Penalties are appropriate, [HHS] shall notify Pfizer of . . .

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<sup>3</sup> The CIA also provided that "Pfizer shall submit to [HHS] annually a report [that] shall include," inter alia, "a summary of Reportable Events . . . identified."

[HHS's] exercise of its contractual right to demand payment of the Stipulated Penalties."

In their complaint, relators allege that a January 5, 2010 email sent by Booker to Pfizer's Corporate Compliance Department, purportedly claiming that Booker's manager was instructing his subordinates to engage in off-label promotion, constituted a "Reportable Event" under the CIA. Because Pfizer did not report this email to HHS, relators allege, Pfizer illegally avoided its "obligation" to pay the CIA's "stipulated penalt[y]" of \$2,500 per day for failure to report a "Reportable Event."

Pfizer argues -- as it did before the district court -- that relators fail to state a claim for reverse FCA liability because Booker's email to the Corporate Compliance Department did not constitute a "Reportable Event." Pfizer points out that the "CIA does not require Pfizer to report all complaints" it receives. Under the CIA, conduct becomes a "Reportable Event" only "if Pfizer determines," after a chance to investigate, that the conduct is a "probable violation" of a specific class of laws. As Pfizer explains, nowhere in their much amended complaint do relators allege that Pfizer ever determined Booker's complaint to be in any way credible and therefore a "Reportable Event."<sup>4</sup>

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<sup>4</sup> Nor did relators seek reconsideration after discovery.



On the record in this case we affirm. We do not decide if, under the CIA, Pfizer's authority to determine whether a "Reportable Event" occurred is subject to an implicit reasonableness limitation that prevents Pfizer from shutting its eyes to conduct that it abides but that a "reasonable person" would think is a "probable violation" of relevant law. Relators did not assert before the district court, nor do they assert on appeal, that the agreement should be construed that way and that Pfizer acted unreasonably in not determining that Booker's complaint constituted a "Reportable Event," so the point is waived. As relators fail to allege that Pfizer determined that a "Reportable Event" occurred, their complaint fails to state a claim for relief. We affirm the dismissal on that basis.

B. Appeal from Summary Judgment on the Remaining FCA Claims

Relators next appeal the district court's grant of summary judgment for Pfizer on their off-label promotion and retaliation claims under the FCA.<sup>5</sup> After reviewing those decisions de novo, "drawing all reasonable inferences in [relators'] favor," Feliciano de la Cruz v. El Conquistador Resort & Country Club, 218 F.3d 1, 5 (1st Cir. 2000), we affirm both.

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<sup>5</sup> Relators do not directly appeal the grant of summary judgment on their AKS-based FCA claim. Instead, they bring challenges to some of the district court's discovery rulings that were germane to that claim. For reasons we explain later, those challenges fail.

1. Off-Label Promotion FCA Claim

Relators sought to prove that after Pfizer resolved its FCA liability with the DOJ in 2009 for, inter alia, knowingly inducing false claims through off-label promotion in violation of 31 U.S.C. § 3729(a)(1)(A), Pfizer continued to induce false claims by promoting Geodon for three off-label uses.<sup>6</sup> Those three uses were (1) as a treatment for children and adolescents, (2) as a bipolar maintenance monotherapy drug, and (3) as a treatment for any condition at excessive dosages. Without deciding whether relators had provided sufficient evidence of continued off-label promotion to survive summary judgment, see Booker II, 188 F. Supp. 3d at 133 n.4, the district court concluded that relators' proffer was fatally devoid of evidence that an "actual false claim" had resulted from any such promotion, id. at 129. We agree.

It is well settled that "[e]vidence of an actual false claim is 'the sine qua non of a False Claims Act violation.'" U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 225 (1st Cir. 2004) (citation omitted), abrogated on other grounds by Allison Engine, 553 U.S. 662. That is, even when a relator can prove that a defendant engaged in "fraudulent conduct affecting

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<sup>6</sup> Geodon is approved by the Food and Drug Administration ("FDA") pursuant to the FDCA as a treatment for "schizophrenia, as monotherapy for the acute treatment of bipolar manic or mixed episodes, and as an adjunct to lithium or valproate for the maintenance treatment of bipolar disorder."

the government," FCA liability attaches only if that conduct resulted in the filing of a false claim for payment from the government. Rost, 507 F.3d at 727. Because claims of fraud are involved, even at the pleading stage relators are required under Fed. R. Civ. P. 9(b) "to set forth with particularity [at least] the who, what, when, where, and how of" an actual false claim alleged to have been filed because of the defendant's actions. Lawton ex rel. U.S. v. Takeda Pharm. Co., 842 F.3d 125, 130 (1st Cir. 2016) (citations omitted). And at the summary judgment stage, relators must produce competent evidence of an actual false claim made to the government.

When FCA liability is predicated on a defendant's alleged off-label promotion of drugs to medical providers, that generally means the "specific medical provider[] who allegedly submitted [the] false claim[], the rough time period[], location[], and amount[] of the claim[], and the specific government program[] to which the claim[] [was] made." Id. at 131 (citations omitted). This court has made clear that where relators offer only "aggregate expenditure data by the government for" the drug at issue, "with[out] identify[ing] specific entities who submitted claims . . . much less times, amounts, and circumstances," their claim falls "far short." U.S. ex rel. Ge v. Takeda Pharm. Co., Ltd., 737 F.3d 116, 121, 124 (1st Cir. 2013).

Relators argue that this is an impossible standard for qui tam relators to meet and that we should change our law. We disagree.

After six years of litigation, relators' only proffered evidence of actual false claims was aggregate data reflecting the amount of money expended by Medicaid for pediatric Geodon prescriptions (an off-label use) between January 2008 and March 2012, according to the National Disease and Therapeutic Index's survey research. See Booker II, 188 F. Supp. 3d at 129-30. We have previously held comparable data insufficient on its own to support an FCA claim, even at the motion to dismiss stage. See, e.g., Lawton, 842 F.3d at 132; Ge, 737 F.3d at 124; cf. U.S. ex rel. Kelly v. Novartis Pharms. Corp., 827 F.3d 5, 13-14 (1st Cir. 2016) ("Merely alleging that a scheme was wide-ranging [and] that a [false] claim was presumably submitted . . . will not suffice.").

Ultimately, "summary judgment . . . is 'the put up or shut up moment in litigation,'" and a relator certainly must make a greater showing than is required in a pleading in order "to get in front of a jury." Jakobiec v. Merrill Lynch Life Ins. Co., 711 F.3d 217, 226 (1st Cir. 2013) (quoting Goodman v. Nat'l Sec. Agency, Inc., 621 F.3d 651, 654 (7th Cir. 2010); see also U.S. ex rel. Quinn v. Omnicare Inc., 382 F.3d 432, 440 (3d Cir. 2004) ("Without proof of an actual claim, there is no issue of material fact to be decided by a jury. [Relator's] theory that the claims

'must have been' submitted cannot survive a motion for summary judgment.").

Relators rely on this court's Neurontin cases for the proposition that their aggregate data is sufficient for them to establish that false claims were submitted. See In re Neurontin Mktg. & Sales Practices Litig. (Harden), 712 F.3d 60 (1st Cir. 2013), cert. denied, 134 S. Ct. 786 (Mem.) (2013) (denying certiorari in all three Neurontin cases); In re Neurontin Mktg. & Sales Practices Litig. (Aetna), 712 F.3d 51 (1st Cir. 2013); In re Neurontin Mktg. & Sales Practices Litig. (Kaiser), 712 F.3d 21 (1st Cir. 2013). But in those cases, we held that plaintiffs could use aggregate data together with strong circumstantial evidence to overcome summary judgment on the distinct issue of whether there was a causal link between fraudulent marketing and demonstrated off-label prescriptions in the distinct context of a civil RICO case -- not that such proof could be used to demonstrate the existence of false claims in an FCA case. See, e.g., Harden, 712 F.3d at 68. Relators' data is woefully inadequate to support their FCA claim.<sup>7</sup> We affirm entry of summary judgment for Pfizer on this core FCA argument.

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<sup>7</sup> As the district court noted, relators' proffer may have a further shortcoming. See Booker II, 188 F. Supp. 3d at 130-31. Pfizer asserts, and relators do not dispute, that several state Medicaid programs do reimburse for the off-label uses of Geodon at issue here. Id. at 131. Thus, even accepting relators' aggregate data as proof that claims for reimbursement for off-label uses of

## 2. Booker's FCA Employment Retaliation Claim

Relators also contend that Pfizer terminated Booker's employment on January 6, 2010 in retaliation for two instances in which Booker complained to his superiors that the company was continuing to promote Geodon for off-label uses after the settlement.

Under the FCA's anti-retaliation provision, an employer is prohibited from retaliating against an employee for any "lawful acts done . . . in furtherance of an [FCA] action . . . or other efforts to stop . . . violations of [the FCA]." 31 U.S.C. § 3730(h)(1). We have defined the type of conduct protected under this provision as "limited to activities that 'reasonably could lead' to an FCA action; in other words, investigations, inquiries, testimonies or other activities that concern the employer's

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Geodon were filed with a Medicaid program, relators' inability to show that any such claim was filed in any non-reimbursing state might render them unable to demonstrate the falsity of any claim filed. Id.; see U.S. ex rel. Banigan v. Organon USA Inc., 883 F. Supp. 2d 277, 294 (D. Mass. 2012) ("[I]f a state Medicaid program chooses to reimburse a claim for a drug prescribed for off-label use, then that claim is not 'false or fraudulent,' and [FCA] liability cannot therefore attach [upon] reimbursement."). However, whether state Medicaid programs actually have the discretion to reimburse for off-label uses of a drug under the Medicaid statute "is up for debate." Id. Because we find that relators' claim easily fails on other grounds, we leave this issue for another day.

knowing submission of false or fraudulent claims for payment to the government."<sup>8</sup> Karvelas, 360 F.3d at 237 (citation omitted).

Relators rely on Booker's deposition testimony about two instances in which Booker objected to directions from his supervisor, District Manager Jon Twidwell. Those directions, they say, were that Booker and other sales representatives promote sales based on Geodon's effect on certain conditions, such as depression and overt anger, though Geodon is not FDA-approved for those uses. Booker II, 188 F. Supp. 3d at 139.

We affirm the grant of summary judgment for Pfizer on this claim, but on different grounds than those relied on by the district court.<sup>9</sup> See Tutor Perini Corp. v. Banc of Am. Sec. LLC,

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<sup>8</sup> While Karvelas interpreted this provision before it was amended to refer to "other efforts to stop . . . violations of [the FCA]," rather than only "acts done . . . in furtherance of an [FCA] action," see Pub. L. No. 111-203, § 1079A(c), 124 Stat. 1376, 2079 (2010), that addition has no effect on Karvelas's application to this case. Courts have understood the amendment as having clarified that the provision covers not only steps in the litigation process, such as investigating or testifying, but also measures, such as internal reporting or objecting to employer directives, which might not be taken in direct furtherance of an actual lawsuit. See, e.g., Halasa v. ITT Educ. Servs., Inc., 690 F.3d 844, 847-48 (7th Cir. 2012); Miller v. Abbott Labs., 648 F. App'x 555, 560 (6th Cir. 2016) (unpublished opinion). Karvelas construed the pre-amendment provision as covering such activities. See 360 F.3d at 238. And the amended provision maintains the requirement, noted in Karvelas, that even those activities must pertain to violations of the FCA, meaning the submission of false claims. See id. at 237.

<sup>9</sup> The court concluded that the undisputed facts were that Booker had not in fact objected to off-label promotion. Booker II, 188 F. Supp. 3d at 139. The court reasoned that the supposed

842 F.3d 71, 84 (1st Cir. 2016) ("[W]e may affirm the summary-judgment holding on any grounds supported by the record, even if not relied on by the district judge."). Even accepting that Booker's objections to the directions were concerned with off-label promotion, such objections, without more, are not enough under Karvelas. See 360 F.3d at 237. Evidence that an employee objected to or reported receipt of instructions to promote a drug's off-label use, absent any evidence that those objections or reports concerned FCA-violating activity such as the submission of false claims, cannot show at the summary judgment stage that the employee engaged in conduct protected by the FCA.

As we stated in Karvelas, the FCA protects only conduct that concerns the "knowing submission of false . . . claims" because only such conduct "'reasonably could lead' to an FCA action." 360 F.3d at 237; see also Rost, 507 F.3d at 727 ("FCA liability does not attach to violations of federal law[s] or

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"off-label conditions" at the center of Booker's protests -- such as depression and overt anger -- were actually either symptoms of conditions for which Geodon is an on-label treatment, like schizophrenia, or side effects associated with such on-label uses of the drug. Id. Thus, the court explained, when Booker objected to the directive to discuss them, he was objecting to a particular manner of purely on-label promotion, which, bearing no connection to the submission of false claims, could not reasonably lead to an FCA action. Id. at 140; see also Karvelas, 360 F.3d at 237. Relators say there is a dispute of material fact about this issue. Our ruling renders it immaterial.



regulations, such as marketing of drugs in violation of the FDCA, that are independent of any false claim [for payment filed with the government]."). Thus, we have rejected, at even the motion to dismiss stage, an FCA retaliation claim to the extent that it was based on an employee's allegations that he had reported "to his superiors" that his employer was "fail[ing] to meet regulatory standards . . . required for reimbursement by Medicare and Medicaid." Karvelas, 360 F.3d at 237. We held that the employee had not alleged protected conduct because he had alleged only that he reported "regulatory failures but . . . not [that he] investigat[ed] or report[ed] . . . false . . . claims knowingly submitted to the government." Id. We reasoned that "[a]lthough '[c]orrecting regulatory problems may be a laudable goal,'" those problems were "not actionable under the FCA in the absence of actual fraudulent conduct," and so reporting them fell outside the purview of the FCA's anti-retaliation provision. Id. (second alteration in original) (citations omitted). Other circuits agree. See, e.g., McKenzie v. BellSouth Telecomms., Inc., 219 F.3d 508, 516 (6th Cir. 2000) ("Although internal reporting may constitute protected activity, the internal reports must allege fraud on the government."); U.S. ex rel. Yesudian v. Howard Univ., 153 F.3d 731, 740 (D.C. Cir. 1998) ("[It is not enough that] an employee[] investigat[ed] . . . his employer's non-compliance with federal or state regulations. . . . [T]he [employee's]

investigation must concern 'false or fraudulent' claims." (citations omitted); U.S. ex rel. Hopper v. Anton, 91 F.3d 1261, 1269 (9th Cir. 1996) (rejecting a retaliation claim where the relator "was not investigating fraud" or "trying to recover money for the government" but "was merely attempting to get [her employer] to comply with Federal and State regulations").

Relators do not assert that the disagreements between Booker and his supervisor concerned the submission of false claims. They thus have no trial-worthy claim of retaliation under the FCA.<sup>10</sup>

### C. Discovery Rulings

Relators challenge the district court's rulings on their two motions to compel the production of documents and their motion to defer summary judgment and compel further production under Fed. R. Civ. P. 56(d). We review a district court's denial of both

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<sup>10</sup> Because relators lack evidence that Booker engaged in FCA-protected conduct, we do not reach Pfizer's alternative argument that relators' retaliation claim fails, in any event, because they lack evidence that "Pfizer's proffered nonretaliatory reason for firing Booker -- his poor sales performance -- was a pretext." Booker II, 188 F. Supp. 3d at 140; see also Harrington v. Aggregate Indus. Ne. Region, Inc., 668 F.3d 25, 31 (1st Cir. 2012). However, the ample evidence that Booker had a long history of negative performance reviews, had been placed on a series of remedial performance plans, and had been notified of his failure to comply with the requirements of his "Final" plan weeks before his termination -- coupled with relators' failure to argue this point in their opening brief -- further supports our conclusion that relators' retaliation claim is without merit.

types of motions for abuse of discretion. See Wells Real Estate Inv. Tr. II, Inc. v. Chardon/Hato Rey P'ship, S.E., 615 F.3d 45, 58 (1st Cir. 2010) (motion to compel); Hicks v. Johnson, 755 F.3d 738, 743 (1st Cir. 2014) (Rule 56(d) motion). We intervene "only upon a clear showing of manifest injustice, that is, where the [district court's decision] was plainly wrong and resulted in substantial prejudice." Bogan v. City of Bos., 489 F.3d 417, 423 (1st Cir. 2007) (citation omitted). We find no error.

1. Motions to Compel

Relators challenge on appeal the district court's handling of their two motions to compel in no more than a perfunctory one-paragraph section of their brief. They argue that the court denied both motions "wholesale," "with the sole exception of ordering Pfizer to produce" one particular class of documents. The record flatly refutes the suggestion that the district court did not pay appropriate attention to relators' requests. The district court was admirably attentive to the many issues in this case. Relators rely on Danny B. ex rel. Elliott v. Raimondo, 784 F.3d 825 (1st Cir. 2015), and cite its statement that "a district court may not impose discovery restrictions that preclude a suitor from the legitimate pursuit of evidence supporting her cause of action." Id. at 835.

Raimondo is inapposite. There, we found that the district court had abused its discretion when it upheld a

magistrate judge's protective order, which categorically precluded the plaintiffs from seeking "all policy or custom discovery." Id. at 837. That suit was one "to impose liability upon official-capacity state defendants under section 1983," and "[i]n such a suit, it is black letter law that the plaintiffs must prove that a policy or custom of the State contributed to the alleged violations of federal law in order to prevail." Id. at 834. Thus, the district court had abused its discretion because it barred the plaintiffs from conducting any discovery germane to an essential element of their claim. Not so here.

## 2. Rule 56(d) Motion

Relators also challenge the district court's denial of their Rule 56(d) motion to defer summary judgment on their AKS-based FCA claim until Pfizer produced a subset of the documents relators had sought in their second motion to compel. We put aside possible waiver by relators for failure to develop any legal argument on appeal and find no error.

"Rule 56(d) relief is not to be granted as a matter of course," and a court "is entitled to refuse a Rule 56(d) motion if it concludes that the [movant] is unlikely to garner useful evidence from supplemental discovery." Hicks, 755 F.3d at 743. Relators were unable to uncover evidence supporting any of the possible bases for their kickback claim after six years of investigating. See Booker II, 188 F. Supp. 3d at 133-34. And a

full year after the court denied their second motion to compel but invited them to proffer further support for their requests at the summary judgment stage, the district court found that relators could muster only "an anecdotal report of possibly coincidental changes in prescription trends" to justify their Rule 56(d) motion. Id. at 135 n.6. We cannot say that the court was "plainly wrong" to conclude that further discovery would likely be fruitless. See Bogan, 489 F.3d at 423.

## II. CONCLUSION

The district court reached the proper outcome as to each of the merits issues before us on appeal, and we find no abuse of discretion in its management of discovery. We affirm the judgment in full. Costs are awarded to Pfizer.