# **United States Court of Appeals**For the First Circuit

No. 17-1610

THOMAS GUILFOILE,

Plaintiff, Appellant,

v.

JOHN M. SHIELDS, SR.; SHIELDS PHARMACY, LLC, d/b/a Shields Health Solutions; UMASS MEMORIAL SHIELDS PHARMACY, LLC, d/b/a Shields Health Solutions; SHIELDS PHARMACY EQUITY, LLC, d/b/a Shields Health Solutions; SHIELDS SPECIALTY PHARMACY HOLDINGS, LLC, d/b/a Shields Health Solutions,

Defendants, Appellees.

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

[Hon. Denise J. Casper, U.S. District Judge]

Before

Howard, <u>Chief Judge</u>, Lipez and Barron, Circuit Judges.

Paul W. Mollica, with whom Tammy T. Marzigliano and Outten & Golden LLP were on brief, for appellant.

Brian J. Leske for appellees.

Michael J. Sullivan and Ashcroft Law Firm, LLC on brief for appellee John M. Shields.

<u>Walter B. Prince</u>, <u>William A. Worth</u>, and <u>Prince Lobel Tye LLP</u> on brief for appellees Shields Pharmacy, LLC, and Shields Pharmacy Equity, LLC.

<u>David C. Casey</u>, <u>Stephen T. Melnick</u>, and <u>Littler Mendelson PC</u> on brief for appellees UMass Memorial Shields Pharmacy, LLC, and Shields Specialty Pharmacy Holdings, LLC.

January 15, 2019

Claims Act, appellant Thomas Guilfoile claims he was fired from his job in retaliation for accusing his employer of violating the Anti-Kickback Statute and making false representations in customer contracts. See 31 U.S.C. § 3730(h); 42 U.S.C. § 1320a-7b(b). The district court dismissed his complaint on the ground that Guilfoile did not allege sufficient facts to show he was engaged in protected conduct within the meaning of the retaliation provision of the False Claims Act. After careful review of the complaint and the law, we affirm as to the contractual language claim but vacate and remand as to the claim involving the Anti-Kickback Statute.

I.

# A. Factual Background

Because this appeal follows the grant of a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), we recite the facts as alleged in the amended complaint. See Davis v. Coakley, 802 F.3d 128, 130 (1st Cir. 2015). We include only those facts relevant to the issues on appeal.

Appellant Guilfoile is a seasoned management professional with 30 years of finance and operations experience. Appellee John Shields, Guilfoile's employer during the period relevant to this case, is the CEO of a collection of health care LLCs, joint ventures, and holding companies that operate in concert as a single integrated entity (the "Integrated Entity"). The

component businesses of the Integrated Entity include appellees Shields Pharmacy, LLC; UMass Memorial Shields Pharmacy, LLC; Shields Pharmacy Equity, LLC; and Shields Specialty Pharmacy Holdings, LLC.<sup>1</sup>

The Integrated Entity partners with hospitals to provide specialty pharmacy services for chronically ill patients by either operating a pharmacy directly in the hospital or by filling specialty prescriptions through an off-site location. The Integrated Entity processes the prescriptions, bills the patient's insurance, provides patients with financial advice, and follows up with patients to ensure their adherence to complex medication regimens. The Integrated Entity regularly bills federal insurance programs, including Medicaid and Medicare, for the services it provides to patients covered by those programs. As a secondary line of business, the Integrated Entity also runs home infusion and high-risk care management programs.

After years of providing free business advice to his long-time friend and neighbor Shields, Guilfoile began to consult for the Integrated Entity in April 2013 and officially joined the Integrated Entity full-time as president in August of that year.

<sup>&</sup>lt;sup>1</sup> All four component corporations are closely-held corporations with a shared principal place of business at an office in Quincy, Massachusetts. Two of the corporations are incorporated in Massachusetts and two are incorporated in Delaware. Shields is the sole manager registered with the Secretary of the Commonwealth of Massachusetts for all four corporations.

Guilfoile's employment contract included terms governing salary, bonuses, an equity stake in the Integrated Entity's joint ventures, an equity vesting schedule, and protocols in the event of termination. Shields was Guilfoile's immediate supervisor. The complaint alleges that during Guilfoile's tenure, Shields Specialty Pharmacy Holdings and UMass Memorial Shields Pharmacy had boards of directors composed of Shields, Guilfoile, and the same two other individuals.<sup>2</sup>

Under Guilfoile's leadership, the Integrated Entity grew from a start-up to a successful operation generating millions of dollars in profit. The Integrated Entity enjoyed overwhelmingly positive feedback from patients, providers, and employees, and Guilfoile's leadership was appreciated by Shields and the Integrated Entity.

However, in the fall of 2015, Guilfoile became concerned that the Integrated Entity was violating the law. At that time, he learned that Shields had previously entered into a contract on behalf of the Integrated Entity with Michael Greene, Shields's long-time friend and a consultant whom several New Jersey hospitals

<sup>&</sup>lt;sup>2</sup> The complaint does not shed much further light on the Integrated Entity's management structure. For ease of reference, we join the parties and refer to the two boards of directors identified in the complaint as "the Board."

<sup>&</sup>lt;sup>3</sup> The pleadings, briefs, and the district court's order sometimes spell the consultant's surname as "Green," but we follow the spelling suggested by appellant and supported by the record.

paid for financial advice. The contract obligated the Integrated Entity to, among other things, pay Greene's consulting firm, the Ayrault Group, \$35,000 per quarter for each hospital contract that Greene successfully referred to the Integrated specifically targeting two hospitals that Greene was working for as a paid consultant: Newark Beth Israel Medical Center ("NBIMC") and University Hospital ("University"). The Integrated Entity, with assistance from Greene, eventually entered into contracts for specialty pharmacy services with both NBIMC and University, and the Integrated Entity paid Greene "referral fees." Guilfoile believed that these payments "had improperly induced [Greene] to steer [the] hospital contracts to the Integrated Entity."

Guilfoile conferred with the Integrated Entity's counsel, who agreed that Guilfoile had valid concerns about the contract with Greene. Guilfoile notified Shields that he believed the contract violated the federal Anti-Kickback Statute because the Integrated Entity had paid Greene to secure contracts with hospitals that would result in the Integrated Entity making claims for payment to federal insurance programs. Such payments are prohibited by the statute, as explained in greater detail below. Guilfoile was especially concerned about the implications of the kickback scheme for the contract with University, which he believed was government owned.

At Guilfoile's insistence, Shields ultimately approached Greene to discuss voiding Greene's contract with the Integrated Entity and obtaining refunds of any payments to the Ayrault Group. After an apparent negotiation, Shields revealed to Guilfoile that Greene agreed to waive payments yet to be made for the University referral but refused to return the money that the Integrated Entity had already paid for the NBIMC referral. Guilfoile believed that by letting the NBIMC payment stand, the Integrated Entity still may have violated the Anti-Kickback Statute. He therefore urged Shields to reveal the matter to the Board and offered to make the disclosure jointly. Shields refused.

In December 2015, Guilfoile learned that the contracts the Integrated Entity had used to form partnerships with hospitals contained a false representation that the Integrated Entity maintained "a fully staffed 24/7 [c]all [c]enter in Quincy, Massachusetts." The Integrated Entity at the time did not have such а center.4 Guilfoile believed that making false representations to government-owned hospitals, like University, about medication management services for chronically ill patients with serious medical conditions was contract fraud and posed a serious threat to public health and safety.

<sup>&</sup>lt;sup>4</sup> The complaint is unclear as to whether the Integrated Entity operated a call center that did not conform with the description in the contracts, or if the Integrated Entity did not operate a call center at all.

Despite Guilfoile's insistence that the Integrated Entity either amend the contracts to remove the representation or create a fully-staffed 24/7 call center, Shields refused to take action or notify the Board. Instead, Shields suggested that the Integrated Entity should address the issue only if a customer complained about the breach. In an effort to bring the Integrated Entity into compliance with the contractual language, Guilfoile alerted the Human Resources department and the Director of Operations that they should prepare to hire enough staff to operate a 24/7 call center.

On December 22, 2015, Shields asked Guilfoile to come to his home office, where Shields expressed his concern about Guilfoile "going over his head" and "airing his dirty laundry" to the Board. Shields told Guilfoile that he viewed the Board as a "third rail" -- i.e., an entity that should be approached with caution -- to which Guilfoile was getting too close. Shields also explained that he felt he "had to protect his interests and his family" and that he could not risk a vote by the Board against him. After Guilfoile rejected Shields's suggestion that the two of them consider "parting ways," the meeting ended without a concrete resolution. Shields stated that he would give the matter additional thought.

A week later, on December 28, Shields terminated Guilfoile's employment in a phone call without further

explanation. The following day, Shields emailed Guilfoile to confirm that his employment was terminated. Shields did not provide any reason for the termination and did not refer to Guilfoile's performance or possible misconduct as a basis for the termination. Guilfoile then received a written notice stating that his termination was retroactive to December 22. The letter did not state that he was being terminated for cause.

After his termination, Guilfoile notified the Board that Shields had terminated him because he feared that Guilfoile would report the suspected violations of law to the Board. Guilfoile subsequently forwarded a letter to the Board memorializing his concerns. Following these disclosures, Shields made repeated threats to file suit against Guilfoile for defamation and tortious interference, which he in fact subsequently did. On February 26, 2016, Guilfoile received a letter from the Integrated Entity discussing its purported right to repurchase Guilfoile's vested equity for a total of \$15. The letter stated, for the first time, that Guilfoile had been "terminated for cause."

## B. Procedural Background

On April 1, 2016, Guilfoile filed this action against the Integrated Entity and Shields alleging "whistleblower retaliation" in violation of the False Claims Act and a variety of state law employment, wage, contract, and tort claims. In the operative amended complaint ("the complaint"), filed after

defendants filed motions to dismiss, Guilfoile alleges that the Integrated Entity retaliated against him for his "efforts to stop violations of the [False Claims Act]," specifically his "disclosures . . . related to the kickbacks [the Integrated Entity] paid Mr. Green[e] in exchange for referrals of federally insured patients, and disclosures related to contracts the Integrated Entity entered into with government-owned hospitals even though the Integrated Entity knew the contracts included fraudulent terms."

Regarding the payments to the Ayrault Group, the complaint alleges that Guilfoile reasonably believed the payments to be "violations of the [Anti-Kickback Statute], a per se violation of the [False Claims Act], resulting in the submission of fraudulent claims to the government," and that "[t]he Integrated Entity violated the [Anti-Kickback Statute] and the [False Claims Act] by willfully paying remuneration to induce a person [Greene] to refer patients for the furnishing of a service for which the Integrated Entity knew payment would be made under federal health care programs." Finally, the complaint alleges that the Integrated Entity retaliated against Guilfoile by terminating his employment, "threatening to sue him, fabricating an after-the-fact contention as to 'cause,' attempting to repurchase his equity for the amount

of \$15, and then making good on their threat to sue him after he instituted this law suit." $^5$ 

Following oral argument on defendants' motions dismiss, Guilfoile requested leave to file a memorandum "in legal authority and factual allegations [d]efendants raised for the first time during oral argument." The last sentence of the brief accompanying the request stated, "If this [c]ourt determines . . . that the present [c]omplaint does not adequately plead a cause of action under the anti-retaliation provision of the [False Claims Act], plaintiff respectfully requests that the [c]ourt allow him the opportunity to file a second amended complaint alleging additional facts, like those set forth in this memorandum and supporting affidavit." Guilfoile's "supporting affidavit" alleged additional facts concerning the Integrated Entity's business, Greene's role in recommending the Integrated Entity to the hospitals for the provision of pharmacy services, and the nature of the 24/7 call center service.

In granting the motions to dismiss, the district court determined that Guilfoile had failed to adequately plead that he was engaged in protected conduct, the first element of a False

<sup>&</sup>lt;sup>5</sup> The complaint alleges that "four days after Mr. Guilfoile initiated this action in federal court . . . Mr. Shields filed suit against [him] in state court, bringing claims for defamation and tortious interference."

Claims Act retaliation claim. The court therefore dismissed the retaliation count without analyzing the other elements of the then declined exercise claim. court. to supplemental jurisdiction over the state law claims and dismissed them without prejudice. In a footnote, the court granted in part and denied in part Guilfoile's request to provide a response to defendants' purportedly new theories and factual allegations presented at oral argument. The court stated that it had considered his briefing as to the legal authority first raised at oral argument, but had not considered factual assertions outside the complaint, presumably including the factual assertions in the "supporting affidavit." The court did not respond to Guilfoile's suggestion in his motion that he be allowed to file a second amended complaint if the court found the operative complaint lacking.

Guilfoile subsequently filed a "Motion to Vacate Judgment and For Leave to Amend the Complaint" pursuant to Federal Rules of Civil Procedure 59(e) and 15(a). After the district court denied the motion, Guilfoile timely appealed both the dismissal of his complaint and the denial of his post-judgment motion.

II.

# A. Standard of Review

We review de novo a district court's grant of a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6).

Haley v. City of Boston, 657 F.3d 39, 46 (1st Cir. 2011). We must

evaluate whether the complaint adequately pleads facts that "state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). In performing this evaluation, we "assume the truth of all well-pleaded facts and give the plaintiff the benefit of all reasonable inferences therefrom." Thomas v. Rhode Island, 542 F.3d 944, 948 (1st Cir. 2008). However, we do not "draw unreasonable inferences or credit bald assertions [or] empty conclusions." Theriault v. Genesis HealthCare LLC, 890 F.3d 342, 348 (1st Cir. 2018) (alteration in original) (internal quotation marks omitted). A suit is properly dismissed "if the complaint does not set forth factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory." U.S. ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 384 (1st Cir. 2011) (emphasis added) (internal quotation marks omitted). Before reviewing the sufficiency of the complaint under this standard, we provide a brief overview of the pertinent statutes.

#### B. False Claims Act

The False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, prohibits, in relevant part, any person from "knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim" to the federal government. 31 U.S.C. § 3729(a)(1)(A) (emphasis added); see Universal Health Servs., Inc. v. United

States ex rel. Escobar, 136 S. Ct. 1989, 1996 (2016) (explaining that the FCA is focused "on those who present or directly induce the submission of false or fraudulent claims"). For purposes of the statute, "a 'claim' . . . includes direct requests to the [g]overnment for payment as well as reimbursement requests made to the recipients of federal funds under federal benefit programs."

Escobar, 136 S. Ct. at 1996 (citing 31 U.S.C. § 3729(b)(2)(A)). The FCA includes a scienter requirement that the false claim be submitted "knowingly." 31 U.S.C. § 3729(a)(1), (b)(1). A "nonsubmitting" entity that knowingly causes the submission of a false claim may be liable under the FCA even if the entity directly submitting the claim to the government lacks the requisite mental state. See Hutcheson, 647 F.3d at 389-90.

The FCA is also "subject to a judicially-imposed requirement that the allegedly false claim . . . be material."

<u>United States ex rel. Loughren v. Unum Grp.</u>, 613 F.3d 300, 307

(1st Cir. 2010).<sup>7</sup> The falsity of a claim is "material" if it has

<sup>&</sup>lt;sup>6</sup> The FCA does not define "false or fraudulent." However, the Supreme Court has held that the phrase encompasses "misrepresentations by omission" in addition to "express falsehoods." Escobar, 136 S. Ct. at 1999.

The FCA defines and uses "material." See 31 U.S.C. § 3729(a)(1)(B), (G), (b)(4). However, § 3729(a)(1)(A), which prohibits the knowing submission of false claims, does not contain the term. We have therefore described the "materiality" requirement in regard to § 3729(a)(1)(A) as judicially created because it derives from a general reading of materiality into all sections of the FCA rather than from the statutory language. See

"a natural tendency to influence or was capable of influencing the [government]'s decision" whether to pay or reimburse the claim.

Id. The Supreme Court has emphasized that the FCA's "materiality standard is demanding," and a plaintiff directly alleging the submission of a false claim<sup>8</sup> must plead facts to support allegations of materiality with "plausibility and particularity."

Escobar, 136 S. Ct. at 2003, 2004 n.6. Whether an express or implied false representation of compliance with statutes or regulations is "material" is ordinarily "a fact-intensive and context-specific inquiry."

New York v. Amgen Inc., 652 F.3d 103, 111 (1st Cir. 2011).

In addition to prohibiting the submission of false claims, the FCA bars an employer from retaliating against an employee "because of lawful acts done . . . in furtherance of an action under this section or other efforts to stop 1 or more violations of [the FCA]." 31 U.S.C. § 3730(h)(1). To prevail on an FCA retaliation claim, "a plaintiff must show that 1) the employee's conduct was protected under the FCA; 2) the employer

<sup>&</sup>lt;u>Hutcheson</u>, 647 F.3d at 388 n.13. Indeed, the Supreme Court has declined to decide "whether § 3729(a)(1)(A)'s materiality requirement is governed by § 3729(b)(4) [the statutory definition of "materiality"] or derived directly from the common law." <u>Escobar</u>, 136 S. Ct. at 2002.

<sup>8</sup> The False Claims Act's "qui tam" provisions authorize private individuals, known as "relators," to bring suit on the government's behalf based on the submission of false claims to the government. See 31 U.S.C. § 3730(b).

knew that the employee was engaged in such conduct; and 3) the employer discharged or discriminated against the employee because of his or her protected conduct." <u>United States ex rel. Karvelas</u> v. <u>Melrose-Wakefield Hosp.</u>, 360 F.3d 220, 235 (1st Cir. 2004), abrogated on other grounds by Allison Engine Co., Inc. v. <u>United States ex rel. Sanders</u>, 553 U.S. 662 (2008). In general, "proving a violation of § 3729 [the false claims provision] is not an element of a § 3730(h) [retaliation] cause of action." <u>Graham Cty. Soil & Water Conservation Dist.</u> v. <u>United States ex rel.</u> Wilson, 545 U.S. 409, 416 n.1 (2005).

The pleading standards for actions directly alleging the submission of false claims, such as qui tam actions pursuant to 31 U.S.C. § 3730(b), and the pleading standards for actions alleging retaliation, differ in crucial ways. In a suit directly alleging the submission of a false claim, a plaintiff must sufficiently plead facts supporting the existence of an actual false claim. See Karvelas, 360 F.3d at 225 ("Evidence of an actual false claim is the sine qua non of a False Claims Act violation." (internal quotation marks omitted)). However, in a suit alleging retaliation under the FCA, a plaintiff must sufficiently plead that he or she was retaliated against based on "conduct that reasonably could lead to a viable FCA action." Id. at 236. We have further explained that "conduct protected under" the FCA retaliation provision encompasses an employee's "investigations, inquiries,

knowing submission of false or fraudulent claims for payment to the government." <u>United States ex rel. Booker v. Pfizer, Inc.</u>, 847 F.3d 52, 59 (1st Cir. 2017) (quoting <u>Karvelas</u>, 360 F.3d at 237). This standard is consistent with the legislative intent that "[p]rotected activity [for purposes of an FCA retaliation claim] should . . . be interpreted broadly." <u>Karvelas</u>, 360 F.3d at 236 (quoting S. Rep. No. 99-345, at 34 (1986), <u>reprinted in 1986 U.S.C.C.A.N. 5266</u>, 5299). Because an FCA retaliation claim "does not require a showing of fraud," a plaintiff alleging retaliation "need not meet the heightened pleading requirements of [Federal Rule of Civil Procedure] 9(b)." <u>Id.</u> at 238 n.23. 10

<sup>9</sup> We derived the "reasonably could lead" standard from the statutory language prohibiting retaliation by an employer "because of lawful acts done by the employee . . . in furtherance of an [FCA] action." See Karvelas, 360 F.3d at 235-36 (quoting 31 U.S.C. § 3730(h)(1)). Therefore, a court must consider whether the conduct of the employee who was allegedly retaliated against -- that is, the employee's whistleblowing or investigative activities -- reasonably could lead to an FCA action. Of course, the question of whether the employer engaged in conduct that could run afoul of the FCA is a necessary component of this inquiry. After all, the employee's conduct must "concern the employer's knowing submission of false . . . claims . . . because only such conduct reasonably could lead to an FCA action." Booker, 847 F.3d at 59-60 (internal quotation marks omitted).

Conversely, because a direct FCA claim does require a showing of fraud, a qui tam plaintiff must "meet the Rule 9(b) pleading standards." Karvelas, 360 F.3d at 238.

## C. Anti-Kickback Statute

The Anti-Kickback Statute ("AKS") criminalizes, relevant part, the "knowing[] and willful[]" offer or payment of "any remuneration (including any kickback, bribe, or rebate)" to induce a person to "recommend . . . ordering any . . . service . . . for which payment may be made in whole or in part under a [f]ederal health care program." 42 U.S.C. § 1320a-7b(b)(2)(B). Relevant considerations for identifying an unlawful kickback include: (1) whether the person being paid the alleged kickback is "in a position to generate [f]ederal health care program business" and (2) whether at least one purpose of the payment could be "to induce or reward the referral or recommendation of business payable in whole or in part by a [f]ederal health care program." OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, 4864 (Jan. 31, 2005). Essentially, the AKS targets any remunerative scheme through which a person is "paid 'in return for' referrals" to a program under which payments may be made from federal funds. United States v. Patel, 778 F.3d 607, 618 (7th Cir. 2015) (quoting 42 U.S.C. § 1320a-7b(b)(1)(A)).

In 2010, the AKS was amended to create an express link to the FCA. The AKS now provides that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C.

§ 1320a-7b(g), as amended by the Patient Protection and Affordable Care Act, Pub. L. No. 1110148, 124 Stat. 119 (2010).

III.

Appellant contends that he was retaliated against within the meaning of the FCA anti-retaliation provision when he was fired after raising concerns to Shields and others about (1) the alleged kickbacks to Greene and (2) the contractual misrepresentations regarding a 24/7 call center. Although appellees attack the sufficiency of the complaint on several grounds, the district court dismissed the FCA claims on the basis that Guilfoile had not plausibly pleaded that he had engaged in protected conduct. Our analysis begins with this first element of an FCA retaliation claim.

# A. Payments to Greene/Ayrault Group

The district court concluded that Guilfoile had failed to adequately plead that his actions in raising concerns about the payments to Greene and the Ayrault Group reasonably could have led to an FCA action. Specifically, the district court reasoned that Guilfoile failed to adequately plead an AKS violation, and that even if he had adequately pleaded an AKS violation, he failed to connect any such violation to a potential false claim within the meaning of the FCA. We disagree with the district court's approach and its conclusion.

Guilfoile has brought an FCA retaliation claim, not a "direct" claim of an FCA violation. As discussed above, adequately pleading an FCA retaliation claim does not require adequately pleading the submission of a false claim or meeting the Rule 9(b) standards for pleading fraud. See Graham Cty., 545 U.S. at 416 & n.1; Karvelas, 360 F.3d at 238 n.23; see also United States ex rel. Grenadyor v. Ukrainian Vill. Pharmacy, Inc., 772 F.3d 1102, 1108-09 (7th Cir. 2014) (affirming dismissal of qui tam claim for failure to plead kickbacks with particularity but reversing dismissal of retaliation claim based on internal reporting of alleged kickbacks). Rather, plaintiffs like Guilfoile need only plead that their actions in reporting or raising concerns about their employer's conduct "reasonably could lead to an FCA action." Booker, 847 F.3d at 59 (internal quotation marks omitted). Put colloquially, rather than plausibly pleading the existence of a fire -- the actual submission of a false claim -- a plaintiff alleging FCA retaliation need only plausibly plead a reasonable amount of smoke -- conduct that could reasonably lead to an FCA action based on the submission of a false claim.

Because this case involves an alleged violation of the AKS, we consider the 2010 amendment to the AKS stating that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA.]" 42 U.S.C. § 1320a-7b(g). We have

previously declined to directly address the impact § 1320a-7b(g) on FCA actions, see Hutcheson, 647 F.3d at 379 n.1, and we do not attempt to assess the full implications of the AKS provision today. We need not do so because the issue before us is not the standard for proving an FCA violation based on the AKS, but rather the requirements for pleading an FCA retaliation claim. For our present purposes, it is enough to say that in light of § 1320a-7b(g), "[a]n AKS violation that results in a federal health care payment is a per se false claim under the FCA." United States ex rel. Lutz v. United States, 853 F.3d 131, 135 (4th Cir. 2017). That is, drawing on the "resulting from" language of the 2010 amendment, if there is a sufficient causal connection between an AKS violation and a claim submitted to the federal government, that claim is false within the meaning of the FCA. See United States ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 96-98 (3d Cir. 2018) (discussing causal connection issue); 11 United States ex rel. Bawduniak v. Biogen Idec, Inc., No. 12-CV-10601-IT, 2018 WL 1996829, at \*5-6 (D. Mass. Apr. 27, 2018) (same).

We further read the AKS amendment as obviating the need for a plaintiff to plead materiality -- that is, to plead that

We note that <u>Greenfield</u> involved a qui tam suit directly alleging an FCA claim based on a violation of the AKS and ultimately turned on the standard for proving such claims at summary judgment. See Greenfield, 880 F.3d at 98.

compliance with the AKS was material to the government's decision to pay any specific claim. This construction inescapably follows from the statute's plain language stating that a claim resulting from a violation of the AKS "constitutes a false or fraudulent claim." 42 U.S.C. § 1320a-7b(g). The statute's use of the term "constitutes" would be meaningless if courts had to engage in a materiality analysis -- for example, by inquiring into whether the entity submitting the claim had certified its compliance with the AKS -- after establishing that a claim resulted from an AKS violation. e.g., United States v. Catholic Health See, Initiatives, 312 F. Supp. 3d 584, 594 (S.D. Tex. 2018) ("Due to [§ 1320a-7b(g)], liability under the FCA for AKS violations does not require the defendants to have expressly certified their compliance with the AKS."); United States ex rel. Kester v. Novartis Pharm. Corp., 43 F. Supp. 3d 332, 364 (S.D.N.Y. 2014) (stating that "from and after [the AKS amendment,] the act of submitting a claim . . . itself implie[d] compliance with the AKS, even in [the] absence of any express certification of compliance." (second alteration in original) (internal quotation marks and citation omitted)).

Our reading of § 1320a-7b(g) is consistent with the legislative history, which indicates Congress's intent to "ensure that all claims resulting from illegal kickbacks are 'false and fraudulent'" and to "strengthen [] whistleblower actions based on

medical care kickbacks . . . [b]y making all claims that stem from an illegal kickback subject to the False Claims Act." 155 Cong. Rec. S10852-01, S10853 (daily ed. Oct. 28, 2009) (statement of Sen. Kaufman). If a plaintiff must plead and prove that compliance with the AKS was "material" to a claim "resulting from" an AKS violation, § 1320a-7b(g) would not represent the strengthening of whistleblower actions that Congress intended. Moreover, § 1320a-7b(g)'s obviation of the "materiality" inquiry essentially codifies the long-standing view that AKS violations are "material" in the FCA context. 12 This codification has the benefit, however, of bypassing judicially created theories of materiality, such as express or implied certification, that "do more to obscure than

Prior to the 2010 AKS amendment, courts had consistently held that compliance with the AKS (or the lack thereof) was "material" to the government's decision to pay a given claim based on the theory that the government's payment was contingent on the submitting entity's express or implied certification that it had complied with the AKS. See, e.g., Amgen, 652 F.3d at 110; United States ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 314 (3rd Cir. 2011), abrogated on other grounds by Escobar, 136 S. Ct. 1989; United States v. Rogan, 517 F.3d 449, 452-53 (7th Cir. 2008); United States ex rel. Westmoreland v. Amgen, Inc., 812 F. Supp. 2d 39, 52 (D. Mass. 2011); United States ex rel. Lisitza v. Johnson & Johnson, 765 F. Supp. 2d 112, 127-28 (D. Mass. 2011) (citing cases). The legislative history suggests that the 2010 amendment was intended to codify the link between AKS violations and false claims within the meaning of the FCA as well as to correct one district court case holding that claims for payment resulting from AKS violations could be "laundered" if the claims were submitted to the government by a party who was unaware that a kickback had occurred. See 155 Cong. Rec. S10852-01, S10853-54 (daily ed. Oct. 28, 2009) (statements of Sens. Kaufman and Leahy); Kester, 41 F. Supp. 3d at 332-35 (discussing the 2010 amendment's legislative history).

clarify the issues before" a court considering an FCA claim.

Hutcheson, 647 F.3d at 385-86.

With this understanding of the AKS amendment in mind, we consider whether Guilfoile has plausibly pleaded that the concerns he raised about the payments to Greene reasonably could have led to an FCA action. The allegations in the complaint, coupled with the reasonable inferences we must draw from them, plausibly pleaded that claims for payment were, or were going to be, submitted to the government in connection with the Integrated Entity's work with the New Jersey hospitals. Specifically, the complaint alleges that the Integrated Entity "regularly bills federal insurance programs[,] including[] Medicaid [and] Medicare, and Guilfoile "believed the contract with Mr. Green[e] violated the federal AKS because the Integrated Entity had paid illegal kickbacks to secure a contract at hospitals where it billed to federal insurance programs." (Emphasis added.) These allegations support the reasonable inference that the government was being billed for services provided by the Integrated Entity in connection with its contracts with the hospitals.

Guilfoile has also plausibly alleged a sufficient causal connection between any submitted claims and the payments to Greene. Specifically, the complaint alleges that the Integrated Entity entered into an agreement to pay Greene "for each hospital contract that [he] successfully referred to the

Integrated Entity, specifically targeting two hospitals that [he] was working for as a paid consultant"; that the Integrated Entity entered into contracts with those two hospitals; and that the Integrated Entity in fact paid him "referral fees." The allegation that Greene was paid pursuant to the agreement supports the reasonable inference that Greene was responsible for connecting the Integrated Entity with the New Jersey hospitals. In other words, we reasonably infer from the complaint's allegations that the Integrated Entity paid Greene to induce him to use his position with the hospitals to influence them to select the Integrated Entity for the contracts at issue. Further, the complaint permits the reasonable inference that, if not for the agreement with Greene, the Integrated Entity would not have been in a position to benefit from federal health care payments arising from its work with the hospitals. See supra 5-6.13

Finally, Guilfoile has plausibly alleged that the payments to Greene were a violation of the AKS. The relationship between the Integrated Entity and Greene -- payment to induce the

<sup>13</sup> In addition to the allegation that Greene was paid for referring the hospitals to the Integrated Entity, the complaint alleges that Greene advised the Integrated Entity on how to bid for the hospital contracts. Contrary to the suggestion by appellees, and drawing all reasonable inferences in Guilfoile's favor, we simply do not read the complaint to allege that the extent of Greene's assistance to the Integrated Entity was providing insider information about the hospitals' bidding process.

generation of federal health care program business -- has the hallmarks of a kickback scheme. See 42 U.S.C. § 1320a-7b(b)(2)(B) (criminalizing payments to "induce [a] person . . . to . . . recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a [f]ederal health care program"). Importantly, the nature of the alleged scheme is materially indistinguishable from the scheme in United States v. Bay State Ambulance & Hospital Rental Service, Inc., 874 F.2d 20 (1st Cir. 1989), which involved a criminal conviction under the AKS. In Bay State, a hospital employee, who was on an advisory committee charged with advising the hospital on accepting bids for an ambulance services contract, was paid by an ambulance company to induce him to recommend that the hospital enter into a contract for ambulance services with that company. See 874 F.2d at 22. There was no allegation that the hospital employee was paid to refer individual patients for individual ambulance trips or that the federal government would pay the hospital simply for entering into the contract with the ambulance company, which contract was the direct outcome of the illegal remuneration scheme. Yet, we held that a crime had occurred under the AKS once the person who was in a position to influence the hospital was paid to use his influence to win the contract for the ambulance company. See id.

The dissent's concern with the "attenuated" nature of the AKS scheme alleged in the complaint is misplaced. 14 although we can see how our colleague drew his interpretation from the language of the AKS, we are bound by Bay State, as the dissent recognizes. Appellees point to no authority for the contention that the AKS scheme as pleaded is materially distinguishable from the scheme in Bay State and outside the compass of the AKS. dissent's attempt to factually distinguish Bay State is also unconvincing. Any suggestion in the dissent that the nature of the kickback scheme is more speculative than the scheme in Bay <u>State</u> fails to adequately recognize the difference between pleading standards for an FCA retaliation claim, at issue here, and standards of proof for a criminal conviction under the AKS, at issue in Bay State. Second, but equally as important, this case gives us no reason to question Bay State. The type of scheme proven in Bay State and alleged in the present case is in the heartland of what the AKS is intended to prevent -- the use of payments to improperly influence decisions on the provision of

<sup>14</sup> As our dissenting colleague articulates his concern: "There is . . . a fair amount of attenuation between the actual transactions that Greene was allegedly induced to 'arrange for' (the hospitals' 'purchas[es]' or 'order[s]' of the Integrated Entity's general pharmacy services) and the transactions 'for which payment may be made . . . under a Federal health care program' (some unknown purchases from an Integrated Entity-run pharmacy of some unknown drugs by some unknown patients who happened to be eligible for reimbursement under a federal health care program)."

health care that lead to claims for payment to federal health care programs. Accepting our colleague's contention — that there is too great a distance between the Integrated Entity's payments to Greene to capture the hospital contracts and the submission of claims to federal insurance programs, which is the unmistakable objective of the contracts — would leave a hole in the statutory scheme and essentially permit pay-offs to capture federal health care funds. See OIG Supplemental Guidance, 70 Fed. Reg. at 4864 (an illegal kickback is a payment whose purpose, at least in part, is "to induce or reward the referral or recommendation of business payable in whole or in part by a [f]ederal health care program").

Further, we disagree with our dissenting colleague that our interpretation of the FCA and the AKS, and our application of the statutory language to the alleged facts in light of our precedent, is foreclosed by the manner in which Guilfoile presented

We also disagree with the dissent that we should consider here arguments not raised in Bay State that would challenge the viability of that decision. Unlike in United States v. DiPina, 178 F.3d 68, 73 (1st Cir. 1999), where we acknowledged that we are not bound by dicta in a prior opinion, accepting the appellees' arguments about attenuation in this case would mean that the holding in Bay State was incorrect and that the case was therefore wrongly decided. The similar facts in Bay State and this case are not "background facts." They are facts that implicate the applicability of the AKS in both cases. It is a fundamental principle that a newly constituted appellate panel cannot overrule a prior panel in the absence of newly announced Supreme Court law, intervening en banc opinion of this court, overruling, or developments in the law. See Lassend v. United States, 898 F.3d 115, 124-25 & n.6 (1st Cir. 2018).

his arguments before us or before the district court. This is not a case where an appellant has tried to introduce on appeal an issue that was never before the district court or to otherwise "sand bag" the other side. Although Guilfoile may not have consistently raised certain arguments, the core issue of whether the payment scheme as pleaded falls within the compass of the AKS was before the district court and is at the core of his appeal. Before the district court and before us, Guilfoile consistently argued that he has adequately alleged an AKS violation for purposes of pleading an FCA retaliation claim. The fact that he did not rely on Bay State or did not consistently present a "market access" theory to support the AKS violation in no way precludes us from reaching our result. In the context of a de novo review necessitating our interpretation of a statute, we routinely employ rationales that have been less than satisfactorily presented by the parties if that is the correct way of resolving the issue under the applicable law. We cannot allow our responsibility to articulate the most sensible resolution of an issue, especially, as here, an issue of statutory interpretation involving our own precedent, to be unreasonably circumscribed by the parties' arguments.

Hence, in summary, after drawing all reasonable inferences in Guilfoile's favor and considering the effect of the statutory language drawing a connection between AKS violations and FCA actions, we conclude Guilfoile has plausibly pleaded that he

engaged in protected conduct within the meaning of an FCA retaliation claim. That is, when Guilfoile raised concerns about the payments to Greene he was engaging in conduct that "reasonably could lead to an FCA action," <u>Booker</u>, 847 F.3d at 59 (internal quotation marks omitted), specifically, an FCA action based on the submission of claims resulting from an AKS violation. 16

In view of its conclusion that Guilfoile had not adequately pleaded that he engaged in protected conduct, the district court did not go on to analyze the other two elements of Guilfoile's FCA retaliation claim: specifically, that (1) his employer knew that he was engaged in protected conduct and (2) his employer retaliated against him because of that conduct. See Karvelas, 360 F.3d at 235. However, we readily conclude that Guilfoile has plausibly alleged that the Integrated Entity knew that he was engaging in protected conduct. Guilfoile specifically

that the complaint does not adequately plead an FCA retaliation claim are clearly inapposite because they apply standards for directly pleading violations of the AKS and FCA, see, e.g., United States ex rel. Kalec v. NuWave Monitoring, LLC, 84 F. Supp. 3d 793 (N.D. Ill. 2015); standards for proving AKS and FCA claims on summary judgment, see, e.g., United States ex rel. Perales v. St. Margaret's Hosp., 243 F. Supp. 2d 843 (C.D. Ill. 2003); standards for assessing criminal conviction under the AKS, see, e.g., Patel, 778 F.3d 607; or standards for evaluating FCA retaliation claims that we do not follow, see, e.g., United States ex rel. Uhlig v. Fluor Corp., 839 F.3d 628, 635 (7th Cir. 2016). The case of United States ex rel. Rost v. Pfizer, Inc., 736 F. Supp. 2d 367 (D. Mass. 2010), predates the 2010 amendment to the AKS and applies an outmoded theory of implied certification.

alleged that "he notified Mr. Shields . . . that he believed the contract with Mr. Green[e] violated the federal AKS because the Integrated Entity had paid illegal kickbacks to secure a contract at hospitals where it billed federal insurance programs."

Guilfoile also has plausibly pleaded that he retaliated against because of his protected conduct, given the close temporal proximity -- about a week -- of his termination to his final conversation with Shields about the payments to Greene. See Harrington v. Aggregate Indus. Ne. Region, Inc., 668 F.3d 25, 32 (1st Cir. 2012) (suggesting that a plaintiff can satisfy the third element of a prima facie retaliation case by plausibly pleading temporal proximity where the retaliatory action occurred two months after the protected conduct). To the extent appellees contend that the complaint does not adequately allege that Guilfoile informed Shields that he was concerned about fraud on the government, see, e.g., McKenzie v. BellSouth Telecomms., Inc., 219 F.3d 508, 516 (6th Cir. 2000), we disagree. The complaint explicitly alleges, for example, that Guilfoile "notified [] Shields . . . that he believed the contract with [] Green[e] violated the federal AKS because the Integrated Entity had paid illegal kickbacks to secure a contract at hospitals where it billed to federal insurance programs."

## B. The 24/7 Call Center

We agree with the district court that Guilfoile has not sufficiently pleaded a connection between the 24/7 call center contractual terms and the submission of any claim. 17 In general, "[i]t is not the case that any breach of contract, or violation of regulations or law, or receipt of money from the government where one is not entitled to receive the money, automatically gives rise to a claim under the FCA." <u>United States ex rel. Hopper v. Anton</u>, 91 F.3d 1261, 1265 (9th Cir. 1996). Even in the FCA retaliation context, there must be a reasonable connection between the alleged conduct and the submission of claims within the purview of the FCA.

For a plaintiff to adequately plead that a contractual breach could reasonably lead to an FCA action, he or she must

Anticipating this possible outcome of our review, Guilfoile asserts that the district court erred by twice rejecting his requests to amend the complaint to correct any pleading deficiencies. But he has not demonstrated that the court abused its discretion and committed a manifest error of law in denying his motion to vacate the judgment and amend the complaint. Markel Am. Ins. Co. v. Díaz-Santiago, 674 F.3d 21, 32 (1st Cir. 2012) (stating that we "review[] the district court's denial of post-judgment relief under Rule 59(e) for abuse of discretion," and that, "[g]enerally, to prevail on a Rule 59(e) motion, the moving party must . . . clearly establish a manifest error of law." (internal quotation marks omitted)); Maldonado v. Dominguez, 137 F.3d 1, 11 (1st Cir. 1998) ("[A] district court cannot allow an amended pleading where a final judgment has been rendered unless that judgment is first set aside or vacated pursuant to Fed. R. Civ. P. 59 or 60.").

adequately plead causation and materiality. <u>See D'Agostino</u> v. <u>ev3, Inc.</u>, 845 F.3d 1, 7-8 (1st Cir. 2016). With respect to the 24/7 call center contractual term, Guilfoile has not pleaded any plausible connection between the alleged contractual breach and the submission of claims to the government, or how the contractual breach would have been material to the payment of any claims. For this reason, the district court correctly dismissed Guilfoile's FCA retaliation claim to the extent it relied on his activities concerning the 24/7 call center. 18

#### IV.

For the foregoing reasons, we affirm dismissal of the complaint as to the 24/7 call center issue but vacate and remand as to the retaliation claim involving a potential violation of the Anti-Kickback Statute. Given this disposition, the district court may need to reconsider its decision to decline supplemental jurisdiction over Guilfoile's state law claims.

# So ordered. Costs to appellant.

## - Concurring and Dissenting Opinion Follows -

<sup>18</sup> Our reasoning and conclusion would be the same if Guilfoile had alleged that the Integrated Entity violated any statute or regulation by not having a 24/7 call center or by falsely stating in its contracts that it had a 24/7 call center. See Booker, 847 F.3d at 60. However, we do not read the complaint to plausibly allege that the Integrated Entity violated any statutes or regulations despite Guilfoile's subjective belief that the alleged false representation "posed a serious threat to public health and safety."

BARRON, Circuit Judge, concurring in part and dissenting To plead a viable retaliation claim under the False Claims Act ("FCA"), 31 U.S.C. § 3730(h)(1), a plaintiff must allege that the conduct that he reported to his employer and that resulted in his termination was "calculated, or reasonably could lead, to a viable FCA action." United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 236 (1st Cir. 2004) (internal quotation marks omitted). Thus, when an FCA retaliation claim relies on a report of a violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C.  $\S$  1320a-7b(g), as is the case here, the plaintiff needs to allege facts that would suffice to show that the conduct that he reported to his employer is of a kind that is actionable under the AKS. See Karvelas, 360 F.3d at 237 (holding that "protected" activities must "concern the employer's knowing submission of false or fraudulent claims for payment to the government" (emphasis added)).

To be clear, the plaintiff in such a case need not prove at the pleading stage that what he complained to his employer about was an actual AKS violation. But, the plaintiff must sufficiently allege that "his reports concerned FCA-violating activity such as the submission of false claims" resulting from conduct that could constitute a violation of the AKS. <u>United States ex rel. Booker</u> v. <u>Pfizer, Inc.</u>, 847 F.3d 52, 60 (1st Cir. 2017). And, for that reason, the allegation in Thomas Guilfoile's complaint in this

case that "he reasonably believed" that the conduct that he was reporting to his employer prior to his termination revealed a "violation[] of the AKS . . resulting in the submission of fraudulent claims to the government" is not itself of any Guilfoile must do more than assert a "legal conclusion couched as a factual allegation" to satisfy his burden at the pleading stage. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting <u>Bell Atl. Corp.</u> v. Twombly, 550 U.S. 544, 555 (2007)); see also Karvelas, 360 F.3d at 224 (setting aside "bald assertions" or "unsupportable conclusions" in an FCA complaint). The crucial question that we must resolve, therefore, is whether, taking as true the complaint's factual allegations about the conduct that Guilfoile reported to his employer, Guilfoile has satisfied his burden to show that the conduct that he allegedly reported is at least of a kind that falls within the scope of the AKS. For, if that conduct alleged is not even of that kind, then I do not see how his FCA retaliation claim -- insofar as it is premised on the report of an AKS violation -- may survive a motion to dismiss.

I.

Guilfoile alleges in his complaint that his employer -several general pharmacy services providers operating as a single
integrated entity (the "Integrated Entity") -- was bidding for
hospital contracts with the assistance of a financial consultant,
Michael Greene, who was simultaneously serving as a financial

advisor to those hospitals. I agree with the majority that Guilfoile sufficiently alleges in his complaint that he was fired by his employer after reporting that it was making payments to the consultant in order to induce him to use his position at the hospitals to steer the hospital contracts the Integrated Entity's way. See Maj. Op. 25. I also agree that these allegations of employer-induced double-dealing are concerning.

Nevertheless, the District Court found those factual allegations -- even if taken as true -- to be legally wanting. The District Court did so because it interpreted the AKS to prohibit only payments made to induce "other providers or individuals [to] directly refer[] or recommend[] patients to specific services" to be paid for with federal health care funds. The District Court then concluded that Guilfoile has not alleged facts sufficient to show that Greene "could or did play a role in referring or recommending federal program patients to Defendants through his financial consultant work with Defendants."

In reaching that conclusion, the District Court rejected Guilfoile's argument that Greene's facilitation of general contracts between the Integrated Entity and the hospitals for general pharmacy services that created the opportunity for "general access to patients amounts to a referral or recommendation" within the meaning of the AKS. The District Court appears to have relied for that determination on the attenuated

relationship between two things: (1) the general contracts for pharmacy services that Greene allegedly arranged between the Integrated Entity and the hospitals; and (2) the particular purchases by particular buyers of drugs from the pharmacies set up by the Integrated Entity in the hospitals.

I see how the text of the AKS lends support to the District Court's logic. As relevant here, the AKS prohibits payments "to induce" the recipient of the payments "to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program[.]" 42 U.S.C. § 1320a-7b(b)(2)(B). The only transactions that Guilfoile has alleged that the Integrated Entity paid Greene to induce him to "arrange for or recommend" directly, however, are the "purchas[es]" or "order[s]" by the hospitals of the specialty pharmacy services provided by the Integrated Entity via the contracts allegedly facilitated by Greene's paid work Integrated Entity. But, "payment . . . under a Federal health care program" is not made for those general services. payment is only made from a federal health care program in consequence of the particular purchases by particular buyers of drugs from the pharmacies set up by the Integrated Entity in the hospitals.

There is, then, necessarily a fair amount attenuation between the actual transactions that Greene was allegedly induced to "arrange for" (the hospitals' "purchas[es]" "order[s]" of the Integrated Entity's general pharmacy services) and the transactions "for which payment may be made . . . under a Federal health care program" (some unknown purchases from an Integrated Entity-run pharmacy of some unknown drugs by some unknown patients who happened to be eligible for reimbursement under a federal health care program). Moreover, that degree of attenuation appears to inhere in the conduct that Guilfoile's complaint alleges took place, given the middleman nature of the general pharmacy services that the Integrated Entity retained Greene to assist it in offering to the hospitals. Thus, nothing about Guilfoile's allegations concerning his report of that conduct to his employer indicates that the progression of the case will reveal the attenuation that concerned the District Court to be any less substantial than it now appears to be.

# II.

The majority rejects the District Court's reasoning regarding the attenuation problem. The majority concludes that <u>United States</u> v. <u>Bay State Ambulance & Hosp. Rental Serv., Inc.</u>, 874 F.2d 20 (1st Cir. 1989), compels us to construe the AKS to encompass situations with this degree of attenuation between general services contracts and any federal payment from a federal

health care program that would result from particular purchases by particular patients availing themselves of those services. See Maj. Op. 26-27. It is true that Bay State did uphold the AKS conviction of an ambulance services company and its president for paying kickbacks to a hospital employee. Bay State did so, moreover, even though that employee "arrange[d] for" only a general ambulance services contract between the hospital and the ambulance services provider, and not any particular purchase of ambulance services by a patient for which the federal government would make a payment. See id. at 25-26, 36.

In my view, however, <u>Bay State</u> is not so clearly controlling a precedent on the attenuation issue as the majority concludes that it is. That is so for three reasons.

First, the attenuation issue was not raised in <a href="Bay State">Bay State</a>. And thus, <a href="Bay State">Bay State</a> did not need to address -- and did not in fact address -- whether what the kickback recipient "arrange[d] for or recommend[ed]" fell within the scope of the AKS or was instead too attenuated from any payment from a federal healthcare program to do so because the parties made no such argument. <a href="See Gately">See Gately</a> v. <a href="Com. of Mass.">Com. of Mass.</a>, 2 F.3d 1221, 1226 (1st Cir. 1993) (describing the "essential principles of stare decisis" to include "(1) an issue of law must have been heard and decided" and "(2) if an issue is not argued, or though argued is ignored by the court, or is reserved, the decision does not constitute a precedent to be

followed"); United States v. DiPina, 178 F.3d 68, 73 (1st Cir. 1999) ("Where, in a prior decision, we have not considered an issue directly and assessed the arguments of parties with an interest in its resolution, that decision does not bind us in a subsequent case where the issue is adequately presented and squarely before us, merely because some of the background facts are the same.").

Second, <u>Bay State</u> is in some respects an easier case in which to find the nexus that the text of the AKS demands between the payment from a federal health care program and the transaction that the payment recipient "arrange[d] for" than this one is. The ambulance services eventually purchased by patients in <u>Bay State</u> were clearly reimbursable under a federal health care program. By contrast, it is less clear to me that the specialty pharmacy service (as opposed to the drugs purchased by patients) is itself reimbursable, thereby making the attenuation issue that concerned the District Court all the more acute. And Guilfoile's complaint does nothing to supply useful clarification.<sup>19</sup>

<sup>19</sup> Contrary to the majority's suggestion that this distinction is insignificant, <u>see</u> Maj. Op. 27-28, it seems to me that the fact that the contracts between the Integrated Entity and the hospitals contemplate the provision of a general service that is not itself reimbursable under a federal healthcare program should give us pause. The text of the relevant AKS provision requires that the "good, facility, service, or item" at issue be one "for which payment may be made in whole or in part under a Federal health care program[.]" 42 U.S.C. § 1320a-7b(b)(2)(B). And I have found no authority -- nor does Guilfoile identify any -- that suggests that the AKS does encompass conduct predicated on the defendant's offering of middleman services of this type. See, e.g., United

Finally, we should, in my view, be wary of extending Bay State in construing the AKS to reach the conduct alleged here. Congress passed the AKS to address a form of corruption that threatens to cheat federal taxpayers and that might also pose a risk to public health. See, e.g., Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. 95-142, 91 Stat. 1183 (1977) (describing the act as one "to strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the [M]edicare and [M]edicaid programs"); United States v. Hancock, 604 F.2d 999, 1001 (7th Cir. 1979) (identifying the "evils Congress sought to prevent by enacting the kickback statutes" to include the "potential for increased costs to the Medicare-Medicaid system and misapplication of federal funds"). In fact, Congress was so concerned about this form of corruption that it even made it a felony to engage in the conduct that the AKS covers. See Pub. L. 95-142 (upgrading an AKS violation to a felony).

States v. Polin, 194 F.3d 863, 864-65 (7th Cir. 1999) (upholding convictions of a doctor and nurse who paid a pacemaker company sales representative a fee for each patient he "referred" to the company for pacemaker monitoring services); United States v. Vernon, 723 F.3d 1234, 1254-55 (11th Cir. 2013) (upholding conviction of specialty pharmacy executive who paid a patient advocate a 45% commission for each prescription that her patients filled at the pharmacy to induce the patient advocate to refer her patients to the pharmacy); United States v. Shoemaker, 746 F.3d 614 (5th Cir. 2014) (upholding conviction of nursing staffing company executive who paid a hospital's board chair \$5 for each staffing hour that the hospital purchased from the nursing company to induce the chair to recommend to the hospital's COO that the hospital increase its hours from the nursing company).

But, the AKS, like any statute that addresses an important public problem, does not have limitless reach. And, as with any statute that imposes criminal liability, as the AKS does, we must be careful to construe its reach in a manner that ensures that it affords those subject to it with due notice and in accordance with the principle that only Congress may impose criminal liability. See Liporata v. United States, 471 U.S. 419, 427 (1985).

I recognize that we would not need to worry about transgressing those interpretive principles here if, as the majority concludes, this case concerns the alleged reporting of conduct that falls within the AKS's "heartland." See Maj. Op. 27. But, I do not see how we could so conclude, no matter how broad the AKS may seem to be. In fact, if the conduct alleged in the complaint before us constitutes conduct that is of a kind that falls within the AKS's heartland, then I would be hard-pressed to conjure the kind of conduct that would reside on its outskirts.

Of course, statutes that have cores also have peripheries. And conduct that falls within the periphery of a statute's scope is no less unlawful than conduct that falls within its core. At the same time, conduct that lies outside even the periphery -- as measured, most clearly, by the words that Congress chose to denominate the statute's bounds -- is not conduct that may give rise to liability. And that is so no matter how much

such conduct may seem to be concerning in its own right and no matter how much that kind of conduct may even bear some resemblance to the kind of conduct that plainly does falls within the statute's scope.

For all of these reasons, then, <u>Bay State</u> does not, in my view, dictate the outcome in this case. And that matters because, although we are generally free to affirm a judgment below on any ground manifest in the record, <u>see MacDonald v. Town of Eastham</u>, 745 F.3d 8, 11 (1st Cir. 2014), we are not equally free to reverse one on a ground that the appellant does not raise on appeal. Yet while Guilfoile did cite <u>Bay State</u> in a footnote in his filings below to support the proposition that "paying inducements for referrals to access markets in order to bill federal health care programs is a cognizable violation of the AKS, and therefore the FCA," he has inexplicably, as the Integrated Entity points out, abandoned that market access argument on appeal. See Igartúa v. United States, 626 F.3d 592, 603 (1st

only in support of the separate points that he adequately alleged that Greene's position as a financial advisor at the hospitals put him on sufficient footing to steer the hospital contracts to the Integrated Entity and that he does not need to show that the alleged arrangement resulted in a drain on the public fisc. Guilfoile does not, however, make any argument on appeal as to how Bay State resolves the attenuation issue in his favor. See González v. Vélez, 864 F.3d 45, 56 n.7 (1st Cir. 2017) ("On appeal, . . . claims are deemed abandoned unless they are, at a minimum, accompanied by some developed argumentation.").

Cir. 2010) (noting that "[a]rguments that are intentionally relinquished or abandoned" or "raised in a perfunctory or not serious manner [are] waived").

Having abandoned that theory for why the attenuation inherent in the conduct that he alleged poses no concern, Guilfoile engages with the attenuation issue on appeal only by invoking cases that discuss whether the plaintiff has sufficiently made out a false claim under the FCA. See, e.g., U.S. ex rel. Hutcheson v.Blackstone Med., Inc., 647 F.3d 377, 383 (1st Cir. 2011) (holding that hospitals' claims for reimbursement of doctor's services using medical devices were "false" under the FCA where the doctors had accepted kickbacks from the medical device manufacturer); United States ex rel. Yesudian v. Howard Univ., 153 F.3d 731, 740 (D.C. Cir. 1998) (holding that plaintiff had "a good faith basis for going forward at the time of retaliation" as to the []submission of a false claim to the federal government | element where the plaintiff knew that 80% of the defendant's money came from the federal government). But, those cases bear only on the separate element of an FCA action that a "false or fraudulent claim" be submitted to the federal government. See 31 U.S.C. §§ 3729(a)(1),(b)(2). Given that Guilfoile's FCA retaliation claim is premised only on the theory that the conduct that he reported to his employer was prohibited by the AKS, see 42 U.S.C. § 1320a-7b(g), that separate issue takes on significance only if Guilfoile

has sufficiently alleged as a threshold matter that the conduct that he was reporting was of a kind that violates the AKS.

III.

Because I do not believe that Bay State is controlling on the critical issue of attenuation, and because Guilfoile has dropped the market access theory that he pressed below, I see no viable basis on appeal for rejecting the District Court's conclusion that Guilfoile "has not set forth sufficient factual allegations to support a plausible anti-kickback violation." To excuse the waiver here is to deprive the appellees of their judgment based on an argument that Guilfoile -- by abandoning that argument on appeal -- gave them no reason to think that they needed to confront and that, understandably, they did Accordingly, I see no reason to decide, without adequate briefing from the parties, the open interpretive question concerning the scope of what constitutes conduct that is of a kind the AKS encompasses on which Guilfoile's retaliation claim necessarily depends. And so, given the posture of this case -- a posture that is of Guilfoile's own making on appeal -- I conclude that we must affirm the District Court's decision.

I therefore respectfully dissent.