

880 F.3d 89 (2018)

UNITED STATES of America, EX REL. Steve GREENFIELD, Appellant**V.****MEDCO HEALTH SOLUTIONS, INC.; Accredo Health Group, Inc.; Hemophilia Health Services, Inc.**No. 17-1152.**United States Court of Appeals, Third Circuit.**

Argued September 27, 2017.

Opinion filed: January 19, 2018.

On Appeal from the United States District Court for the District of New Jersey, (D.C. Civil Action No. 1-12-cv-00522), District Judge: Honorable Noel L. Hillman.

Ross Begelman, Marc M. Orlow, Regina D. Poserina, (Argued), Begelman Orlow & Melletz, 411 Route 70 East, Suite 245, Cherry Hill, NJ 08034, Counsel for Appellant.

Paul E. Boehm, Enu Mainigi, Craig D. Singer, (Argued), Daniel M. Dockery, Williams & Connolly, 725 12th Street, N.W., Washington, DC 20005, Counsel for Appellees.

Chad A. Readler, Acting Assistant Attorney General, William E. Fitzpatrick, Acting United States Attorney, Katherine T. Allen, (Argued), Michael S. Raab, Charles W. Scarborough, United States Department of Justice, Civil Division, Appellate Staff, 950 Pennsylvania Avenue, N.W., Washington, DC 20530, Counsel for Amicus Curiae in Support of Neither Party United States of America.

91 *91 Before: AMBRO and KRAUSE, Circuit Judges, and CONTI^[*], Chief District Judge.

90 *90 **OPINION OF THE COURT**

AMBRO, Circuit Judge.

Accredo Health Group, Inc., a specialty pharmacy that provides home care for patients with hemophilia (a rare condition that prevents blood from clotting properly), made donations to charities, two of which allegedly recommended Accredo as an approved provider for hemophilia patients. This raises whether the donations came with something expected in return for the recommendations, which might trigger violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and, if so, whether Accredo's healthcare reimbursement claims for persons who may have received the charities' recommendations ran afoul of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A)-(B). No federal agency, however, made a claim against Accredo. In stepped Steve Greenfield, a private citizen and a former area vice president of Accredo, who sued it and affiliates Medco Health Solutions, Inc., and Hemophilia Health Services, Inc. (for simplicity, all are referred to as "Accredo") for alleged violations of the two federal statutes.^[1] If Greenfield prevailed, he would get at least 25% of any civil penalty or damages award.

The District Court, at the end of discovery, entered summary judgment against Greenfield and for Accredo, and the Government here has chosen not to intervene. It found that Greenfield failed to provide evidence of even a single federal claim for reimbursement by Accredo that was linked to the alleged kickback scheme. As he disagrees, Greenfield appeals to us.

I. BACKGROUND

Accredo delivers clotting medication (medically called "clotting factor") to patients at their homes and provides nursing assistance that is tailored to hemophilia patients' needs. Along with its pharmaceutical services, Accredo makes donations to various charities, including two that are pertinent to this appeal: Hemophilia Services, Inc. ("HSI"), and Hemophilia

Association of New Jersey ("HANJ," and collectively with HSI, "HSI/HANJ"). From 2007 to 2012, Accredo's donations to HSI/HANJ ranged from approximately \$200,000 to \$550,000 on an annual basis.

Accredo contributed funds to HSI, which in turn provided grants to HANJ. HSI's grants served two purposes — an insurance program for patients who are not eligible for Medicare or Medicaid, and support for outpatient hemophilia treatment centers. Accredo believed its donations went to HANJ's insurance program, but was aware that HANJ also funded treatment centers.

92 HANJ purportedly recognized Accredo's contributions by identifying it as an HSI-approved provider or HSI-approved vendor on its website. It stated HSI-approved vendors "maintain the highest *92 quality of care while providing [a] continuity of services and constantly supporting the community in numerous ways." It also directed users to "[r]emember to work with our HSI [approved] providers" and included hyperlinks to the approved providers' websites. HANJ also provided treatment centers with lists identifying specialty pharmacies that were designated as HSI-approved providers. Accredo was noted in one list as one of four HSI-approved vendors that "continually contribute to this community."

Although Accredo donated approximately \$363,000 to HSI/HANJ in 2010, it informed both charities that it planned to reduce its annual donation to \$175,000 in the following year. In response, HSI sent a letter to its members informing them of Accredo's reduced pledge and encouraging them to request that Accredo restore funding. HSI's letter focused on the possible shortfalls to HANJ's private insurance program; in HSI's view, Accredo's funding cuts would "place[] the Insurance Program in jeopardy of being 'phased out' and ceasing to exist in the foreseeable future." HSI also forwarded a copy of the letter to treatment centers, stating that "[t]he attached [letter] is self explanatory. [Hemophilia Health Services]/Accredo has behaved despicably, while enjoying the fruits of HANJ's labor."

As a result of HSI's letter, Accredo received approximately 75 letters from HSI members requesting an increase in funding. It then asked Greenfield (as noted, an area vice president for Accredo) to analyze the potential return on investment if it were to increase its annual donation from \$175,000 to \$350,000. It also requested him to project the "likely business deterioration to [its New Jersey] market share" if it opted not to increase funding. Greenfield's analysis indicated that, absent a funding increase to \$350,000, "all new and existing business [could be] at risk," and Accredo could expect to "lose 100% of the margin" associated with patients who switched out of Accredo's services. Based on this analysis, Accredo restored its annual donation to \$350,000 in 2012.

Greenfield thereafter filed a *qui tam* suit against Accredo, alleging it violated the False Claims Act by falsely certifying it complied with the Anti-Kickback Statute.^[2] Although the statutory scheme gave the Government the option to intervene in the suit, it declined to do so. See 31 U.S.C. § 3730(b)(2).

93 The case proceeded to summary judgment, where the parties' cross-motions presented differing theories on whether Greenfield had established a False Claims Act violation. He argued Accredo violated the Act by paying kickbacks to HSI/HANJ in the form of charitable contributions to induce recommendations and referrals of Accredo by HSI/HANJ to its members. In Greenfield's view, Accredo's alleged kickback scheme amounted to a False Claims Act violation because at least some referrals or recommendations were directed to Medicare beneficiaries and because Accredo falsely certified compliance with the Anti-Kickback Statute while submitting Medicare claims for payment.^[3] Accredo argued *93 Greenfield could not prove a violation of the False Claims Act, as there was no evidence any federally insured patient purchased its prescriptions because of its contributions to HSI/HANJ.

The District Court denied Greenfield's motion for summary judgment while granting that of Accredo. In the Court's view, his claim required him to (1) "establish that defendants violated the [Anti-Kickback Statute] through [their] alleged *quid pro quo* arrangement with HANJ/HSI" and (2) "show that, as a result of defendants' [Anti-Kickback Statute] violation, defendants received payment from the federal government" in violation of the False Claims Act. *United States ex rel. Greenfield v. Medco Health Sys., Inc.*, 223 F.Supp.3d 222, 227 (D.N.J. 2016). For purposes of its analysis, the Court did not determine whether Greenfield established an Anti-Kickback Statute violation.^[4] Instead, it focused its analysis on the second prong of the inquiry and concluded that, even if an Anti-Kickback Statute violation were assumed, Greenfield did not show sufficient evidence of a False Claims Act violation.

Although discovery revealed that Accredo submitted claims for 24 federally insured patients during the relevant time period, the Court concluded this evidence alone did not provide "the link between defendants' 24 federally insured customers and defendants' donations to HANJ/HSI." *Id.* at 230. Instead, it explained Greenfield must show that federally insured patients

were referred to Accredo as a result of its donations to HSI/HANJ. "Absent some evidence... that those patients chose Accredo because of its donations to HANJ/HSI," the Court reasoned, Greenfield could not carry his burden on his claim. *Id.* Thus it entered summary judgment for Accredo.

Greenfield appeals, arguing the District Court erred in requiring him to prove a direct link between the alleged kickback scheme and each false claim. The Government appears as an *amicus curiae* in support of neither party, contending the Court erred to the extent it required Greenfield to prove that patients chose Accredo because of HSI/HANJ's referrals and recommendations. In its view, all that needed to be shown was a claim that sought reimbursement for medical care that was provided in violation of the Anti-Kickback Statute. In response, Accredo maintains, *inter alia*, that the District Court correctly stated Greenfield's burden in establishing a False Claims Act breach.

II. STANDARD OF REVIEW

Our review of a district court's grant of summary judgment is *de novo*. See *Thomas v. Cumberland County*, 749 F.3d 217, 222 (3d Cir. 2014). Summary judgment is proper when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A genuine dispute exists "if the evidence is such that a reasonable jury could return a verdict for the non[-]moving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). The non-moving party must "go beyond the pleadings" and "designate specific facts" in the record "showing that there is a genuine issue for trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 324, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986) (internal quotation marks omitted). "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *94 *Anderson*, 477 U.S. at 248, 106 S.Ct. 2505.

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III. ANALYSIS

A. Must an HSI/HANJ Member Subjectively Choose to Use Accredo Because of the Alleged Kickback Scheme?

As noted, Greenfield contends the District Court erred by requiring a direct "link" between the donations to HSI/HANJ by Accredo and its 24 federally insured customers. He argues Accredo violated the False Claims Act because it certified compliance with the Anti-Kickback Statute while paying HSI/HANJ via donations in exchange for recommendations. Accordingly, he claims no need to identify specific false claims related directly to the alleged kickback scheme.

1. The False Claims Act

The False Claims Act imposes liability on any person who "(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or] (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."^[5] 31 U.S.C. § 3729(a)(1). A false or fraudulent claim may be either factually false or legally false. "A claim is factually false when the claimant misrepresents what goods or services ... it provided to the Government...." *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011). It is legally false when the claimant lies about its compliance with a statutory, regulatory, or contractual requirement. See *id.*

Where, as here, a plaintiff contends a defendant's claim is legally false, he or she must also prove the defendant's misrepresentation about its compliance with a legal requirement is "material to the Government's payment decision." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, ___ U.S. ___, 136 S.Ct. 1989, 1996, 195 L.Ed.2d 348 (2016). "[P]roof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Id.* at 2003.

2. The Anti-Kickback Statute

To repeat, Greenfield contends Accredo's claims were legally false because they were incorrectly certified as compliant with the Anti-Kickback Statute. In pertinent part, the Statute prohibits "knowingly and willfully" offering or paying "any remuneration... to any person to induce such person ... to refer an individual to a person for the furnishing ... of any item or service for which payment may be made *95 in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2)(A). It also prohibits "knowingly and willfully solicit[ing] or receiv[ing]" kickbacks "in return" for such conduct. *Id.* § 1320a-7b(b)(1)(A).

Congress amended the Anti-Kickback Statute in 2010 to provide "a claim that includes items or services resulting from a violation of [that Statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act]." *Id.* § 1320a-7b(g). Although the amendment is not retroactive, see Wilkins, 659 F.3d at 312 n.19, plaintiffs may still bring a False Claims Act case for claims submitted before 2010, as the amendment "clarif[ied], [but did] not alter, existing law that claims for payment made pursuant to illegal kickbacks are false under the False Claims Act," United States ex rel. Westmoreland v. Amgen, Inc., 812 F.Supp.2d 39, 52 (D. Mass. 2011); see also United States ex rel. Quinn v. Omnicare, Inc., 382 F.3d 432, 439 (3d Cir. 2004) (False Claims Act case premised on alleged Anti-Kickback Statute violations brought before the Anti-Kickback Statute was amended in 2010).

3. Proving a False Claims Act Violation at Summary Judgment

As noted, the District Court granted summary judgment to Accredo because Greenfield did not link its claims for reimbursement to the alleged kickback scheme. Indeed, its holding went further than that, arguably requiring a causal relationship — Greenfield must provide "some evidence" that federal beneficiaries "chose Accredo because of its donations to HANJ/HSI." Greenfield, 223 F.Supp.3d at 230. That evidence, in the Court's view, is "an essential element" of Greenfield's claim. *Id.*

Greenfield and the Government contend that proof of subjective intent is not required. They assert Congress enacted the False Claims Act and Anti-Kickback Statute to impose liability independent of patients' subjective medical decisions. Accredo counters that the statutory scheme requires Greenfield to prove that federal beneficiaries would not have used Accredo's services but for the alleged kickback violation. It insists that this is the correct evidentiary burden, even if it would require plaintiffs to delve into patients' intent. At issue, therefore, is what "link" is sufficient to connect an alleged kickback scheme to a subsequent claim for reimbursement: a direct causal link, no link at all, or something in between.

When interpreting a statute, "[o]ur task is to give effect to the will of Congress, and where Congress's will has been expressed in language that has a reasonably plain meaning, that language must ordinarily be regarded as conclusive." Byrd v. Shannon, 715 F.3d 117, 122 (3d Cir. 2013). Where a statute's language is arguably not plain, we consider statutory language "in the larger context or structure of the statute in which it is found." United States v. Tupone, 442 F.3d 145, 151 (3d Cir. 2006); see also Alli v. Decker, 650 F.3d 1007, 1012 (3d Cir. 2011) (same). Our effort to discern Congress's intent may resort to legislative history as an aid or cross-check. See Universal Church v. Geltzer, 463 F.3d 218, 223 (2d Cir. 2006).

For convenience, we repeat that, under the Anti-Kickback Statute, "a claim that includes items and services resulting from a violation of [that Statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act]." 42 U.S.C. § 1320a-7b(g). The Statute does not define the term "resulting from." However, *Black's Law Dictionary* defines "result" as "a ... logical ... or legal consequence; to proceed as an outcome or conclusion." *Black's Law Dictionary* (10th ed. 2014).

*96 In line with this definition, Accredo argues its interpretation of "resulting from" is consistent with how the Supreme Court has construed those words in other statutes, most notably the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* See Burrage v. United States, ___ U.S. ___, 134 S.Ct. 881, 887-88, 187 L.Ed.2d 715 (2014) ("Results from' imposes, in other words, a requirement of actual causality.... [T]his requires proof the harm would not have occurred in the absence of — that is, but for — the defendant's conduct." (internal quotation marks omitted)). The Government responds that imposing but-for causation in this context would lead to the incongruous result whereby "a defendant could be convicted of criminal conduct under the [Anti-Kickback Statute] for paying kickbacks to induce medical referrals, but would be insulated from civil [False Claims Act] liability for the exact same conduct, absent additional proof that each medical decision was in fact corrupted by the kickbacks." Gov't Amicus Br. at 22.

To determine if a particular reading of a statute produces incongruous results, we ask whether that reading is consistent with the drafters' intentions. See United States v. Zats, 298 F.3d 182, 187 (3d Cir. 2002). It appears the drafters of the Anti-

Kickback Statute intended "to strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the [M]edicare and [M]edicaid programs," H.R. Rep. No. 95-393, at 1 (1977), because "fraud and abuse among practitioners ... is relatively difficult to prove and correct," *id.* at 47. "Since the medical needs of a particular patient can be highly judgmental, it is difficult to identify program abuse as a practical manner unless the overutilization is grossly unreasonable." *Id.* This counsels requiring something less than proof that the underlying medical care would not have been provided but for a kickback.

Similarly, Congress passed § 1320a-7b(g) in 2010 as part of an overall effort to "strengthen[] whistleblower actions based on medical care kickbacks" and "to ensure that *all* claims resulting from illegal kickbacks are considered false claims for the purpose of civil action[s] under the False Claims Act." 155 Cong. Rec. S10852, S10853-54 (daily ed. Oct. 28, 2009) (Sen. Kaufman) (emphasis added); see also *United States ex rel. Kester v. Novartis Pharm. Corp.*, 41 F.Supp.3d 323, 332 (S.D.N.Y. 2014) ("There is no indication in either the law itself or the legislative history that Congress intended to narrow the scope of 'falsity' under the [False Claims Act] when it amended the [Anti-Kickback Statute] to add Section 1320a-7b(g)."). Although the legislative history of the provision does not explain the term "resulting from," the Congressional Record indicates it was enacted to avert "legal challenges that sometimes defeat legitimate enforcement efforts." 155 Cong. Rec. at S10853.

The False Claims Act's legislative history echoes these points. There Congress stated the "Act is intended to reach *all* fraudulent attempts to cause the Government to pay ou[t] sums of money or to deliver property or services," and "[a] false claim for reimbursement under Medicare, Medicaid, or similar program ... may be false even though the services are provided as claimed." S. Rep. No. 99-345, at 9 (1986) (emphasis added). Thus the Anti-Kickback Statute and False Claims Act were not drafted to cabin healthcare providers' liability for certain types of false claims or for certain types of illegal kickbacks. Instead, Congress intended both statutes to reach a broad swath of "fraud and abuse" in the federal healthcare system. H.R. Rep. No. 95-393, at 47 (1977).

97 As such, the Government correctly observes that Accredo's reading of § 1320a-7b(g) is inconsistent with the drafters' intentions underlying both statutes. Per Accredo's *97 reasoning, a plaintiff would have to prove a kickback actually influenced a patient's or medical professional's judgment. Such a requirement would hamper False Claims Act cases under that provision even though Congress enacted it to "strengthen[] whistleblower actions based on medical care kickbacks," 155 Cong. Rec. at S10853, and stated that healthcare fraud "is relatively difficult to prove and correct," H.R. Rep. No. 95-393, at 47. Moreover, it would dilute the False Claims Act's requirements vis-à-vis the Anti-Kickback Statute, as direct causation would be a precondition to bringing a False Claims Act case but not an Anti-Kickback Statute case.^[9] It follows that the broad statutory context of the False Claims Act and the Anti-Kickback Statute supports the Government's reading, as neither requires a plaintiff to show that a kickback directly influenced a patient's decision to use a particular medical provider. Accordingly, Accredo's interpretation of § 1320a-7b(g) does not control the inquiry here, as it would lead to results not intended by Congress.

Case law from our Court supports this conclusion. In *Wilkins*, 659 F.3d at 314, we stated that a participant in a federal healthcare program complies with the False Claims Act by "refrain[ing] from offering or entering into payment arrangements which violate the [Anti-Kickback Statute], while making claims for payment to the Government under that program." *Id.* at 314. We observed that "[t]he Government does not get what it bargained for when a defendant is paid ... for services tainted by a kickback."^[7] *Id.* (internal quotation marks omitted) (alteration in original).

Our view is also consistent with the language in CMS Form 855s, which requires providers to certify that "the claim and the underlying transaction" (*i.e.*, the medical care being reimbursed) comply with the Anti-Kickback Statute. As is apparent from its language, the Form directs the provider's attention to the medical care that is the subject of a claim. It makes no mention of a patient's reason(s) for selecting a specific provider and does not require a provider to engage in an intent-based inquiry before submitting a claim for reimbursement.

98 The Government presented several hypotheticals to illustrate this standard. *98 For example, "if a medical service provider pays kickbacks to a doctor to induce referrals and then submits claims to Medicare for services it provided to patients who were referred by that doctor, the claims are false because the medical care was not provided in compliance with the [Anti-Kickback Statute]." Gov't Amicus Br. at 17. This outcome is the same "regardless of whether the doctor would have referred the patients absent the kickbacks ... and regardless of whether the patients would have chosen the service provider absent the referral." *Id.*

Consistent with this standard, Greenfield does not need to prove HSI/HANJ's referrals actually caused their members to use a particular healthcare provider. A "link" is required, but it is less than espoused by Accredo: For a False Claims Act violation, Greenfield must prove that at least one of Accredo's claims sought reimbursement for medical care that was provided in violation of the Anti-Kickback Statute (as a kickback renders a subsequent claim ineligible for payment).^[8] How this plays out is where we turn.

B. Assuming There Was an Anti-Kickback Statute Violation, What Must Greenfield Provide to Prevail at Summary Judgment for a False Claims Act Violation?

Even under our reading of the statute, Greenfield contends the District Court erred by requiring him to show an actual claim linked to Accredo's alleged kickback scheme. He argues this is too stringent a requirement. In his view, a temporal connection is sufficient to prove a False Claims Act violation at summary judgment. Because Accredo's contributions to HSI, its forwarding those monies to HANJ, HSI/HANJ recommending Accredo as an approved provider to their members, and Accredo filing reimbursement claims for 24 federally insured patients all took place in close proximity between 2007 and 2012, Greenfield contends Accredo necessarily violated the False Claims Act because all of its 24 claims incorrectly certified that it did not pay any illegal kickbacks.

We disagree. A plaintiff cannot "merely ... describe a private scheme in detail but then ... allege ... that claims requesting illegal payments must have been submitted, were likely submitted[,] or should have been submitted to the Government." United States ex rel. Clausen v. Lab. Corp. of Am., 290 F.3d 1301, 1311 (11th Cir. 2002).^[9] Instead, he must provide "evidence of the actual submission of a false claim" to prevail at summary judgment. Quinn, 382 F.3d at 439.

99 Consistent with these principles, we rejected a similar argument in Quinn, where the plaintiff argued the defendant violated the False Claims Act by reselling unused, *99 returned medications that were already paid by Medicaid (*i.e.*, "recycled medications") and then submitting a second Medicaid claim for the medication's full value. See *id.* According to the relator, "false claims must have been submitted" because the defendant admitted that "approximately 60 percent of its business is Medicaid and that it accepts returned medications for recycling." *Id.* at 440. We held that argument insufficient to survive summary judgment because the relator did not show "a single claim that [the defendant] actually submitted to Medicaid which covered a [recycled] medication for which [the defendant] had previously submitted a claim." *Id.* With this failure "to link [the defendant's] recycling and crediting practices to the actual submission of a false claim," there was no genuine "issue of material fact to be decided by a jury." *Id.*; see also Wilkins, 659 F.3d at 308 ("It is true that to recover under the [False Claims Act] we have recognized that ultimately a plaintiff must come forward with at least a 'single false [or fraudulent] claim' that the defendants submitted to the Government for payment." (quoting Quinn, 382 F.3d at 440) (emphasis omitted)).

Our sister circuits have applied the same analysis, holding that plaintiffs must provide evidence of at least one false claim to prevail on summary judgment. For example, in United States ex rel. Booker v. Pfizer, Inc., 847 F.3d 52, 58 (1st Cir. 2017), the First Circuit held that "aggregate [information] reflecting the amount of money expended by Medicaid" on off-label prescriptions was "insufficient on its own to support a[] [False Claims Act] claim" because it did not show "an actual false claim made to the [G]overnment." Likewise, the Seventh Circuit concluded a plaintiff failed to carry his burden during summary judgment because he failed to provide any claim associated with the defendant's alleged Medicare fraud. United States ex rel. Crews v. NCS Healthcare of Ill., Inc., 460 F.3d 853, 857 (7th Cir. 2006); see United States v. Kitsap Physicians Serv., 314 F.3d 995, 997 (9th Cir. 2002) ("It seems to be a fairly obvious notion that a False Claims Act suit ought to require a false claim. Yet, the plaintiff-appellant in this case filed his action, proceeded to summary judgment, and prosecuted this appeal without ever seeing or presenting to a court a single false claim submitted by the defendants-appellees. This flaw is fatal to a *qui tam* action under the False Claims Act.").

It follows that Greenfield may not prevail on summary judgment simply by demonstrating that Accredo submitted federal claims while allegedly paying kickbacks. Nor may he prevail by hypothesizing that at least some of HSI/HANJ's recommendations must have been directed to federal beneficiaries because Accredo submitted claims for 24 federally insured patients during the relevant time period. Instead, he must point to at least one claim that covered a patient who was recommended or referred to Accredo by HSI/HANJ.

He has not done so here. He fails to demonstrate that any of Accredo's 24 federally insured patients viewed HSI/HANJ's approved provider list or that HSI/HANJ referred the federally insured patients to Accredo through some other means. He even fails to establish that the 24 federally insured patients were members of HSI/HANJ and thus recipients of HSI/HANJ's communications. The closest he comes is when he asks us to assume that all 24 were members because "[e]ssentially all hemophiliacs in New Jersey are HANJ members." Reply Br. at 5. But "it is impossible to rule out the chance" that none of the 24 were HSI/HANJ members or that none of the 24 members were exposed to an illegal referral or recommendation.

100 *100 Quinn, 382 F.3d at 443. Thus the evidence does not link Accredo's alleged kickback scheme to any particular claim.

Despite this evidentiary shortcoming, Greenfield insists that the taint of a kickback renders every reimbursement claim false. Because Accredo was violating the Anti-Kickback Statute while submitting federal claims for reimbursement, he argues, the alleged kickbacks need not have any connection to the claims or the underlying medical care. Again we disagree. A kickback does not morph into a false claim unless a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient. Even if we assume Accredo paid illegal kickbacks, that is not enough to establish that the underlying medical care to any of the 24 patients was connected to a breach of the Anti-Kickback Statute; we must have some record evidence that shows a link between the alleged kickbacks and the medical care received by at least one of Accredo's 24 federally insured patients. Because Greenfield provides no such evidence (not that any of the 24 received a referral or recommendation to use Accredo's services or even that any of the 24 were members of HSI/HANJ), his case cannot proceed to trial. Accordingly, the District Court correctly entered summary judgment for Accredo.

IV. CONCLUSION

The Anti-Kickback Statute prohibits kickbacks regardless of their effect on patients' medical decisions. Because any kickback violation is not eligible for reimbursement, to certify otherwise violates the False Claims Act. Yet there must be some connection between a kickback and a subsequent reimbursement claim. It is not enough, as Greenfield contends, to show temporal proximity between Accredo's alleged kickback plot and the submission of claims for reimbursement. Likewise, it is too exacting to follow Accredo's approach, which requires a relator to prove that federal beneficiaries would not have used the relevant services absent the alleged kickback scheme. Instead, Greenfield must show, at a minimum, that at least one of the 24 federally insured patients for whom Accredo provided services and submitted reimbursement claims was exposed to a referral or recommendation of Accredo by HSI/HANJ in violation of the Anti-Kickback Statute. Because he has failed to do so, we affirm.

[*] Honorable Joy Flowers Conti, Chief Judge of the United States District Court for the Western District of Pennsylvania, sitting by designation.

[1] The legalese term for this type of private-suit piggybacking on federal statutes is a *qui tam* action. "*Qui tam* is short for the Latin phrase *qui tam pro domino rege quam pro se ipso in hac parte sequitur*, which means 'who pursues this action on our Lord the King's behalf as well as his own.'" Vt. Agency of Nat. Res. v. United States ex rel. Stevens, 529 U.S. 765, 768 n.1, 120 S.Ct. 1858, 146 L.Ed.2d 836 (2000). A private person, called a *qui tam* relator, brings an action "'for the person and for the United States Government' against the alleged false claimant, 'in the name of the Government.'" *Id.* at 769, 120 S.Ct. 1858 (quoting 31 U.S.C. § 3730(b)(1)).

[2] Greenfield initially brought multiple claims against Accredo, but his operative complaint alleges only False Claims Act violations.

[3] When billing Medicare for a federal claim, Accredo needed to certify its compliance with the Anti-Kickback Statute on CMS Form 855s, which states in relevant part "I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with [Medicare] laws, regulations, and program instructions (including, but not limited to, the Federal [A]nti-[K]ickback [S]tatute ...), and on the supplier's compliance with all applicable conditions of participation in Medicare."

[4] Like the District Court, we express no view on whether Accredo's charitable contributions were illegal kickbacks under the Anti-Kickback Statute.

[5] Although Congress amended the False Claims Act in 2009 by enacting the Fraud Enforcement and Recovery Act ("FERA"), it did not substantially alter the provisions of the pre-FERA version of the False Claims Act, which imposed liability on

any person who —

(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; [or]

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government.

31 U.S.C. § 3729(a)(1)-(2).

Because only § 3729(a)(1)(B) of FERA is retroactive to June 7, 2008, both the pre-FERA and FERA versions of the False Claims Act apply in our case. See Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21 § 4(f)(1), 123 Stat. 1617, 1625 (2009). The minor differences in the two versions of the statute do not affect our analysis.

[6] Although Congress did not intend two different standards of causation to apply in False Claims Act and Anti-Kickback Statute cases, it is worth repeating that the elements of the statutes differ. Unlike the False Claims Act, the Anti-Kickback Statute criminalizes a "knowing[] and willful[] offer" to pay a kickback. 42 U.S.C. § 1320a-7b(b)(2). Thus an offer alone may amount to a violation of the Anti-Kickback Statute, but is not enough to prove a violation of the False Claims Act. See *id.* § 1320a-7b(g) ("[A] claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act]." (emphasis added)).

[7] Other courts have gone further, expressly stating that causation is not required in this context. For instance, in *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377, 393 (1st Cir. 2011), the First Circuit rejected the defendant's argument that the claims "were not false or fraudulent because [they] were for services that would have been provided in the absence of the alleged [Anti-Kickback Statute] violations." Instead, the Court concluded "the ... claims were ineligible for payment" because "the underlying transaction violated the [Anti-Kickback Statute]." *Id.* (internal quotation marks omitted). More recently, the Southern District of New York rejected a defendant's argument pressing the same theory of causation Accredo now advances, reasoning that "Congress gave absolutely no indication ... it intended ... to limit the [False Claims Act's] reach where kickbacks were concerned" and that "any claim connected in any way to an [Anti-Kickback Statute] violation [is] ineligible for reimbursement" under § 1320a-7b(g). *Kester*, 41 F.Supp.3d at 332, 335.

[8] Even if Greenfield proves that one of Accredo's claims sought reimbursement for medical care that was provided in breach of the Statute, he must also satisfy the False Claims Act's materiality requirement, as falsity and materiality are distinct requirements in this context. See *Escobar*, 136 S.Ct. at 2002 ("[A] misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act.").

[9] Although the Eleventh Circuit stated the above in the context of Federal Rule of Civil Procedure 9(b)'s pleading requirements, its statement also is apt during summary judgment because a non-movant's "evidentiary burden ... in a summary judgment motion is significantly greater than in a motion to dismiss." *Reese v. Anderson*, 926 F.2d 494, 498 (5th Cir. 1991).

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