No. 17-1152

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

UNITED STATES OF AMERICA, ex rel. STEVE GREENFIELD,

Plaintiff-Appellant,

v.

MEDCO HEALTH SOLUTIONS, INC., et al.,

Defendants-Appellees.

On Appeal from the United States District Court
for the District of New Jersey

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE IN SUPPORT OF NEITHER PARTY

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INTEREST OF THE UNITED STATES

This case presents the question of when a violation of the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b), renders a claim for medical care false under the False Claims Act (FCA), 31 U.S.C. § 3729(a)(1). The United States submits this amicus brief to make clear that a claim for reimbursement for medical care that was not provided in compliance with the AKS is "false" within the meaning of the FCA, regardless of whether the violation of the AKS caused the claim.

In this case, a former vice president of a medical service provider contends that his former company and related defendants paid kickbacks to two charities in order to induce the charities to refer patients to defendants and to recommend that patients use defendants' services. The district court granted defendants' motion for summary judgment on the ground that, even assuming relator had shown a violation of the AKS, he had not shown that the kickbacks caused the charities' referrals and recommendations, or that those referrals and recommendations caused the patients' decisions to use defendants' services. Relator appealed. The United States submits this brief as amicus curiae in support of neither party. *See* 28 U.S.C. § 517; Fed. R. App. P. 29(a).

The FCA is the federal government's primary tool to combat fraud and recover losses due to fraud in federal programs. The United States has a substantial interest in ensuring that courts properly interpret the FCA and the statutes and regulations governing the public health insurance programs. A claim that seeks payment for

medical care that was not rendered in compliance with the AKS is "false" within the meaning of the FCA. The district court erred to the extent that it required relator to also show that the kickbacks caused the relevant medical decisions. Such a requirement would significantly hamper the government's ability to prevent illegal kickbacks and is not required by the statute. The purpose of the AKS is to ensure that medical decision-making is based on the medical needs of patients rather than on financial considerations. Because Congress recognized that kickbacks inherently corrupt medical decision-making, a false claim exists whenever a claim is submitted for a patient referred by the recipient of the kickback. To establish that a kickback violation rendered a claim false under the FCA, it is sufficient for a plaintiff to show that the claim seeks reimbursement for medical care that was the subject of the violation. The United States takes no position on the adequacy of relator's factual showings on summary judgment.

STATEMENT OF THE CASE

A. The False Claims Act

The False Claims Act is "the Government's primary litigative tool" for combatting fraud. S. Rep. No. 99-345, at 2 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5266. The Act applies broadly to address a wide variety of fraudulent schemes, and it was drafted "expansively . . . to reach all types of fraud, without qualification, that might result in financial loss to the Government." *Cook Cty. v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003) (quotation marks omitted).

Under the current version of the Act, the FCA imposes liability when a person "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). The FCA also imposes liability when a person "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *Id.* § 3729(a)(1)(B).[1]

Suits to collect statutory damages and penalties under the Act may be brought either by the Attorney General or by a private person (known as a *qui tam* relator) in the name of the United States. 31 U.S.C. § 3730(a), (b)(1). If a *qui tam* action is filed, the government may intervene and take over the case. *Id.* § 3730(b). If the government declines to intervene, as here, the relator conducts the litigation, *id.* § 3730(c)(3)—though the government may still file an amicus brief in the litigation to protect its broader interests. Monetary awards from a *qui tam* suit are divided between the government and the relator. *Id.* § 3730(d).

B. The Anti-Kickback Statute

The Anti-Kickback Statute prohibits knowingly and willfully offering or paying remuneration to any person "to induce such person" to (A) "refer an individual to a person for the furnishing . . . of any item or service for which payment may be made in

[1] This version of the statute took effect on May 20, 2009. *See* Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1621. Previous versions phrased these provisions differently. *See* 31 U.S.C. §§ 3729(a)(1), (2) (2006). Although some conduct in this case predates 2009, *see* JA 6, the differences are not material to the issues in this case. "JA" refers to the Joint Appendix. "Dkt." refers to the district court docket number.

whole or in part under a Federal health care program" or to (B) "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). The AKS also prohibits knowingly and willfully receiving kickbacks "in return" for the same conduct. *Id.* § 1320a-7b(b)(1).

The AKS ensures that health care provided to beneficiaries of the public health insurance programs results from sound medical judgment, not an illegal kickback. Congress adopted the AKS to "strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the medicare and medicaid programs." H.R. Rep. No. 95-393, at 1 (1977). The House Report explained that this stronger capability was needed, in part, because doctors' "[f]urnishing" of "excessive services" is "relatively difficult to prove and correct," "[s]ince the medical needs of a particular patient can be highly judgmental." *Id.* at 47. The House Report underscored the importance of the AKS, explaining that "fraud in these health care financing programs . . . cheats taxpayers who must ultimately bear the financial burden of misuse of funds in any government-sponsored program," and "diverts from those most in need . . . scarce program dollars that were intended to provide vitally needed quality health services." *Id.* at 44.

Violation of the AKS is a felony. 42 U.S.C. § 1320a-7b(b). Violation of the AKS also may result in civil monetary penalties of $50,000 per violation, treble damages, and exclusion from participation in public health insurance programs. *Id.* §§ 1320a-7a(a)(7),

1320a-7b(b). Courts have recognized that claims for reimbursement for medical care tainted by illegal kickbacks are "false" claims within the meaning of the FCA. *See, e.g.*, *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295 (3d Cir. 2011); *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 392-93 (1st Cir. 2011). And in 2010, Congress amended the AKS to clarify that "[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. Bluewave Healthcare Consultants, Inc.*, No. 16-1597, 2017 WL 1097132, *1 (4th Cir. March 23, 2017). The statute provides: "[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).

C. District Court Proceedings

The relator, Steve Greenfield, is a former vice president of defendant Accredo Health Group, Inc. He filed this *qui tam* action on behalf of the United States against Accredo and other related defendants. Accredo provides specialty pharmacy services to hemophilia patients. Defendant Medco Health Solutions, Inc. owns Accredo. Hemophilia Health Services, Inc. provides hemophilia therapy management services and is a wholly owned subsidiary of Accredo. JA 5. We refer to the defendants collectively as Accredo.

Relator alleged a kickback scheme between Accredo and two charitable organizations: the Hemophilia Association of New Jersey, Inc. (HANJ) and Hemophilia Services, Inc. (HSI). Relator claimed that from 2007 to 2011, Accredo made donations

to the charities in amounts of $175,000 to $500,000, or more, with the intent to induce the charities to refer hemophilia patients to Accredo and to recommend that the patients use Accredo's services. JA 6. In his summary judgment briefing, relator advanced three theories as to how the charities made "referrals" and "recommendations" within the meaning of the AKS. First, relator argued that the charities listed Accredo as an approved provider on their websites and communicated with their members that Accredo had made donations to the charities. Dkt. 151, at 23-25. Second, relator argued that the charities made grants to hemophilia treatment centers and communicated to the centers that Accredo was a preferred provider, which resulted in the centers referring patients to Accredo. *Id.* at 25-26. Third, relator argued that the charities sent letters to its members suggesting that they punish Accredo for reducing its donations to the charities by using other companies' services. *Id.* at 30-31; JA 13 n.12. Relator argued that Accredo violated the FCA by submitting claims for twenty-four federally insured patients in New Jersey for approximately $39 million and receiving approximately $25 million in federal reimbursements. Dkt. 151, at 37-38.

The district court granted Accredo's motion for summary judgment. JA 5. The court explained that relator must (1) "establish that defendants violated the AKS through its alleged quid pro quo arrangement with [the charities]" and (2) "show that as a result of defendants' AKS violation, defendants received payment from the federal government." JA 12.

The court declined to determine whether Accredo violated the AKS. Instead, the court assumed that relator could establish an AKS violation and held that relator had not offered sufficient evidence of an FCA violation. The court noted that it had twice dismissed relator's complaints because he had failed to show a "link between defendants' alleged quid pro quo arrangement and payment from the federal government." JA 14. The court found that the evidence showed that Accredo billed the federal government for twenty-four hemophilia patients in the amount of $39 million during the relevant period. JA 16. But the court concluded that "[t]his data does not . . . show that any of these twenty-four patients were referred from [the charities] or [a hemophilia treatment center] as a result of defendants' donations." *Id.*

The court rejected relator's argument that if Accredo violated the AKS in its arrangement with the charities, "any and all claims" submitted by Accredo to the government for hemophilia patients, "regardless of how the patients came to be customers of [Accredo]," violate the FCA. JA 16. Instead, the court held that relator needed to show that "each claim submitted to the government for payment would not have been paid by the government had it known about defendants' false representation that they complied with the AKS." JA 17. The court explained that the "FCA does not suggest that one false claim for payment submitted to the government causes all other claims for payment, regardless of whether those other payments were shown to be false, to be violations of the FCA." JA 18.

The court found that relator's proof would have been sufficient to establish an FCA claim "only if he had also shown that each of defendants' claims to the government for payment was directly linked to defendants' donations to HANJ/HSI." JA 21. The court elaborated that the necessary link had not been established because the evidence shows that "each HANJ/[HSI] related patient was free to make his or her own choices regarding providers," and that the charities did not "refer patients to the providers it endorsed for any particular or specific services." *Id.* The court concluded that simply listing Accredo as a preferred provider and acknowledging its contributions to the charities was "too attenuated a causal connection." *Id.* Without some evidence "that those particular patients chose Accredo because of its donations to HANJ/[HSI]," the court concluded that relator could not carry his burden on this element of his FCA claim. JA 22.

ARGUMENT

Claims Seeking Reimbursement For Medical Care That Was Provided In Violation Of The Anti-Kickback Statute Are False

The district court properly rejected relator's argument that any AKS violation by Accredo rendered all claims by Accredo false, regardless of how the patients associated with those claims came to be customers of Accredo. Instead, to establish a false claim, relator had to show a connection between the alleged kickbacks paid by Accredo to the charities and the claims Accredo submitted for federal beneficiaries. The district court

erred, however, to the extent that it required relator to prove a causal connection between the kickbacks and the claims.

1. In order to establish FCA liability, a relator must establish a "false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)-(B); *see United States ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432, 440 (3d Cir. 2004). As explained below, a claim seeking payment for medical care that was provided in violation of the AKS is "false" because the claim is ineligible for payment.

Compliance with the AKS is critical to the government's decision to pay federal health benefits claims. The AKS makes it a felony to pay kickbacks to induce referrals, recommendations, or the actual purchase of items or services "for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b). The AKS ensures that the government pays only for conflict-free medical care that is provided in the best interests of the patient. A kickback eliminates any sound basis for such assurance because it taints medical decisions with financial interests. In *United States ex rel. Wilkins v. United Health Group, Inc.*, this Court recognized that "[t]he Government does not get what it bargained for when a defendant is paid by [the government] for services tainted by a kickback." 659 F.3d 295, 314 (3d Cir. 2011). And the Court concluded that "[c]ompliance with the AKS is clearly a condition of payment under Parts C and D of Medicare." *Id.* at 313. Similarly, in *United States ex rel. Schmidt v. Zimmer, Inc.*, this Court recognized that the Medicare regulations make "[a] certificate of compliance with federal health care law," including the AKS, "a prerequisite to

eligibility under the Medicare program." 386 F.3d 235, 243 (3d Cir. 2004) (citing 42 C.F.R. § 413.24(f)(4)(iv)). Compliance with the AKS is thus a fundamental aspect of what the government purchases when it pays for medical care for federally insured beneficiaries.

Accordingly, this Court and other courts of appeals have unanimously concluded that claims for medical care that was tainted by a violation of the AKS are "false" under the FCA. *See Wilkins*, 659 F.3d at 313; *United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 94 (3rd Cir. 2009); *Schmidt*, 386 F.3d at 243; *United States ex rel. McNutt v. Haleyville Med. Supplies*, 423 F.3d 1256, 1259-60 (11th Cir. 2005); *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 392-93 (1st Cir. 2011). Courts have used different terminology—*e.g.*, misrepresentation, false certification—and have relied on various regulations, agreements, and cost reporting forms, but the central reasoning is the same: a claim for medical care that was tainted by a violation of the AKS is false because compliance with the AKS is a fundamental condition of payment by the government. *See, e.g., Hutcheson*, 647 F.3d at 392 (claims "misrepresented" compliance with a material precondition of payment); *McNutt*, 423 F.3d at 1257 (claims that are ineligible for payment are false).

In *Wilkins*, this Court held that a relator states a claim under the FCA when he alleges that the defendant "knowingly violated the AKS while submitting claims for payment to the Government under the federal health insurance program." 659 F.3d at 313; *see id.* at 314. The Court reasoned that when a provider submits a claim to the

government for reimbursement, it implicitly represents that it complied with the AKS. *Id.* at 305, 313. Accordingly, if the provider "submitted claims for payment to the Government at a time that they knowingly violated" the AKS, that representation is false. *Id.* at 313. The Supreme Court recently recognized that "the False Claims Act encompasses claims that make . . . certain misleading omissions," which can include "omit[ting] [the defendant's] violations of statutory, regulatory, or contractual requirements." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1999 (2016).[2]

In addition, medical providers sign an agreement with Medicare in which they "agree to abide by [applicable] Medicare laws, regulations and program instructions," and acknowledge that they "understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with . . . the Federal anti-kickback statute." JA 10 (quoting Medicare Enrollment Application Form 855S); *see Hutcheson*, 647 F.3d at 392-93.[3] If such a provider submits a claim for payment

[2] The Court addressed only the situation where the claim "makes specific representations about the goods or services provided," and did not reach the question "whether all claims for payment implicitly represent that the billing party is legally entitled to payment." *Escobar*, 136 S.Ct. at 2000-01. Accordingly, *Escobar* leaves intact this Court's holding in *Wilkins*, which did not require specific representations, but instead recognized that "'implied false certification' liability . . . attaches when a claimant seeks and makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment." 659 F.3d at 305; *see also id.* at 313.

[3] Medicare Enrollment Application Form 855S applies to suppliers enrolled in Medicare Part B. There are provider agreement forms with similar language for other

for medical care that was provided in violation of the AKS or where the underlying transaction violated the AKS, the express certification of compliance with the AKS is false for that claim. *Hutcheson*, 647 F.3d at 392-93.

Finally, Congress amended the AKS in 2010 "to clarify that 'a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." *Wilkins*, 659 F.3d at 311 n.19 (quoting 42 U.S.C. § 1320a-7b(g)) (first alteration added).

2. In this case, the district court assumed that Accredo had violated the AKS, but nonetheless concluded that relator had failed to show that any of the federal claims Accredo actually submitted were actionable under the FCA. *See* JA 13-22. The United States does not take a position on the adequacy of relator's factual submissions for purposes of summary judgment, and we therefore take no position on whether the district court was ultimately correct in granting Accredo's motion for summary judgment. We instead address the correct legal standard.

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types of medical care providers. The current versions of these forms are available at https://www.cms.gov/medicare/provider-enrollment-and-certification/medicareprovidersupenroll/enrollmentapplications.html. Accredo contended in district court that Form 855S applies only to Medicare Part B, and thus is not applicable to Accredo's claims for reimbursement from other federal programs (Medicaid, Tricare, and Medicare Part C). *See* Dkt. 131 at 14. The district court did not address the argument. JA 21 n.15. Because we take no position on the underlying facts of this case, we also do not address the argument. However, we note that, as this Court recognized in *Wilkins*, "[e]ach month," participants in Medicare Part C "certify to [the government] that they continue to comply with all of the [Medicare Part C] guidelines, including . . . the AKS." 659 F.3d at 300.

The disputed issue is what type of connection a plaintiff must show between a violation of the AKS and a claim for payment from the government in order to establish that the claim is "false" under the FCA. As discussed above, when a medical provider submits a claim to the government for reimbursement, he represents that the medical care for which he seeks reimbursement and the underlying transaction complied with the AKS. The express certification in the provider agreement makes this clear: "payment of a claim by Medicare is conditioned upon *the claim* and *the underlying transaction* complying with" the AKS. Accordingly, a plaintiff has demonstrated that a claim is false if he shows that the claimed medical care was not provided in compliance with the AKS or the underlying transaction did not comply with the AKS.

In classic kickback scenarios, the connection between the kickbacks and the claims is obvious because the claimed medical care is the subject of the kickback scheme. For example, if a medical service provider pays kickbacks to a doctor to induce the doctor to refer patients to the provider, and the provider then submits claims to Medicare for the services it rendered to patients referred by *that doctor*, the claims are false. Similarly, if a pharmaceutical company pays kickbacks to a doctor to induce the doctor to administer the company's drugs to his patients, and the doctor subsequently submits claims to Medicare for administering *the company's drugs*, the claims are false. In both scenarios, all of the claims for the items or services that were the subject of the kickbacks would be false.

Consistent with these principles, the district court correctly explained that the "FCA does not suggest that one false claim for payment submitted to the government causes all other claims for payment, regardless of whether those other [claims for] payments were shown to be false, to be violations of the FCA." JA 18. And the district court properly rejected relator's argument that "because defendants violated the AKS in their quid pro quo arrangement with HANJ/HSI, any and all claims submitted to the government for hemophilia patients, regardless of how the patients came to be customers of defendants, violate the FCA." JA 16.

For example, if a medical service provider pays kickbacks to only one doctor and then submits claims to Medicare for services it provided to patients referred by that doctor, the claims would be false. But if the service provider also submits claims to Medicare for patients referred by a different doctor, to whom the medical service provider did not pay any kickbacks, those claims would not be rendered false by virtue of the AKS violation with respect to the first doctor. Indeed, for the patients referred by the second doctor, the certification in the provider agreement that "the claim" and "the underlying transaction" complied with the AKS would not be false.

The same principle applies here. Relator contends that Accredo paid kickbacks to the charities, which then referred patients to Accredo or recommended that patients use Accredo's services, in violation of the AKS. Relator also contends that Accredo submitted claims to the federal government for twenty-four hemophilia patients in New Jersey. As in the example, Accredo's claims would be false only for those patients who

were referred by the charities or to whom the charities recommended Accredo's services. The district court was correct to the extent that it required relator to make that showing in order to establish that the claims Accredo submitted to the government were "false."

However, to the extent that certain aspects of the district court's decision could be read to suggest that there is a need for proof of a causal effect between the kickbacks and the claims, the court erred. The district court appeared to require relator to show that Accredo's federal claims sought reimbursement for medical care that would not have been provided but for the kickback scheme. In other words, the district court incorrectly appeared to believe it was necessary for relator to show that the kickbacks *in fact* corrupted the charities' decision to refer patients to Accredo and recommend Accredo's services, and that those referrals and recommendations *in fact* corrupted the patients' decisions to use Accredo's services.

The court stated that the evidence that Accredo billed the government for twenty-four hemophilia patients in New Jersey "does not . . . show that any of these twenty-four patients were referred from HANJ/HSI or an HTC *as a result of* defendants' donations." JA 16 (emphasis added). The court also stated that relator failed to show that the twenty-four patients for whom Accredo billed the federal government "*chose* Accredo *because of* its donations to HANJ/[HSI]." JA 22 (emphasis added). The court observed that "the record evidence establishes that each HANJ/[HSI] related patient was free to make his or her own choices regarding providers." JA 21. The court stated

that the connection between the charities' referrals and the patients' choices to use Accredo was "too attenuated a *causal* connection." *Id.* (emphasis added).

The district court was wrong to require this sort of patient-specific causal proof in order to establish that a claim is "false" under the FCA. The court appeared to add a causation requirement to the statutory requirement of a "false" claim.[4] The statute does not require this showing, and such a requirement would significantly hamper the government's efforts to prevent healthcare fraud because the government would have to prove that a kickback actually influenced a specific doctor's or patient's medical decision. As explained above, a plaintiff establishes falsity if he shows that the claim seeks reimbursement for medical care that was not provided in compliance with the AKS. Medical care that was the subject of an illegal kickback scheme was not provided in compliance with the AKS, regardless of whether the illegal kickbacks caused the doctor's or patient's medical decisions. Proof that the medical care would not have been provided in the absence of the kickback is not required. Indeed, the AKS was enacted in part to eliminate the need for individualized proof of medical decisionmaking given the inherent difficulties of doing so; instead, kickbacks are presumed to corrupt medical judgments.

[4] This case does not involve the FCA provisions that impose liability when one "causes to be presented" a false claim for payment or "causes to be made or used" a false statement material to a false claim. 31 U.S.C. § 3729(a)(1). Relator claims that Accredo itself "present[ed]" false claims to the government.

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 AKS. That is so 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. Similarly, if a pharmaceutical company pays kickbacks to a doctor to induce the doctor to administer the company's drugs, and the doctor subsequently submits a claim to Medicare for administering the company's drugs, that claim is false because the medical care was rendered in violation of the AKS. That is so regardless of whether the doctor would have prescribed the drugs absent the kickbacks. The claims are false because the medical care was not provided in compliance with the AKS, and it is thus irrelevant whether the same claims might have been submitted even absent the kickback.

The government insists on compliance with the AKS precisely to ensure that medical care is being provided based on the best interests of the patient, without having to second-guess particular medical decisions. The government is purchasing the provision of services that are conflict-free, and "[t]he Government does not get what it bargained for when a defendant is paid by [the government] for services tainted by a kickback." *Wilkins*, 659 F.3d at 314; *cf. United States v. Science Applications Int'l Corp.*, 626 F.3d 1257, 1266-71 (D.C. Cir. 2010) (government contractor's failure to comply with conflict-of-interest rules rendered claims false). Indeed, Congress adopted the AKS to

avoid the need for proof regarding the appropriateness of medical judgments. The AKS was designed to strengthen the government's ability to prosecute fraud, in part, because "the medical needs of a particular patient can be highly judgmental," so it is "relatively difficult" to prove that a practitioner abused the program by furnishing "excessive services." H.R. Rep. 95-393 at 47. There is thus no need to prove that the kickback actually influenced a doctor's medical decision.

For similar reasons, a plaintiff does not need to prove that a physician's referral or recommendation caused the patient's choice to use a particular provider. Where a medical service provider pays a physician a financial inducement to make a referral or recommendation, the objective medical judgment of the physician that is critical to helping a patient make informed decisions about fundamental health care issues has been corrupted. There is thus no assurance that the referral or recommendation was made based on the best interests of the patient.

Courts have recognized that a plaintiff does not have to prove that a specific claim was for services that were not medically necessary in order to show that the claim is false. In *United States v. Rogan*, 517 F.3d 449 (7th Cir. 2008), the Seventh Circuit held that claims for patients who were referred by doctors who had received illegal kickbacks were false under the FCA. The court explained that the claims were false because the conditions for payment were not satisfied, and thus it did not matter whether the patients "received some medical care—perhaps all the care reflected in the claims

forms," or that "if the patients had gone elsewhere, the United States would have paid for their care." *Id.* at 453.[5]

In *Hutcheson*, the First Circuit rejected the argument that certain claims "were not false or fraudulent because the claims were for services that would have been provided in the absence of the alleged AKS violations." 647 F.3d at 393. There, the defendants argued that even if the physicians received kickbacks to use the defendant's products in certain spinal surgeries, the physicians' claims were not false because they billed Medicare for medically necessary surgeries, not for the devices. The court explained that "[t]his argument does not address the complaint's allegation that under the express terms of the [provider agreement], the 'underlying transaction' violated the AKS and therefore that the resulting claims were ineligible for payment." *Id.* at 393.

This Court has similarly recognized that "[e]ven if the physician performs some service" in exchange for a kickback, "the potential for unnecessary drain on the Medicare system remains." *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985). And when Congress amended the FCA, the Senate Report recognized that "claims may be false even though the services are provided as claimed if, for example, the claimant is ineligible to participate in the program." S. Rep. No. 99-345 at 9; *see also id.* at 10 (citing

[5] District courts have likewise held that claims for medical services that were not rendered in compliance with the AKS are false, regardless of whether the services were necessary or were actually provided. *See United States ex rel. Pogue v. American Healthcorp., Inc.*, 914 F. Supp. 1507, 1509-13 (M.D. Tenn. 1996); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017, 1047-48 (S.D. Tex. 1998).

Peterson v. Weinberger, 508 F.2d 45 (5th Cir. 1975)). These cases and the legislative history support the principle that a claim is false if the claimed medical care was tainted by a kickback because the claim is ineligible for payment, regardless of whether the same claim would have been submitted absent the kickback.

The 2010 amendment to the AKS confirms that claims for medical services that were provided in violation of the AKS are "false" claims within the meaning of the FCA. The provision states: "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). In district court, Accredo argued that the "resulting from" language requires "a direct causal connection between an AKS violation and a violation of the FCA." Dkt. 110-2, at 32. The argument is incorrect for multiple reasons, and the Southern District of New York recently rejected it. *See United States ex rel. Kester v. Novartis Pharm. Corp.*, 41 F. Supp. 3d 323, 331-335 (S.D.N.Y. 2014).

The 2010 amendments to the AKS were intended "to strengthen," rather than to limit, "fraud enforcement." 155 Cong. Rec. S10852, 10854 (daily ed. Oct. 28. 2009); *see also id.* at S10853 (the amendment "strengthens whistleblower actions based on medical care kickbacks"). As the Southern District of New York explained, "[t]here is no indication in either the law itself or the legislative history that Congress intended to narrow the scope of 'falsity' under the FCA when it amended the AKS to add Section 1320a-7b(g)." *Kester*, 41 F.Supp.3d at 334. The amendment thus in no way undermines pre-existing law, which supported the principle that a plaintiff need not show that a

kickback caused a claim for reimbursement from the federal government in order to establish that the claim is false. Indeed, prior to 2010, courts had already rejected arguments that plaintiffs must prove that medical care was unnecessary in order to show that a claim for care tainted by a kickback was false. *See Rogan*, 517 F.3d 449; *Thompson*, 20 F. Supp. 2d 1017; *Pogue*, 914 F. Supp. 1507. And later courts likewise held that claims are false when the claimed medical care or the underlying transaction violated the AKS, relying on the pre-2010 statute and provider agreements. *See Wilkins*, 659 F.3d at 311-14; *Hutcheson*, 647 F.3d at 392-95.

Consistent with these decisions, Congress amended the AKS to "clarify," *Wilkins*, 659 F.3d at 312 n.19, that "all claims resulting from illegal kickbacks are 'false or fraudulent,' even when the claims are not submitted directly by the wrongdoers themselves," 155 Cong. Rec. S10853. Congress added this provision to overrule an erroneous district court decision, which had held that when a doctor was paid a kickback to use a medical device, a claim by an innocent hospital for the procedure to implant the medical device was not false under the FCA. *See* 155 Cong. Rec. S10853. The phrase "resulting from" was intended to indicate that the taint from an illegal kickback remains with an item or service, regardless of when the claim to the federal government is made for the item or service and regardless of who submits the claim. In addition, the legislative history also states that the 2010 amendment was intended to cover claims that "stem from" or "aris[e] from" illegal kickbacks, 155 Cong. Rec. at S10853, which are not strictly limited to claims that were caused by the kickbacks. The

2010 amendments also relaxed the scienter requirements for the AKS, *see id.* at S10853, which underscores that the amendments were intended to strengthen enforcement of that statute.

Finally, Accredo's argument would have the odd result that a defendant could be convicted of criminal conduct under the AKS for paying kickbacks to induce medical referrals, but would be insulated from civil FCA liability for the exact same conduct, absent additional proof that each medical decision was in fact corrupted by the kickbacks.

CONCLUSION

For the foregoing reasons, this Court should hold that while relator is required to prove that the patients for whom Accredo billed the government were referred to Accredo by the charities or received recommendations for Accredo's services from the charities, relator is not required to prove that the kickbacks caused the charities to make the referrals and recommendations or that the referrals and recommendations caused the patients to use Accredo's services.

Respectfully submitted,

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April 2017

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Federal Rule of Appellate Procedure 32(a). This brief contains 5,890 words. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Word 2013 in size 14 point Garamond font.

/s/ Katherine Twomey Allen
KATHERINE TWOMEY ALLEN

CERTIFICATE OF SERVICE

I hereby certify that on April 17, 2017, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Third Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

/s/ Katherine Twomey Allen
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CERTIFICATE OF VIRUS SCAN

I hereby certify that on April 17, 2017, a virus check was performed using Symantec Endpoint Protection version 12.1.6 (definition Sunday, April 16, 2017 r19) and no virus was detected.

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