No. 10-2215

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

UNITED STATES OF AMERICA, ex rel. PETER ROST,
Plaintiff-Appellant,

v.

PFIZER, INC. AND PHARMACIA CORPORATION,
Defendants-Appellee.

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

BRIEF FOR *AMICUS CURIAE* THE UNITED STATES OF AMERICA IN SUPPORT OF APPELLANT

TONY WEST
Assistant Attorney General

CARMEN ORTIZ
United States Attorney

DOUGLAS N. LETTER
(202) 514-3602
CHARLES W. SCARBOROUGH
(202) 514-1927
Attorneys, Appellate Staff
Civil Division, Room 7244
Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20530-3001

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases:

Rules:

Statutes:

Miscellaneous:

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

No. 10-2215

UNITED STATES OF AMERICA, ex rel. PETER ROST,
Plaintiff-Appellant,

v.

PFIZER, INC. AND PHARMACIA CORPORATION,
Defendants-Appellee.

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

BRIEF FOR *AMICUS CURIAE* THE UNITED STATES OF AMERICA
IN SUPPORT OF APPELLANT

INTRODUCTION AND STATEMENT OF INTEREST

Pursuant to Fed. R. App. P. 29 and 28 U.S.C. § 517, the United States submits this brief as *amicus curiae* supporting reversal of the judgment below.

In this action under the False Claims Act ("FCA"), 31 U.S.C. § 3729*, et seq.*, the *qui tam* relator alleges that defendant Pharmacia – the manufacturer of the human-growth hormone Genotropin – paid kickbacks to physicians to induce them to prescribe Genotropin while knowing that this kickback scheme would cause pharmacies to submit claims for reimbursement of Genotropin to state

Medicaid agencies. The relator alleges that those claims were false under the FCA because claims for drugs, devices, or medical services induced by kickbacks are ineligible for reimbursement under Medicaid.

The district court granted the defendants' motion for summary judgment. Drawing a threshold distinction between "factually false" and "legally false" claims under the FCA, and a further distinction between claims involving express and implied certifications of compliance with relevant conditions of payment, the court held that the Medicaid claims submitted by the pharmacies did not contain any *express* certifications of compliance with the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320-7b, and that such claims could not be deemed to contain *implied* certifications of compliance with the AKS with respect to the underlying transaction but only with respect to the pharmacies themselves. See Applt's Br. Addend., at 22. Thus, the court concluded, a drug manufacturer that paid kickbacks to induce the use of its products – and consequently caused the submission of kickback-tainted claims to Medicaid – could not be held liable under the FCA "where the person who submitted the claim was innocent of wrongdoing *and* where (a) the claim was not factually false, (b) the claim was not legally false due to an express certification of compliance with the AKS or (c) compliance with the federal statute was not an expressly stated condition of payment." *Id*. at 24 (emphasis in the original).

The district court's decision cannot be reconciled with this Court's recent decisions in *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377 (1st Cir. 2011), *cert denied*, 2011 WL 3841271 (Dec. 5, 2011), and *New York v. Amgen, Inc.*, 652 F.3d 103 (1st Cir. 2011), *pet. for cert. dismissed*, 2011 WL 4403614 (Dec. 27, 2011). In those cases, this Court reversed the dismissal of similar *qui tam* suits alleging that drug and device manufacturers paid kickbacks to increase the use of their products and thereby caused the submission of claims tainted by kickbacks to Medicare and Medicaid. In so doing, this Court expressly rejected the analytical distinctions the district court in this case relied upon (*i.e.*, factually and legally false claims, and express and implied certification), stressing that such categories "may do more to obscure than clarify" the circumstances under which the FCA extends to unlawful kickback schemes. *Blackstone*, 647 F.3d at 385. Moreover, this Court confirmed that compliance with the prohibition against kickbacks is a well-established condition of payment under Medicare and Medicaid, and specifically rejected the argument – which the district court here appeared to accept – that "a claim can only be false or fraudulent due to an implied legal misrepresentation if it fails to comply with the express requirements of a statute or regulation." *Id*. at 386. See also *Amgen*, 652 F.3d at 110.

This Court's decisions in *Blackstone* and *Amgen* compel reversal of the judgment below. Those decisions make clear that a claim for medical services,

drugs, or devices is "false" within the meaning of the FCA if it fails to comply with a material condition of payment established by the government, and that an entity that knowingly causes the submission of kickback-tainted claims to Medicare or Medicaid cannot avoid liability under the FCA simply because such claims are submitted by "innocent" third parties – here, the pharmacies submitting claims for Genotropin – who have no knowledge of the underlying kickbacks. As this Court explained in *Blackstone*, the FCA imposes liability on any person who "knowingly presents, *or causes to be presented*," a false or fraudulent claim to the government, 31 U.S.C. § 3729(a)(1), and the leading cases in this context "do not hold that a submitting entity's representations concerning its own conduct somehow immunize a non-submitting entity from liability under the 'causes' clauses of the FCA." *Blackstone*, 647 F.3d at 389-90 (emphasis in the original). See also *Amgen*, 652 F.3d at 110-11 (holding that the sole question "is whether the claims at issue misrepresented compliance with a material precondition of payment forbidding the alleged kickbacks"). Because the district court's decision conflicts with these basic legal principles, it must be reversed.

Although this Court's decisions in *Blackstone* and *Amgen* control the outcome in this case, the United States is participating as *amicus curiae* in this appeal because the government has a significant and ongoing interest in the proper application of the FCA to *qui tam* suits based upon kickback allegations.

The FCA is a critical tool in the government's efforts to combat health care fraud, and kickback schemes have a particularly pernicious effect on the integrity of health care programs such as Medicare and Medicaid because such schemes create powerful financial incentives to perform medically unnecessary procedures and to use inferior or inappropriate drugs or devices, thereby increasing costs and potentially jeopardizing the health and safety of federal health care beneficiaries. Moreover, such schemes are difficult to detect because – as this case illustrates – the entities that actually submit the claims for reimbursement are often unaware of the underlying kickbacks. Thus, although the United States declined to intervene in this case below, we are participating as *amicus curiae* in this appeal, as we did in *Blackstone* and *Amgen*, to ensure the continued viability of FCA actions to deter and redress health care fraud predicated upon illegal kickbacks.

STATEMENT OF FACTS

I. Statutory Background.

A. Medicaid.

Medicaid is a cooperative federal-state public assistance program established by Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 - 1396v, under which federal matching funds are available to states that elect to pay for all or part of specified care and services furnished to needy individuals. See *Harris*

v. McRae, 448 U.S. 297, 301 (1980); *Long Term Care Pharmacy Alliance v. Ferguson*, 362 F.3d 50, 51 (1st Cir. 2004). To participate in Medicaid, all medical providers must sign enrollment agreements, which vary slightly from state to state, but generally establish that claims may not be paid if they are affected by kickbacks. See *Amgen*, 652 F.3d at 112-15 (concluding that provider agreements and most states' statutes and regulations establish that compliance prohibition on kickbacks is a condition of payment).

B. The Anti-Kickback Statute.

The Anti-Kickback Statute ("AKS") prohibits any person from knowingly offering to pay any remuneration to another person to induce the purchase, order, or recommendation of any good 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). In addition to criminal penalties, violations of the AKS may result in civil monetary penalties of up to $50,000 per violation, an assessment of up to three times the amount of remuneration paid, and exclusion from participation in federal health care programs. 42 U.S.C. § 1320a-7a(a)(7).

These substantial penalties reflect the significance of the prohibition against kickbacks as a critical tool in the fight against health care fraud. *See* H. Rep. 95-393, 95th Cong., 1st Sess. at 44, *reprinted in* 1977 U.S.C.C.A.N. 3039, 3047 (explaining that fraud in federal health care programs "cheats taxpayers who

must ultimately bear the financial burden of misuse of funds in any government-sponsored program"). Indeed, as part of the comprehensive health care reform legislation enacted earlier this year, Congress amended the AKS to clarify 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 False Claims Act]." Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub. L. No. 111-148, § 6402(f), 124 Stat. 119 (codified at 42 U.S.C. § 1320a-7b(g)).

C. The False Claims Act.

The False Claims Act imposes civil liability when a person "knowingly presents, or causes to be presented" to the government "a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1), or "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," *id*. § 3729(a)(2).[1] The Attorney General may bring a civil action if he finds that a person has committed a violation. *Id.* § 3730(a). Alternatively, a private person may bring a *qui tam*

[1] The Fraud Enforcement and Recovery Act of 2009 ("FERA"), Pub. L. No. 111-21, 123 Stat. 1617 (2009), modified and renumbered the subsections of 31 U.S.C. § 3729(a), but only the amendments to former Section 3729(a)(2) were made retroactive. Pub. L. No. 111-21, § 4, 123 Stat. 1625. Because the analysis in this case is not affected by which version of these provisions applies, we have cited the former version of the FCA, which the district court applied. *See United States ex rel. Loughren v. Unum Group*, 613 F.3d 300, 306 n.7 (1st Cir. 2010) (applying old version of the FCA where analysis would be the same under either version).

action "for the person and for the United States Government." *Id*. § 3730(b)(1); *United States ex rel. Eisenstein v. City of New York*, 129 S. Ct. 2230, 2232 (2009). If a *qui tam* suit results in the recovery of damages or civil penalties, the award is divided between the government and the relator. 31 U.S.C. § 3730(d).

II. Proceedings In This Case.

This case involves FCA claims brought by a *qui tam* relator, Peter Rost, against defendants Pharmacia Corp and Pfizer, Inc., which acquired Pharmacia after the events at issue in this case. The relator alleges that Pharmacia – the manufacturer of Genotropin, a drug intended for the treatment of growth hormone deficiency – paid illegal kickbacks to physicians to induce them to prescribe Genotropin and also engaged in an illegal scheme to promote that drug for off-label pediatric use.[2] The relator further alleges that Pharmacia knew its kickback scheme would cause the submission of false claims to state Medicaid agencies.

After the United States declined to intervene in this case, the district court initially dismissed on the ground that the relator's complaint failed to satisfy the heightened pleading requirement of Fed. R. Civ. P. 9(b). In *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720 (1st Cir. 2007), this Court largely affirmed that

[2] Because the district court dismissed the off-label marketing claim, and the relator has not challenged that ruling on appeal, see Appellant Br. at 3, we have not addressed that claim in this brief.

ruling, but remanded for the district court to consider the relator's request for leave to amend his complaint. On remand, the district court allowed an amended complaint and permitted discovery on the relator's claims. Following discovery, the court granted the defendants' motion for summary judgment.

In dismissing the kickback claims in this case, the district court explained that the kickbacks Pharmacia allegedly paid to physicians to induce them to prescribe Genotropin "took three forms: (1) remuneration and personal benefits for physicians for attendance and participation at Pharmacia-sponsored events; (2) paid participation in the Kabi International Growth Study (KIGS); and (3) participation in the Bridge Program." Applt Br. Addend., at 7-8. After outlining the relator's allegations with respect to each type of kickback, *id*. at 9-14, the court then considered the argument "that defendants' payment of kickbacks to physicians caused false on-label and off-label claims to be submitted to the government," *id*. at 16.

Under the heading "False Claims Act and Implied Certification Theory," the court began by drawing a distinction between "factually false" and "legally false" claims." *Id.* at 16. The court described "legally false" claims as "those that falsely certify compliance with applicable statutes and regulations when the government conditions payment on such compliance." *Id.* at 16-17. *W*ithin this category, the court focused on the "implied false certification theory of liability,"

which the court characterized as "an evolving area of the law," *id*. at 17, stating that some courts have not yet adopted that theory while others have limited its application, *id*. at 18-19.

Having confined the FCA claims in this case to a specific category ("legally false") and a specific theory of liability ("implied certification"), the court stated that "the difficult legal question in this case is whether or not the claims submitted by the innocent third parties, the pharmacies, can be 'false or fraudulent' under the theory of implied certification." *Id.* at 19. While conceding that the "Supreme Court has long held that a person may be liable under the FCA for causing an innocent third party to submit a false claim to the government without knowing it is false," *ibid*., the court stated that "[a] claim cannot be false merely because the activity underlying the claim was illegal," *id*. at 20.

Instead, the court concluded, "it is the false certification of compliance which creates liability." *Ibid*. (internal quotations omitted) (quoting *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996)). Distinguishing *Mason v. Medline Indus., Inc.*, 2010 WL 653542 (N.D. Ill. 2010) – which allowed similar kickback claims to proceed under the FCA – the district court stated that "there is no evidence of any false express certification of compliance with the AKS by either the pharmacies or the prescribing physicians who had to seek prior approval." *Id*. at 21. Thus, the court treated the absence of

express certifications of compliance with the AKS as dispositive in an *implied* certification case.[3]

The district court also rejected the government's argument "that when you bill Medicaid you are impliedly certifying that no kickbacks have been paid in the underlying transactions." *Id*. at 22. Relying in large part upon the district court's decision in *Blackstone* – which this Court has now reversed – the district court concluded that "the pharmacies that submitted the claims implicitly certified compliance with applicable statutes and regulations only with respect to themselves and those persons they control (*e.g.*, employees)." *Ibid*.

Likewise, the court rejected the government's argument that "the payment of a kickback renders subsequent claims factually false under the FCA, without regard to who submits the claim or whether there is a certification that no such kickback was accepted." *Id.* at 23. Furthermore, while recognizing that the AKS was recently amended to make clear that a claim that includes items or services resulting from a violation of the AKS is "false," the court stressed that this

---

[3] Similarly, the court sought to distinguish its own prior decision allowing FCA claims to proceed "even if there is no express certification of compliance with the statute," *In re Pharmaceutical Ind. Average Wholesale Price Litig.*, 491 F. Supp. 2d 12, 18 (D. Mass. 2007), on the ground that it "did not address a situation where, as here, the claim was not factually false (*i.e.*, because of a false price) but where the AKS was violated." Applt. Br. Addend., at 21.

provision was not retroactive and "was not effective at the time the claims in question were submitted to the state Medicaid agencies." *Id.* at 24.

Summarizing the ways in which it believed the relator's kickback claims were deficient, the district court stressed that it was not aware of:

> any cases that have stretched an implied certification theory to reach back to impose FCA liability on a payer of kickbacks where the person who submitted the claim was innocent of wrongdoing *and* where (a) the claim itself was not factually false; (b) the claim was not legally false due to an express false certification of compliance with the AKS; or (c) compliance with the federal statute was not an expressly stated precondition of payment.

Id. at 24 (emphasis in the original). The court declared that "the implied certification theory should be applied with caution in only limited circumstances," and held that the "relator's implied certification theory fails as a matter of law." *Ibid*. Accordingly, the court did not address the "difficult and important question" of whether the payments made by the defendants constituted illegal kickbacks. *Ibid.*

SUMMARY OF ARGUMENT

The district court's decision in this case is contrary to this Court's recent decisions in *Blackstone* and *Amgen*, and reversal is required on this basis alone. In those cases, this Court reversed the dismissal of *qui tam* suits predicated upon allegations that the defendants paid kickbacks to induce the use of their products and thereby knowingly caused the submission of claims to the government that

are "false" because they do not comply with a fundamental condition of payment under all government health care programs: the prohibition against kickbacks.

Compliance with the AKS is a cornerstone for reimbursement under Medicare and Medicaid because kickbacks destroy an essential premise upon which the reimbursement of all health care claims depends: that the medical services, devices, or drugs are being furnished because they are medically necessary for the patient and not simply because they advance the financial interests of the ordering physician. Thus, as this Court held in *Blackstone* and *Amgen*, a defendant that knowingly causes third parties to submit claims tainted by kickbacks to the government cannot avoid liability under the FCA simply because the third party has no knowledge of the underlying kickbacks or makes no express certifications regarding compliance with the AKS.

In dismissing the kickback claims in this case, the district court relied on legal principles and district court decisions that this Court conclusively rejected in both *Blackstone* and *Amgen*. The district court erred in at least three ways.

First, the district court employed several categories to analyze the relator's claims – *i.e.*, distinctions between "factually false" and "legally false" claims, and distinctions between express and implied certification – that this Court has now rejected on the ground that they "do more to obscure than clarify the issues before us." *Blackstone*, 647 F.3d at 385-86.

Second, the district court's analysis rests at least in part on the absence of express certifications of compliance with the AKS in the claims submitted by pharmacists to state Medicaid agencies – a point that both *Blackstone* and *Amgen* make clear is wholly irrelevant to determining whether a claim is "false."

Finally, although it is not entirely clear what significance the district court attached to its observation that "compliance with the federal statute was not an expressly stated precondition of payment," Applt. Addend. at 24, this Court has now made clear that compliance with the AKS is a fundamental condition of payment under Medicare and Medicaid, and that this condition need not be expressly set forth in statutes or regulations in order to render a claim "false" under the FCA when that condition is not satified. *Blackstone*, 647 F.3d at 386-87; *Amgen*, 652 F.3d at 110.

Because a company that pays kickbacks to induce the use of its products may be held liable for knowingly causing the submission of false claims to federal health care programs such as Medicare and Medicaid, this Court should reverse the district court's decision and remand for further proceedings consistent with the legal principles set forth in *Blackstone* and *Amgen*.

ARGUMENT

THE DISTRICT COURT ERRED IN DISMISSING THE KICKBACK CLAIMS IN THIS CASE.

A. Defendants Who Pay Kickbacks To Induce The Use of Their Products Are Liable Under The FCA Where They Know This Conduct Is Likely To Cause The Submission of Ineligible, Kickback-Tainted Claims To Federal Health Care Programs.

The FCA imposes civil liability where a person "knowingly presents, or causes to be presented," to the government "a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1), or "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," *id*. § 3729(a)(2).

In enacting the FCA, "Congress wrote expansively, meaning 'to reach all types of fraud, without qualification, that might result in financial loss to the Government.'" *Cook County, Illinois v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003) (quoting *United States v. Neifert-White Co.*, 390 U.S. 228, 233 (1968)). Thus, both the Supreme Court and this Court have long recognized that a person may be liable under the FCA not only for submitting a false claim directly to the government but also for causing another person to submit a false claim. See *United States v. Bornstein*, 423 U.S. 303 (1976) (holding that claims submitted by an innocent prime contractor were "false" within the meaning of the

FCA due to fraudulent acts of subcontractor); *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943) (holding subcontractor liable under FCA where its bid-rigging scheme caused contractor to present inflated claims to government); *United States v. Rivera*, 55 F.3d 703, 707-09 (1st Cir. 1995).

Applying these principles, a drug or device manufacturer that pays kickbacks to physicians to induce the use of its products is liable for causing the submission of false claims under the FCA if it knows that the natural and foreseeable consequence of such conduct is to cause third parties (*i.e.*, hospitals, and pharmacies) to submit claims tainted by kickbacks to federal health care programs such as Medicare or Medicaid. That is the fundamental point this Court recently confirmed in *Blackstone* and *Amgen*, and the district court's contrary ruling in this case must therefore be reversed.

In *Blackstone*, this Court reversed the dismissal of a *qui tam* suit alleging that a medical device manufacturer paid kickbacks to various doctors to use its devices, which in turn caused hospitals that had no knowledge of the underlying kickback scheme to submit claims to Medicare for services tainted by kickbacks. In so doing, the Court rejected several limitations on FCA liability proposed by the defendant. As an initial matter, the Court rejected many of the "conceptual divisions" and "judicially-created categories" that some courts have used to analyze FCA claims. *Blackstone*, 647 F.3d at 385. Noting that the district court's

decision in that case "turned on distinctions between (1) factually false or fraudulent claims and legally false or fraudulent claims, as well as (2) claims rendered legally false by an 'express certification' and claims rendered legally false by an 'implied certification,'" this Court emphasized that none of these distinctions appeared in the text of the FCA. *Ibid*. Thus, while recognizing that judicially-created categories may sometimes be useful, the Court declined to employ these distinctions because it believed "these categories do more to obscure than clarify the issues before us." *Id*. at 385-86.

The Court also rejected two limitations on liability proposed by Blackstone. First, the Court rejected the argument that "a claim can only be false or fraudulent due to an implied legal misrepresentation if it fails to comply with the express requirements of a statute or regulation." *Id*. at 386. While recognizing that the Second and Ninth Circuit appear to limit the implied certification theory of liability in this manner, the Court stressed that both the Tenth Circuit and the D.C. Circuit have rejected arguments that conditions of payment must be expressly stated in statutes or regulations. *Id*. at 386 (citing *United States ex rel. Conner v. Salina Regional Health Ctr.*, 543 F.3d 1211, 1218 (10th Cir. 2008), and *United States v. Science Apps. Int'l Corp. ("SAIC")*, 626 F.3d 1257, 1268-69 (D.C. Cir. 2010)). Second, the Court rejected the argument that "a claim can be false or fraudulent only if the submitting entity knew or

should have known of the underlying falsehood or fraudulence." *Blackstone*, 647 F.3d at 388. Citing *Bornstein* and *Hess*, this Court explained that the Supreme Court has never conditioned liability for causing another person to submit a false claims "on whether the submitting entity knew or should have known about the non-submitting entity's unlawful conduct." *Id*. at 390. See also *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244 (3d Cir. 2004) (stating that liability under the FCA "did not turn on whether the actual presenters were 'duped' or participated in the fraudulent scheme").

In *Amgen*, this Court reiterated the basic legal principles announced in *Blackstone* and made clear that the same legal analysis applies to Medicaid claims tainted by kickbacks. In that case, this Court reversed the dismissal of a suit brought by a *qui tam* relator and several states under state statutes analogous to the federal FCA alleging that Amgen, a drug manufacturer, paid kickbacks to increase the use of Aranesp, a drug used in the treatment of anemia. As in *Blackstone*, the Court rejected artificial and non-textual distinctions drawn by the district court between legal and factual falsity and express and implied certification. See *Amgen*, 652 F.3d at 110. The Court also confirmed that the touchstone for determining whether a claim is false under the FCA is whether it "misrepresented compliance with a material condition of payment forbidding the alleged kickbacks." *Id*. at 110-11. The Court then analyzed the relevant state

statutes, regulations, and provider agreements and determined that "claims are not entitled to Medicaid payment if they are affected by kickbacks," *id*. at 113, under every state reimbursement scheme except Georgia's, where it was unclear from the evidence whether "it is a precondition of payment that claims not be affected by kickbacks," *id*. at 116. Thus, while the Court did not specifically address claims seeking to recover the *federal* share of funds disbursed under Medicaid, the Court made clear that defendants are equally liable under the federal FCA where they knowingly cause third parties to submit claims that violate the federal Anti-Kickback Statute, which is a well-established condition of payment under both Medicare and Medicaid.

B. The District Court's Decision In This Case Is Contrary To *Blackstone* and *Amgen* and Must Therefore Be Reversed.

As explained above, the district court in this case dismissed a *qui tam* suit alleging that Pharmacia paid kickbacks to physicians to prescribe Genotropin while knowing that this illegal kickback scheme would cause pharmacies to submit kickback-tainted claims for Genotropin to state Medicaid agencies. While the precise legal grounds for the court's ruling are not entirely clear, there can be no doubt that the court relied on legal distinctions and limiting principles that this Court decisively rejected in *Blackstone* and *Amgen*. At a minimum, the decision

below must be reversed because the district court erred in at least three important ways in analyzing the relator's kickback allegations in this case.

As an initial matter, the district court employed a number of categories and legal distinctions that this Court repudiated and declined to use in *Blackstone* and *Amgen*. For example, the court drew distinctions between legally and factually false claims and express and implied certification theories of liability, and then characterized the relator's claim solely as an implied certification claim. Applt. Br. Addend. at 16-19. Having pigeonholed those claims, the court then relied on precedent from other circuits imposing limitations on the implied certification theory of liability and distinguished various cases holding defendants liable for *causing* third parties to submit false claims on the ground that those decisions involved express certifications, *id*. at 20, or "factually false" claims, *id*. 21.

The district court's analysis cannot be reconciled with this Court's rulings in *Blackstone* and *Amgen*. As explained above, this Court expressly rejected the same judicially-created categories that the district court relied upon, stating that they "do more to obscure than clarify the issues before us." *Blackstone*, 647 F.3d 385-86. This fact alone provides ample grounds for reversal and remand, but the flaws in the court's analysis run much deeper. The court did not merely use terminology that this Court has since disapproved, but instead imposed substantive limitations on FCA liability based on its understanding of the

requirements necessary to state a claim under the various categories and legal theories it invoked. Most notably, the court appeared to believe some combination of the following factual and legal distinctions precludes liability where: (1) the claim is submitted by an "innocent" third party, (2) the claim is not "factually false," (3) the claim is not "legally false" due to express certifications of compliance with the AKS, and (4) compliance with the AKS is not "an expressly stated precondition of payment." *Id*. at 24.

As the Court's decisions in *Blackstone* and *Amgen* make clear, none of these distinctions immunizes a defendant that pays kickbacks to induce the use of its products from liability under the FCA where the defendant knows that this conduct will cause the submission of ineligible, kickback-tainted claims to federal health insurance programs such as Medicaid. This Court expressly rejected identical arguments in *Blackstone* that the "innocence" of a third party with no knowledge of the unlawful kickbacks precludes the "certifications" of compliance with the AKS made by that party from rendering the claim "false" within the meaning of the FCA. *Blackstone*, 647 F.3d at 388-92. Indeed, the Court made clear that the falsity of a claim does not depend on "certifications" made by *any* party, *id*. at 389, or on any putative distinction between factually false and legally false claims, *id*. at 390. Instead, the sole question for purposes of FCA liability is whether the defendant caused the submission of claims for payment that do not

satisfy a material condition of payment – a theory of liability that this Court specifically found was not too broad because it was constrained by the causation and knowledge requirements in the statute. *Id*. at 391.

Likewise, the district court plainly erred to the extent it rested its decision on the observation that "compliance with the federal statute was not an expressly stated precondition of payment." *Id*. at 24. In this respect, the court appeared to adopt a limitation on "implied certification" liability that some, but not all, courts have adopted. *Compare Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001), *with United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 314-15 (3d Cir. 2011). But this Court not only held that judicially-created categories such as "implied certification" are unhelpful, it also specifically rejected the argument that conditions of payment must be expressly set forth in statutes or regulations in order to render a claim "false" under the FCA when that condition is not satisfied. See *Blackstone*, 647 F.3d at 386-87; *Amgen*, 652 F.3d at 110. In so doing, the Court confirmed that compliance with the AKS is a fundamental condition of payment under Medicare and Medicaid – a point the district court here did not appear to dispute – and that a defendant who causes the submission of claims for payment that do not satisfy this condition are liable under the FCA.

Because *Blackstone* and *Amgen* conclusively undermine all the stated bases for the district court's decision, this Court should simply reverse and remand

without addressing any of the alternate grounds for affirmance that the defendants may present (and the relator has addressed) in this appeal. Although this Court may affirm the judgment below on any ground apparent from the record, see *Mulloy v. Acushnet Co.*, 460 F.3d 141, 145 (1st Cir. 2006), the district court did not reach what it characterized as "the difficult and important question" of whether the payments to certain physicians qualified as illegal kickbacks. Applt. Br. Addend. 24.[4] Rather than reaching out to decide this fact-bound issue – or similarly fact-based questions of causation – in the first instance, this Court should remand to the district court to allow more full consideration of these issues in additional proceedings under the proper legal standards announced in *Blackstone* and *Amgen*

[4] While the court summarily stated that "neither the KIGS program nor the Bridge program functioned as illegal kickbacks," *id*. at 2, it plainly did not believe these conclusions were sufficient to dispose of this case.

CONCLUSION

For the foregoing reasons, the district court's decision should be reversed and the judgment below should be vacated.

Respectfully submitted,

TONY WEST
Assistant Attorney General

CARMEN ORTIZ
United States Attorney

s/ Charles W. Scarborough
DOUGLAS N. LETTER
(202) 514-3602
CHARLES W. SCARBOROUGH
(202) 514-1927
Attorneys, Appellate Staff
Civil Division, Room 7244
Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20530-3001

JANUARY 2012

BRIEF FORMAT CERTIFICATION

I hereby certify that the foregoing brief complies with the requirements of Fed. R. App. P. 29(d) and Fed. R. App. P. 32(a)(7)(B) in the following manner:

The Brief was prepared using Corel Wordperfect 12.0. It is proportionately spaced in 14-point type, and contains 5346 words.

s/ Charles W. Scarborough
CHARLES W. SCARBOROUGH
Attorney for the United States

CERTIFICATE OF SERVICE

I hereby certify that on this 17th day of January, 2012, I caused a copy of the foregoing brief to be filed electronically with the Court's CM/ECF system, and that counsel of record will be served by the CM/ECF system:

s/ Charles W. Scarborough
CHARLES W. SCARBOROUGH