No. 11-269

IN THE

Supreme Court of the United States

BLACKSTONE MEDICAL, INC.,
Petitioner,

v.

UNITED STATES OF AMERICA EX REL.
SUSAN HUTCHESON,
Respondent.

On Petition For A Writ of Certiorari to the
United States Court of Appeals
For the First Circuit

BRIEF IN OPPOSITION

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QUESTION PRESENTED

The Petition poses broad questions unrelated to the facts of this case. This is a case about a federal healthcare supplier whose bribes and kickbacks caused the submission of false claims. Rather than focusing on the question that was pending in this case, Petitioner addresses only the speculative impact of this decision on "unrelated" parties. The question presented to the court of appeals was:

1. Whether a medical device supplier that pays kickbacks to providers can be held liable under the False Claims Act when its actions cause claims to be submitted to the United States in violation of Anti-Kickback Statute.

RULE 29.6 STATEMENT

Pursuant to Rule 29.6 of the Rules of the Supreme Court of the United States, Respondent submits this Statement:

Respondent Susan Hutcheson is an individual residing in Florida and was the Relator-Appellant in the First Circuit.

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INTRODUCTION

Blackstone seeks a writ of *certiorari* to the United States Court of Appeals for the First Circuit with respect to its decision reversing dismissal at the pleading stage of this False Claims Act (FCA) case concerning Blackstone's scheme to cause submission of claims to federal healthcare programs by illegally paying kickbacks to physicians. In the petition, Blackstone studiously ignores the fact that the courts of appeal have unanimously held that illegal kickbacks that cause the submission of claims violate the FCA. Nor does it acknowledge that after an errant district court held to the contrary, Congress amended the Anti-Kickback Statute (AKS) precisely to clarify that claims resulting from kickbacks violate the FCA. The issue thus will not recur, nor is it extraordinary, as it is fully in line with the overwhelming consensus of the courts and recent clarification by Congress.

Indeed, Blackstone does not contend that the court of appeals departs from any other appellate decision involving kickback schemes. Rather, it speculates about the application of the First Circuit's decision to potential fact patterns not presented here, based on its claims that the decision conflicts with legal standards in other circuits. But there is no genuine conflict about the applicable legal standard. The court of appeals took a straightforward approach to the well-established principles under the False Claims Act, holding that government subcontractors are liable for causing the submission of false claims that they know are in violation of conditions of payment. As this Court recently reaffirmed, government subcontractors are responsible for the

natural, ordinary, and reasonable consequences of their conduct. *Allison Engine Co. v. United States ex rel. Sanders,* 553 U.S. 662, 672 (2008).

Even had Blackstone identified an actual conflict, this case would be an unsuitable vehicle for its resolution because the outcome is the same under every judicial application of the legal standard urged by Blackstone. This case does not involve facts that lay on the outskirts of liability (the so-called technical "peccadillo" focused on by the petition). Rather, it exemplifies one of the most serious abuses of scarce federal health care dollars — payment of bribes to the gatekeepers of patient care decisions. Relator, a Blackstone insider, sets forth extensive detail about kickbacks of the most pernicious kind, including cash payments and lavish entertainment, paid by Blackstone to surgeons to induce them to use Blackstone's medical devices in spine surgeries paid for by federal health care programs. Relator alleges in detail, including emails from the owners of the corporation, that Blackstone knew (indeed, intended) that the foreseeable consequence of its scheme was submission of claims to federal healthcare programs by physicians and hospitals. Moreover, Blackstone knew that all participants in federal healthcare programs must comply with the AKS as a condition of federal payment, including by provider certification that all transactions are kickback-free before billing the United States.

The court of appeals correctly determined that Relator states a claim under the FCA, consistent with the text of the statute, the other courts of appeal, and the decisions of this Court. It warrants no further review.

STATEMENT

1. False Claims Act. The FCA 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." 31 U.S.C. § 3729(a)(1)(A)-(B).[1]

The FCA reaches "all fraudulent attempts to cause the Government to pay [out] sums of money or to deliver property or services." S. Rep. No. 99-345, at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274. As this Court has elaborated, "Congress wrote expansively, meaning 'to reach all types of fraud, with qualification, that might result in financial loss to the government.'" *Cook Cnty. v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003) (quoting *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968)).

2. The Anti-Kickback Statute and Federal Health Care Reimbursement. The AKS prohibits any person from knowingly and willfully 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 by a federal healthcare program. 42 U.S.C. § 1320a-7b(b)(1)-(2). In addition to criminal penalties, violations of the AKS may result in civil monetary

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[1] The FCA was amended by the Fraud Enforcement and Recovery Act of 2009 (FERA), Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1621 (2009). The decisions below did not address the application of FERA.

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. *Id.* § 1320a-7a(7).

The legislative history of the AKS establishes beyond doubt the intent to prohibit claims to Medicare and Medicaid induced by kickbacks. *E.g.,* 123 Cong. Rec. 31767 (Sept. 1977) (AKS intended "give a clear, loud signal to the thieves and the crooks and the abusers that we mean to call a halt to their exploitation of the public and the public purse"); H. Rep. No. 95-393, at 44 (1977), *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"). The statute was amended in 1987 to mandate exclusions for those convicted of program-related kickbacks and to broaden the Secretary's authority to exclude providers from the program for fraud, kickbacks, or other abuses.[2]

The Secretary of Health and Human Services has consistently enforced these prohibitions, making it clear in Alerts and other Guidance that claims caused by kickbacks–including those induced by manufacturers and suppliers—constitute fraud against the United States.[3]

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[2] Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, § 2, 101 Stat. 680, 680 (1987) (amending 42 U.S.C. § 1320a-7(a)-(b)). *See also* S. Rep. No. 100-109, at 1-2 (1987), *reprinted in* 1987 U.S.C.C.A.N. 682, 682-83.

[3] *E.g.,* Office of Inspector Gen., U.S. Dep't of Health & Human Servs. Special Fraud Alert, Joint Venture Arrangements (1989), *reprinted in* 59 Fed. Reg. 65372 (Dec. 19, 1994); OIG

Providers submit claims for payment to the United States subject to the condition that the items and services for which payment is sought are delivered in compliance with the AKS. Indeed, health care providers affirmatively agree that they will comply with the AKS in order to establish eligibility to receive federal health care payments.

Specifically, the Provider Agreement promulgated by the Center for Medicare and Medicaid Services (CMS) provides for the following express certification from every provider:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. . . . I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare.

Pet. App. 8a. In addition, hospitals must submit a Hospital Cost Report along with their claims for reimbursement. Cost reports must state:

> Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified

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Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23737 (May 5, 2003).

> in this report [were] provided or procured through the payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result.

The signatory of the Hospital Cost Report certifies:

> To the best of my knowledge and belief, it [the Hospital Cost Report] is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provisions of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

Id. 9a.

The federal healthcare claims process is organized such that hospitals and physicians bill separately for services associated with a single procedure. Hospitals submit claims to federal programs for inpatient costs associated with surgery, which include the cost of the medical device selected by the surgeon. Surgeons bill separately for their professional services.[4] Thus, when Blackstone pays

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[4] CMS has established standardized rates for the payment of hospital claims based on a diagnosis-driven coding system. These are called "Diagnosis-Related Group" ("DRG") rates. Although Blackstone argues that the hospital does not "seek payment for any individual component of the care a patient receives[,]" Pet. 7, the reimbursement is carefully constructed to compensate the hospital for all costs associated with a surgery,

a kickback to a physician, intending thereby to induce use of its products, it causes the submission of a false claim by both the hospital and the physician for that surgery.

3. The Facts. Relator Susan Hutcheson was a Blackstone sales manager. She alleges that Blackstone paid kickbacks to physicians to induce them to perform spine surgeries using Blackstone's devices. These kickbacks included sham consultant payments, royalties, and unrestricted grants; stock options; and lavish travel and entertainment, including strip clubs and bars. *Id.* 7a. Relator alleges that these kickbacks were the driving force of Blackstone's sales plan, with the purpose and effect of incentivizing the doctors – gatekeepers of the decision whether to perform surgery – to schedule more surgeries using Blackstone's medical devices. *Id.* 43a.

Relator also alleges that Blackstone knew that the beneficiaries of federal healthcare programs represented a significant percentage of spine surgery patients, and that its sales and marketing practices were subject to federal healthcare laws, including the AKS. *Id.* 7a, 43a. Relator alleges BMI intended that its kickbacks to physicians cause the submission of claims by hospitals and physicians for surgeries using its products, and that this was the foreseeable result of its nationwide scheme to increase its sales through the widespread payment of illegal kickbacks to physicians. *Id.*

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including devices. DRG rates are annually recalculated based on, among other things, claims data submitted in hospital cost reports.

By knowingly causing the submission of claims to federal healthcare programs that violated material conditions of payment, Blackstone violated the False Claims Act.

4. Proceedings Below. Relator[5] filed the qui tam action on September 29, 2006. The case was unsealed on November 21, 2008. The United States notified the court that it was not intervening at that time, but that its investigation is ongoing. Pet. App. at 42a. It provided amicus support to Relator in both the district court and in the appeal to the circuit court. *Id.* at 3a.

Blackstone moved to dismiss the case on multiple grounds,[6] including for failure to state a claim under Fed. R. Civ. P. 12(b)(6). The district court accepted Blackstone's argument that kickback violations give rise to FCA violations only through payment conditions created by express false certification in provider agreements, but that those conditions are personal to the claimant. Pet. App. 74a-75a. Regarding hospital claims resulting from Blackstone's kickbacks, the district court held that FCA liability was precluded based on its finding that the provider certification limits liability to schemes where the actual submitter of the false claim knows or participates in the kickback scheme. *Id.*

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[5] The district court dismissed a co-relator, Phil Brown, for failure to satisfy the original source provisions under 31 U.S.C. § 3730(e)(4)(B). This aspect of the district court's decision was not appealed.

[6] Blackstone also challenged Relator's complaint under the first to-file and public disclosure provisions of the False Claims Act, 31 U.S.C. § 3730(b)(5), (e)(4). The district court denied Blackstone's jurisdictional challenges and Blackstone did not appeal.

With respect to physician claims that resulted from Blackstone's kickback scheme, the district court held that although the doctor, who accepted kickbacks, knew and participated in the scheme, FCA liability was precluded because only a showing of lack of medical necessity would establish the materiality of kickbacks to the claim.

5. Decision Below. In a unanimous opinion by Chief Judge Lynch, the court of appeals reversed. It concluded that the district court's decision essentially immunized third party suppliers from liability under the "causes" clause of the FCA (Pet. App. 38a), and held that the provider agreement established that the underlying transaction must comply with the AKS in order to be paid. The court concluded that, under this Court's cases, Blackstone could be liable for causing the submission of claims in violation of the material conditions of Blackstone's billing agreement.

In so holding, the court rejected Blackstone's argument that a claim could be false only if it (1) stated false facts; or (2) violated a precondition to payment which was expressly denoted as such in a statute or regulation.[7]

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[7] Pet. App. 18a-20a; *see also id.* 64a-74a (district court decision). Blackstone based its argument on the Second Circuit decision in *Mikes v. Straus*, 274 F.3d 687, 696 (2d Cir. 2001). However, the court of appeals was "not persuaded" that "the Second Circuit would extend that rule to situations like the one before us" – an express condition of payment stated in a contract – and noted that, since the decision in *Mikes*, courts of appeal had extended FCA liability in many other contexts, including in cases involving violations of material terms of a contract. Pet. App. 21a.

The court found that this categorical approach "obscure[d] and distort[ed]" the FCA's requirements, as well as the basic issue before it: Whether Blackstone caused the submission of false claims by paying kickbacks to doctors. *Id.* 17a-18a. The court specifically rejected defendant's argument that the potential reach of the FCA would be too broad if such categorical limitations were not employed. Instead, the court concluded that: "The text of the FCA and our case law make clear that liability cannot arise under the FCA unless a defendant acted knowingly and the claim's defect is material." *Id.* 23a-24a.

Following the plain text of the FCA, the court evaluated the misrepresentations at issue and concluded, consistent with every appellate court to address the issue, that the provider agreement and hospital cost report make it "abundantly clear that AKS compliance is a precondition of Medicare payment and makes no exceptions for violations caused by third parties like Blackstone." *Id.* 34a.[8] The court of appeals also concluded the misrepresentations were material, following the standard set out by this Court in *Neder v. United States*, 527 U.S. 1, 16 (1999) *quoted in United States ex rel. Loughren v. Unum Grp.,* 613 F.3d 300, 307 (1st Cir. 2010) (a false statement is material if it has "a natural tendency to influence, or [is] capable of influencing, the decision of the decisionmaking body to which it was addressed.") (alteration in original). Blackstone did not seek reconsideration of this decision.

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[8] The court of appeals did not address whether the language and legislative history of the AKS also established a condition of payment, since the documents identified were sufficient to support relator's claim. *Id.* 32a.

The First Circuit's straightforward analysis, entirely consistent with the large body of FCA cases based on kickbacks, does not present a basis for further review.

REASONS FOR DENYING THE WRIT

The court of appeals' decision is correct and does not conflict with any decision of this Court or of any other court of appeals. Moreover, Congress has resolved any issue for future cases. Further review is not warranted.

I. The Court of Appeals Followed a Bedrock Principle Under the FCA: Entities That Pay Kickbacks Are Liable for Resulting False Claims.

Blackstone's petition ignores the basic question presented to and resolved by the appellate court: whether a medical device supplier that pays illegal kickbacks to providers can be held liable under the False Claims Act when its actions cause claims to be submitted to the United States.

Blackstone's attempt to create a basis for review is fundamentally disconnected from the facts at issue here. Blackstone does not once mention that the decision below, premised on Blackstone's own kickback violations, is consistent with every appellate court to address an FCA case premised on kickbacks, nor does it mention that the legal issue below centered on the application of the "causes" clause of the FCA.

The issue presented in this case is not complicated. The court of appeals engaged in straightforward application of settled False Claims Act principles. Consistent with the decisions of this Court and every court of appeals to address the issue, it held that under the "causes" clause of the FCA, a defendant can be liable for causing the submission of a claim in knowing violation of material conditions of payment of the claim. Pet. App. 27a-31a.

A. Blackstone's real dispute is with the long-settled principle that it is liable for causing false claims. Blackstone conceded before the district court that compliance with the AKS is a condition of payment of federal healthcare claims.[9] Its real dispute was whether it can be liable for *causing* the submission of false claims. It argued that because innocent submitters (the hospitals) consummated its fraudulent scheme and it did not, itself, sign the claim or accompanying certification, it could not be liable.

The court of appeals correctly rejected Blackstone's argument. The FCA imposes liability on any person who "knowingly . . . causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). If a government program supplier could immunize itself from FCA liability by duping the actual submitter of the claim, this would essentially read out the "causes" clause of

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[9] Blackstone conceded this point in the district court. Def.'s Reply in Supp. of Mot. to Dismiss 11 (Sept. 2, 2009) (ECF No. 62). Nor could this be credibly disputed. *See infra* pp. 14-16.

the FCA. As the court correctly reiterated, it could not "rewrite statutes." *Id.* 31a.

Moreover, the court of appeals correctly concluded that Blackstone's argument was "at odds with the holdings of controlling decisions of both [the First Circuit] and [this] Court." Pet. App. 30a. This Court has long held that a subcontractor may be liable for knowingly causing another to submit a false or fraudulent claim, regardless of the submitter's own knowledge. *See United States ex rel. Marcus v. Hess*, 317 U.S. 537, 544-45 (1943) (language of the FCA "indicate[s] a purpose to reach any person who knowingly assisted in causing the government to pay claims which were grounded in fraud[.]"); *United States v. Bornstein*, 423 U.S. 303, 309-13 (1976) (reaffirming that a subcontractor is liable under the FCA for causing a contractor to submit claims seeking payment for materials that, unbeknownst to the contractor, violated contractual specifications).

There has been no dispute on this point since. *E.g.*, *United States v. Hawley*, 619 F.3d 886, 897 (8th Cir. 2010) (defendant liable for causing ineligible farmers to make claims against insurance policies that were reinsured by government); *United States ex rel. Longhi v. Lithium Power Techs. Inc.*, 575 F.3d 458, 471-73 (5th Cir. 2009), *cert. denied*, 130 S. Ct. 2092 (2010) (causing false claims by material false statements on grant application); *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1177 (9th Cir. 2006) *cert. denied,* 550 U.S. 903 (2007) (liability for causing submission of claims under student loan programs where it knowingly failed to comply with conditions of participation in programs); *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244 (3d Cir. 2004) (causing the submission

of false claims "did not turn on the whether the actual presenters were 'duped' or participated in the fraudulent scheme"); *United States v. Rivera*, 55 F.3d 703, 710-12 (1st Cir. 1995) (a "false claim may be presented through an innocent third party"); *Murray & Sorenson v. United States*, 207 F.2d 119, 123-24 (1st Cir. 1953) (causing the submission of false or fraudulent claims which inflated bids).

In short, Blackstone just gets it wrong: Subcontractors and suppliers are accountable for "the natural, ordinary and reasonable consequences" of their conduct. *Allison Engine*, 553 U.S. at 672. This is precisely what is alleged here, that Blackstone fully intended that its scheme would result in submission of claims for surgeries to federal healthcare programs.

B. All Appellate Courts Agree that FCA Cases Are Properly Premised on AKS violations. The outcome in this case is uncontested. Though Blackstone does not acknowledge this in its Petition, *every court of appeals to address the question* has concluded that FCA cases are properly premised on kickback violations. *United States ex rel. Wilkins v. United Health Grp., Inc.*, No. 10-2747, 2011 U.S. App. LEXIS 13322, at *12-13 (3d Cir. June 30, 2011) (kickbacks paid by Medicare Advantage plan providers to medical clinic to refer patients);[10] *United States. v. Rogan*, 517 F.3d 449, 452 (7th Cir. 2008) (kickbacks paid by hospitals to physicians); *McNutt*

[10] *See also United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 94 (3d Cir. 2009) (kickbacks paid by outpatient clinic to medical practice in exchange for referrals); *Zimmer*, 386 F.3d at 243 (kickbacks paid by medical supply company to hospitals in exchange for purchasing its products).

ex rel. United States v. Haleyville Med. Supplies, Inc., 423 F.3d 1256, 1259 (11th Cir. 2005) (kickbacks paid by medical services companies to various providers); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899 (5th Cir. 1997), *on remand,*[11] 20 F. Supp. 2d 1017 (S.D. Tex. 1998) (kickbacks paid by hospitals to physicians for referrals).[12]

Indeed, the federal "courts, ***without exception,*** agree that compliance with the Anti-Kickback Statute is a precondition of Medicare payment, such that liability under the False Claims Act can be predicated on a violation of the [AKS]." *United States ex rel. Westmoreland v. Amgen, Inc.*, No. 06-10972-WGY, 2011 U.S. Dist. LEXIS 104809, at *43 (D. Mass Sept. 15, 2011) (collecting cases) (emphasis added); *see also United States ex rel. Lisitza v. Johnson & Johnson,* 765 F. Supp. 2d 112, 128 n.25 (D. Mass. 2011) ("majority of trial courts" have held that "violations of the AKS cause any resulting claims to be false."); *United States ex rel. Pogue v.*

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[11] The Fifth Circuit remanded for further factual development relating to defendant's argument that payment was not conditioned on the certification, *Thompson*, 125 F.3d at 903, and the district court concluded affirmatively, *Thompson*, 20 F. Supp. 2d at 1049.

[12] Two other circuits have cited with approval the proposition that kickback violations can properly form the basis of an FCA claim. *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1223 n.8 (10th Cir. 2008) (complaint otherwise fails for failure to plead under Fed. R. Civ. P. 9(b)); *Frazier ex rel. United States v. IASIS Healthcare Corp.,* 392 F. App'x 535, 538 (9th Cir. 2010) (unpublished). (reversing dismissal with prejudice under Rule 9(b) to allow a relator to replead FCA claims based on violations of the Anti-Kickback and Stark laws)

Diabetes Treatment Ctrs. of Am., Inc., 565 F. Supp. 2d 153, 159 (D.D.C. 2008) ("[l]egion [of] other cases that have held violations of AKS . . . can be pursued under the FCA, since they would influence the Government's decision of whether to reimburse Medicare claims.").

There is, in short, overwhelming consensus that compliance with the AKS is a material condition of payment of federal health-insurance claims.[13]

C. Recent Amendments to the AKS Fully Resolve Any Issue Prospectively. Even if there remained a credible dispute that FCA liability was properly premised on AKS violations, it is not a recurring one worthy of certiorari. Days after the district court's decision in this case, the Patient Protection and Affordable Care Act (PPACA) of 2010 amended the AKS to squarely 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]." Pub. L. No. 111-148, § 6402(f)(1), 124 Stat. 119, 759, (amending 42 U.S.C. § 1320a-7b).

The legislative record reflects that part of the impetus for the clarifying language was the decision

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[13] *E.g., Wilkins*, No. 10-2747, 2011 U.S. App. LEXIS 13322, at *12 ("Compliance with the AKS is clearly a condition of payment under Parts C and D of Medicare and appellees do not refer us to any judicial precedent holding otherwise. In fact, the precedents hold the opposite"); *Rogan,* 517 F.3d at 452 (squarely rejecting the argument that the kickbacks were immaterial to the payment of Medicare and Medicaid claims); *McNutt,* 423 F.3d at 1259 ("compliance with federal health care laws, including the [AKS], is a condition of payment by the Medicare program").

in *United States ex. rel. Thomas v. Bailey*, No. 4:06-CV-465, 2008 U.S. Dist. LEXIS 91221 (E.D. Ark. Nov. 6, 2008). *Thomas* was an FCA case pending against petitioner Blackstone, in which Blackstone paid kickbacks to two Arkansas doctors, one of whom was convicted of health care fraud. The *Thomas* court adopted similar arguments to those later adopted by the district court below, that the hospital certification was personal to the hospital, and that BMI was not liable for causing false claims by the hospital unless the hospital knew of its kickback scheme.

As the amendment sponsors explained, the "bill remedies the problem [of *Thomas*] by amending the anti-kickback statute to ensure 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 (Oct. 28, 2009) (statements of Senator Ted Kaufman) (criticizing *Thomas* as allowing a claim premised on kickbacks "to be laundered into a 'clean' claim when an innocent third party finally submits the claim to the government for payment"); *see also id.* S10854 (statements of co-sponsor Senator Patrick Leahy).[14]

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[14] The intent of Congress is properly culled from the events surrounding the passage of PPACA. *See SEC v. Capital Gains Research Bureau, Inc.*, 375 U.S. 180, 199-200 (1963) (the relevant context for examining Congressional intent is at the time of enactment). Subsequent legislation declaring the intent of an earlier statute is similarly entitled to great weight in statutory construction. *See Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 380-81 (1969); *Williams-Ward v. Lorenzo Pitts, Inc.*, 908 F. Supp. 48, 56 (D. Mass. 1995). Moreover, this amendment is consistent with the holdings of the courts of

The district court decisions below and in *Thomas* are the only two which have held that kickbacks paid by a federal healthcare supplier cannot cause the submission of a false claim. As this Court noted in *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson,* referring to the 1943 amendments, Congress "promptly reacted . . . by amending the statute." 130 S. Ct. 1396, 1406 (2010).

Based on the consistent view of the court of appeals and the recent amendment of the statute to expressly conform to that long-held view, there is little prospective impact of the court of appeals decision on FCA cases premised on AKS violations.

II. Blackstone's Speculation about Future Cases Does Not Transform This AKS Case Into a Suitable Vehicle for Review.

Blackstone's lament about the doomsday effects of this straightforward decision is not credible. There is no basis to support a different outcome in any jurisdiction, and no conflict created by the court's application of settled principles.

A. There is No Basis to Posit That Any Court Would have Reached A Different Outcome. At the outset, Blackstone's conjecture that this case may have been decided differently in any other jurisdiction is unsupported by existing law. Every appellate court to have addressed the issue has determined that FCA liability is properly premised

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appeal to address this issue, and with the long-standing position of the United States (*see supra* n. 3).

on kickback violations, and Congress has since clarified the law to align with that jurisprudence.

The fact that Blackstone's petition flatly ignores this compelling and unanimous body of law is nowhere more apparent than when it speculates that the Third Circuit and the Fifth Circuits might have decided differently (Pet. App. 30a) without admitting that these very courts have *already held* that AKS violations are a proper basis for FCA liability. *Wilkins*, 2011 U.S. App. LEXIS 13322, at *12-13; *Zimmer,* 386 F.3d at 243; *Thompson*, 125 F.3d at 902-03, *on remand,* 20 F. Supp. 2d 1020-21.[15]

Indeed, the only case Blackstone cites in opposition to the overwhelming conclusion of the appellate and other federal courts that kickbacks for proper FCA cases is the district court decision in *United States ex rel. Kennedy v. Aventis,* 610 F. Supp.2d 938 (N.D. Ill. 2009). The case is a true outlier, which itself is in conflict with the Seventh Circuit's decision in *United States v. Rogan*, 517 F.3d at 452 (affirming a verdict against the defendant for causing the submission of claims procured through kickbacks).

Blackstone's argument for review, however, is unrelated to the express requirement of compliance with the AKS at issue here. Rather, it argues that the decision below will allow a swarm of qui tam relators to convert every "administrative peccadillo" into an FCA action. Pet. 31. But this case involves

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[15] Blackstone also argues the Tenth Circuit may have reached a different outcome, although *Conner,* the decision it references, cites with approval the proposition that kickback violations can properly form the basis of an FCA claim. 543 F.3d at 1223 n.8.

no "administrative peccadillo." It involves *felony kickback violations*, prohibited *per se* by statute, compliance with which is specifically certified by every person who seeks to bill federal healthcare programs. If Blackstone believes these to be "administrative peccadillos," it is hardly surprising that it finds itself in hot water.

More to the point, nothing in the decision below supports this wild assertion. There is no basis in the decision of the court of appeals for the unbounded standard portrayed by Blackstone and its fellows, who profess concern that the decision extends to the most remote "administrative noncompliance" of "unrelated parties" in the supply chain.[16] "Administrative noncompliance" is not even at issue in this case. Here, the court of appeals determined that the terms of the provider agreement explicitly established that compliance with the AKS was a condition of payment, akin to the many FCA cases affirming liability based on violations of express contract terms. Pet. App. 32a, 35a.[17]

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[16] No court, in fact, has held that liability is unbounded in this manner. Not only does Blackstone's argument ignore basic causation principles, it also ignores that courts have consistently held that defendant's challenges to the clarity of regulatory requirements are appropriately handled by the knowledge requirements of the FCA. *See*, *e.g.*, *Minn. Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1053 (8th Cir. 2002); *United States ex rel. Oliver v. Parsons Co.*, 195 F.3d 457, 463 (9th Cir. 1999).

[17] Nothing in the court's decision remotely supports Blackstone's additional inference that FCA liability could originate from the isolated statements of an agency representative. Pet App., 28a. Rather, any agency statements that contradict rather than conform to the known conditions of a provider's payment are routinely utilized by a defendant to

Blackstone's arguments completely ignore the court's conclusion that FCA liability requires: (1) a misrepresentation of compliance with a precondition of payment; that (2) was material to the decision to pay. *Id.* 32a.[18] The court of appeals correctly rejected Blackstone's unsupported contentions of overbreadth, finding that the statute text properly cabins liability to the *knowing* actions of defendants to *cause* the submission of claims with defects that are *material* to payment.

B. There is No Genuine Conflict Among the Circuits. Blackstone's attempt to manufacture a conflict among a subset of circuit decisions simply

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rebut that its conduct was knowing. *See*, *e.g.*, *United States ex rel. A+ Homecare*, *Inc. v. Medshares Mgmt. Grp., Inc.*, (400 F.3d 428, 454 n.21 (6th Cir.), *cert. denied sub nom.*, *Winters v. United States ex rel. A+ Homecare, Inc.*, 546 U.S. 1063 (2005). Notably, Blackstone also complains that the court did not look *enough* at the administrative scheme when evaluating condition of payment. But there is no argument that an administrative scheme could supplant the FCA (e.g., *United States v. General Dynamics Corp.,* 19 F.3d 770, 774 (2d Cir. 1994)). While courts may evaluate administrative schemes when determining whether the compliance at issue was a condition of payment (*see*, *e.g.*, *Conner,* 543 F.3d at 1222, calling conditions tangential to payment, conditions of "participation"), this is completely irrelevant to the analysis here, though, where the court needed to look no further than the unambiguous conditions contained in the provider agreement.

[18] The court used the definition adopted by this Court and now codified in the amended FCA that a false statement is material if it has "a natural tendency to influence, or [is] capable of influencing, the decision of the decisionmaking body to which it was addressed." Pet. App 37a (citing *Neder,* 527 U.S. at 16); *see also* 31 U.S.C. § 3729(b)(4).

does not present an occasion for the Court's review nor, as Blackstone would have it, to provide a tutorial on False Claims Act principles unrelated to this case. Though Blackstone argues that the court of appeals' decision is expansive or novel, its application of the requirements that a complaint allege knowing and material false statements has long been a basic framework for FCA analysis. A long line of circuit court decisions have concluded that FCA cases are properly premised on materially false statements,[19] materially false omissions,[20] material misrepresentations of eligibility for payment,[21] and material violations of contract provisions.[22]

Here, the court of appeals applied these basic principles, finding that Blackstone's violations of the AKS caused a material misrepresentation by the

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[19] *See*, *e.g.*, *United States v. United Techs. Corp.*, Nos. 08-4256/08-4257, 2011 U.S. App. LEXIS 1398, at *13 (6th Cir. Jan. 24, 2011) (false cost estimates for Air Force contract were material); *A+ Homecare,* 400 F.3d at 447 (false pension accrual on cost report was material).

[20] *See*, *e.g.*, *Rogan*, 517 F.3d at 452 (kickbacks were material omissions); *United States ex rel. Berge v. Bd. of Trustees of the Univ. of Ala.*, 104 F.3d 1453, 1460-61 (4th Cir.), *cert. denied*, 522 U.S. 916 (1997) (omissions in progress reports for grants were not material to principal purpose of project).

[21] *See*, *e.g.*, *McNutt*, 423 F.3d at 1260 (kickbacks); *Longhi*, 575 F.3d at 472 (false statements to ensure research grants).

[22] *See*, *e.g.*, *Shaw v. AAA Eng'g & Drafting, Inc.*, 213 F.3d 519, 531-33 (10th Cir. 2000) (invoices for full payment despite knowing violation of silvery recovery requirements in contract); *United States ex rel. Compton v. Midwest Specialties, Inc.*, 142 F.3d 296, 302-03 (6th Cir. 1998) (claims in violation of testing provisions of contract).

providers submitting the claims, who had contracted with the United States to bill for only kickback-free transactions. Pet. App. 37a-38a.

Blackstone assails at the simplicity of this analysis, reviewing at length distinctions some courts have made between "factually false" and "legally false" claims, and liability theories based on "express" and "implied" certification. However, the court of appeals properly viewed these distinctions as conceptual abstractions not germane to the issue of whether Blackstone's kickback violations caused false claims.

As the court of appeals explained:

> Courts have created these categories in an effort to clarify how different behaviors can give rise to a false or fraudulent claim. Judicially-created categories sometimes can help carry out a statute's requirements, but they can also create artificial barriers that obscure and distort those requirements. The text of the FCA does not refer to "factually false" or "legally false" claims, nor does it refer to "express certification" or "implied certification." Indeed, it does not refer to "certification" at all. In light of this, and our view that these categories may do more to obscure than clarify the issues before us, we do not employ them here.

Id. 17a-18a (citation omitted).

Rather, the court of appeals' straightforwardly employed an analysis that has long been employed under the FCA and by other appellate courts, whether the false statement or fraudulent course of conduct at issue was a "prerequisite to a government

benefit," material to the decision to pay.[23] As the court of appeals correctly concluded, more than a hundred years of FCA cases, including in seminal cases of this Court, have demonstrated that the false and fraudulent conduct of defendants are rarely limited to fraud that is apparent on the face of the claim. *See Bornstein*, 423 U.S. at 307 (subcontractor violation of standard for procuring radio tubes incorporated in prime contract); *Hess*, 317 U.S. at 539 & n.1 (subcontractor collusive bidding to obtain contract). [24]

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[23] *E.g., Longhi*, 575 F.3d at 467-68 & n.5 (FCA liability for material false statements to receive funds to which not entitled); *Rogan*, 517 F.3d at 452-53 (affirmed judgment for material omissions on claim forms); *Harrison v. Westinghouse Savannah River Co.* (*Harrison II*), 352 F.3d 908, 913 (4th Cir. 2003) (a "false statement or . . . fraudulent course of conduct" must be knowing and material to establish FCA liability); *Minn. Ass'n of Nurse Anesthetists*, 276 F.3d at 1053-56 (FCA liability for services in violation of billing prerequisites for payment); *Peterson v. Weinberger*, 508 F.2d 45, 52-54 (5th Cir. 1975) (submission of claims which are ineligible for payment are actionable under the FCA); *see also United States ex rel. Vigil v. Nelnet, Inc.*, 639 F.3d 791, 796 (8th Cir. 2011) (dismissing marketing regulation violations that were not material to the Government's decision to pay); *United States ex rel. Yannacopoulos v. General Dynamics*, 652 F.3d 818, 2011 U.S. App. LEXIS 15374, at *23 (11th Cir. 2011) ("[N]o reasonable jury could think . . . failure to check the proper box . . . was a material false statement.").

[24] As Congress squarely noted:

> [A] false claim may take many forms, the most common being a claim for goods or services not provided, or provided in violation of contract terms, specification, statute, or regulation. . . .

S. Rep. No. 99-345, at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274. Moreover, Medicare or Medicaid

Blackstone ignores these well-established principles and instead takes issue with how other courts may have employed "implied certification" as the theory of liability. Yet courts using this rubric have ultimately applied the same analysis as did the First Circuit here–examining whether or not the claim misrepresented a condition of its payment.[25] "Implied certification" is simply another expression for the basic principle, also recognized below, that if "the government defines its bargain in a manner that requires adherence to a statute or regulation, compliance with that statute or regulation is implied by virtue of a request for payment."[26]

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claims may be false "even though the services are provided as claimed if, for example, the claimant is ineligible to participate in the program. . . ." *Id.*

[25] *E.g., United States ex rel. Wilkins v. United Health Grp., Inc.*, No. 10-2747, 2011 U.S. App. LEXIS 13322, at *9 (3d Cir. June 30, 2011) ("[M]ust show that compliance with the regulation . . . [is a] condition of payment from the Government."); *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 997 (9th Cir. 2010) (certification, whether express or implied, "is a prerequisite to obtaining government benefits"); *Conner*, 543 F.3d at 1218 (analysis focuses on the "underlying contracts, statutes, or regulations themselves to ascertain whether they make compliance a prerequisite to the government payment"); *United States ex rel. Augustine v. Century Health Servs., Inc.*, 289 F.3d 409, 415 (6th Cir. 2002) (violations of "continuing duty to comply with the regulations on which payment is conditioned"); *United States ex rel. Siewick v. Jamieson Sci. & Eng'g, Inc.*, 214 F.3d 1372, 1376 (D.C. Cir. 2000) (inferring "certification from silence" when prerequisite to the government action sought"); *Ab-Tech Constr., Inc. v. United States*, 31 Fed. Cl. 429, 434 (1994) (submission of the claims "represented an implied certification . . . of [defendant's] continuing adherence to the requirements for participation in the . . . program.").

[26] *United States ex rel. Willard v. Humana Health Plan,* 336 F.3d 375, 382 (5th Cir. 2003) (quoting district court).

However, Blackstone's selective rendering of the subtle differences in vernacular among the courts that employed such distinctions do not require deconstruction.[27] While the court of appeals harmonized basic FCA principles without complicated vernacular, Blackstone's basic argument *in this case* was not whether a condition of payment was called "implied certification" or vice versa, but whether it could be liable under the FCA for *causing* the submission of claims. Blackstone argues it could not be liable unless it violated a statute or regulation that expressly stated compliance is a condition of payment, based on the Second Circuit decision in

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[27] In addition to not being relevant to the ultimate issue, Blackstone's circuit-by-circuit review is selective and inaccurate. For example, Blackstone does not cite *Rogan*, which affirms liability in the Seventh Circuit based on material omissions in an FCA case premised on kickbacks, 517 F.3d at 452; nor cites the Fifth Circuit decision in *Longhi*, which evaluated whether a defendant's material false statements and omissions for small business funding rendered it liable under the FCA, 575 F.3d at 468-70; nor cites the Sixth Circuit decisions in *Compton*, 142 F.3d at 302-04, or *United States ex rel. Varljen v. Cleveland Gear Co.*, 250 F.3d 426, 431-32 (6th Cir. 2001), holding contractors liable under the FCA for violations of material conditions of their contract; nor the Eighth Circuit decision in *United States v. Cooperative Grain and Supply Co.*, 476 F.2d 47, 60-61, (8th Cir. 1973), which holds a contractor liable under the FCA to the basic conditions of its contract; nor the Tenth Circuit's decisions in *Shaw,* holding a contractor liable for material violations of contract conditions, 213 F.3d at 531-33, or *United States ex rel. Lemmon v. Envirocare, Inc.*, 614 F.3d 1163, 1170-71 (10th Cir. 2010), holding a complaint need only plead false statements material to the decision to pay. Blackstone's selective citations are not further reviewed here, as they do not create a genuine conflict and, more to the point, are not relevant to the issue actually raised on appeal.

Mikes, 274 F.3d at 687, the only circuit to have created such a limit.[28]

Mikes, however, was not a case predicated on a violation of the AKS, explicitly identified by the provider agreement as a condition of payment. Rather, the issue was whether violation of professional calibration standards for a diagnostic machine gave rise to liability under the FCA because it violated the statutory requirement that claims be "reasonable and necessary." *Id.* at 694. The Second Circuit found the professional standard "tangential to the service for which reimbursement was sought" and the court concluded that "it would be anomalous to find liability when the alleged noncompliance would not have influenced the government's decision to pay" or would be "irrelevant to the government's disbursement decisions." *Id.* at 697.[29]

Mikes's crabbed analysis has not been followed by any court of appeals, and it has been limited to its facts. *E.g., United States v. Sci. Applications Int'l Corp.* (*SAIC*), 626 F.3d 1257, 1269 (D.C. Cir. 2010). Indeed, as the D.C. Circuit recently noted, adoption of *Mikes* would leave a "counterintuitive gap in the FCA by imposing a legal requirement found nowhere in the statute's language." *Id.* at 1270. "Under this

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[28] In *United States ex rel. Kirk v. Schindler Elevator Corp.*, the Second Circuit explained that the analysis in *Mikes* was based on the language of the statute, which "links the wrongful activity to the government's decision to pay." 601 F.3d 94, 114 & n.15 (2d Cir. 2010) (citation omitted), *rev'd on other grounds*, 131 S. Ct. 1885 (2011).

[29] *Mikes*' conclusion was tailored to its concern that FCA liability in that context would create the federalization of medical malpractice standards arising outside federal healthcare reimbursement rules. 274 F.3d at 700.

scenario, a contractor could escape liability in situations in which it knew it violated a contract requirement, recognizes that violation was material to the Government's decision to pay, and submits a claim anyway." *Id.* SAIC properly cabined *Mikes* to its facts, *id.* at 1269-70, as did the court below.

That the First Circuit, like other courts, properly limited *Mikes* to its facts does not warrant further review. The First Circuit, like other circuits, properly evaluated whether Blackstone caused the submission of claims in violation of conditions which are prerequisites to payment.

C. This Case is Not a Suitable Vehicle for Review. Blackstone's arguments, even if they held water, are immaterial to the outcome of this case. This case is a basic causation case, premised on AKS violations, consistent with a massive body of FCA jurisprudence on AKS violations. Moreover, even under the strictest application of Blackstone's and the amici's urged standard, the facts of this case support FCA liability. Here, the complaint alleges the affirmative and specific certification of the providers that the underlying transaction complied with the AKS, which the court of appeals identifies as an express and material term of the provider's agreement with the United States. Pet. App. 34a - 35a. As Amici Amgen concedes,[30] this is consistent

[30] Amgen Amicus Br. 4. Amgen filed its brief as amicus based on its own petition from in *New York v. Amgen*, 652 F.3d 103, (1st Cir. 2011), that was pending at the time of its filing. Amgen, a pharmaceutical company, argues, similar to Blackstone, that it cannot be liable for causing the submission of false claims through an innocent submitter (Amgen Amicus Br. 7, 9) and that the *Mikes* fact pattern compels a categorical

with the "basic theory" with which every federal circuit – including the Second Circuit in *Mikes* – agrees, that affirmative, specific certifications properly form the basis for FCA liability.[31] What's more, as the court appeals holds, this proposition is also consistent with the many courts that have found that noncompliance with express contract terms can result in false claims. Pet. App. 35a-36a (citing *SAIC*, 626 F.3d at 1269; *Shaw,* 213 F.3d at 531-532; *Lemmon*, 614 F.3d at 1170).

Blackstone and its chorus of *amici* assert that the First Circuit's opinion will cause "grave issues" in regard to other fact patterns and an "unprecedented ballooning of FCA litigation."[32] Obviously, the lower courts are well-equipped to deal with actual cases, rather than near-hysterical prognostications submitted on petition. Certainly, at this time, there is nothing to support to support the speculative parade of horribles embodied in their briefs. The two appellate decisions published since the First Circuit's decision do not support such speculation, as

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rule for the evaluation of claims. Notably, Amgen's case involved the analysis of state FCA's, not the express terms of the provider agreements and hospital cost reports involved in this case. *Id.* 8.

[31] *See also Chesbrough,* 2011 U.S. App. LEXIS 17515, at *11; *Conner*, 543 F.3d at 1217; *United States ex rel. Gross v. Aids Research Alliance-Chicago*, 415 F.3d 601, 605 (7th Cir. 2005); *Zimmer*, 386 F.3d at 243; *Minn. Ass'n of Nurse Anesthetists,* 276 F.3d at 1053; *Mikes*, 274 F.3d at 697; *Siewick,* 214 F.3d at 1376; *Harrison v. Westinghouse Savannah River Co.* (*Harrison I*), 176 F.3d 776, 786 (4th Cir. 1999); *Thompson*, 125 F.3d at 902; *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996), *cert. denied*, 519 U.S. 1115 (1997).

[32] Pet. 32; Chamber of Commerce Amicus Br. 17.

both dismissed factual allegations that were not material to payments of claims and, notably, affirmed FCA liability premised on kickbacks.[33] Blackstone and its supporters' generic references to past FCA recoveries are completely irrelevant to the identification of any certworthy issue related to the First Circuit's decision.[34]

Neither Blackstone nor its supporters cite any FCA case premised on kickbacks that has been decided differently by any appellate court, much less on facts similar to these. In patent illustration of the speculative nature of these arguments, the Chamber of Commerce lists decisions that all resulted in

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[33] In *Wilkins*, the Third Circuit concluded a defendant was liable under the FCA for kickback violations, and dismissed allegations based on regulatory violations that it determined were not material to payment of a claim. 2011 U.S. App. LEXIS 13322, at *41-42, 48. The Sixth Circuit, in *Chesbrough*, similarly affirmed dismissal of allegations based on testing standards it determined were not material to the payment of a claim. 2011 U.S. App. LEXIS 17515, at *13.

[34] Though citing increases in FCA recoveries over past two years (*see, e.g,* Brief of Chamber of Commerce, et al., at 17), they fail to acknowledge that the majority of those cases involve large pharmaceutical frauds. In fact, of the top ten federal False Claims Act settlements in fiscal year 2010, eight involved fraud committed by pharmaceutical companies, accounting for $2.4 billion of the more than $3.16 billion recovered. Office of Pub. Affairs, U.S. Dep't of Justice, *Dep't of Justice Recovers $ 3 Billion in False Claims Act Cases in Fiscal Year 2010* (Nov. 22, 2010); Taxpayers Against Fraud, *FY 2010 False Claims Act Settlements* (Oct. 30, 2010), *available at* http://www.taf.org/total2010.htm (last visited Oct., 30, 2011). Most recently, *amicus* Amgen announced in October 2011 that it has set aside $780 million to resolve several ongoing criminal and civil investigations. Andrew Pollack, NY Times, *Amgen to Pay $780 Million to Settle Suits on its Sales* (Oct 24, 2011).

dismissals of allegations that other appellate courts found did not support violations of material conditions of payment. Though arguing that these *dismissals* may somehow transform into future ballooning litigation in the First Circuit, there is no basis to conclude that the First Circuit's finding regarding the express terms of the provider agreement would compel it to disagree with other court's factual findings regarding conditions of payment.[35] This pure conjecture, unrelated to this

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[35] Blackstone, the Chamber, and Amgen even take issue with the Second Circuit decision in *Kirk* for the proposition that damages are being sought under expansive theories (*e.g.*, Pet. 33; Chamber of Commerce Amicus Br. 19). Yet, the decision, issued more than a year before this one, satisfies the standard they urge under *Mikes*, that the statute expressly states that compliance was required to be paid. 601 F.3d at 116-17. The other amici make similarly irrelevant challenges. The Ass'n of Private Sector Colls. & Univs. (APSCU), written by counsel for defendant in *Hendow*, challenges a line of cases involving fraud schemes relating to the government funding of student loans, similar to those upheld in *Hendow*, 461 F.3d at 1166, in *United States ex rel. Main v. Oakland City Univ.*, 426 F.3d 914 (7th Cir. 2005), *cert. denied*, 547 U.S. 1071 (2006). Notably, the Court previously denied the *Hendow* defendant's petition for certiorari. 550 U.S. 903 (2007). The National Defense Industry Association (NDIA) challenges military contractor cases, and by way of example, cases involving Iraq War contracts. The NDIA's position, beside also being unrelated to kickbacks, is concerning, given the consistent case law finding military contractors liable under the FCA for material violations of their contracts, and the at least $31 billion of contract fraud identified by the Commission of Wartime Contracting in Iraq and Afghanistan. *Final Report to Congress: Transforming Wartime Contracting, Controlling Costs, Reducing Risks,* http://www.wartimecontracting.gov/docs/CWC_FinalReport-lowres.pdf (August 2011).

case, or any other kickback case, does not warrant the Court's attention.

Blackstone and the amici also claim that the court of appeals' decision does not provide businesses with enough information to assess their "litigation risk" or to get "adequate notice" of which of its violations will result in FCA liability. Pet. 32; Chamber of Commerce Amicus Br. 10. But Blackstone does not argue it did not have notice in this case. The statutory prohibition at issue here could not be more clear: *if you pay kickbacks to federal healthcare providers, the False Claims Act will apply to your conduct.* The courts are virtually unanimous on this point, and the AKS has been amended to expressly conform to that long held understanding. As the Third Circuit recently observed:

> [P]articipants making claims to the Government under the federal health care programs have to ensure that they are not violating the federal health care laws which they agreed to follow when they entered into contracts with CMS. . . We do not think this is an unreasonable requirement to impose on federal health care contractors, for as Justice Holmes once wrote: "Men must turn square corners when they deal with the Government."

Wilkins, 2011 U.S. App. LEXIS 13322, at *50 (quoting *Rock Island, A. & L. R. Co. v. United States,* 254 U.S. 141, 143 (1920))

Addressing the same parade of horribles almost 40 years before *Wilkins*, the Eighth Circuit had no problem holding that persons who deal with the government are required to know and comply with

the laws and regulations that govern its eligibility for payment:

> Put in a broad context, this case presents an increasingly important and commonly-faced problem, namely how must a citizen act in applying for government payments and be free from possible liabilities under the False Claims Act? . . . *The applicant for public funds has a duty to read the regulations or be otherwise informed of the basic requirements of eligibility*.

Cooperative Grain, 476 F.2d at 56 (emphasis supplied).

At bottom, there is simply nothing remarkable about the First Circuit's straightforward application of these basic principles under the FCA. Blackstone's speculative concerns about its future liability under the FCA simply do not warrant review of this case, which clearly follows the well-established principle that defendant is liable for causing the submission of false claims in violation of the Anti-Kickback Statute.

CONCLUSION

The petition for writ of certiorari should be denied.

Respectfully submitted,

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