No. 11-____

IN THE

Supreme Court of the United States

BLACKSTONE MEDICAL, INC.,

Petitioner,

v.

UNITED STATES OF AMERICA EX REL.
SUSAN HUTCHESON,

Respondent.

Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Many federal programs involve hundreds, if not thousands, of statutory, regulatory, and contractual requirements. The courts of appeals have developed conflicting frameworks for evaluating when an alleged lack of compliance with a program requirement transforms a claim seeking payment for goods provided or services rendered into a "false or fraudulent" claim actionable under the False Claims Act. Describing these claims as "legally false," rather than "factually false," some circuits have adopted variations of an "express certification" theory of legal falsity; others have adopted variants of an "implied certification" theory; yet others attempt to discern program requirements that are "conditions of payment" from "conditions of participation," with only the former actionable under the FCA. The First Circuit rejected all of these frameworks and announced its own. The questions presented are:

1. Whether an allegation that a defendant has committed a statutory violation renders a claim submitted by an unrelated party "legally false" for purposes of the FCA, where no statute or regulation expressly conditions payment of the unrelated party's claim on the defendant's compliance.

2. Whether and when a private citizen is authorized to use a "legally false" theory under the FCA as a generalized enforcement mechanism for statutes, regulations, contractual obligations, or other program requirements that are not otherwise privately enforceable.

PARTIES TO THE PROCEEDINGS AND RULE 29.6 STATEMENT

The following list provides the names of all parties to the proceedings below.

Petitioner, Blackstone Medical, Inc. ("Blackstone"), was the defendant-appellee in First Circuit. Blackstone is 100% owned by Orthofix Holdings, Inc., which is 100% owned by Victory Medical Limited, which is 100% owned by Intavent Orthofix Limited, which is 100% owned by Orthofix II B.V., which is 100% owned by Orthofix International B.V., which is 100% owned by Orthofix International N.V., a publicly held company. No publicly held company owns 10% or more of the stock of Orthofix International N.V.

Respondent, Relator Susan Hutcheson, was a plaintiff-appellant in the First Circuit.

The other party named in the caption in the proceedings below, Relator Philip Brown, was dismissed from the case in the District Court and did not appeal that dismissal to the First Circuit.

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1 John T. Boese, *Civil False Claims and Qui Tam Actions* § 2.03[G] (4th ed. 2011) 31

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Office of Inspector General, Dep't of Health & Human Servs., *Medicare Hospital Prospective Payment System: How DRG Rates Are Calculated and Updated* (Aug. 2001), *available at* http://www.oig.hhs.gov/oei/reports/oei-09-00-00200.pdf 7

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Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

PETITION FOR A WRIT OF CERTIORARI

Petitioner Blackstone Medical, Inc. ("Blackstone") respectfully petitions this Court for a writ of certiorari to review the judgment of the United States Court of Appeals for the First Circuit in this case.

OPINIONS BELOW

The opinion of the First Circuit is reported at __ F.3d __, 2011 WL 2150191 (1st Cir. June 1, 2011) and reproduced at page 1a of the appendix to this petition ("Pet. App."). The District Court decision granting Blackstone's motion to dismiss is reported at 694 F. Supp. 2d 48 (D. Mass. 2010) and reproduced at Pet. App. 39a.

JURISDICTION

The judgment of the First Circuit was entered on June 1, 2011. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The False Claims Act ("FCA") states, in relevant part, that:

> [A]ny 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;
>
> * * * is liable to the United States Government for a civil penalty * * * plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1) (2010).[1]

INTRODUCTION

This case presents an issue over which the federal circuits are increasingly divided, and which is of exceptional importance to the administration of

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[1] This statutory language reflects amendments to the FCA enacted in 2009 as part of the Fraud Enforcement Recovery Act, Pub. L. No. 111-21, 123 Stat. 1617 (2009). The petition, like the Amended Complaint in this matter, refers to the current provisions of the FCA; the issues in the petition do not implicate the changes made to the statute in the 2009 amendments.

federal government programs involving billions of dollars every year. It asks the Court, in light of conflicting instruction from various courts of appeals, to clarify whether and when liability under the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, attaches to hospitals, universities, contractors, manufacturers, financial institutions, and many others who participate directly and indirectly in federal programs, as well as all those who do business with federal program participants.

A rapidly expanding number of FCA *qui tam* cases are premised on a theory of "legal"—as contrasted with "factual"—falsity. Under a "legal falsity" theory, *qui tam* relators assert that despite being factually true, claims submitted to the government are somehow "legally false," because the claims (explicitly or implicitly) represent compliance with some underlying statutory, regulatory, contractual, or other condition related to a government program. Different circuits have developed conflicting formulations of the "legal falsity" theory and the proof required thereunder. And in the decision below, the First Circuit developed a particularly expansive variant of "legal falsity" test. After the First Circuit's decision, a relator's allegations that claims are "legally false" state a cause of action under the FCA anytime a relator alleges that wrongful conduct occurred somewhere in a chain of transactions among various entities, one of which ultimately submitted a claim—even if the claim itself contains no false statement about the allegedly wrongful conduct and even if no statute or regulation conditions payment of a claim on such compliance.

As the First Circuit acknowledged in its decision, its holding conflicts with the holdings of several other courts of appeals. And as multiple courts and commentators have observed following the First Circuit's decision, the court of appeals' ruling vastly expands the potential grounds for FCA complaints against any of an array of entities that participate in government programs or are parties to government contracts—as well as those who are once (or twice, or thrice) removed from those programs or contracts.

This petition accordingly presents the Court with an opportunity to dispel the persistent confusion among federal circuits when addressing the so-called "legal falsity" theory of false claims jurisprudence. The petition also, and relatedly, seeks to restore the reasonable limitation, true to the statute's terms, that FCA actions involve *claims* that are *false*—not merely acts that are wrongful.

STATEMENT OF THE CASE

The Rise of the "Legal Falsity" Theory. The FCA was enacted in 1863, a legislative response to unscrupulous contractors billing the Union Government for supplying nonexistent, worthless, or inferior goods to the Union Army during the Civil War. In its current form, the FCA penalizes (among other things) the submission of "false or fraudulent claims" for payment. 31 U.S.C. § 3729(a)(1)(A), (B). It contains *qui tam* provisions that allow private citizens who have suffered no individualized injury to bring civil actions in the name of the government as "relators" and claim a bounty on any recovery. *Id.* § 3730(b). The FCA requires a relator to file a *qui tam* complaint under seal and serve it on the government, which can either intervene and assume

responsibility for the suit or decline the suit. *Id.* § 3730(b)(2), (4). If the United States declines to intervene, the relator retains the exclusive right to pursue the FCA claim.

A defendant found liable under the FCA is subject to both treble damages and a civil penalty of between $5,500 and $11,000 per claim. 31 U.S.C. § 3729(a)(1); 28 C.F.R. § 85.3(a)(9). The relator is entitled to a percentage of any recovery or settlement. 31 U.S.C. § 3730(d)(1)-(2).

For over a hundred years after the FCA's enactment, the typical false claims suit involved allegations of claims for work not performed or for inferior or defective goods. *See, e.g., United States* v. *Bornstein*, 423 U.S. 303, 307 (1976) ("The tubes that United sent to Model under this subcontract were not of the required quality, but were falsely marked by United to indicate that they were."); *Hughes Aircraft Co.* v. *U.S. ex rel. Schumer*, 520 U.S. 939, 942-43 (1997) (relator alleged that costs charged to one contract were for work performed on a different contract). But the lower courts more recently have confronted a barrage of FCA suits premised on the theory that claims submitted to the government may be factually accurate, but nonetheless are "legally false," because they misrepresent, expressly or even "implicitly," compliance with a welter of regulatory requirements. *See Schindler Elevator Corp.* v. *U.S. ex rel. Kirk*, 131 S. Ct. 1885, 1894 (2011) (describing range of typical regulatory certifications, from " 'how [federal contractors] dispose of hazardous materials to their affirmative action plans' ") (quoting Amicus Curiae Brief of U.S. Chamber of Commerce, *et al.*).

Courts have responded to this "legal falsity" theory by developing several frameworks—which vary from circuit to circuit—for assessing the "legal falsity" of a claim. Some courts ask whether the claim is submitted with an *express* statement of compliance with regulatory requirements. Other courts ask whether the claim contained some *implied* representation of compliance with a legal requirement that the relator alleges was not satisfied. Still other courts ask which program obligations are conditions of program participation and which are conditions of payment, with only violations of the latter constituting "legally false" claims.

The Anti-Kickback Statute. The FCA complaint in this case was premised on a violation of the Anti-Kickback Statute ("AKS"). That statute makes it unlawful, among other things, to pay kickbacks to doctors to influence decisions about goods or services that are reimbursed by a federal health care program. 42 U.S.C. § 1320a-7b(b). A person or company convicted of violating the AKS is subject to a number of administrative remedies, including exclusion from participation in the federal health care programs. 42 U.S.C. § 1320a-7(a), (b)(7).[2] The AKS does not contain a private right of action. *See, e.g., West Allis Mem'l Hosp., Inc.* v. *Bowen*, 852 F.2d 251, 255 (7th Cir. 1988).[3]

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[2] Exclusion is a prospective remedy that, once imposed, prohibits the excluded person or entity from continuing to participate in the federal health care programs; exclusion has no effect on past claims submitted by that provider. 42 U.S.C. § 1320a-7(c)(2)(A).

[3] In the 2010 Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010), Congress

Medicare Reimbursements Generally. Under the Medicare system, a hospital seeks payment for an entire bundle of inpatient items and services by submitting a claim for the appropriate "diagnosis-related group" or "DRG" rate. The claim seeks a standardized, fixed fee for treating a patient based on the patient's diagnosis at discharge, regardless of the actual cost of the treatment provided.[4] Under the DRG system, a hospital claim does not identify or seek payment for the cost of any individual component of the care that a patient receives, including which particular devices are purchased for use in surgery.

A physician claim, separate from a hospital claim, seeks payment for the physician's professional services—e.g., for performing a surgical procedure.

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added a new provision to the AKS stating that in addition to the penalties already provided, "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]." 124 Stat. at 759 (enacted as 42 U.S.C. § 1320a-7b(g)). The PPACA amendments, which are not retroactive, "are not applicable to pending cases." *Schindler Elevator*, 131 S. Ct. at 1889 n.1; *Graham Cnty. Soil & Water Conservation Dist.* v. *U.S. ex rel. Wilson*, 130 S. Ct. 1396, 1400 n.1 (2010).

[4] *See* Office of Inspector General, Dep't of Health & Human Servs., *Medicare Hospital Prospective Payment System: How DRG Rates Are Calculated and Updated* 1 (Aug. 2001), *available at* http://www.oig.hhs.gov/oei/reports/oei-09-00-00200.pdf ("This system is a per-case reimbursement mechanism under which inpatient admission cases are divided into relatively homogeneous categories called diagnosis-related groups (DRGs). In this DRG prospective payment system, Medicare pays hospitals a flat rate per case for inpatient hospital care so that efficient hospitals are rewarded for their efficiency and inefficient hospitals have an incentive to become more efficient.").

Physician claims request the standardized, fixed-fee amount set forth in the Physician Fee Schedule, *see* 42 C.F.R. § 414.58(a), and determined by the Current Procedural Terminology code ("CPT code") applicable to the procedure. The claim amount is set annually and is based on the procedure performed; it does not vary based on what drugs the physician orders or what devices are used or implanted.

Hospitals and physicians complete Medicare enrollment applications to establish their eligibility to seek reimbursement from the Medicare program. The provider (whether hospital or physician) signs a certification stating that "I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]" and "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." Form CMS-855A; Form CMS-855I.

Hospitals are also required to submit annual Medicare cost reports. 42 U.S.C. § 1395g(a); 42 C.F.R. § 413.20. These cost reports, which compile aggregate data for the entire year of providing services to every patient treated in the hospital, are the hospital's final accounting of payment due to the hospital from the Medicare program for services rendered to program beneficiaries. The directions *alone* for the cost report take up over 300 pages in the Medicare Provider Reimbursement Manual. *See* Medicare Provider Reimbursement Manual, Chapter

36. The annual cost report includes a statement that "[t]o the best of my knowledge" 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," and 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." Pet. App. 72a.

Hutcheson's FCA lawsuit. Blackstone markets and distributes to hospitals spinal implant and related biologic products for use in surgeries. Blackstone itself does not submit claims for payment to private insurance companies or to the federal government's Medicare program.

Relator Hutcheson was employed as a regional manager for Blackstone from January 2004 until she was fired in January 2006. Pet. App. 5a. After her termination, she filed a False Claims Act suit against her former employer, alleging that Blackstone had violated the AKS by paying unlawful remuneration to physicians to induce them to use Blackstone devices in spinal surgeries. She contended that as a result, the admitting hospitals' Medicare claims for providing inpatient services to surgical patients and the physicians' claims for performing surgeries were "false claims" within the meaning of the FCA. Specifically, Hutcheson argued that the alleged unlawful kickback from Blackstone to the physicians "tainted" the claims later submitted by the hospital and the claims for the physician's surgical services, rendering them "false claims" that Blackstone "caused to be submitted."

The United States declined to intervene. The District Court dismissed Hutcheson's Amended Complaint on Blackstone's motion under Rule 12(b)(6) for failure to state a claim, concluding that the claims at issue were not actionable under the FCA. Pet. App. 62a-76a.[5] As the court explained, courts had developed "three theories under which a claim may be 'false or fraudulent' under the False Claims Act," including "(1) factual falsity; (2) legal falsity under an express certification theory; and (3) legal falsity under an implied certification theory." Pet. App. 64a-65a.

The court explained that a "factually false" claim is "a claim in which the goods or services are either incorrectly described" or "never provided." Pet. App. 65a (citing *Mikes* v. *Straus*, 274 F.3d 687, 697 (2d Cir. 2001)). A "legally false" claim, the court continued, is one in which a party certifies its compliance with a statute or regulation despite having not complied with that statute or regulation. Pet. App. 65a-66a (citing *U.S. ex rel. Conner* v. *Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008); *U.S. ex rel. Quinn* v. *Omnicare, Inc.*, 382 F.3d 432, 440-41 (3d Cir. 2004); *Mikes*, 274 F.3d at 697; *U.S. ex rel. Siewick* v. *Jamieson Sci. & Eng'g, Inc.*, 214 F.3d 1372, 1375-76 (D.C. Cir. 2000); *Harrison* v. *Westinghouse Savannah River Co.*, 176 F.3d 776, 785-87 (4th Cir. 1999); *U.S. ex rel. Thompson* v. *Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997); *U.S. ex rel. Hopper* v. *Anton*, 91 F.3d 1261, 1265-66 (9th Cir. 1996)).

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[5] The District Court also dismissed a second relator, Philip Brown, from the case because of a jurisdictional bar in the FCA. Brown did not appeal that ruling. Pet. App. 5a n.2.

The court further noted that the circuits to have addressed the "legal falsity" theory—for at that point the First Circuit "ha[d] not defined legal falsity in the context of the [FCA]," Pet. App. 66a—parsed the theory into two types: *express* and *implied* certification. Express certification occurs where a party "expressly states that it has complied with the applicable statutes' regulations, where such compliance is a precondition of payment." *Id.* (citing *Conner*, 543 F.3d at 1217). As for implied certification, various courts had developed "three definitions of the implied certification theory of legal falsity." *Id.* For example, the Sixth and Tenth Circuits hold that a claim is legally false under an implied certification theory "where a claimant makes no express statement about compliance with a statute or regulation, but by submitting a claim for payment implies that it has complied with any preconditions to payment." Pet. App. 67a (citing cases). Other courts treat implied certification as "essentially a materiality analysis" into whether the government would have paid the claim if it knew of a violation. Pet. App. 67a (citing cases). And yet other courts hold that "implied certification exists where a statute requires express certification, but the claimant did not expressly certify." *Id.* (citing cases).

The District Court concluded that it would adopt the first of the three standards above—the one applied by the Sixth and Tenth Circuits. The District Court also endorsed the Second Circuit's holding in *Mikes* that liability under an implied certification theory of legal falsity should be restricted to situations involving "compliance with expressly stated preconditions of payment found in the relevant statute or regulation." Pet. App. 68a.

The court then concluded that Hutcheson did not state a claim under the FCA. The hospital claims could not be "false claims" under an express certification theory of legal falsity because the only certifications to which Hutcheson pointed were those in the hospital's Medicare enrollment form and a hospital's annual cost report. The certifications made by the hospital in these documents spoke only to the *hospital's* compliance with the AKS; they did not expressly or impliedly certify that *Blackstone's* interactions with physicians (who are neither hospital employees or agents) had complied with the AKS. Pet. App. 73a & n.13. As the court explained, a hospital's annual certifications did not obligate the hospital to determine whether every interaction between every physician and every device, drug, or other product manufacturer complied with the AKS. Nor did they condition payment to the hospital on conducting such an investigation. Pet. App. 74a. And the hospital's Medicare enrollment form did not somehow transmute an upstream wrongful act into a violation of a precondition to Medicare payment to the hospital under an implied certification theory, for preconditions to payment "cannot be hidden in an enrollment form"; they must be in a statute or regulation. *Id.*

The District Court also concluded that there was no viable theory rendering the separate physician claims actionable under the FCA. As the court explained, the "doctor is purely seeking reimbursement for his services"—not for the Blackstone device that was the subject of the alleged kickback. Pet. App. 76a. The hospital's DRG payment was a bundled payment for the hospital services, including everything from time in the

operating room to any device implanted and all of the cotton balls used.

The District Court dismissed the action. Relator appealed.

The First Circuit reversed. And in reversing, the First Circuit explicitly and repeatedly rejected multiple other circuits' case law articulating the scope of actionable "legally false" claims. Pet. App. 16a-18a; *see also* Pet. App. 4a-5a, 19a-22a, 32a. According to the First Circuit, other courts of appeals had created "artificial barriers" to FCA liability that "obscure and distort" the statute's purpose. Pet. App. 18a. So the First Circuit opted to create its own new framework for assessing the viability of FCA claims.

The First Circuit began by rejecting the view endorsed by other circuits that "implied" false certification claims should be limited to those conditions expressly articulated in a statute or regulation. *See* Pet. App. 19a-20a. The First Circuit acknowledged that "[i]t is true that the Second Circuit" upheld such a limitation, *id.*, and that "[i]t is also true that the Ninth Circuit" employed a similar limitation, *id.*—but the First Circuit declared itself "not persuaded" by those circuits' formulations. Pet. App. 23a. The First Circuit also observed that "other courts" have concluded that a precondition to payment can be stated in a contract rather than a statute or regulation, including in circumstances where "the contract does not specify that compliance with the contract term is a condition of payment." Pet. App. 22a (citing *United States* v. *Science Apps. Int'l Corp.* ("*SAIC*"), 626 F.3d 1257, 1269 (D.C. Cir. 2010)).

After declaring itself to be on the most expansive end of the "legally false implied certification" spectrum of theories, the First Circuit then took a step well beyond even that. With respect to the question of what the court called "non-submitting party conduct," the court of appeals held that conduct by a party somewhere in the supply chain may render a federal claim for payment false or fraudulent *even if* the claim is submitted by a third party (here, a hospital) with no connection to any alleged wrongdoing, and *even if* all of the certifications that the third-party makes in connection with a claim are accurate and truthful. Pet. App. 24a-31a. According to the First Circuit, "a submitting party's representations concerning its own conduct" do not "immunize a non-submitting entity from liability under the 'causes' clause of the FCA." *Id.* at 28a.

This petition followed.

REASONS FOR GRANTING THE WRIT

I. THE FIRST CIRCUIT'S DECISION EXACERBATES A CIRCUIT SPLIT OVER THE SCOPE AND LIMITS OF "LEGALLY FALSE" FCA THEORIES.

As the First Circuit acknowledged, the circuit courts take conflicting approaches to, and place differing limits on, the "legally false" theory of FCA liability. And the First Circuit's reading expands the theory to the greatest degree yet: On its face, it authorizes private citizens to sue and recover damages based on any knowing violation of any contractual or program requirements, even if those violations are unknown to the entity filing the claim,

and even if the entity's statements as to its own compliance are quite truthful. That approach conflicts in a number of significant respects with other circuits' interpretations of the FCA.

A. Each Circuit Has Adopted Its Own Framework For When A Relator Can Pursue Allegations Of Legally False Claims Under the FCA.

The circuits are starkly divided on how best to accommodate the "legal falsity" theory of FCA liability without turning the FCA into a "blunt instrument" to enforce compliance with all sorts of statutes, regulations, and contractual and other program requirements. *Mikes,* 274 F.3d at 699. *See also U.S. ex rel. Steury* v. *Cardinal Health, Inc.*, 625 F.3d 262, 268 (5th Cir. 2010) (FCA was never meant to be "a general 'enforcement device' for federal statutes, regulations, and contracts; *U.S. ex rel. Wilson* v. *Kellogg Brown & Root, Inc.*, 525 F.3d 370, 373 (4th Cir. 2008) (FCA was not intended to allow *qui tam* relators to "shoehorn" a contract breach or garden-variety administrative matter "into a claim that is cognizable under the False Claims Act."; *but see SAIC*, 626 F.3d 1269-71 (FCA can be used to litigate any material breach of a contract). The First Circuit's new, and unprecedentedly expansive, decision only heightens the need for the Court's intervention.

The current jumble of legal-falsity standards follows:

Second Circuit. The Second Circuit adopted the "legal falsity" theory of FCA liability in 2001, joining several other circuits in accepting a theory of "legally

false" claims, as distinguished from "factually false" claims. *Mikes*, 274 F.3d at 697. A claim is actionable as a "legally false" claim "only where a party certifies compliance with a statute or regulation as a condition to governmental payment." *Id.* The court emphasized that "not all instances of regulatory noncompliance will cause a claim to become false." *Id.* Rather, a false certification could occur in one of two ways: (1) expressly, where the claim contains an explicit misrepresentation of the defendant's compliance with a legal requirement identified as a precondition to payment, or (2) impliedly, where a party submits a claim knowing that a statute or regulation expressly mandates that the provider comply with certain obligations to be paid. *Id.* at 697-98, 700. The court cautioned that the implied false certification theory must be approached with caution to avoid "improperly broaden[ing] the Act's reach." *Id.* at 699.

Again addressing the "more difficult to assess" theory of legal falsity in *U.S. ex rel. Kirk* v. *Schindler Elevator Corp.*, the court of appeals reiterated that "not every instance in which a false representation of compliance with a regulatory regime is made will lead to liability." 601 F.3d 94, 114 (2d Cir. 2010).[6] Nevertheless, the court held that noncompliance with a requirement to submit a report to the Department of Labor listing the number of Vietnam veterans the contractor employed could render all of the contractors' claims false, rejecting the argument

[6] This Court reversed the Second Circuit's decision based on a separate issue regarding the whether a FOIA response is a public disclosure under the FCA's public disclosure bar. *See* 131 S. Ct. 1885 (2011). Schindler Elevator did not seek certiorari on the Second Circuit's certification ruling.

that the administrative mechanisms designed to monitor the accuracy of these reports—rather than the FCA—were the appropriate way to remedy any noncompliance. *Id.* at 116-17.

Third Circuit. The Third Circuit recognized the express certification theory of legal falsity in 2004. *U.S. ex rel. Schmidt* v. *Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir. 2004); *U.S. ex rel. Quinn* v. *Omnicare, Inc.*, 382 F.3d 432, 441-42 (3d Cir. 2004). The court refused, however, to allow a legally true claim to be rendered false by events happening after its submission. *Quinn*, 382 F.3d at 438.

After the First Circuit's decision in this case, the Third Circuit also adopted an implied certification theory of legal falsity—but acknowledged that its approach differed from the First Circuit. *U.S. ex rel. Wilkins* v. *United Health Group, Inc.*, __ F.3d __, 2011 WL 2573380, at *8 (3d Cir. June 30, 2011). Like the Second Circuit, the Third Circuit held that the implied certification theory "should not be applied expansively" to prevent the FCA from becoming a " 'blunt instrument to enforce compliance' " with all the regulations of the federal health care programs. *Id.* (citing *Mikes*, 274 F.3d at 699). The Third Circuit concluded that the implied certification theory could *not* be used to litigate alleged violations of Medicare marketing regulations, because those regulations were "conditions of participation" properly enforced through administrative mechanisms, not "conditions of payment" enforceable through the FCA. *Id.* at *11 (citing *Conner,* 543 F.3d at 1220, and explaining that allowing a relator to bring a FCA suit based on such alleged non-compliance "would short-circuit the very

remedial process the Government has established to address non-compliance with those regulations"). The Third Circuit answered the "close question" whether an implied certification FCA theory could proceed based on an alleged improper kickback in the affirmative. It did not look to the administrative (and criminal) mechanisms in place to penalize and remedy AKS violations; nor did the court require a nexus "between the alleged AKS violations and the claims [the defendants] submitted to the Government." *Id.* at *14.

Fourth Circuit. While recognizing that other courts have allowed legally false claims to proceed based on express or implied false certifications of compliance with various statutory or regulatory requirements, the Fourth Circuit has found it was "questionable" whether an implied certification cause of action was valid at all. *Harrison*, 176 F.3d at 786-87 n.8. Under Fourth Circuit law, "there can be no False Claims Act liability for an omission without an obligation to disclose." *Id.* While the *Harrison* court permitted one claim to proceed based on an express false certification with a conflict-of-interest provision, it refused to read a continuing duty to disclose into the contract under an implied certification theory. *Id.* at 793-94.

Fifth Circuit. The Fifth Circuit, like the Second (among others), has emphasized that "[t]he FCA is not a general 'enforcement device' for federal statutes, regulations, and contracts," in discussing when it is "fair" to find a false certification can trigger FCA liability. *Steury*, 625 F.3d at 268-69 (citing *Mikes*, 274 F.3d at 699). It takes the view that even if a contractor falsely certifies compliance

with a statute, regulation, or contract provision, "the underlying claim for payment is not 'false' within the meaning of the FCA *if the contractor is not required to certify compliance in order to receive payment*." *Id.* at 269 (emphasis added). Thus, like the Third (and Eighth and Tenth) Circuits, it distinguishes between regulations and statutes that govern participation in a federal program and those that govern payments in the program. *U.S. ex rel. Bowan* v. *Education Am., Inc.*, 116 F. App'x 531, 531-32 (5th Cir. 2004) ("False certifications of compliance with applicable regulations and statutes governing participation in federal student financial aid programs * * * did not constitute a basis for imposing liability on the defendants under the [FCA] because the relator did not allege that the defendants made certifications of compliance with particular regulations on which payment was conditioned."). The Fifth Circuit has repeatedly declined to address whether FCA liability can be inferred from implied certifications. *See, e.g., U.S. ex rel. Marcy* v. *Rowan Cos.*, 520 F.3d 384, 389 (5th Cir. 2008)

Sixth Circuit. The Sixth Circuit adopted a "continuing-duty" version of the "implied certification" theory of "legal falsity" in *U.S. ex rel. Augustine* v. *Century Health Servs., Inc.*, 289 F.3d 409, 414-15 (6th Cir. 2002). It held that a cost report including a certification that "to the best of my knowledge and belief, [the cost report] is a true, correct, and complete report prepared from the books and records of the provider in accordance with applicable instructions, except as noted" was an implied representation that the defendant would *continue to comply* with Medicare regulations after submitting the cost report. *Id.* The court noted that

not all courts were in agreement on implied certification and recognized a "concern that holding a defendant liable under a theory if implied false certification vitiates the FCA's scienter requirement." *Id.* at 415-16; *see also Chesbrough* v. *VPA, P.C.*, __ F.3d __, 2011 WL 3667648, at *4 (6th Cir. Aug. 23, 2011) (reiterating continuing-duty theory of implied certification)

Seventh Circuit. The Seventh Circuit requires that a claim of legal falsity be based on an *express* certification, not an implied one. As the Seventh Circuit said in *U.S. ex rel. Lamers* v. *City of Green Bay*, "[t]he FCA is a fraud prevention statute; violations of * * * regulations are not fraud unless the violator knowingly lies to the government about them." 168 F.3d 1013, 1020 (7th Cir. 1999).

The Seventh Circuit recently reinforced its express certification requirement in *U.S. ex rel. Yannacopoulos* v. *General Dynamics*, __ F.3d __, 2011 WL 3084932 (7th Cir. July 26, 2011). The relator in that case argued that the defendant had violated the Arms Export Control Act, which (according to the relator) barred payment for the claims submitted. In some circuits, that violation would have amounted to a "false claim," on the theory that the defendant had implicitly certified compliance with all necessary preconditions to payment. But the Seventh Circuit found it dispositive that the defendant did not *actually* certify compliance with the Arms Export Control Act. *Yannacopoulos*, 2011 WL 3084932, at *3 n.4. The court also attempted to distinguish between a defendant who "falsely claims to be in compliance with [a] contract to obtain payment" and a defendant

who breaches a contract; in the Seventh Circuit, only the former is actionable under the FCA. *Id.* at *3.[7]

Eighth Circuit. The Eighth Circuit generally recognizes the theory of legal falsity, *see*, *e.g.*, *Minnesota Ass'n of Nurse Anesthetists* v. *Allina Health Sys. Corp.*, 276 F.3d 1032, 1053 (8th Cir. 2002), but has emphasized that "[t]he FCA is not concerned with regulatory noncompliance. Rather, it serves a more specific function, protecting the federal fisc by imposing severe penalties on those whose false or fraudulent claims cause the government to pay money." *U.S. ex rel. Vigil* v. *Nelnet, Inc.*, 639 F.3d 791, 795–96 (8th Cir. 2011).

In *Vigil*, the Eighth Circuit carefully limited the reach of the "legal falsity" theory to prevent the FCA from supplanting traditional administrative enforcement procedures. As the court observed, when a statute creates " 'a complex monitoring and remedial scheme that ends * * * payments only as a last resort,' it would 'be curious to read the FCA, a statute intended to protect the government's fiscal interests, to undermine the government's own regulatory procedures.' " *Id.* at 799 (citing *Connor*, 543 F.3d at 1222). The court thus joined the Second

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[7] In *U.S. ex rel. Main* v. *Oakland City University*, the Seventh Circuit adopted a "promissory inducement" theory of FCA liability; applying that theory, it held that all claims for funds from federal financial aid programs were "false claims" if the university had falsely certified on its *initial* application that it would comply with a condition of participation. 426 F.3d 914, 917 (7th Cir. 2005). The *Main* decision thus rejected the distinction between conditions of participation and conditions of payment and introduced a "promissory inducement" theory of FCA liability for legally false claims where there is an initial express certification that a party fails to uphold.

and Tenth Circuits in holding that the violation of a condition of *participation* in a federal program—as opposed to the violation of a condition of *payment*—does not trigger FCA liability. As the court put it: "[I]f the regulatory violations [are] only conditions of * * * participation, they 'are enforced through administrative mechanisms, and the ultimate sanction for violation of such conditions is removal from the government program,' " not FCA liability. *Id.* at 799 (citing *Connor*, 543 F.3d at 1220).

Ninth Circuit. In *Hopper*, 91 F.3d at 1266, the Ninth Circuit held that the legally false theory of FCA liability could only be triggered by an express false certification of compliance with a law, rule, or regulation—and only when that law, rule, or regulation was a *sine qua non* of receiving the payment requested. The reason the court offered for imposing this limitation was straightforward: "[v]iolations of laws, rules, or regulations alone do not create a cause of action under the FCA." *Id.* Rather, it is the express false certification itself, confirming the party's compliance with an explicit condition of funding, that creates a cause of action under the FCA. *Id.* at 1267 ("[A]bsent actionable false certifications upon which funding is conditioned, the False Claims Act does not provide such a remedy.").

A different Ninth Circuit panel retreated from *Hopper* a few years later. In *U.S. ex rel. Hendow* v. *Univ. of Phoenix*, the court held that there is nothing "talismanic" about a "certification," and that FCA liability can attach anytime a party makes an " 'intentional, palpable lie' " about its compliance with a regulation on which the government's funding

is conditioned, regardless of whether that lie is part of "a certification, assertion, statement, or secret handshake." 461 F.3d 1166, 1172 (9th Cir. 2006). According to *Hendow*, FCA liability can be triggered by a subsequent violation of a statutory requirement with which a party's original program application indicated it "will comply." The court also directly rejected the distinction between conditions of participation and conditions of payment. *Id.* at 1176. According to that panel, *all* conditions of participation are also conditions of payment; there need not be "[a]n explicit statement * * * to make a statutory requirement a condition of payment." *Id.* at 1177.

Then, last year, in *Ebeid ex rel. U.S.* v. *Lungwitz*, 616 F.3d 993 (9th Cir. 2010), the court adopted a standard for *implied* false certification. It held that the implied false certification theory of legal falsity can trigger FCA liability if "an entity has previously undertaken to expressly comply with a law, rule, or regulation, and that obligation is implicated by submitting a claim for payment even though a certification of compliance is not required in the process of submitting the claim." *Id.* at 998.

Tenth Circuit. The Tenth Circuit was the first circuit to *reject* the broad certification language in the annual Medicare hospital cost report as a basis for FCA liability under an "implied certification" theory. *Connor*, 543 F.3d at 1219. The court reasoned that such broad certification language referencing compliance with all applicable Medicare statutes and regulations did not identify a condition of payment; for the government had never expressly stated that payment of a hospital's claims required

perfect compliance with all Medicare statutes and regulations. *Id.* at 1221 ("[A]lthough the government considers substantial compliance a condition of ongoing Medicare *participation*, it does not require perfect compliance as an absolute condition to receiving Medicare *payments* for services rendered.").

As the Tenth Circuit explained, the government has an established administrative scheme for monitoring compliance and bringing hospitals back into compliance when they fell short of the program's requirements. "Conditions of participation * * * are enforced through administrative mechanisms, and the ultimate sanction for violation of such conditions is removal from the government program," while "[c]onditions of payment are those which, if the government knew they were not being followed, might cause it to actually refuse payment." *Id.* at 1220.

Eleventh Circuit. In *McNutt ex rel. U.S.* v. *Haleyville Medical Supplies, Inc.*, 423 F.3d 1256 (11th Cir. 2005), the Eleventh Circuit adopted an expansive view of the legally false theory of liability. The court rejected the defendants' argument that an FCA plaintiff pursuing a claim of legal falsity must prove that the defendant expressly certified its legal compliance. *Id.* at 1259. Instead, a claim can be based on a mere "violation of the [governing] regulations" so long as compliance with those regulations is a condition of participation in the relevant program. *See id.* The court declined to limit the implied certification theory to conditions of payment, holding that whenever the alleged violation would render a party ineligible to participate in a government program, the party is

liable under the FCA for submitting false claims. *Id.* Moreover, in contrast to the Seventh Circuit, *see Main*, 426 F.3d at 917, the Eleventh Circuit does not require proof that the defendant intended to violate the conditions of participation from the outset. Rather, "the violation of the regulations and the corresponding submission of claims for which payment is known by the claimant not to be owed make the claim false" under the FCA. *McNutt*, 423 F.3d at 1259.

D.C. Circuit. Until the First Circuit's ruling below, the D.C. Circuit had adopted the broadest view of legally false claims. Last year, in *SAIC*, that court held that claims for payment under a federal government contract can be legally false under an implied certification theory if contract provisions are not satisfied "regardless of whether the contract expressly designates those requirements as conditions of payment." *SAIC*, 626 F.3d at 1261. Rather than treat a breach of a contract provision as a breach of contract, the court held that a breach of contract can be the predicate for a FCA suit *even if* the contract does not expressly designate a legal requirement as a precondition to payment. *Id.* at 1268-69. The court thus rejected the Second Circuit's holding that preconditions for payment that could subject a defendant to FCA liability must be expressly identified in advance. And it staked out its position "fully understand[ing] the risks created by an excessively broad interpretation of the FCA"—including that "the implied certification theory is prone to abuse by the government and *qui tam* relators who, seeking to take advantage of the FCA's generous remedial scheme, may attempt to turn the

violation of minor contractual provisions into an FCA action." *Id.* at 1270.

First Circuit. The First Circuit has (quite implausibly, at this point in the circuit lineup) managed to carve out yet another path. In conflict with the Second and Ninth Circuits, and in apparent agreement with the D.C. Circuit, the First Circuit has rejected the theory that a claim can only be false or fraudulent based on non-compliance with a legal condition of payment if that condition is "expressly stated in a statute or regulation." Pet. App. 4a; *accord New York* v. *Amgen Inc.*, __ F.3d __, 2011 WL 2937420, at *5 (1st Cir. July 22, 2011) (reiterating holding from *Hutcheson*). In conflict with the Third, Fifth, Eighth, and Tenth Circuits, it has declined to recognize any difference between conditions of participation and conditions of payment when it comes to assessing which claims qualify as "false" for purposes of the FCA. In conflict with the Eighth and Tenth Circuits, it has held that the generic language in a hospital cost report certification is a certification of compliance. And in a twist all its own, the First Circuit has concluded that those generic certifications certify not just the submitters' own compliance, but that of all upstream entities, too. Pet. App. 32a-36a.

To review the bidding, then: Some of the circuits assessing "legal falsity" look for a false *express* certification before assigning liability. Others look for a falsely *implied* certification of compliance with an *expressly* stated precondition of payment in a statute or regulation. Others look for a falsely implied certification of compliance with contract obligations that are—or, in some circumstances, are

not—identified as conditions of payment. And still others advance the notion that there are legally relevant differences between conditions of participation and conditions of payment that determine whether an FCA cause of action can go forward. In embracing the most expansive option yet, the First Circuit has held that allegations of non-compliance by upstream third-parties can render a hospital's claim "false" and actionable under the FCA regardless of the fact the hospital fully complied with its obligations and provided a truthful claim seeking payment for services actually rendered.

B. The Entrenched Circuit Splits Over "Legal Falsity" Lead To Different Outcomes Across The Country On The Same Facts.

All of these disparities and divergences among the circuits are not just superficial, nor are they a matter of semantics. They are outcome determinative.

Take the various circuits' "implied certification" tests for legal falsity under the FCA. If a claim for federal payment is submitted in New York or Arizona, the only thing the claim "implies," for purposes of any implied certification theory of legal falsity, is the submitter's compliance with a statute or regulation that specifically states that it must be complied with for payment to be authorized. *Mikes*, 274 F.3d at 700; *Ebeid*, 616 F.3d at 998. But if the same claim is submitted in Colorado, the claim *also* implies that contract requirements on which payment is conditioned are met. *Connor*, 543 F.3d at 1218. If the same claim is submitted in D.C., it impliedly represents that the submitter complied with even contract provisions that do not indicate

that compliance is required for payment. *SAIC*, 626 F.3d at 1269. But across the border in Maryland, if the same claim again were submitted, the Fourth Circuit would not reach the same conclusion; that court holds the view that the FCA "surely cannot be construed to include a run-of-the-mill breach of contract action." *Wilson*, 525 F.3d at 378; *see also Harrison*, 176 F.3d at 786-87 n.8 (finding implied certification theory "questionable"). Meanwhile, in Michigan, even if all of the certifications submitted with the claim are true at the time, by submitting a claim, the party impliedly certifies that it will not engage in *later* noncompliance of some sort. *Augustine*, 289 F.3d at 415. And now, in Massachusetts, the only limitations on FCA implied certification flow from whether the underlying misconduct is knowing or material—for any sort of noncompliance anywhere in the stream of commerce connected to a federal claim can cause that claim to be false. Pet. App. 21a-22a.

Another example. How can a contracting entity identify the "conditions of payment" that may lead to a claim being "legally false"? In New York, the contractor can look to the statutes or regulations governing the program. *Mikes*, 274 F.3d at 700. In Texas, though, an agency need not offer its opinion on whether a particular requirement is a condition of payment until the FCA litigation itself. *E.g.*, *Thompson,* 125 F.3d at 902 (remanding for determination of whether certification of compliance was a condition of payment); *U.S. ex rel. Thompson* v. *Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017, 1025 (S.D. Tex. 1998) (relying on declaration from acting chief of HCFA to find that payment was conditioned on certification). Companies in New

Mexico, Iowa, and New Jersey, for their part, must differentiate conditions of participation from conditions of payment. *Connor*, 543 F.3d at 1220; *Wilkins*, 2011 WL 2573380, at *12; *Vigil*, 639 F.3d at 795–96. And—again—in Massachusetts, under the First Circuit's ruling, conditions of payment can apparently be found anywhere the court, or a relator, wants to look for them. Pet. App. 36a ("[W]e are not creating a rule that non-compliance with a contractual term is any more necessary to establish that a claim is false or fraudulent than non-compliance with an express statute or regulation, or an express misrepresentation on a form submitted with payment.").

One last example: The facts of this case. Under this case's facts, the Second Circuit applying *Mikes* and the Ninth Circuit applying *Ebeid* would have found the relator's claims not actionable under the FCA because the alleged implied certification came from a program enrollment application—one that was not even signed by Blackstone. *See, e.g.*, *U.S. ex rel. Kennedy* v. *Aventis Pharms., Inc.*, 610 F. Supp. 2d 938, 946 (N.D. Ill. 2009) (applying *Mikes* to alleged AKS violation and holding that the AKS does not expressly state that a kickback renders the claim ineligible for payment). The Tenth Circuit, applying *Connor*, would have held that by submitting an annual cost report, a hospital only implies that the hospital itself is continuing to comply with the requirements of participation and does not speak at all to third parties' upstream conduct; it is "far from clear that the government intended the cost report certification to condition payment on full regulatory compliance," in light of the government's "complex monitoring and remedial scheme that ends Medicare

payments only as a last resort." 543 F.3d at 1222. And the Fifth and Eighth Circuits, under *Bowan* and *Vigil*, would have scrutinized the AKS to determine whether the AKS made Blackstone's upstream compliance a condition of payment to the hospital. Since it does not, they too would have ruled in favor of Blackstone. The Third Circuit, too, which has found that it is a "close question" whether an AKS violation by the entity that certifies its own compliance can render a claim false, would not endorse the sort of transient property reasoning that third-party upstream misconduct makes false the claim submitted by the hospital for services it provided in compliance with all Medicare requirements.

It should be clear from all of the foregoing that the current interplay among the circuits is not a shallow split, nor is it a passing jurisprudential phase. *Every circuit* has staked out at least some ground on the issue of "legally false" FCA claims and their parameters, and the circuits are not so much split as they are splintered. It is time for this Court to take up the issue.

II. THE ISSUE PRESENTED IS RECURRING AND IMPORTANT.

In just the past ten years, as each of the circuits has endeavored to define the proper scope of what constitutes a "legally false" claim, over 5,000 FCA lawsuits were filed—nearly 4,000 of them by *qui tam* relators. *See* United States Dep't of Justice, Civil Division, *Fraud Statistics–Overview, Oct. 1, 1987-Sept. 30, 2010*, *available at* http://www.justice.gov/civil/docs_forms/C-FRAUDS_FCA_Statistics.pdf. The terms "legally false" and "false certification" are

discussed in literally hundreds of decisions from the lower courts; and those decisions in turn have then been dissected by FCA treatises seeking to discern any unifying principles as to what, exactly, the "legally false" theory is and how it operates. *See, e.g.*, 1 John T. Boese, *Civil False Claims and Qui Tam Actions* § 2.03[G] (4th ed. 2011) ("In a growing number of FCA cases, it is alleged that a violation of a federal statute, regulation or contract term can serve as the basis for liability under the FCA even in the absence of a facially false claim."); Claire M. Sylvia, *The False Claims Act: Fraud Against the Government* § 4:33 (updated Apr. 2011) ("One type of case that has generated significant confusion is the 'false certification' case.").

All of this confusion among the circuits—and the resulting uncertainty about what triggers FCA liability, and when, and why—is, to put it mildly, bad for business, and bad for the people who own and work in those businesses. It is critical for parties doing business directly and indirectly with the government to know what liability risks inure to that business. The current state of the law among the circuits provides no insight as to when allegations of noncompliance will be investigated and resolved by the government itself—through the administrative procedures specifically formulated to redress certain types of violations—and when relators will be able to circumvent those own enforcement mechanisms by converting every administrative peccadillo into an FCA action carrying with it the specter of staggering liability and enormous settlement pressure.

Manufacturers, contractors, hospitals, universities, financial institutions, grant recipients, and everyone

else doing business with the government needs to know when the submission of a factually accurate claim for goods provided or services rendered might nevertheless subject the claim submitter, or a company like Blackstone that does business with a claim submitter, to FCA liability.[8] All of the companies and individuals who do business with those claim-submitting organizations need to know when some upstream course of conduct will be considered to "cause" a claim that is truthful and accurate to become "false" for purposes of the FCA.

The confusion among the circuits over "legally false" FCA liability is only one of the problems contractors and their business affiliates currently face, however. The sheer scope of some circuits' treatment of the "legal falsity" theory causes its own grave issues. There are statutory and administrative mechanisms in place to address and remedy a contractor's failure to comply with a regulatory or contractual term, including everything from fines to action plans to exclusion from future participation in

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[8] While the hospitals who submitted the claims were not named as defendants in the complaint in this case, the First Circuit held that those entities submitted false claims. The knowing submission of false claims is directly actionable. 31 U.S.C. § 3729(a)(1)(A). Thus, if named in a suit by a relator like Hutcheson, these hospitals—and other institutions who similarly submit truthful claims for services provided and are in compliance with all program requirements—would be left only to argue that they should avoid liability because they did not meet the FCA's "knowing" requirement, which requires only "reckless disregard." Moreover, given the FCA's addition of liability for retaining an overpayment in 2009—*i.e.*, money paid on ineligible claims—those parties risk facing yet another FCA suit if they do not remit back to the Government the money paid on such "false" claims. *See* 31 U.S.C. §§ 3729(a)(1)(G), 3729(b)(3); 42 U.S.C. § 1320a-7k(d)(4)(B).

a government program. Many of those remedies are subject to the federal government's exclusive control; there are no "private rights of action" to enforce such instances of administrative noncompliance. Permitting private relators to use the FCA, with all its heavy remedial artillery, to pursue allegations of administrative noncompliance renders those carefully calibrated government mechanisms largely superfluous, and potentially subjects contractors to crippling and outsized penalties. *See*, *e.g.*, *Hendow*, 461 F.3d at 1169 (allowing relator's suit based on alleged noncompliance with provision of agreement governing how student recruiters are paid even though Department of Education had promulgated specific range of remedies and penalties for such noncompliance). The looming threat of financial ruin is even further exacerbated in the context of the "legally false" theory of FCA liability, because relators wielding the theory often assert that some sort of noncompliance renders *every claim* connected to the defendant, often over many years, "false," and therefore subject to a treble damages recovery. *See, e.g., Schindler Elevator*, 131 S. Ct. at 1890 (relator alleged that failure to file accurate annual report stating number of Vietnam veterans employed by company transformed hundreds of claims covering one hundred million dollars' worth of elevator repair work into "false claims" subject to treble damages and per-claim penalties); *Hendow*, 461 F.3d at 1168 (relator alleged that how University paid its student recruiters transformed into "false claims" hundreds of millions of dollars' worth of student financial aid, subject to treble damages and per-claim penalties).

Underscoring the importance of the issue, the First Circuit's unprecedentedly broad interpretation

of the FCA has received significant attention from courts and commentators alike. The District of Massachusetts itself emphasized that the First Circuit had "*departed from the holdings of many of its sister circuits*" in its reasoning about what constitutes a legally false claim. *U.S. ex rel. Nowak* v. *Medtronic, Inc.*, __ F. Supp. 2d __, 2011 WL 3208007, at *28 (D. Mass. July 27, 2011) (emphasis added). And the trade press picked up on the same point: "The ruling *significantly expands the scope of drug and device manufacturer liability under the FCA*, particularly where the entity submitting an allegedly false claim is unaware of any underlying kickback payments or other improper conduct on the part of the manufacturer." *1st Circuit Ruling Expands Scope of Liability for Drug, Device Manufacturers Under False Claims Act*, 20 No. 5 FDA Enforcement Manual Newsletter (July 2011).

Other commentators similarly have reiterated the unprecedented breadth of the First Circuit's ruling and its impact: "the First Circuit ruled broadly, rejecting the analytical framework that many federal courts have developed to decide FCA cases. Following this ruling, whistleblowers may find it easier to assert FCA claims in the First Circuit." Pamela Johnston, *et al.*, *First Circuit Rejects False Claims Act Analysis And Rescues Anti-Kickback Claims Against Medical Device Company*, Mondaq (June 20, 2011). Because of the varied frameworks adopted in different circuits, "the proper standard for reviewing FCA claims will not be known until the Supreme Court addresses this circuit split." *Id.*; *see also First Circuit Adopts Expansive Implied Certification Theory of FCA Liability*, 6 No. 4 Government Contract Costs, Pricing & Accounting

Report (July 2011); P. Bantz, *Restrictions on FCA liability are rejected by 1st Circuit*, Massachusetts Lawyers Weekly (July 12, 2011).

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The First Circuit's unapologetically radical extension of the FCA's scope transforms the statute into a remedy for virtually all instances of noncompliance with a federal statute, regulation, rule, contractual term, or program requirement by companies who do business directly or even indirectly with the government. It is wrong, and it should be reversed.

CONCLUSION

For the foregoing reasons, the petition should be granted.

Respectfully submitted,

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APPENDICES