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

REPLY BRIEF FOR PETITIONER

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The False Claims Act ("FCA") requires, before anything else, a false claim. But the First Circuit held in this case that allegations of bad acts by upstream third parties can render a claim "false," *even if* the claimant fully complied with its obligations and filed a factually truthful claim, and *even if* the claimant did not know of the alleged upstream third-party conduct. That ruling expanded and intensified an already-broad circuit split—in which twelve of the thirteen federal circuits are represented—on the question of how, when, and in what circumstances an entity may be deemed to have submitted a "legally false" claim for government funds.

Respondent answers little of this on its terms. Instead the recurring theme of her Brief in Opposition is this: Kickbacks are bad. And because kickbacks are bad, Respondent argues that a hospital's claim is a "tainted" claim—and therefore a *false* claim—if an upstream supplier is accused of paying kickbacks to a third party.

But there are statutes designed to punish those who pay kickbacks: the Anti-Kickback Statute, for one. The question in *this* case is whether *False Claims Act* liability attaches to a government claim because someone else, somewhere up the supply chain, violated another federal statute (or regulation, or contract term). In trying to reach bad acts wherever they might have been committed, the First Circuit converted the FCA into a pervasive anti-bad-acts statute, which this Court time and again has explained it is not. And as the wide range of *amici* in support of certiorari have argued, the decision below creates vast operational uncertainties, and potentially treble-damages FCA liability, for any federal contractor or any entity doing business with a federal contractor, regardless of the content of the claim. Certiorari should be granted.

1. The First Circuit expressly acknowledged that the federal circuits have taken widely divergent approaches to resolving when factually true claims are nevertheless "legally false" and thus actionable under the FCA. Pet. App. 16a-18a, 19a-20a, 22a-23a. One readily discernible marker of that divergence is the fact that the District Court below—applying standards and limitations that the Second, Sixth, and Tenth Circuits apply when reviewing claims of "legal falsity"—ruled in favor of Blackstone. Pet.

App. 67a-68a; *see also id.* at 16a (district court "d[rew] on case law from some other circuit courts"). Rejecting those other circuits' approaches as imposing "artificial barriers that obscure and distort" the requirements for liability under the FCA, the First Circuit ruled in favor of Respondent. *Id.* at 18a; *see also id.* (other circuits' case law "obscure[s]" the issues).

The Opposition nonetheless repeatedly argues that the First Circuit engaged in a "straightforward" application of "well-established" principles. BIO 1, 11, 12, 18, 23, 33. But all that repetition does not make it so. There is nothing "straightforward" about the decision below, and nothing "established" about this area of the law.

Quite the contrary. The lower courts have struggled for years to define the scope and limits of the "legal falsity" theory of FCA liability. At one end of the spectrum, the Second and Ninth Circuits require a statute or regulation to set out the sort of legal non-compliance that would render a claim false before a defendant can be held to have "impliedly" certified compliance by the act of submitting a claim. *See, e.g.*, *Mikes* v. *Straus*, 274 F.3d 687, 700 (2d Cir. 2001); *Ebeid ex rel. U.S.* v. *Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010). At what once was the other end (until this case), the D.C. Circuit takes the broad view that *any* violation of a statutory, regulatory, or contractual term may render a claim "false" and actionable under FCA, even if that requirement is not identified as a condition of payment. *See United States* v. *Science Apps. Int'l Corp.*, 626 F.3d 1257, 1269-70 (D.C. Cir. 2010). And now the First Circuit has adopted the most expansive interpretation of the

FCA yet, holding that a claim can be "false" even if the submitting entity's representations as to its own compliance are wholly truthful, so long as there is an allegation of unsavory conduct somewhere—anywhere—upstream. Pet. App. 26a.

These decisions reflect more than mere "differences in vernacular." BIO 26. As the Petition explained, they are outcome-determinative: the same FCA action will meet varying fates based solely upon where it happens to be filed. Pet. 27-30; *see also* Brief for Ass'n of Private Sector Colleges & Univs. ("APSCU") as *Amicus Curiae* 12-13 (elaborating on the same point). The First Circuit's unprecedentedly broad interpretation of the statute transforms a vast range of statutory, contractual, and regulatory violations into privately enforceable federal fraud, punishable with crippling damages awards.

2. Respondent does not respond head-on to the undeniable circuit split over how to identify and define "legally false" claims. Instead she contends that the alleged violation here—of the Anti-Kickback Statute ("AKS")—somehow alters the analysis. BIO 14.[1] It does not. The First Circuit's expansive decision was not limited to AKS cases. *See*, *e.g.*, Pet. App. 18a ("Two purely legal issues are raised on

[1] Respondent suggests in passing that Blackstone "conceded" in the District Court that compliance with the AKS is a condition of payment. BIO 12. That is wrong. Blackstone consistently explained in the District Court—and, later, in the Court of Appeals—that FCA liability must turn on the "content of the claim" itself, not just the mere allegation of a kickback somewhere up the supply chain. Def.'s Reply in Support of Mot. To Dismiss 11, ECF No. 62 (Sept. 2, 2009).

appeal concerning when implied misrepresentations and third-party actions can give rise to a false or fraudulent claim under the FCA."); *see also id.* at 19a-31a (setting out principles for addressing those two legal issues before evaluating Respondent's allegations under those principles).

In fact, within weeks of the First Circuit's decision, district courts within the First Circuit began applying the court of appeals' pioneering approach in a variety of contexts. *See U.S. ex rel. Dyer* v. *Raytheon Co.*, 2011 WL 3294489, at *9-10 (D. Mass. Jul. 29, 2011) (federal contractor allegedly violated Federal Acquisitions Regulations); *U.S. ex rel. Nowak* v. *Medtronic, Inc.*, __ F. Supp. 2d __, 2011 WL 3208007, at *7-9 (D. Mass. Jul. 27, 2011) (medical device manufacturer allegedly violated FDA requirements); *U.S. ex rel. Saltzman* v. *Textron Sys. Corp.*, 2011 WL 2414207, at *3 (D. Mass. June 9, 2011) (federal contractor allegedly violated contract term regarding workers' compensation insurance costs). Relators, too, agree that the First Circuit's ruling extends well beyond the limited scope of AKS violations. *See U.S. ex rel. Jones* v. *Brigham & Women's Hosp.*, 1st Cir. Case No. 10-2301, Appellant's Reply Br. 2, 20-21 (filed July 18, 2011) (arguing that the First Circuit's ruling compels a finding that a hospital, medical school professor, and others violated the FCA by failing to properly investigate scientific misconduct allegations, in violation of National Institutes of Health regulations). And the multiple *amicus* briefs submitted in support of certiorari further confirm that the standard articulated in the First Circuit's decision was not limited to FCA suits premised on AKS violations. *See infra* at 10-11.

Moreover, even the premise of Respondent's argument—that the AKS is different—is mistaken. Merely alleging a kickback does not save a legally deficient FCA complaint from dismissal. Indeed, one circuit has expressly *rejected* reliance on the same hospital cost report certification that formed the basis of the First Circuit's holding, *see U.S. ex rel. Conner* v. *Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1222 (10th Cir. 2008), and another has found it "questionable" whether an implied misrepresentation can be actionable *at all* under the FCA. *Harrison* v. *Westinghouse Savannah River Co.*, 176 F.3d 776, 786-87 n.8 (4th Cir. 1999).[2]

Respondent does not cite a single case—anywhere—in which another court has held that allegations of a supply-chain kickback involving third-parties transform a hospital's truthful and accurate claim into a "false" one. The cases Respondent cites stand for the far more limited proposition—which even so has been described as a "close call"—that a claimant cannot *itself* pay a kickback (for example, to get a federal program patient on its billing rolls) and then bill the federal government for treating that patient. *U.S. ex rel.*

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[2] District courts applying Second, Seventh, and Eighth Circuit law (in addition to the District Court below) also have dismissed FCA cases premised on AKS violations. *See*, *e.g.*, *U.S. ex rel. Kennedy* v. *Aventis Pharms., Inc.*, 610 F. Supp. 2d 938, 946 (N.D. Ill. 2009); *U.S. ex rel. Thomas* v. *Bailey*, 2008 WL 4853630, at *9 (E.D. Ark. Nov. 6, 2008); *U.S. ex rel. Barmak* v. *Sutter Corp.*, 2002 WL 987109, at *5-6 (S.D.N.Y. May 14, 2002). *See also*, *e.g.*, Lisa Michelle Phelps, *Note, Calling Off the Bounty Hunters: Discrediting the Use of Alleged Anti-Kickback Violations to Support Civil False Claim Actions*, 51 Vand. L. Rev. 1003, 1017-22 (1998).

Wilkins v. *United Health Group, Inc.*, __ F.3d __, 2011 WL 2573380, at *15 (3d Cir. June 30, 2011); *see also U.S. ex rel. Kosenske* v. *Carlisle HMA, Inc.*, 554 F.3d 88, 95 (3d Cir. 2009) (claimant hospital allegedly paid kickbacks to get patients referred to the hospital for reimbursable services); *McNutt ex rel. U.S.* v. *Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1257-58 (11th Cir. 2005) (claimant pharmacy defendants allegedly paid kickbacks for referrals). None of those cases holds that a claim-submitting hospital must monitor for, or expressly or impliedly certify, a kickback-free, multi-link supply chain.[3]

3. Respondent next argues that because this case involves the "causes to be presented" prong of the FCA, it was appropriate to assign FCA liability to Blackstone based on a hospital's later claim for payment. As Respondent puts it, the question is whether Blackstone can be liable if its actions "cause[d] claims to be submitted to the United States." BIO 11. That statement contains a telling omission. For Blackstone cannot be liable unless it caused "*false or fraudulent* claims"—not just "claims"—to be submitted to the United States. The inquiry must start with the claim itself; if the claim is not false or fraudulent, it does not matter who submitted it or "caused" it to be submitted.

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[3] The two OIG "guidance" documents Respondent cites (at BIO 4-5 n.3) do not speak to the FCA at all. They contain suggestions to help identify suspect "joint ventures" that could result in business arrangements that violate the AKS, 59 Fed. Reg. 65372 (Dec. 19, 1994), and suggestions for pharmaceutical companies trying to structure effective compliance plans, 68 Fed. Reg. 23731 (May 5, 2003).

Respondent cites (and can cite) no case to the contrary. Instead, she looks for support to *United States* v. *Rivera*, 55 F.3d 703, 707 (1st Cir. 1995) (BIO 14), where the First Circuit held that the defendants could be liable for causing inflated insurance claims to be submitted. But the claims in *Rivera* were false because they were inflated. Similarly, *United States* v. *Hawley*, 619 F.3d 886, 897 (8th Cir. 2010), cited at BIO 13, involved whether an insurance agent could be liable for causing ineligible farmers to submit claims for payment. The claims were false because the farmers were ineligible. Other of the cases Respondent cites did not even involve the "causes to be presented" prong at all; the defendant itself submitted false claims. *See*, *e.g.*, *U.S. ex rel. Longhi* v. *Lithium Power Techs. Inc.*, 575 F.3d 458 (5th Cir. 2009) (cited at BIO 13). In *United States* v. *Bornstein*, 423 U.S. 303, 307 (1976), the claims at issue were what the federal courts generally now refer to as "factually" false claims—in that case, tubes for a radio kit that were of an inferior quality.[4] And *U.S. ex rel. Marcus* v. *Hess*, 317 U.S. 537 (1974), was a fraudulent inducement case; the government was defrauded by

[4] *Bornstein* also involved the unique way in which subcontractors present to prime contractors certifications that the parts being supplied meet the government's requirements. *See United States* v. *Bornstein*, 504 F.2d 368, 370 (3d Cir. 1974) (subcontractor shipped falsely branded tubes to prime contractor with a certification that the tubes complied with the government's purchase order). Seeking to create an analogy where none exists, Respondent refers to Blackstone as a "subcontractor" who has a "billing agreement" with the government. BIO 1, 9. Blackstone is not a subcontractor. Nor does it have any billing agreement with the government.

a bid-rigging scheme that voided the foundation for the contract.

The issue in this case, in contrast, is whether the claims at issue were "false" at all. The First Circuit's free-form approach to answering that question conflicts with dozens of decisions from other circuits that emphasize, through various constructs each circuit has developed, that "unsavory conduct is not, without more, actionable under the FCA." *U.S. ex rel. Cafasso* v. *General Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1058 (9th Cir. 2011); *see also U.S. ex rel. Steury* v. *Cardinal Health, Inc.*, 625 F.3d 262, 268-69 (5th Cir. 2010) ("The FCA is not a general 'enforcement device' for federal statutes, regulations, and contracts").

4. Respondent also argues that a 2010 amendment to the AKS, which states that a claim is false if it "includes" items or services "resulting from" an AKS violation, vitiates the need for this Court's review. BIO 16-18. That is also wrong, for multiple reasons. For starters, the amendment leaves no question that the First Circuit found "falsity" in a claim where no statute or regulation required upstream compliance by a supplier as a condition of payment to a downstream claimant hospital. The later-enacted amendment, which is not retroactive, only reinforces the First Circuit's radical approach.[5]

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[5] The amendment also contains more of a limiting principle than the First Circuit's decision. Under the amendment, a claim is false only if it "includes" items or services "resulting" from an AKS violation. 42 U.S.C. § 1320a-7b(g). But neither the hospital's diagnosis-related group (or "DRG") claim for a pre-set amount not based on the use or cost of any particular item to treat the patient, nor the surgeon's claim for performing

In addition, because the amendment is not retroactive, its impact, if any, will be limited to the subset of FCA cases involving an alleged AKS violation filed after 2016, at which time the FCA's 6-year statute of limitations will no longer permit litigating pre-2010 conduct. For a statute generating *$3 billion* in government recoveries last year *alone*, that is a long and costly length of time. *See* U.S. Dep't of Justice, Press Release: Department of Justice Recovers $3 Billion in False Claims Cases in Fiscal Year 2010 (November 22, 2010).

Finally, as we earlier explained, the amendment has no impact on the general framework the First Circuit articulated for addressing when claims for services actually rendered are nevertheless "false" because of some alleged underlying non-compliance somewhere in the stream of commerce related to the claims—whether the AKS or any one of thousands of other statutes, regulations, or contracts governing the relationship between the federal government and a federal contractor or claimant.

5. In that regard, the *amicus* submissions in support of the petition highlight the critical role for this Court in resolving the uncertainty among the circuits about the proper approach to "legally false" FCA claims. A wide variety of businesses and organizations—defense contractors, colleges and universities, health care providers, financial institutions, and many, many others—all submit claims to the government in connection with federal grants, contracts, loans, and other programs. Those

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a medically necessary surgery, "resulted" from an AKS violation. Pet. 7-8 & n.4.

entities are currently subject to a "dizzying array of rules and regulations," Brief for Chamber of Commerce of the U.S. and Pharmaceutical Research & Manufacturers of America as *Amici Curiae* 4, all overseen and enforced by the responsible federal agencies. *See also* Brief for National Defense Indus. Ass'n ("NDIA") as *Amicus Curiae* 4 (describing "massive and complex * * * contracting arrangements" in the defense contract industry); APSCU Br. 2 (describing the "numerous statutes, regulations, and contractual requirements" accompanying federal student financial aid programs).

The First Circuit's interpretation of the FCA turns each of those rules, regulations, and contract terms into a potential source of treble-damages *qui tam* actions brought by eager private litigants. And as the Chamber of Commerce and PhRMA explain (at 14), by failing to "articulate any workable test for determining which of these terms, conditions, and obligations are conditions of payment," the decision below "allows prosecutors, bureaucrats, and relators to make *post hoc* determinations as to what conduct is actionable under the FCA." It thus is little wonder that the *amici* express such concern that the First Circuit's approach—not to mention the broader confusion in the law—creates "profound uncertainty" for organizations that receive federal funds, APSCU Br. 9, and "presents a severe threat to the law and practice of federal government contracting," NDIA Br. 13. The circuits' current hodgepodge of conflicting and ill-defined theories of legal falsity "is simply not a rational or workable environment in which to do business with the government." Chamber of Commerce and PhRMA Br. 4.

CONCLUSION

Several Terms ago, this Court reversed a judicial interpretation of the False Claims Act that "threaten[ed] to transform the FCA into an all-purpose antifraud statute." *Allison Engine Co.* v. *U.S. ex rel. Sanders*, 553 U.S. 662, 669, 672 (2008). The decision below goes even further than the ruling reversed in *Allison Engine*: It transforms the Act into an all-purpose anti-*wrong* statute. But the foundational inquiry in every False Claims Act case must be whether there is a "false or fraudulent claim" at issue. *United States* v. *McNinch*, 356 U.S. 595, 599 (1958). The First Circuit's decision assigns False Claims Act liability to acts that are not claims, and to claims that are not false.

For the foregoing reasons, and those in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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