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 OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICI CURIAE* SUPPORTING PETITIONER

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INTEREST OF *AMICI CURIAE*[1]

The Chamber of Commerce of the United States of America ("Chamber") is the world's largest business federation. The Chamber represents 300,000 direct members and indirectly represents the interests of more than 3 million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases that raise issues of concern to the nation's business community.

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is an association whose membership comprises the country's leading research-based pharmaceutical and biotechnology companies. See http://www.phrma.org/about/member-companies (listing approximately 40 members, affiliates, and research associates). PhRMA members are responsible for the vast majority of innovative pharmaceutical products approved for marketing in the United States, and are recognized by the federal government as partners in the delivery of life-saving medications to federal health care program beneficiaries. PhRMA members invest billions of

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[1] Pursuant to Supreme Court Rule 37.6, *amici* state that no counsel for any party authored this brief in whole or in part and no entity or person, aside from *amici*, their members, and their counsel, made any monetary contribution toward the preparation and submission of this brief. Pursuant to Supreme Court Rule 37.2(a), counsel of record for all parties have received timely notice of *amici*'s intent to file this brief and have consented to the filing of this brief.

dollars every year in discovering and developing new medicines that help patients live longer, healthier, and more productive lives. PhRMA closely monitors legal issues that impact the pharmaceutical industry and regularly participates as *amicus curiae* in cases before this Court.

Compliance with health care statutes, contracting requirements, and other laws is vitally important, and *amici*'s members dedicate significant resources each year to internal compliance programs that complement the government's efforts to prevent misconduct. *Amici* support appropriate enforcement of the False Claims Act. At the same time, a balance must be maintained, as contemplated by Congress, between enforcement and preventing vexatious and unnecessary litigation that does not serve the Act's purposes. *Amici* have a substantial interest in ensuring that the False Claims Act is properly and uniformly interpreted so that businesses can manage their affairs with the government in a rational and predictable legal environment. Accordingly, both groups have previously participated as *amicus curiae* in cases before this Court involving the False Claims Act. See *Schindler Elevator Corp.* v. *United States ex rel. Kirk*, 131 S. Ct. 1885 (2011); *Graham Cnty. Soil & Water Cons. Dist.* v. *United States ex rel. Wilson*, 130 S. Ct. 1396 (2010); *Allison Engine Co.* v. *United States ex rel. Sanders*, 553 U.S. 662 (2008).

INTRODUCTION

The Court should grant certiorari because the decision below dramatically and unjustifiably expands the scope of liability under the False Claims Act ("FCA") for companies and other entities that participate in government programs, or otherwise provide products or services that may at some point

in the supply chain be reimbursed by the federal government. Expressly rejecting the standards developed and applied by other circuits for determining whether a claim for payment is "false or fraudulent" under the FCA, the First Circuit in this case held that a claim for payment is false whenever the party submitting it—or any other party in the supply chain—fails to comply with any standard that a bureaucrat or federal court later deems a precondition to payment, regardless of whether the party expressly misrepresented its compliance with that standard, and regardless of whether the standard is set forth expressly as a condition of payment in any statute or regulation. That decision implicates a question of exceeding importance that warrants this Court's review, for two reasons.

First, as petitioner has shown, the circuits are in entrenched disarray as to the proper standards for judging falsity under the FCA. Most circuits have held that a party's failure to comply with a condition of payment renders a claim false or fraudulent only when (1) the party expressly and falsely certifies its compliance with that condition; or (2) the condition is expressly set forth as a precondition to payment in a statute or regulation. These courts have correctly recognized that not every regulatory infraction or breach of contract redressable through other administrative or legal processes gives rise to treble damages liability for defrauding the government under the FCA. In the decision below, however, the First Circuit expressly rejected these limitations and adopted the most expansive view to date of the "legally false" theory of FCA liability. Only this Court can end the confusion and bring uniformity and stability to this critically important area of the law.

Second, the First Circuit's erroneous interpretation of the FCA creates an intolerable level of uncertainty for the thousands of companies that participate in government programs and contracts. Under the rule adopted below, a company cannot predict in advance what rules, regulations, or program requirements will be deemed preconditions to payment, and thus cannot conform its conduct to the law's requirements. Unless the company ensures perfect compliance with every requirement governing its participation in a federal program—a virtual impossibility given the dizzying array of rules and regulations governing complex programs such as Medicare—the company risks potentially devastating FCA liability every time it submits, or causes another party to submit, a claim for payment to the government. This is simply not a rational or workable legal environment in which to do business with the government.

REASONS FOR GRANTING THE PETITION

I. THIS CASE PRESENTS A DEEP AND MATURE CIRCUIT SPLIT AS TO THE NATURE OF ACTIONABLE FALSITY UNDER THE FALSE CLAIMS ACT.

The decision below sharpens multiple conflicts among federal courts over the nature of actionable falsity under the FCA. The prototypical FCA suit alleges that the defendant submitted a "factually false" claim—*i.e.*, a request for payment for goods or services that were not provided as claimed. In recent years, relators have inundated the courts with suits advancing novel theories of "legal falsity." These theories assert that by submitting a claim for payment, a defendant certifies that it has complied with governing statutory, regulatory, contractual, or other conditions of payment. If some condition of

payment was not met, the certification is deemed "legally false," even if the goods or services were provided as claimed. These inventive suits have generated substantial and well-documented confusion and division among the lower courts.

The First Circuit below adopted an especially expansive approach to the "legally false" theory of FCA liability. Respondent alleges that petitioner paid unlawful "kickbacks" to physicians to induce them to use its medical devices in surgeries. Pet. App. 2a–3a, 39a–40a. The admitting hospitals and treating physicians subsequently submitted claims for government payment, which respondent alleges were "legally false" because they were "tainted" by supposed kickbacks. Responded sued petitioner on the theory that it "caused" those claims to be submitted. *Id.* The First Circuit held that the suit could proceed, even though the hospitals and physicians rendered the goods and services as claimed. In reaching that decision, the First Circuit exacerbated several disagreements regarding the scope of FCA liability.

1. The decision below deepened disagreement among the courts of appeals regarding whether FCA liability can arise from an "implied certification." Circuits adopting the implied certification theory have held that a party can violate the FCA simply by submitting a claim for payment knowing that the party has not complied with some condition of payment—even if the party has not expressly certified compliance. See *Mikes* v. *Straus*, 274 F.3d 687, 700 (2d Cir. 2001); *United States ex rel. Wilkins* v. *United Health Grp., Inc.*, No. 10-2747, 2011 WL 2573380, at *8–9 (3d Cir. June 30, 2011); *United States ex rel. Augustine* v. *Century Health Servs., Inc.*, 289 F.3d 409, 414–15 (6th Cir. 2002); *Ebeid ex rel.*

United States v. *Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010); *United States* v. *Sci. Apps. Int'l Corp.*, 626 F.3d 1257, 1269 (D.C. Cir. 2010) ("*SAIC*"). These courts reason that "the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment." *Mikes*, 274 F.3d at 699.

On the other hand, three other circuits have rejected or seriously questioned the validity of the implied certification theory. The Seventh Circuit has held that FCA liability cannot arise unless a party expressly certifies compliance. See *United States ex rel. Yannacopoulos* v. *Gen. Dynamics*, No. 09-3037, 2011 WL 3084932, at *3 n.4 (7th Cir. July 26, 2011) ("if General Dynamics never certified compliance with the Arms Export Control Act, then any violations of that act would not support a claim under the False Claims Act"). In so doing, the Seventh Circuit has stressed that merely "[t]ripping up on a regulatory complexity does not entail a knowingly false representation." *United States ex rel. Main* v. *Oakland City Univ.,* 426 F.3d 914, 917 (7th Cir. 2005). Likewise, the Fourth and the Fifth Circuits have repeatedly declined invitations to approve implied certification claims, reserving the question even while suggesting likely disapproval. See *Harrison* v. *Westinghouse Savannah River Co.,* 176 F.3d 776, 786 n.8 (4th Cir. 1999) (describing the implied certification theory as "questionable"); *United States ex rel. Herrera* v. *Danka Office Imaging Co.*, 91 F. App'x 862, 865 (4th Cir. 2004) (per curiam) (same); *United States ex rel. Marcy* v. *Rowan Cos.*, 520 F.3d 384, 389 (5th Cir. 2008) (deferring the question whether "implied certifications" may give rise to FCA liability).

Entering into this fray, the First Circuit threw open the door to implied certification claims. See Pet. App. 18a–24a. To be sure, the court purported to eschew the categories of "'express certification' or 'implied certification.'" *Id.* at 18a. But the import of its decision is clear: The First Circuit rejected the district court's limits on claims of "impliedly misrepresenting compliance with a legal condition of payment," and thus expanded the universe of actionable implied certifications. *Id.* Moreover, the First Circuit affirmed its broad approach to implied certifications in a subsequent decision. See *New York* v. *Amgen, Inc.*, No. 10-1629, 2011 WL 2937420, at *8–9 (1st Cir. July 22, 2011), *petition for cert. filed*, No 11-363 (Sept. 19, 2011). As a result, the First Circuit has further intensified the conflict with the Seventh Circuit, as well as the likely disagreement with the Fourth and Fifth Circuits.

2. The decision below also deepened the acknowledged split regarding what constitutes a false implied certification. The nebulous implied certification theory raises a host of questions about what precisely a party certifies when it submits a claim for payment. The stakes are high, as parties that engage the government are subject to myriad requirements scattered about statutes, regulations, informal agency statements, contracts, and the like. If submitting a claim for payment certifies compliance with each one of those requirements, FCA liability, with its severe sanctions, would expand dramatically.[2] Despite that risk, and in acknowledged conflict with other circuits, the First Circuit staked out an extreme position on several points.

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[2] 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).

First, the decision below consciously sharpened conflicts regarding the permissible sources of conditions of payment. In a leading decision, the Second Circuit restricted the implied certification theory to cases in which "the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid." *Mikes*, 274 F.3d at 700 (emphasis in original). The Second Circuit explained that the FCA was not intended "for use as a blunt instrument to enforce compliance with all medical regulations—but rather only those regulations that are a precondition to payment." *Id.* at 699. For that reason, the court requires that the implied certification pertain to a statutory or regulatory provision that expressly makes compliance a precondition to payment. *Id.* at 699–700. The Ninth Circuit has approved the Second Circuit's formulation. See *Ebeid*, 616 F.3d at 998 ("The Second Circuit's analysis in *Mikes* of the implied false certification theory is persuasive and consistent with our precedent.").

In the decision below, however, the First Circuit expressly rejected the requirement that "implied conditions of payment can only be found in statutes and regulations." Pet. App. 20a; see also *id*. at 23a. In so doing, the court acknowledged its departure from the Second Circuit's jurisprudence, *id.* at 21a, and instead endorsed the Tenth Circuit's position that conditions of payments can arise in contracts, as well as statutes and regulations, *id.* (citing *United States ex rel. Connor* v. *Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1218 (10th Cir. 2008)). In addition, the First Circuit approvingly discussed the D.C. Circuit's decision in *United States* v. *Science Applications International Corp.*, 626 F.3d 1257, 1261 (D.C. Cir. 2010), which held that a condition of payment may

arise in a statute, regulation, or contract. *Id.* In the First Circuit's view, there are apparently no limitations on where a condition of payment may be found.

Second, the First Circuit disregarded the crucial distinction other circuits have drawn between conditions of payment and conditions of participation. The Second Circuit requires that the applicable statute or regulation "*expressly* stat[e] the provider must comply in order to be paid." *Mikes*, 274 F.3d at 700 (emphasis in original). Such an express statement makes clear that the requirement is a condition of payment, and not merely a condition of participation enforced through the regulatory process rather than by withholding payment. The Third, Fifth, Eight, and Tenth Circuits have also recognized that FCA liability should be limited to implied certifications of compliance with express conditions of payment. See *Wilkins*, 2011 WL 2573380, at *9; *United States ex rel. Steury* v. *Cardinal Health, Inc.*, 625 F.3d 262, 270 (5th Cir. 2010); *United States ex rel. Vigil* v. *Nelnet, Inc.*, 639 F.3d 791, 795–96 (8th Cir. 2011); *Connor*, 543 F.3d at 1219. As these courts recognize, conditions of participation—which include program requirements that are subject to other remedies such as administrative review, sanction, or even exclusion—simply are not a trigger for punitive FCA liability.

In contrast, the First Circuit joined the D.C. Circuit in disclaiming any requirement that the condition expressly state that compliance is required for payment. Pet. App. 20a–21a; see *SAIC*, 626 F.3d at 1261. As a result, in the First and D.C. Circuits, FCA liability may not be avoided just by complying with requirements that expressly indicate they are conditions of payment. Instead, parties dealing with

the government are subject to a "fact-intensive and context-specific inquiry" into whether the requirement would be perceived by the government as precondition to payment. *Amgen*, 2011 WL 2937420, at *6. This Court should grant review both to harmonize the discord among the circuits and to bring certainty to parties who deal with the government.

3. Finally, it bears mention that the conflict as to the validity and scope of the implied certification theory extends beyond the federal courts. Federal law provides financial incentives for states to adopt laws that establish false-claims liability to the state based upon the same conduct that gives rise to FCA liability. 42 U.S.C. § 1396h(b)(1). As a result, many states have adopted laws substantially mirroring the federal FCA. This carries two important implications. *First*, as illustrated by the First Circuit's decision in *Amgen*, the dispute between the circuits regarding FCA interpretation extends beyond federal law into these state false claims acts. Thus, the impact of the circuit split is multiplied because it affects interpretation of state law. *Second*, clear guidance regarding the scope of liability under these state laws is important not only to entities contracting with state governments, but also to the state governments themselves, which must comply with 42 U.S.C. § 1396h(b)(1) to retain the incentive funds.

II. THE STANDARD ADOPTED BELOW DEPRIVES COMPANIES OF FAIR NOTICE OF WHAT CONSTITUTES A FALSE CLAIM.

As the foregoing discussion demonstrates, the lower courts are deeply and intractably split as to the appropriate standards for determining when a claim for payment is "false" for purposes of the FCA. These disagreements alone warrant review in this Court. But in this case a grant of certiorari is further

warranted because of the broad and deleterious impact of the resulting legal uncertainty.

1. The rule of law requires at a bare minimum that the law be accessible and apprehendible. As this Court has recognized, laws that are vague beyond recognition are no law at all: A statute cannot be enforced if it is framed "'in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application.'" *United States* v. *Lanier*, 520 U.S. 259, 266 (1997). So too, laws that are unknowable, whether because they lack any workable or identifiable principle, or because they are adopted or applied *ex post facto*, are similarly invalid. See, *e.g.*, *Bouie* v. *City of Columbia*, 378 U.S. 347, 352–53 (1964). While ignorance of the law may not be an excuse, basic notions of procedural due process require at a minimum that the laws be fairly discoverable.

The implied certification theory endorsed by the court of appeals and some other circuits undermines these core rule-of-law values by subjecting companies to the FCA's draconian penalties without fair notice of what conduct will be deemed to render a claim false or fraudulent. As numerous commentators have observed, the implied certification theory of FCA liability is marked by a "high degree of uncertainty," Marcia G. Madsen, *False Claims Act: What Government Contractors Should Know about the Implied Certification Theory of Liability*, PLI No. 28982, at 481 (Sept. 14, 2011), and "little predictability," Richard J. Weber, *Exploring the Outer Boundaries of False Claims Act Liability: Implied Certifications and Materiality*, 36 Procurement Law., Winter 2001, at 14, 14 (2001).

The uncertainty and unpredictability arise in large part because "the implied certification theory has the

effect of putting words—false ones, at that—into the defendant's mouth, and then penalizing the defendant for those alleged falsities." 1 John T. Boese, *Civil False Claims and Qui Tam Actions* § 2.03 (2011). A party considering the submission of a "factually false" claim—for example, claiming reimbursement for the purchase of ten hammers when only one was in fact purchased—fully controls the ability to know (or not to know) the truth or falsity of the claim. Likewise, a party who expressly certifies its compliance with a particular condition knows in advance what conduct it can be held accountable for. But because an "implied certification" arises by operation of law rather than from anything the party actually says, the party may have no way to determine *ex ante* what conditions it may impliedly certify compliance with when it eventually submits a claim for payment, and thus cannot predict what conduct could potentially give rise to an FCA claim.

For that reason, the better reasoned decisions have carefully cabined the implied certification theory to instances in which the preconditions to payment are expressly set forth as such in a statute or regulation—and thus are fairly knowable in advance. See, *e.g.*, *Ebeid*, 616 F.3d at 998; *Mikes*, 274 F.3d at 697, 700. As those courts have recognized, any broader application of the theory would improperly transform the FCA into "a general 'enforcement device' for federal statutes, regulations, and contracts," *Steury*, 625 F.3d at 268–69, and allow qui tam relators to "shoehorn" what are, in essence, minor or unrelated regulatory infractions or breaches of contract "into a claim that is cognizable under the False Claims Act," *United States ex rel. Wilson* v.

Kellogg Brown & Root, Inc., 525 F.3d 370, 373 (4th Cir. 2008).

By jettisoning these critical limitations, the decision below will create circumstances in which the contours of a false claim are virtually unknowable at the time a party joins a federal program, submits a claim for payment, or produces a good or service that may cause another party subsequently to submit a claim for reimbursement. Most companies that do business with the government are subject to a vast array of complex rules, regulations, program documents, and other formal and informal guidance. Medicare is just one particularly notorious example "where relators rely on some alleged violation of one of the vast number of complex rules and regulations relating to that program as the basis for an FCA claim." Susan C. Levy, Daniel J. Winters & John R. Richards, *The Implied Certification Theory: When Should the False Claims Act Reach Statements Never Spoken or Communicated, But Only Implied?*, 38 Pub. Cont. L.J. 131, 139 (2008). Keeping abreast of regulatory developments is a constant challenge. In the 2010 Federal Register alone, there are at least 477 public notices, proposed rules, and publications regarding Medicare, totaling 10,316 pages of Medicare-related guidance. This does not include the thousands of informal guidance documents that are not issued pursuant to an agency's rulemaking power and "are therefore extremely difficult for companies to track." *Id.* at 148.[3]

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[3] The uncertainty is further compounded where, as here, the plaintiff seeks to shoehorn enforcement of another statute through the FCA. Respondent alleges an underlying violation of the Anti-Kickback Statute—itself a highly complex statutory scheme, characterized by a sweeping prohibition on payments to induce federally reimbursed purchases, accompanied by highly

The approach adopted by the First Circuit does not articulate any workable test for determining which of these terms, conditions, and obligations are conditions of payment, and thus allows prosecutors, bureaucrats, and relators to make *post hoc* determinations as to what conduct is actionable under the FCA. See *United States ex rel. Bidani* v. *Lewis*, 264 F. Supp. 2d 612, 615 (N.D. Ill. 2003) (relying on a DOJ statement of interest stating that "since [the Anti-Kickback Statute] is a critical provision of the Medicare statute, compliance with it is material to the government's treatment of claims for reimbursement"); *United States ex rel. Thompson* v. *Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017, 1046 (S.D. Tex. 1998) (relying on declaration of agency chief that payment was conditioned on defendant's certification that the Medicare services identified in annual hospital cost reports complied with the laws and regulations governing provision of healthcare

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technical and complex statutory and regulatory exceptions. *See*, *e.g.*, Michael M. Mustokoff & Robin Locke Neagle, *Health Care Providers Do Not Deserve To Be Treated As "Drug Dealers": An Analysis Of The Criminal Intent Standard Under The Anti-Kickback Act*, 13 Health Law., June 2001, at 13, 15 (observing that "[t]he Kafkaesque complexities of the Anti-kickback Act, which is punctuated by exceptions and safe harbors, each requiring its own interpretations, make it a lawyer's dream and a provider's nightmare"); Edward S. Kornreich, *E-Health Litigation: Legal Issues*, 1216 PLI/Corp. 553, 565 (2000) (explaining that "the complex federal anti-kickback regulatory scheme" includes the Anti-Kickback Statute, its statutory exceptions, its safe harbors, and "other informal letters and statements by the Office of the Inspector General and the Health Care Financing Administration"). In these circumstances, the First Circuit's decision subjects companies to "regulation" that is announced for the first time in an FCA case. This is inconsistent both with the requirements of the FCA itself and with the proper administration of a regulatory agency, including the obligations imposed by the Administrative Procedure Act.

services). From a planning perspective, this is intolerable: Businesses are left either to guess which requirements will be deemed a condition of payment, or to assume that every requirement could potentially be the basis for FCA liability.

This uncertainty is particularly crippling given the enormous penalties that can be levied under the FCA, where noncompliance with a condition of payment may be deemed to "taint" every dollar paid to a company under a government program or contract involving millions or billions of dollars. See, *e.g.*, Weber, *supra*, at 18 ("The implied certification basis for a false claim has the potential to vastly expand the consequences of a breach of contract or a violation of a regulation through trebled damages and statutory penalties for every 'false' invoice submitted."); *Schindler Elevator Corp.* v. *United States ex rel. Kirk*, 131 S. Ct. 1885, 1890 (2011) (relator alleged that defendant impliedly certified compliance with requirement to report number of qualified veterans employed by the company when it submitted invoices for over $100 million on government contracts); *SAIC*, 626 F.3d at 1264 (government contractor found liable for more than $6.5 million in damages and penalties where jury assessed damages for breach of contract at only $78).

In short, businesses need clear, predictable, and well-defined standards of liability. See, *e.g., Town of Concord, Mass.* v. *Bos. Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990) (Breyer, J.) (noting that legal rules "must be clear enough for lawyers to explain them to clients," "must be administratively workable," and "must be designed with the knowledge that firms ultimately act, not in precise conformity with the literal language of complex rules, but in reaction to what they see as the likely outcome of court

proceedings"). Yet the decision below creates the opposite: an unclear, unpredictable, ill-defined standard of liability under which companies will be unable to meaningfully ensure their compliance with the FCA or to rationally assess the costs and risks of doing business with the government. Now more than ever, FCA jurisprudence requires authoritative clarification to remove a cloud of uncertainty that could stunt economic growth and prevent businesses from efficiently delivering the goods and services they provide to the government, and may even deter them from participating in federal programs altogether.

2. This uncertainty is all the more troubling because of the increasing ubiquity of the FCA, which affects businesses in nearly every sector of the economy, from healthcare to defense to education.[4] In addition to these traditional targets for FCA claims, Congress has recently expanded the FCA's reach to recipients of federal funding, such as the financial services companies that receive federal "bailout" and stimulus funds. See Fraud Enhancement and Recovery Act of 2009, Pub. L. No. 111-21, 123 Stat. 1617. And the Department of Justice has recently launched investigations and filed complaints in the banking and mortgage context, seeking penalties of unprecedented size. See, *e.g.* Compl., *United States* v. *Deutsche Bank AG*, No. 11 Civ. 2976 (S.D.N.Y. May 3,

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[4] Each field of FCA enforcement itself comprises myriad programs, with accompanying rules, regulations, and guidance. To look solely at health care, the federal government funds a number of separate federal health care programs, including Medicare, Medicaid, TRICARE, CHIP, the VA, SPAP, the Indian Health Service, and PHS. Health care programs proliferate further at the state level. California, for example, has at least 30 distinct state health care programs. *See* http://www.dhcs.ca.gov/services/Pages/AllServices.aspx.

2011) (alleging that Deutsche Bank and its subsidiary submitted false annual certifications of compliance to maintain status in a residential mortgage program insured by the federal government); Mark D. Hopson & Kristin Graham Koehler, *Financial Institutions Face New Challenges Under False Claims Act,* 97 Banking Rep. (BNA) 197 (July 26, 2011).

The breadth of the FCA's reach is matched only by the volume of the litigation it has spawned. In recent decades the federal courts have seen an unprecedented ballooning of FCA litigation, as aggressive prosecutors and qui tam relators, armed with increasingly creative theories of "legal falsity," have brought the FCA to bear on virtually every aspect of government funding and regulation. Between 1996 and 2010, qui tam plaintiffs filed over 300 FCA actions per year. See Civil Div., U.S. Dep't of Justice, *Fraud Statistics Overview: October 1, 1987–September 30, 2010*, at 1 (Jan. 10, 2011). In all but one of those years, settlements and judgments under the FCA totaled over a billion dollars. See Gregory Klass & Michael Holt, Georgetown Business, Economics and Regulatory Law Research Paper No. 11-03, *Implied Certification under the False Claims Act*, Pub. Cont. L.J. (forthcoming 2011).

This surge in litigation has been even more pronounced most recently. From January 2009 to January 2011, the Department of Justice recovered more than $6.8 billion in FCA cases, and in fiscal year 2010, FCA relators were awarded $385 million. Hopson & Koehler, *supra*; Press Release, Dep't of Justice, *Department of Justice Recovers $3 Billion in False Claims Cases in Fiscal Year 2010* (Nov. 22, 2010). Those figures are far greater than any other two-year period in history. Hopson & Koehler, *supra*.

And, significantly, individual implied certification cases have resulted in awards of almost $100 million. See, *e.g.*, *United States ex rel. Tyson v. Amerigroup Ill., Inc.*, 488 F. Supp. 2d 719, 738 (N.D. Ill. 2007).

This dramatic expansion of FCA enforcement compounds the notice problem faced by *amici*'s members, as it amounts to regulation through litigation—often at the behest of private relators who are enticed by the prospect of a lucrative bounty and who lack the institutional wisdom that tempers the zeal of federal prosecutors. As a result, contracts and program agreements entered years ago are now subject to challenge based on legal theories that did not exist at the time, undermining good-faith efforts to comply with the law.

3. Finally, encouraged by the expansive implied certification theories adopted by some lower courts, relators increasingly bring FCA claims based on allegations that the defendant "failed to comply with the mandates of a statute, regulation or contractual term that is only tangential to the service for which reimbursement is sought." *Mikes*, 274 F.3d at 697; see also Claire M. Sylvia, *The False Claims Act: Fraud Against the Government* § 4.33 (2011) ("concerns about the potential use of the False Claims Act to impose liability for minor regulatory violations that are unrelated to defrauding the Government are heightened in implied certification cases"). Below are but a few examples of FCA cases showcasing how any alleged noncompliance with any statute or regulation, or even nonbinding standards or advisory documents, can be occasion for a claim for treble damages and civil penalties under the FCA. Under the First Circuit's standard, any or all of these cases could easily have resulted in FCA liability:

- **Industry Standards**. In *Chesbrough* v. *VPA P.C.*, No. 10-1494, 2011 WL 3667648 (6th Cir. Aug. 23, 2011), the Sixth Circuit rejected allegations that, by submitting Medicare and Medicaid claims for radiology studies, the defendant impliedly certified compliance with an industry standard derived from Medicare regulations as a whole. The court explained: "Medicare does not require compliance with an industry standard as a prerequisite to payment." *Id.* at *4.
- **Affirmative Action Plans**. In *United States ex rel. Kirk* v. *Schindler Elevator Corp.*, 601 F.3d 94 (2d Cir. 2010), *rev'd on other grounds*, 131 S. Ct. 1885 (2011), the Second Circuit addressed allegations that by submitting invoices after failing to file an annual report of the number of veterans employed, the defendant impliedly certified compliance with the Vietnam Era Veterans Readjustment Assistance Act. *Id.* at 113–15.
- **Environmental Regulations**. In *United States ex rel. Marcy* v. *Rowan Cos.*, 520 F.3d 384 (5th Cir. 2008), the Fifth Circuit rejected allegations that by making lease payments, the defendant impliedly certified compliance with environmental statutes, because environmental requirements "were not prerequisites to continuation of the lease." *Id.* at 390.
- **Marketing Regulations**. In *United States ex rel. Wilkins* v. *United Health Group, Inc.*, No. 10-2747, 2011 WL 2573380 (3d Cir. June 30, 2011), the Third Circuit affirmed dismissal of allegations that, by submitting Medicare claims, the defendant impliedly certified

compliance with Medicare marketing regulations. Because the marketing regulations did not condition payment on compliance, there was no basis for liability. *Id*. at *11–12.

- **Agency Guidelines**. In *United States ex rel. Yannacopoulos* v. *General Dynamics*, No. 03-3012, 2007 WL 495257 (N.D. Ill. Feb. 13, 2007), the court rejected allegations that, by submitting an invoice and certification of compliance with the contract, a defense contractor impliedly certified compliance with Defense Security Assistance Agency guidelines. The court held that "evidence that [the contractor] may have failed to technically comply with a particular guideline not referenced in its Certification does not establish an FCA violation." *Id*. at *3–4.

- **Antidiscrimination Statutes**. In *United States ex rel. Willard* v. *Humana Health Plan of Texas*, 336 F.3d 375 (5th Cir. 2003), the Fifth Circuit affirmed dismissal of allegations that an HMO's submissions to the government impliedly certified compliance with antidiscrimination statutes. The court rejected the claim because neither the government contract nor the statutes themselves expressly conditioned payment on compliance. *Id*. at 382.

- **Advisory Documents**. In *United States ex rel. Swafford* v. *Borgess Medical Center*, 98 F. Supp. 2d 822 (W.D. Mich. 2000), *aff'd*, 24 F. App'x 491 (6th Cir. 2001), the court rejected an FCA claim alleging that, by charging the government for vascular ultrasound services, the defendant impliedly certified that the services satisfied the

standard of care in the Medicare Carriers Manual. The court explained that the Manual did not condition payment on compliance, and so could not form the basis for liability. *Id*. at 831.

- **Procurement Manuals**. In *United States ex rel. King* v. *F.E. Moran, Inc*., No. 00-3877, 2002 WL 2003219 (N.D. Ill. Aug. 29, 2002), the court rejected allegations that by seeking payment on a contract that referred to a general contract, which in turn was informed by minority contracting requirements from the Postal Service's Procurement Manual, the contractor impliedly certified compliance with the procurement manual. *Id*. at *11–12.

Under the First Circuit's approach, any one of these sources of authority (and many others) could give rise to an implied condition of payment and therefore render a claim false or fraudulent. But the FCA was not intended to be a general fraud statute or to federalize tort and contract laws, and it certainly was not intended to supplant the well-developed administrative procedures and remedies that accompany most federal programs. See *Allison Engine Co*. v. *United States ex rel. Sanders*, 553 U.S. 662, 669, 672 (2008) (the FCA should not be "transform[ed]" through judicial interpretation into "an all-purpose antifraud statute"). Yet the decision below threatens precisely that. Under the standard adopted below, virtually any statutory, regulatory, contractual, or other program requirement could form the basis for FCA liability, even though the defendant did not expressly certify its compliance with the requirement and had no advance notice that it would be deemed a condition of payment.

The lack of clear notice as to the contours of a false claim will seriously undermine businesses' ability to provide necessary goods and services to the government, and to plan the investments and research and development necessary to further economic growth and job creation in the United States. To prevent these results, and to bring clarity and predictability to this important area of the law, *amici* respectfully urge the Court to grant the petition for certiorari and reverse the decision below.

CONCLUSION

For these reasons, and those stated by petitioner, the petition for certiorari should be granted.

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