No. 15-513

IN THE

Supreme Court of the United States

STATE FARM FIRE AND CASUALTY COMPANY,

Petitioner,

v.

UNITED STATES OF AMERICA, EX REL.
CORI RIGSBY; KERRI RIGSBY,

Respondents.

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

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BRIEF FOR THE ACADEMY ADVISORS AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS CURIAE* THE ACADEMY ADVISORS[1]

The Academy Advisors (TAA) is a policy coalition associated with the Health Management Academy, whose leading health systems members provide integrated health care delivery in 28 states across the country. Specifically, TAA's members collectively provide 290 million outpatient visits, 50 million emergency room encounters, and 130 million inpatient days annually. TAA was founded in 2010 with the objective of leveraging the collective expertise and breadth of the nation's leading health systems to conduct policy analysis and contribute to the health policy debate.

More than any other sector in the economy, the health care industry is a target of False Claims Act (FCA) litigation, and is under siege by *qui tam* relators at an increasing rate. Of the 14,583 FCA cases brought between 1987 and 2014, 45%, have involved the health care industry.[2] This ratio has

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[1] Pursuant to Supreme Court Rule 37.6, counsel for *amicus* represents that it authored this brief in its entirety and that none of the parties or their counsel, nor any other person or entity other than *amicus*, its members, or its counsel, made a monetary contribution intended to fund the preparation or submission of this brief. Counsel for *amicus* also represents that counsel of record received timely notice of this brief, that all parties have consented to its filing, and that letters reflecting such consent have been filed with the Clerk.

[2] *See* U.S. Dep't of Justice ("DOJ"), *Fraud Statistics – Health and Human Services: October 1, 1987 – September 30, 2014* 1–2 (2015) [hereinafter "*Fraud Statistics – Health and Human Services*"], *available at* http://www.justice.gov/file/fcastatspdf/download.

steadily increased in the last few years. Over 60% of all *qui tam* actions filed each year since 2008 have involved the health care industry.[3] Indeed, two thirds of new *qui tam* actions filed in fiscal year 2014 involved the Department of Health and Human Services as the primary client agency.[4] Fiscal year 2014 also saw an astounding 713 new *qui tam* actions—the second consecutive year with more than 700 new *qui tam* cases.[5]

These figures are troubling because most *qui tam* litigation against health care providers appears to be meritless. The Department of Justice elected to pursue less than a third of *qui tam* cases brought against health care defendants between 1987 and 2005.[6] Moreover, 92% of all *qui tam* cases in which the government declined to intervene between 1987 and 2004 were dismissed without recovery.[7] And

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[3] *Id.* There was no available data for fiscal year 2015 at the time of this filing.

[4] *Id.*

[5] Press Release, DOJ, *Justice Department Recovers Nearly $6 Billion from False Claims Act Cases in Fiscal Year 2014* (Nov. 20, 2014), *available at* http://www.justice.gov/opa/pr/justice-department-recovers-nearly-6-billion-false-claims-act-cases-fiscal-year-2014.

[6] U.S. Gov't Accountability Office, *Information on False Claims Act Litigation: Briefing for Congressional Requesters* at 29 (Dec. 15, 2005), *available at* http://www.gao.gov/new.items/d06320r.pdf.

[7] *See* Broderick, *Qui Tam Provisions and the Public Interest: An Empirical Analysis*, 107 Colum. L. Rev. 949, 975 (2007); *see also*, Canni, *Who's Making False Claims, the Qui Tam Plaintiff or the Government Contractor? A Proposal to Amend the FCA to Require That All Qui Tam Plaintiffs Possess Direct Knowledge*, 37 Pub. Cont. L.J. 1, 9 (2007).

those that are not dismissed represent a small fraction of the total amount recovered in settlements and judgments. From 1987 to 2014, *qui tam* relators prosecuting suits without the government's intervention were responsible for only 2.8% of the total amount recovered in *qui tam* actions against health care defendants.[8]

The recent marked increase in *qui tam* litigation takes a toll on health care providers at the expense of patients, especially in economically depressed rural areas.[9] Yet recent amendments to the FCA and related health care statutes, and new judicially crafted grounds for FCA liability, all but guarantee that *qui tam* actions against health care providers will continue to mushroom.[10]

The decision of the Fifth Circuit Court of Appeals below adversely affects the interests of the nation's leading health systems by unjustifiably expanding liability under the FCA. The scienter standard adopted by the court of appeals not only decreases the liability threshold under the FCA contrary to congressional intent, but also exacerbates an acknowledged circuit split. The differing interpretations coupled with the plethora of regulations governing billing practices under federal

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[8] DOJ, *Fraud Statistics – Health and Human Services* 2.

[9] *See* Hyer, *The Good, the Bad, and the Ugly: The Unnecessarily Broad Impact of Qui Tam Civil False Claims Act Cases on Rural Health Care Providers*, 23 Health Matrix 459, 488 (2013).

[10] *See* Cohen, *Kaboom! The Explosion of Qui Tam False Claims Under the Health Reform Law*, 116 Penn St. L. Rev. 77, 96–102 (2011); Belanger and Bennett, *The Continued Expansion of the False Claims Act*, 4 J. Health & Life Sci. L. 26, 28 (2010).

programs such as Medicare and Medicaid, leave the nation's leading health systems at a loss to understand the boundaries of FCA liability in the health care context and exposes them to treble damages and massive penalties for what can amount to simple human error. The Fifth Circuit's erroneous scienter standard will also embolden *qui tam* relators and their counsel to bring even more questionable FCA cases in hopes of extracting settlements by preying on the reluctance of many health care providers to risk the uncertainty of a trial, not only because of possible monetary impact, but also the potential for catastrophic collateral consequences of FCA liability such as exclusion from federal health care programs.[11]

The decision below thus has the effect of draining limited resources that could otherwise be used to provide health care services, thereby compromising the availability and quality of care that the leading health systems strive to provide patients nationwide. For this and other reasons, TAA has a strong interest in this Court's review and eventual reversal of the Fifth Circuit's decision.

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[11] *See* 42 U.S.C. § 1320a-7(b)(7), permitting the Secretary of the United States Department of Health and Human Services to exclude "[a]ny individual or entity that the Secretary determines has committed an act which is described in section 1320a-7a, 1320a-7b, or 1320a-8 of this title," which would include the submission of a claim that "is for a medical or other item or service and the person knows or should know the claim is false or fraudulent." 42 U.S.C. § 1320a-7a(a)(1)(B).

SUMMARY OF ARGUMENT

The element of scienter is what grounds the FCA as a fraud statute, rather than a regulatory enforcement mechanism based on strict liability or mere negligence. The Fifth Circuit's failure to insist on a clear linkage between evidence of scienter and the specific claims for payment that are alleged to be false extends FCA liability far beyond the bounds Congress intended.

The Fifth Circuit's decision essentially holds that plaintiffs can establish the element of scienter based on evidence of generalized intent to perpetrate a fraudulent scheme without tying that generalized intent to the preparation and submission of allegedly false claims. The Fifth Circuit thus held that FCA liability could exist even where there was a lack of connection between the elements of "falsity" and "scienter" *with respect to a particular claim*.

The Fifth Circuit's decision not only exacerbates the existing circuit split, but could have far-reaching consequences for the health care industry. Federal health care programs impose numerous highly complex regulatory requirements related to the performance, documentation, and billing of services covered by those programs. These regulations are often ambiguous and confusing, requiring deliberations among employees of health care providers to interpret and apply them in particular health care settings. The standard articulated by the Fifth Circuit could be exploited to use the existence of disagreements or deliberations regarding specific requirements as evidence of a generalized fraudulent intent. FCA liability could

then be wrongly imposed by connecting that generalized intent to claims that may be inaccurate but ***not*** fraudulent because those preparing and approving them were unaffected by the generalized intent and acted in good faith.

The complexity of the regulatory environment already makes health care institutions susceptible to allegations of FCA liability based on a variety of legislative and judicial expansions of FCA liability. These include, for instance, a number of circuits that have endorsed "implied certification" of compliance with regulatory requirements as a basis for liability, and recent legislation imposing liability for the failure to return Medicare overpayments.

The number of FCA lawsuits connected to the health care industry has skyrocketed in recent years, and the vast majority of those cases brought by *qui tam* relators are meritless. The Fifth Circuit's expansion of how scienter can be proven for individual claims, combined with the fact that scienter can be generally pled consistent with Rule 9(b)'s pleading requirements, creates a magnet for private relators to sue in a disproportionately influential jurisdiction. This case presents a clean and timely vehicle for the Court to take up this important pure question of law.

ARGUMENT

I. Scienter Distinguishes the False Claims Act as a Fraud Statute Rather Than a Broad Regulatory Enforcement Mechanism

A. Knowledge Is Indispensable to Proving the Existence of Fraud

Scienter is a critical element for imposing liability under the False Claims Act because only scienter marks a false claim as being the result of fraud. FCA liability is premised on proof of four elements, none of which, in isolation, is sufficient to impose liability. Rather, the first three elements create an interconnected chain of causation that culminates in the fourth element, a claim for payment. As explained in *United States ex rel. Owens v. First Kuwaiti General Trading & Contracting Co.*, 612 F.3d 724 (4th Cir. 2010), a FCA relator must show that the defendant "(1) made a false statement or engaged in a fraudulent course of conduct;" that "(2) *such* statement or conduct was made or carried out with the requisite scienter;" that (3) "the statement or conduct was material" to payment; and that (4) the statement or conduct resulted in the submission of a claim for payment. 612 F.3d at 729 (citing *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 913 (4th Cir. 2003)) (emphasis added). The Ninth Circuit has cited the role of scienter in the chain of causation even more succinctly, characterizing the requisite scienter under the False Claims Act as "the knowing presentation of what is known to be false."

United States ex rel. Hagood v. Sonoma Cty. Water Agency, 929 F.2d 1416, 1421 (9th Cir. 1991).

A break in the chain of causation between scienter and the elements of falsity and presentment negates a finding of liability. Thus, the False Claims Act does not penalize factually inaccurate statements that are made without knowledge of their falsity, even if they result in a claim for payment. As the statutory language makes evident[12] and as nearly every federal court has concluded, "[i]nnocent mistakes or negligence are not actionable" under the False Claims Act. *Hindo v. Univ. of Health Sci./Chi. Med. Sch.*, 65 F.3d 608, 613 (7th Cir. 1995) (citation omitted); *see also United States ex rel. Ubl v. IIF Data Sols.*, 650 F.3d 445, 452 (4th Cir. 2011) (quoting *Owens*, 612 F.3d at 728).

What differentiates an innocent error from an error that results in liability is the element of scienter, which makes scienter "critical to the operation of the False Claims Act . . . ." *United States ex rel. Hochman v. Nackman*, 145 F.3d 1069, 1073 (9th Cir. 1998); *see also United States ex rel. Main v. Oakland City Univ.*, 426 F.3d 914, 916 (7th Cir. 2005) (acknowledging that the FCA requires a causal connection between fraud and payment).

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[12] The term "knowingly" is defined as actual knowledge, reckless disregard, or deliberate ignorance. 31 U.S.C. § 3729(b)(1). Congress added this definition of scienter, to make "firm . . . its intention that the act not punish honest mistakes or incorrect claims submitted through mere negligence." S. Rep. No. 99-345, at 7 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5272.

The element of scienter has thus been cited as the critical hurdle that prevents the FCA from being turned into an enforcement mechanism for punishing these kinds of mistakes or mere negligence. In response to a FCA defendant's concern over the possibility of "greater liability for innocent regulatory violations," for instance, the Ninth Circuit stated that "unintentional violations do not lead to False Claims Act liability." *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1175 (9th Cir. 2006). Liability attaches to defendants only when they act "*knowingly* . . . with the intent to deceive." *Id.*; *see also United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999) (The FCA "is not an appropriate vehicle for policing technical compliance with administrative regulations. The FCA is a fraud prevention statute; violations of Federal Transit Act regulations are not fraud unless the violator knowingly lies to the government about them.").

B. Scienter Is Critical to Distinguishing Fraud from Mistakes or Mere Negligence in a Complex Regulatory Environment

The requirement that a plaintiff prove scienter is especially important for defendants participating in federal health care programs that have a multitude of complex, frequently ambiguous regulations and, increasingly, turgid subregulatory guidance. As the Fourth Circuit observed more than twenty years ago, the federal Medicare and Medicaid regulations

> are among the most completely impenetrable texts within human

> experience. Indeed, one approaches them at the level of specificity herein demanded with dread, for not only are they dense reading of the most tortuous kind, but Congress also revisits the area frequently, generously cutting and pruning in the process and making any solid grasp of the matters addressed merely a passing phase.

Rehabilitation Ass'n of Va., Inc. v. Kozlowski, 42 F.3d 1444, 1450 (4th Cir. 1994).

Health care providers are thus confronted with a highly complex regulatory regime and an army of *qui tam* relators and their counsel who have a powerful financial incentive to leverage garden-variety regulatory infractions into massive FCA bounties or *in terrorem* settlement payments. The chances of being wrong about aspects of governing rules and guidance that affects the content of a claim are high. The difficulty of reasonably construing these regulations, and the potential peril of being wrong, is demonstrated in a recent case, *United States ex rel. Saldivar v. Fresenius Medical Care Holdings, Inc.*, No. 1:10-CV-1614-AT (N.D. Ga. Oct. 30, 2015), ECF No. 255.

In *Saldivar*, the relator alleged that the defendant dialysis provider's practice of billing for the "overfill" portion of an injectable medicine violated Medicare billing requirements. Overfill is the extra amount of medicine contained in individual vials of expensive injectable drugs. As providers "honed their ability to extract not only all of the labeled amount of medicine in the vial, but the overfill as well," slip op. at 103, they were able to

administer the overfill amount to other patients. Defendant billed for the overfill that it actually administered to patients. The legal issue was whether such billing was appropriate, because overfill had already been factored into the Medicare reimbursement methodology, and was thus "free" to the provider when, instead of discarding it, the provider administered it to another patient.

The assumptions that underlay the existing billing methodology changed through technical innovation, opening a gap for how billing rules should have been applied in a circumstance not contemplated by the regulator. Ultimately, the court held that applicable rules prohibited billing for overfill during the relevant time period, and that because Fresenius's request for reimbursement was inconsistent with Medicare rules, it constituted a "false" claim for purposes of the False Claims Act. That, however, was insufficient for FCA liability. The court opined that although defendant may have been negligent in its failure to conclude that the overfill was considered "free" and could not be billed, and it may have even negligently failed to inquire when it learned that at least some in the industry believed billing for overfill actually administered was impermissible, defendant's negligence never rose to the level of reckless disregard of falsity because of the efforts that the defendant made to ascertain the correct application of the rules. *Id.* Defendant did not "knowingly" submit a claim that it "knew" was false; its submission of a "false" claim was not the result of its reckless disregard of the applicable rules.

The ambiguity discussed in this example is not unique or even an unusual instance of the regulatory

complexity encountered by providers participating in federal health care programs. Nor is it unusual for ambiguity to spur significant disagreement within the industry and among the employees of a single provider. In *United States ex rel. Williams v. Renal Care Group, Inc.*, 696 F.3d 518 (6th Cir. 2012), the defendant "created a wholly-owned subsidiary to take advantage of loopholes in the Medicare regulatory scheme that would permit it to increase profits." 696 F.3d at 520–21. The United States and relators brought suit alleging that the defendant's actions constituted FCA violations. The district court granted summary judgment in favor of the plaintiffs, and the Sixth Circuit reversed. There was clear evidence that some of defendant's employees thought that the plan to utilize a wholly-owned subsidiary was impermissible, with one management employee stating bluntly in an email that "I do not think it is legal to force our patients into a Method II arrangement simply to increase profits of our Company." *Id.* at 522–23.

However demonstrative of intent to defraud this email might have been, it failed to support liability under the False Claims Act because it was not part of the chain of causation that resulted in the submission of false claims. In *Williams*, the court held that the defendant filed claims that were false because they failed to conform to what was ultimately decided to be the correct interpretation of the applicable regulations. However, these claims did not result from the defendant's reckless disregard of the falsity of the claims. The chain linking evidence of "scienter" (that defendant was on notice of illegality through the above email and other evidence) with submission of the claim was broken

because other employees independently determined that the plan was legal. As it turned out, these employees came to the wrong conclusion, but they acted in good faith, and their good faith determination, not a fraudulent scheme, was the cause of the submission of false claims. The "'storm warnings' along the way" that might have been evidence of fraudulent intent did not *cause* any false claims, and therefore FCA liability was inappropriate. *Id.* at 535 (concurring opinion).

C. The Fifth Circuit's Decision Significantly Lowers the Burden of Showing That a Claim Is the Result of Guilty Knowledge

In this case, the Fifth Circuit articulated a standard of scienter that does not appear to require a link between the guilty knowledge of an employee and the submission of false claims. The Fifth Circuit opinion picks up the various strands of evidence introduced at trial that can be viewed as evincing intent on the part of State Farm employees to commit fraud, but never articulates a standard of culpability that required these strands to be tied to the submission of the claim at issue. The Fifth Circuit characterized State Farm's theory of FCA liability as "constricted," allowing "managers at an organization to concoct a fraudulent scheme—leaving it to their unsuspecting subordinates to carry it out on the ground." Pet. App. 37a. Left out of this construction, however, is any specific indication that the Fifth Circuit found or required evidence that such a management-concocted "fraudulent scheme" *actually led to the filing of false claims*. In so doing, it appeared to endorse a standard for scienter that

could impose liability based on the "collective knowledge" of an entity's employees, with elements of that knowledge being only loosely associated, rather than part of a chain culminating in the submission of a false claim.[13]

The court's citation of decisions that rejected the "ignorant certifier" defense, *see id.*, including *Harrison*, 352 F.3d 908, is inapt. As the court in *Harrison* stated, the "collective knowledge" theory would allow "a plaintiff to prove scienter by piecing together scraps of 'innocent' knowledge held by various corporate officials, even if those officials never had contact with each other or knew what others were doing in connection with a claim seeking government funds." 352 F.3d at 918 n.9. Contrary to the Fifth Circuit's citation, *Harrison* did not impose liability based on the collective knowledge of multiple employees. Rather, *Harrison* zeroed in on the knowledge of a single employee who knew that the relevant entity was bidding for a contract, knew that entity had an organizational conflict of interest ("OCI"), was warned not to allow that entity access to sensitive information, and understood that access to such information would create an OCI on the part of the entity submitting the bid. Thus, one employee

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[13] "Collective knowledge" is the "totality of what all of the employees know within the scope of their employment." *Harrison*, 352 F.3d at 918 n.9 (citing *United States v. Bank of New England*, 821 F.2d 844, 855 (1st Cir. 1987)). The D.C. Circuit in *United States v. Science Applications International Corp.*, 626 F.3d 1257 (D.C. Cir. 2010), rejected this standard for imposing liability under the False Claims Act if the scienter required for FCA liability could be established only by aggregating the independent knowledge of multiple employees. 626 F.3d at 1274.

knew that a contract was being sought, and knew of or recklessly disregarded facts that he knew would constitute an improper OCI. The court concluded that the entity knew through this employee that its no-OCI certification was false when it was submitted.[14] *Id.* at 919–20.

"The False Claims Act does not create liability merely for a health care provider's disregard of Government regulations or improper internal policies unless, *as a result of such acts*, the provider *knowingly* asks the Government to pay amounts it does not owe." *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002) (emphasis added). Just as innocent mistakes are insufficient to give rise to FCA liability, so too, loose talk that could be used as evidence of fraudulent intent is insufficient to establish FCA liability if it does not result in the submission of false claims for payment. Yet, the Fifth Circuit standard permits the imposition of liability under

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[14] The Fifth Circuit also cited *Grand Union Co. v. United States*, 696 F.2d 888 (11th Cir. 1983), in which cashiers assisted customers in defrauding the federal food stamp program, but the cashier who submitted the false claims knew nothing of the scheme. 696 F.2d at 889–90. *Grand Union* appears to apply a "collective knowledge" standard that is "applicable in an ordinary civil action in which an employee's knowledge is imputed to a defendant corporation." *Id.* at 891 (dissenting opinion). This standard is improper for finding scienter under the False Claims Act, which imposes penalties in addition to compensating a party's economic loss. At a minimum, "the government was required to present some showing that a Grand Union employee knew his or her actions would result in Grand Union filing a false claim against the government or otherwise result in the government being defrauded." *Id.* at 892 (dissenting opinion).

the FCA based on potentially random associations between discussions or deliberations among employees that are deemed to show a fraudulent intent, and claims that were false for reasons that are disconnected from those discussions.

II. Scienter is Especially Important to Distinguishing Fraud from Mistakes or Mere Negligence in Emerging Theories of FCA Liability Applied to Health Care Providers.

A. Scienter is a Critical Counterweight to the Judicially Created "Implied Certification" Theory of Falsity.

Scienter is now even more critical to preventing the FCA from being transformed into a blunt and costly regulatory enforcement mechanism that Congress never intended because of judicial expansion of the grounds for FCA liability that has occurred in recent years. This trend is exemplified by the "implied certification" theory of liability, in which a plaintiff alleges that the defendant made a request for payment and "withheld information about its noncompliance with material contractual [or regulatory] requirements." *See United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1269 (D.C. Cir. 2010). "An implied false certification claim is based on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment." *Mikes v. Straus*, 274 F.3d 687, 699 (2d Cir. 2001). Under this theory, the "pertinent inquiry" is "whether, through the act of

submitting a claim, a payee knowingly and falsely implied that it was entitled to payment." *United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1169 (10th Cir. 2010).

Thus, implied-certification liability – which is a creature of judicial invention[15] – attaches even though the defendant did not submit claims that were false on their face or make any false statements related to those claims. This approach has been accepted as a viable theory of FCA liability by nine circuit courts of appeals, including in cases brought against health care companies. *See, e.g.*, *United States v. Triple Canopy, Inc.*, 775 F.3d 628, 636–37 (4th Cir. 2015); *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 313 (3d Cir. 2011) (adopting theory of implied certification in case alleging violation of Medicare health plan marketing regulations but rejecting liability on grounds of materiality); *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 996–98 (9th Cir. 2010) (adopting theory in Medicare dispute but affirming dismissal of complaint for failure to plead with particularity alleged implied certifications); *McNutt ex rel. United Sates v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005) (adopting theory in Medicare dispute alleging health care providers impliedly certified compliance with Anti-Kickback Statute); *United States ex rel. Augustine v. Century Health Servs., Inc.*, 289 F.3d 409, 415 (6th Cir. 2002) (adopting theory in case alleging health

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[15] *See United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 385 (1st Cir. 2011) (noting that the text of the FCA "does not refer to . . . 'express certification' or 'implied certification' [or] 'certification' at all").

care providers impliedly certified compliance with Medicare regulations pertaining to cost reports); *Mikes*, 274 F.3d at 699–700 (adopting theory of implied certification in case alleging providers violated Medicare standard of care regulations, but dismissing on grounds of materiality).[16]

But several of those courts and others have cautioned that implied-certification liability must be carefully cabined lest it run amok, particularly in health care cases. *Wilkins*, 659 F.3d at 307 ("As several courts of appeals have held, . . . the implied certification theory of liability should not be applied expansively, particularly when advanced on the basis of FCA allegations arising from the Government's payment of claims under federally funded health care programs."); *Sci. Applications Int'l Corp.*, 626 F.3d at 1270 (noting that the Second Circuit, in adopting the implied certification theory, "worried that broad application of the FCA in [the health care] setting would operate as an inappropriately 'blunt instrument to enforce compliance with all medical regulations'").

A critical means of doing so is strict enforcement of the FCA's scienter standard. Thus, for example, in adopting the implied certification theory, the D.C. Circuit emphasized the importance of vigilant enforcement of the FCA's scienter standard,

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[16] Two circuits have declined to adopt implied certification as a theory of FCA liability. *See United States v. Sanford-Brown Ltd.*, 788 F.3d 696, 711–12 (7th Cir. 2015); *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 270 (5th Cir. 2010).

including explicit rejection of the "collective knowledge" doctrine:

> [W]e fully understand the risks created by an excessively broad interpretation of the FCA. . . . [W]ithout clear limits and careful application, 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. In our view, however, instead of adopting a circumscribed view of what it means for a claim to be false or fraudulent, this very real concern can be effectively addressed through strict enforcement of the Act's materiality and scienter requirements. . . .
>
> If the plaintiff proves [scienter], and does so based on the proper standard for knowledge—*which as we explain below excludes 'collective knowledge*,' . . . —then it will have established that the defendant sought government payment through deceit . . . .

Sci. Applications Int'l Corp., 626 F.3d at 1270–71 (emphasis added).

The First, Fourth and Tenth Circuits have likewise emphasized the importance of strict enforcement of the FCA's scienter standard to prevent abuse of the implied certification theory. *Triple Canopy, Inc.*, 775 F.3d at 637 ("The best

manner for continuing to ensure that plaintiffs cannot shoehorn a breach of contract claim into an FCA claim is strict enforcement of the Act's materiality and scienter requirements.") (internal quotation marks and citations omitted); *Hutcheson*, 647 F.3d at 388 (noting that overextension of FCA liability through the implied certification theory can be prevented through "strict enforcement" of the scienter element to "cabin the breadth of the phrase 'false or fraudulent'"); *Shaw v. AAA Eng'g & Drafting, Inc.*, 213 F.3d 519, 533 (10th Cir. 2000) (stating that "this court holds that when FCA liability is premised on an implied certification of compliance with a contract, the FCA nonetheless requires that the contractor knew, or recklessly disregarded a risk, that its implied certification of compliance was false").

The FCA scienter standard created by the Fifth Circuit in this case runs directly contrary to the precedents cited above. When coupled with expansive "implied certification" theory of liability, the lax scienter standard at issue here may very well convert the FCA into "an inappropriately 'blunt instrument to enforce compliance with all medical regulations,'" *Sci. Applications Int'l Corp.*, 626 F.3d at 1270, in contravention of congressional intent.

B. A Lax Scienter Standard Would Too Easily Convert Strict-Liability Stark Law Violations Into FCA Liability.

The FCA's scienter standard also serves as a bulwark against undue expansion of FCA liability that is specific to cases brought against health care providers based on the "Stark Law," which prohibits

an entity from billing the Medicare program for designated health services when they are ordered by physicians with specified financial interests in the entity. *See* 42 U.S.C. § 1395nn. The Stark Law imposes strict liability for such conduct, and can result in substantial per claim civil fines and Medicare program exclusion unless one of several narrow and complex exceptions apply. 42 U.S.C. § 1395nn(g)(3); 42 C.F.R. §§ 411.353 to 411.357. Stark Law violations are often boot-strapped into alleged FCA liability through the implied- ertification theory. *See, e.g.*, *Ebeid*, 616 F.3d at 1000 ("[T]he Stark Act may provide a valid basis from which to imply certification, because it expressly conditions payment on compliance . . . .").

The Stark Law's "steep civil sanctions and program exclusions may be ruinous. Health care providers are open to extensive liability, their financial security resting uneasily upon a combination of their attorneys' wits [and] prosecutorial discretion." *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 393 (4th Cir. 2015) (concurring opinion) (internal quotation marks and citations omitted). "Indeed, the Stark Law is infamous among health care lawyers and their clients for being complicated, confusing and counterintuitive; for producing results that defy common sense, and sometimes elevating form over substance." *Id.* In short, "even for well-intentioned health care providers, the Stark Law has become a booby trap rigged with strict liability and potentially ruinous exposure—especially when coupled with the False Claims Act." *Id.* at 395.

Given the Stark Law's strict-liability standard, and its use as the basis for FCA liability under a

theory of implied certification, the FCA's scienter element is all that stands between health care providers attempting to comply in a good faith with an excruciatingly complex regulatory regime and crippling fraud liability. For example, in *Drakeford*, "a nonprofit hospital [in] a small, largely rural community that is a federally-designated medically underserved area" was subjected to FCA damages and penalties totaling more than $237 million – even though it sought and relied upon the advice of a prominent regional law firm, a national consulting firm that specialized in physician compensation, a former Inspector General of the Department of Health and Human Services, and an attorney at a prominent healthcare law firm. *Id.* at 370–71. The result was "a likely death sentence for a community hospital in an already medically underserved area [based on] [a]n impenetrably complex set of laws and regulations." *Id*. at 390.

In *Drakeford*, a jury found the requisite FCA scienter because there was evidence that the hospital ignored conflicting advice about the Stark implications of its physician compensation program and nonetheless intentionally proceeded with the program and the submission of affected Medicare claims. *See id.* at 370–73. But under the Fifth Circuit's new standard, no such proof would be required to impose a FCA "death sentence" on institutions that attempt to comply in good faith with the Stark Law. Rather, the government or the relator need only show some sort of generalized intent and that *someone* within the institution at *some point – even after the claims at issue were submitted* – was aware or deliberately ignorant of, or recklessly disregarded, a Stark Law violation. No

connection between such intent or "knowledge" and particular claims would be required. *See* Pet. App. 37a–39a.

C. Scienter Is Critical to Establishing Fraud in Cases Alleging FCA Liability Based on a Failure to Return Medicare Overpayments

A further example of the daunting FCA landscape faced by health care providers, and the importance of the FCA's scienter standard, comes in the context of so-called "reverse" false claims. Under this aspect of the FCA, liability attaches for knowingly and improperly retaining money or property that should have been returned to the government. *See* 31 U.S.C. § 3729(a)(1)(G). Pursuant to a provision in the recently enacted Patient Protection and Affordable Care Act ("ACA"),[17] health care providers can be held liable under the FCA's reverse-false-claims provision for failing to return Medicare overpayments within 60 days after such overpayments are "identified." 42 U.S.C. § 1320a-7k(d)(1)–(4).

One of the few courts to address this new provision recently interpreted "identified" to mean notice of any *potential* overpayment. *United States ex rel. Kane v. Healthfirst, Inc.*, No. 11 Civ. 2325(ER), 2015 WL 4619686, at *8–16 (S.D.N.Y. Aug. 3, 2015). In adopting this interpretation of an ambiguous statutory term, the court recognized that it was imposing "a demanding standard of

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[17] Pub. L. No. 111-148, § 10104(j)(2), 124 Stat. 119, 901–02 (2010) (the "ACA").

compliance in particular cases, especially in light of the penalties and damages available under the FCA." *Id.* at *13. The court observed that while "[t]he ACA itself contains no language to temper or qualify this unforgiving rule," a violation would only be actionable under the FCA "when an obligation is *knowingly concealed* or *knowingly and improperly avoided or decreased* . . . ." *Id.* In other words, just as in the case of "implied certification," the FCA's scienter standard is a key protection against punishing innocent good-faith conduct where the 60-day-repayment rule serves as the basis for reverse-false-claims liability.

CONCLUSION

A clear scienter standard is essential to keeping the FCA tethered to its moorings as a fraud statute. The Fifth Circuit's new sweeping scienter construct would bring entirely new categories of conduct within the ambit of the FCA, contrary to the precedents discussed herein and congressional intent, and in the process would impose massive new litigation costs on health care providers already besieged by meritless *qui tam* litigation. This aspect of the Fifth Circuit's decision should be reviewed by this Court and reversed.

Respectfully submitted,

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