No. 15-7

IN THE

Supreme Court of the United States

UNIVERSAL HEALTH SERVICES, INC.,
Petitioner,

v.

UNITED STATES AND COMMONWEALTH OF MASSACHUSETTS EX REL. JULIO ESCOBAR AND CARMEN CORREA,
Respondents.

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

BRIEF OF INTERESTED HEALTHCARE PROVIDERS AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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INTEREST OF *AMICI CURIAE*[1]

Amici are healthcare providers and trade associations of healthcare providers who serve patients across the United States, including millions of beneficiaries of Medicare, Medicaid, and other federal healthcare programs.

Amicus American Clinical Laboratory Association (ACLA) is a not-for-profit organization whose primary purposes are to advocate for laws and regulations recognizing the essential role that laboratory services play in delivering cost-effective healthcare; encourage the highest standards of quality, service, and ethical conduct among its members; and promote public awareness about the value of laboratory services in preventing illness, diagnosing disease, and monitoring medical treatment.

Amicus Ardent Health Services provides hospitals and clinics the tools they need to succeed through investments in facilities, technologies, and human resources in the healthcare community. Ardent supports three health systems, including 14 hospitals and 12,000 employees, along with three physician groups with 270 employed physicians.

Amicus California Association of Physician Groups (CAPG) represents over 100 medical groups and independent physician associations serving over 20 mil-

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[1] Pursuant to Supreme Court Rule 37.6, *amici curiae* state that no counsel for any party authored this brief in whole or in part and that no entity or person, aside from *amici curiae*, their members, and their counsel, made any monetary contribution towards the preparation and submission of this brief. Respondents have filed a letter with the Court granting blanket consent to the filing of *amici curiae* briefs. Petitioner has granted consent to this *amici* brief in the letter accompanying this filing.

lion patients in California. It is the leading U.S. trade association for and the voice of accountable physician organizations. The mission of CAPG is to assist accountable physician groups to improve the quality and value of healthcare provided to patients.

Amicus DaVita HealthCare Partners Inc. is an innovative healthcare community that is committed to providing the highest quality care for patients suffering from chronic kidney disease, including health-management resources that keep patients off dialysis as long as possible and appropriate dialysis treatments for those patients that need it. DaVita's HealthCare Partners division is one of the country's leading operators of medical groups and physician networks, providing integrated healthcare management services that help ensure quality, accessible, and affordable patient care.

Amicus Fresenius Medical Care offers industry-leading coordinated healthcare services to patients with kidney failure and other chronic diseases in all 50 states and across the globe through a network of more than 2,200 dialysis facilities, outpatient cardiac and vascular labs. Consistent with its integrated approach to patient care, Fresenius also operates the United States' largest practice of hospitalist and post-acute providers, offers specialty pharmacy and laboratory services, and manufactures and distributes a comprehensive line of dialysis equipment, disposable products, and renal pharmaceuticals.

Amicus U.S. Renal Care is one of the nation's preeminent dialysis providers, offering in-center and at-home dialysis services to patients in 33 states through joint venture partnerships with leading local nephrologists.

Amici and their members are directly and profoundly impacted by the "implied certification" theory. As Petitioner convincingly demonstrates, this theory empowers enterprising *qui tam* relators and aggressive prosecutors to hold government contractors such as *amici* and their members liable for treble damages and civil penalties under the False Claims Act (FCA) without any evidence that the contractor made the type of "false or fraudulent" claim the Act requires for a violation. 31 U.S.C. § 3729(a)(1)(A); Petr's Br. 28–33.

Merely submitting a claim for payment, the theory goes, somehow constitutes an "implied" affirmative representation that the contractor has complied with every regulatory standard and contractual obligation that conceivably could apply to its business, regardless of whether the claim itself contains any such representation or whether Congress has made clear that a violation of that standard or obligation renders claims for reimbursement actionable under the FCA. By this logic, a claim for payment can be "false or fraudulent" if the contractor is in violation of *any* legal requirement that a relator or prosecutor—or, as happened in this case, a court acting *sua sponte*—may characterize *after the fact* as a condition of payment.

Healthcare providers like *amici* and their members face especially severe risks when they are targeted with this theory. As participants in Medicare, Medicaid, and other federal healthcare programs, *amici* and their members are subject to thousands of complex regulations, sub-regulatory standards, and contractual provisions—a substantial percentage of which are ambiguous, and some of which even conflict with one another. Although the FCA is designed solely to prohibit *fraud*, "implied certification" expos-

es healthcare providers to litigation whenever they are alleged to have failed to meet any of these contractual, regulatory, or sub-regulatory requirements. As a result of the application of this theory, healthcare providers are subject to substantial and unnecessary litigation costs, the threat of excessive damages and penalties, and unreasonable compliance obligations. Congress simply never intended this.

SUMMARY OF ARGUMENT

The implied certification theory is utterly unmoored from the FCA's text and purpose and should be rejected. The theory's application in the healthcare industry makes this starkly clear. The theory's core premise is that a claim submitted by a contractor may be "false or fraudulent" under the FCA, and thus subjects the contractor to the Act's extraordinary damages and penalties, if the contractor is not in compliance with *any* legal obligation, even if not referenced in a claims form or any statute and even if ambiguous, obscure, or tangential to the Government's payment decision.

I. This is an enormous problem for healthcare providers like *amici* and their members. Relators (and their lawyers) seeking a payout under the FCA use the implied certification theory to allege falsity under federal regulations, sub-regulatory documents, and state and local rules—many of which are ambiguous. It is no exaggeration, then, to say that a healthcare provider may find itself defending against an FCA claim based on the disputed meaning of a single phrase somewhere within hundreds of thousands of pages of regulatory and contractual obligations. *Infra* Part I.

II. This problem alone should expose the theory's absurdity, but the theory should be rejected not solely

because it is implausible, but because it is contrary to the statute itself and to accepted interpretive principles. *Infra* Part II. The FCA imposes liability for "false or fraudulent claim[s]," 31 U.S.C. § 3729(a)(1)(A); the implied certification theory imposes liability based on conduct divorced from the "claim" itself.

Beyond the statutory text, there is good reason to think Congress did not intend, and indeed could not have intended, this result. First, the implied certification theory deprives healthcare providers of any fair notice regarding what the FCA prohibits and what it does not. The vast majority of the thousands of regulatory and contractual requirements applicable to healthcare providers are not designated as conditions to the Government's payment of claims in any claims form, nor otherwise specified by Congress as predicates for FCA liability. But "implied certification" allows relators and prosecutors to argue—after the fact—that a court should construe them as material conditions of payment as if they were expressly identified as such on a claims form or by Congress. This raises important constitutional "fair notice" concerns, especially because a violation of the FCA carries "essentially punitive" penalties—*i.e.*, treble damages and per-claim civil penalties. *Vt. Agency of Nat. Res.* v. *United States ex rel. Stevens*, 529 U.S. 765, 784 (2000); see also *BMW of N. Am., Inc.* v. *Gore*, 517 U.S. 559, 574 (1996) ("Elementary notions of fairness enshrined in our constitutional jurisprudence dictate that a person receive fair notice not only of the conduct that will subject him to punishment, but also of the severity of the penalty…."); *infra* Part II. Indeed, the threat of exclusion from federal healthcare providers—a professional "death penalty"—hangs over the head of every healthcare provider accused of vio-

lating the FCA. See 42 U.S.C. § 1320a-7(a), (b). As a matter of constitutional avoidance, the statute should be read to avoid these infirmities.

Second, the implied certification theory transforms regulatory ambiguity into hunting grounds for *qui tam* litigation and improperly duplicates existing remedies. The healthcare regulatory agencies have numerous tools available for enforcing compliance with federal healthcare regulations, guidance documents, and contracts including administrative penalties, breach-of-contract suits, and exclusion from participation in federal healthcare programs. Under the implied certification theory, private relators decide which regulatory and sub-regulatory requirements warrant FCA litigation (and resulting government investigations and the potential application of FCA penalties) and which do not. By permitting relators to enforce regulatory standards, the implied certification theory disrupts the carefully calibrated regime of administrative remedies reflected in essentially every federal and state healthcare program.

III. The overbreadth of the implied certification theory cannot be justified or resuscitated based on the FCA's "materiality" and "scienter" requirements. *Infra* Part III. As Petitioner powerfully shows, these requirements cannot protect government contractors from the abuse of the FCA's "falsity" requirement that the implied certification theory allows. Petr's Br. 53–56. Indeed, FCA litigation involving healthcare providers has demonstrated time and again that these separate elements of FCA liability are inherently ambiguous and fact-bound, and typically cannot be resolved at the early stages of a case. Reliance on these elements to screen out meritless FCA complaints thus exacerbates, rather than ad-

dresses, the challenges that the implied certification theory creates.

IV. These problems must be solved by rejecting the implied certification theory entirely so that healthcare providers doing business with the Government can understand precisely what is expected of them and courts can consistently apply the law. The solution should be straightforward: A claim for payment may be "false or fraudulent" in three circumstances. First, the claim may misrepresent the goods or services provided. Second, the claim may contain a false certification of compliance with a rule that is expressly, specifically, and unambiguously referenced on the claims form and which itself is unambiguous. Finally, a claim may be "false or fraudulent" if the underlying services were performed in violation of a statute that Congress itself has expressly, specifically, and unambiguously declared renders claims for those services false within the meaning of the FCA. *Infra* Part IV. This rule would allow the Government to impose FCA liability for the true acts of knowing misconduct that Congress intended to cover when it enacted the FCA, and would grant providers, relators, the Department of Justice, and the courts clear notice of what conduct the FCA specifically prohibits. This clarity is essential, particularly in healthcare. To ensure a regime of clarity, the Court should make clear that the Government cannot address the infirmities of the "implied certification" theory by requiring healthcare providers and other government contractors to certify, on claims forms, to compliance with "all laws" or "all rules." Such a solution does not give providers proper notice of what specific laws or rules are truly critical.

ARGUMENT

I. THE IMPLIED CERTIFICATION THEORY EXPOSES HEALTHCARE PROVIDERS TO EXTRAORDINARY LEGAL RISKS.

The implied certification theory imposes particularly acute risks on healthcare providers. Healthcare is perhaps the most heavily regulated industry in the country. Providers, like *amici* and their members, are subject to a complex labyrinth of thousands of federal healthcare regulations, sub-regulatory standards, and contractual provisions, which vary from federal program to federal program and, in the case of Medicaid, from state to state. Indeed, by one count, "there are 130,000 pages of government health care rules, over 100,000 applying to Medicare" alone. Victor E. Schwartz & Phil Goldberg, *Carrots and Sticks: Placing Rewards As Well As Punishment in Regulatory and Tort Law*, 51 Harv. J. Legis. 315, 350 (2014). As this Court has recognized, Medicare, just one of the many federal healthcare programs, is "a massive, complex health and safety program … embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations," *Shalala* v. *Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000), and Medicaid is "a morass of bureaucratic complexity," *Herweg* v. *Ray*, 455 U.S. 265, 279 (1982) (Burger, J., dissenting).

Even a preliminary glance at this vast expanse of federal healthcare regulations and standards demonstrates that the implied certification theory is untenable. For instance, the Medicare program's Conditions for Coverage for healthcare organizations, which are set forth in regulations and associated agency commentaries from the Centers for Medicare & Medicaid Services (CMS), consume thousands of pages of the Federal Register. The Conditions for

Coverage applicable to end-stage renal care facilities, such as those operated by the *amici* DaVita, Fresenius, and U.S. Renal Care, alone encompass hundreds of pages, addressing a broad range of topics from "Patient Safety" and "Patient Care," 42 C.F.R. §§ 494.30–130, to personnel issues like the training and educational backgrounds of "social worker[s]" and "dietitian[s]," *id.* § 494.140. Others impose amorphous record-keeping obligations like the need to "maintain complete, accurate, and accessible records on all patients." *Id.* § 494.170. Still others relate to services provided to a facility by downstream contractors. See, *e.g.*, *id.* § 413.241 (requiring facility to "ensure that the pharmacy" that provides drugs has the "capability" to provide them in a "timely manner").

Clinical laboratories such as the members of *amicus* ACLA are subject to a similarly vast array of rules. Such laboratories are governed by the Clinical Laboratory Improvement Amendments (CLIA), 42 U.S.C. § 263a, which have led to over a hundred CLIA-related entries in the Federal Register and Code of Federal Regulations and hundreds of pages of interpretive guidelines. See Centers for Disease Control and Prevention, *Chronology of CLIA Related Documents in the Federal Register & Code of Federal Regulations*, http://wwwn.cdc.gov/clia/ Regulatory/Chronology.aspx; CMS, *State Operations Manual Chapter 6 - Special Procedures for Laboratories and Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services*. The requirements imposed by such rules and regulations are diverse—from the minimum education standards for laboratory employees, 42 C.F.R. § 493.1351 *et seq.*, to the information required on a laboratory test request form, *id.* § 493.1241.

Neither Congress nor CMS has designated any of these diverse and far-reaching Conditions of Coverage requirements as a condition to Medicare's *payment* of any claim for healthcare services. Indeed, these regulations contain independent frameworks for enforcement. See 42 C.F.R. §§ 488.604, 488.606. So too, the CLIA rules contain a regulatory enforcement mechanism for laboratories that violate those rules. See *id.* §§ 493.1800–1850. And none of these requirements is the subject of any certification contained in a claims form itself. Yet under the implied certification regime, a *qui tam* relator or a prosecutor can allege that even a minor departure from the most obscure of these provisions renders a claim for payment "false or fraudulent," potentially subjecting a healthcare provider to treble damages, penalties, and exclusion from federal healthcare programs.

The concern that this vast array of rules could form the basis for an FCA claim is well founded. Relators have filed suits alleging that healthcare providers committed fraud under the FCA by supposedly failing to comply with regulations that have no clear (or even apparent) correlation to the Government's payment decision. See, *e.g.*, Compl., *United States ex rel. Troxler* v. *Warren Clinic, Inc.*, No. 11-CV-808-TCK-FHM, (N.D. Okla. Dec. 30, 2011) (alleging violation of FCA based on alleged violation of "rule" prohibiting medical assistants from collecting illness information during office visits); Compl., *United States ex rel. Williams* v. *Renal Care Group, Inc.*, No. 09-0738 (M.D. Tenn. June 21, 2005) (alleging violation of FCA based in part on failure to provide product warranties).

This tangle does not stop with alleged violations of federal regulatory standards. Courts have held that a healthcare provider's alleged non-compliance with *interpretive guidance* from a federal agency is a valid

basis for an FCA claim. See, *e.g.*, *In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318, 354 (D. Conn. 2004) (alleged failure to comply with the 1986 Medicare Hospital Manual). Under this approach, any of the commentary in the thousands of pages of guidance on Medicare Conditions for Coverage could also support an FCA claim. See CMS, *End Stage Renal Disease (ESRD) Program Interpretive Guidance* (Oct. 3, 2008), https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertification GenInfo/downloads/ SCletter09-01.pdf. But, as set forth above, Conditions for Coverage bear their own administrative penalties, and, similarly, violations of interpretive rules can trigger administrative repayment obligations. See 42 C.F.R. Subpart C ("Suspension of Payment, Recovery of Overpayments, and Repayment of Scholarships and Loans"). Nothing in the statutory or regulatory structure indicates that FCA actions brought by whistleblowers are intended to play a role in enforcing these rules.

Further still, according to some courts and relators, even non-compliance with *state and local* regulatory standards can trigger *federal* FCA liability. The Conditions for Coverage for hospitals, such as *amicus* Ardent Health Services, require hospitals participating in Medicare to be in compliance with numerous state and local laws. See, *e.g.*, 42 C.F.R. § 482.11 (requiring hospitals to "meet[ ] standards for licensing established by the agency of the State or locality responsible for licensing hospitals" and to "assure that personnel are licensed or meet other applicable standards that are required by State or local laws."); see also *id.* § 494.20 (requiring healthcare providers to comply "with applicable Federal, State, and local laws and regulations pertaining to licensure and any other relevant health and safety requirements" as a

Medicare Condition for Coverage). *Qui tam* relators have alleged that healthcare providers committed fraud against the federal Government through their alleged non-compliance with such local standards. See, *e.g.*, Second Am. Compl. *United States ex rel. Foglia* v. *Renal Ventures Mgmt., LLC*, No. 09-cv-01552 (D.N.J. Dec. 13, 2011) (alleging that defendants violated the FCA by violating New Jersey regulations mandating certain staff-to-patient ratios at dialysis facilities); Third Am. Compl., *United States ex rel. West* v. *Ctr. for Diagnostic Imaging, Inc.*, No. CV05-0058RSL (W.D. Wash. Sept. 16, 2010) (state corporate practice of medicine laws); Compl., *United States ex rel. Lee* v. *Fairview Health Sys.*, No. 02-CV-270 RHK/SRN (D. Minn. Jan. 29, 2002) (state regulations prohibiting athletic trainers from providing physical therapy services).

Apart from the sheer *number* of healthcare requirements that providers are required to follow, many of the requirements are hopelessly ambiguous. To make matters worse, the Government often deliberately chooses—in the face of repeated calls by healthcare providers for more precise guidance—to leave such ambiguities unaddressed.

For example, when asked to clarify the type of payments or benefits that would be protected under a safe harbor to the Anti-Kickback Statute for payments for "practitioner recruitment," the Government "decline[d]" and said the issue would "be evaluated on a case-by-case basis." Final Rule, Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63,518, 63,544 (Nov. 19, 1999). Likewise, when asked to clarify the various "generic criteria," such as the meaning of "fair market value," that the HHS Office of Inspector

General ("OIG") would apply when considering whether various business arrangements could meet one of the safe harbors to the Anti-Kickback Statute, OIG declined to do so, claiming that the "the subjectivity or arbitrariness in applying the standards to individual fact situations" would make a uniform set of standards of "extremely limited value." Final Rule, Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,956 (July 29, 1991).

And more recently, when asked to clarify a vague requirement in the Stark Law (42 U.S.C. § 1395nn) that payments to physicians not "take[] into account" the volume or value of referrals, the Government again "decline[d] to do so." Final Rule, Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, 80 Fed. Reg. 70,886, 71,313 (Nov. 16, 2015). These are not isolated incidents, but a recurrent failure to clarify the law.

Furthermore, regulatory standards applicable to healthcare providers are sometimes inconsistent or contradictory. For instance, situations arise in which actions consistent with state law are nonetheless alleged to be violations of the FCA. See *Gonzalez* v. *Fresenius Med. Care N. Am.*, 689 F.3d 470, 478 (5th Cir. 2012) (addressing relator's claim that healthcare provider violated FCA through conduct permitted by state laws addressing physicians' delegation of responsibilities to medical staff).

It is difficult enough for providers to wade through this environment within the confines of the existing administrative system *without* the specter of FCA litigation and penalties suspended over their heads. The implied certification theory, however, invites eager relators and prosecutors to search the dark cor-

ners of the federal healthcare rule books for ambiguous regulatory standards and accuse healthcare providers of fraud when they interpret those rules differently. In fact, under the implied certification framework, the mere *allegation* that a provider is not in compliance with any such standard can burden the provider with expensive and time-consuming *qui tam* litigation for years, diverting the organization's focus, resources, and attention. *Infra* Part III.

II. THE IMPLIED CERTIFICATION THEORY IS UNJUSTIFIABLY BROAD.

The FCA is *not* an "all-purpose antifraud statute," *Allison Engine Co.* v. *United States ex rel. Sanders*, 553 U.S. 662, 672 (2008), nor a "blunt instrument to enforce compliance with all medical regulations," *Mikes* v. *Straus*, 274 F.3d 687, 699 (2d Cir. 2001). Instead, Congress has made clear that a "false or fraudulent claim" is the core component of an FCA violation. 31 U.S.C. § 3729(a)(1)(A); see also *United States ex rel. Atkins* v. *McInteer*, 470 F.3d 1350, 1357 (11th Cir. 2006) (the submission of a false claim is the "'*sine qua non*'" of an FCA violation). The implied certification theory is inconsistent with these key precepts, imposing a legal fiction that the act of submitting a claim for payment constitutes an affirmative representation by the submitter that it is in compliance with every legal requirement applicable to it.

"Distilled to its core," the implied certification theory "lacks a discerning limiting principle." *United States* v. *Sanford-Brown, Ltd.*, 788 F.3d 696, 711 (7th Cir. 2015), *petition for cert. filed*, 84 U.S.L.W. 3349 (U.S. Dec. 2, 2015) (No. 15-729). Under this theory, merely submitting a claim for payment somehow "impliedly" certifies that the claimant has complied with every conceivable regulatory requirement or contractual provision that could influence the Gov-

ernment's decision to pay the claim. See, *e.g.*, Pet. App. 17 n.14. In other words, any claim for payment can be "false or fraudulent" if it is made when the provider is in violation of *any* legal standard that a court deems—after-the-fact—to be "material" to the Government's payment decision. As Petitioner explains, liability attaches under this theory, even if the claim itself contains no "affirmative misstatement" whatsoever. Petr. Br. 23–24.

The healthcare context makes the intolerable breadth of this theory plain. This theory impermissibly conflates violations of healthcare regulations with false claims for reimbursement. Rather than focusing the FCA on contractors who submit claims knowingly designed to deceive the Government into making undeserved payments, implied certification empowers plaintiffs—typically *qui tam* relators—to threaten healthcare providers with the FCA's treble damages and penalties based on perceived violations of contract provisions, regulatory standards, and subregulatory guidance documents. The effect is a view of falsity that is as limitless as it sounds. Indeed, as history has shown, *supra* at 10–12, the potential bases for an implied certification lawsuit are limited effectively only by the imagination of *qui tam* relators.

The FCA was never meant to play this unfair and disruptive role, with its distorting impact. Indeed, when it is used it in this manner, at least three significant problems result—all of which confirm why the implied certification theory of falsity should be rejected.

1. First, the "implied certification" framework deprives healthcare providers of any fair notice about what the FCA prohibits and what it does not. That is particularly problematic as the FCA imparts "essentially punitive" penalties. *Vt. Agency of Nat. Res.*, 529

U.S. at 784; *BMW of N. Am.*, 517 U.S. at 574 (Due Process demands that a "person receive fair notice not only of the conduct that will subject him to punishment, but also of the severity of the penalty.").

The core problem is that the vast majority of the thousands upon thousands of rules that have been promulgated do not definitively state whether a requirement is or is not a condition of payment. Thus, it is generally impossible for a provider to know in advance what conduct may trigger FCA liability under the implied certification theory. Notwithstanding this lack of notice, courts applying the implied certification theory have imposed FCA liability for violations of a broad array of healthcare rules. See, *e.g.*, *United States ex rel. Bidani* v. *Lewis*, 264 F. Supp. 2d 612, 615 (N.D. Ill. 2003) (accepting Government's post-hoc assertion that compliance with a specific federal law was a "material" condition of the Government's reimbursement of a claim). Under the logic of these cases, the operative rules for healthcare providers become anyone's guess, decided court-by-court, retrospectively and on an ad hoc basis.

To be sure, some rules are labeled as a "condition of payment." But labeling a rule a "condition of payment," standing alone, should mean only that a payor agency can decline to reimburse (or administratively recoup payment from) a provider if the provider fails to satisfy the rule; it should not render a violation of the rule actionable under the FCA. For FCA liability to attach, conditions of payment must be specifically referenced in the claim itself; providers are not on proper notice of what they are certifying to if they must search through the vast array of regulatory rules to identify the "conditions of payment" to which they are purportedly impliedly certifying.

The Constitution dictates that "regulated parties should know what is required of them so they may act accordingly." *FCC* v. *Fox Television Stations, Inc.*, 132 S. Ct. 2307, 2317 (2012). The implied certification theory does not put healthcare providers and other government contractors on adequate notice of the rules to which they are certifying compliance. That raises substantial Due Process concerns, and the statute should be read to avoid them. We encourage the Court to avoid this significant constitutional problem by adopting the interpretation of the Act set forth at Part IV, *infra*. See, *e.g.*, *Concrete Pipe & Prods. of Cal., Inc.* v. *Constr. Laborers Pension Trust for S. Cal.*, 508 U.S. 602, 629 (1993) (interpreting federal statute narrowly to avoid Due Process concerns).

2. Second, the implied certification theory renders the FCA duplicative of existing remedies—a good sign that Congress did not plan for the FCA to sweep so far. The healthcare regulatory agencies have numerous tools available for enforcing compliance with federal healthcare contracts, regulations, and guidance documents, including administrative penalties, breach-of-contract suits, and exclusion from participation in federal healthcare programs. *United States ex rel. Hobbs* v. *Medquest Assocs., Inc.*, 711 F.3d 707, 717 (6th Cir. 2013). By establishing this detailed framework of administrative penalties and sanctions, Congress did not intend the FCA to displace these regulatory mechanisms whenever a *qui tam* relator believes that "implied" certification might be alleged. See *Alexander* v. *Sandoval*, 532 U.S. 275, 289–91 (2001) (statutes authorizing "agencies to enforce their regulations" indicate that a "private remedy" is unnecessary).

Under the implied certification theory, private relators decide which regulatory and sub-regulatory requirements warrant FCA litigation (and resulting government investigations and the potential application of FCA penalties) and which do not. The FCA authorizes relators to continue a suit even after the Government declines to intervene, and while DOJ has the authority to dismiss cases over the objections of relators, 31 U.S.C. § 3730(b), it virtually never exercises that authority. Because DOJ intervenes in only a small fraction of FCA cases, providers are typically forced to negotiate with private parties seeking their share of a treble-damages recovery.

By permitting relators to enforce regulatory standards, the implied certification theory disrupts the carefully calibrated regime of administrative remedies reflected in essentially every federal and state healthcare program. For instance, in the case of Medicare, that program delegates the supervision of healthcare providers' compliance with federal healthcare standards to the agencies responsible for them. See 42 U.S.C. § 1395cc(b)(2); 42 C.F.R. § 488.28(a), (c), and (d); *id.* § 424.535(a)(1). Involving relators in these complicated regulatory issues interferes with government control of the programs through the exercise of agency remedies for noncompliance. Indeed, enforcement of the FCA through the implied certification theory excuses regulators from the obligation to regulate—in a clear and transparent fashion—in favor of "burden[ing] the federal courts with deciding whether medical services were performed in full compliance with a host of Medicare [and other federal healthcare] regulations." *United States ex rel. Conner* v. *Salina Regional Health Ctr.*, 543 F.3d 1211, 1221 (10th Cir. 2008).

Courts are adept at resolving cases involving actual fraud, but "courts are not the best forum" to police all regulatory violations in the first instance; rather, the agencies that oversee these regulations are often better placed. *Mikes*, 274 F.3d at 700. Forcing courts to clarify federal healthcare regulations in the context of *qui tam* suits—rather than letting agencies address them—"short-circuit[s] the very remedial process the Government has established." *United States ex rel. Wilkins* v. *United Health Grp., Inc.*, 659 F.3d 295, 310 (3d Cir. 2011).

3. Third, the implied certification theory encourages excessive litigation over ambiguous regulatory standards, and subjects providers to litigation costs and collateral consequences that Congress could not have intended. FCA litigation has exploded in the years since the implied certification theory has been embraced by many of the lower courts. "From 1987 to 2013, the annual number of *qui tam* actions jumped from 31 to 752, breaking the previous record for number of *qui tam* suits in a given year by 100, which was set the prior year." Steven Harrison et. al., *Health Care Fraud*, 52 Am. Crim. L. Rev. 1223, 1285 (2015). Even the Justice Department has been "struck by the sheer volume of the cases that are brought …. under this statute." Remarks of Stuart F. Delery, Acting Att'y Gen. of the U.S., (June 7, 2012), http://www.justice.gov/opa/speech/acting-assistant-attorney-general-stuart-f-delery-speaks-american-bar-association-s-ninth.

But the sheer number of *qui tam* suits tells only part of the story of the burden imposed by the implied certification theory. An implied certification complaint filed by a *qui tam* relator can trigger significant costs for a provider even before it becomes a litigable case. *Qui tam* complaints under the FCA are

automatically sealed upon filing, to provide the Government time to investigate and determine whether to intervene. 31 U.S.C. § 3730(b)(2). These investigations take time. Though the FCA provides that complaints are to be sealed for only 60 days to allow the government to investigate, *id.*, in practice, it takes an average of 13 months to two years. See Letter from Ronald Weich, Assistant Att'y Gen., U.S. Dep't of Justice and Jim Esquea, Assistant Sec'y, U.S. Dep't of Health & Human Servs. to Sen. Charles E. Grassley (Jan. 24, 2011); David Freeman Engstrom, *Private Enforcement's Pathways: Lessons from Qui Tam Litigation*, 114 Colum. L. Rev. 1913, 1961 n.146 (2014). Providers incur significant costs during this period cooperating with DOJ investigations.

These investigations are likely to become even more lengthy—and complex—in the future, due to recent changes in the federal enforcement environment. First, as matter of DOJ policy, "all new *qui tam* complaints are [now] shared by the Civil Division with the Criminal Division as soon as the cases are filed … to determine whether to open a parallel criminal investigation" as well. Remarks of Leslie R. Caldwell, Asst. Att'y Gen. of the United States (Sept. 17, 2014). Any complaint filed by a *qui tam* relator on implied certification grounds is, thus, automatically subject to federal criminal investigation. Second, pursuant to another recent policy announcement, DOJ has promised to "fully leverage its resources to identify culpable *individuals* at all levels in corporate cases." Memorandum from Sally Quillian Yates, Deputy Att'y Gen. of the U.S. (Sept. 9, 2015) (emphasis added). In short, recent changes to DOJ policy have increased the risk that DOJ will respond to a *qui tam* complaint alleging implied certification by subjecting a defendant healthcare provider to significant—and

costly—investigations of criminal wrongdoing and individual liability on the basis of an alleged violation of any one of thousands upon thousands of administrative rules.

All of these factors create an unlevel playing field, to the detriment of healthcare providers and other government contractors. The "dirty little secret" of FCA litigation is that "given the civil penalty provision and the costs and risks associated with litigation, the rational move for [FCA defendants] is to settle the action even if the [plaintiff's] likelihood of success is incredibly small." Robert Salcido, *DOJ Must Reevaluate Use of False Claims Act In Medicare Disputes*, Wash. Legal Found., at 4 (Jan. 7, 2000), http://goo.gl/YyZTdS. Indeed, the FCA's punitive structure "places great pressure on defendants to settle even meritless suits." John T. Boese & Beth C. McClain, *Why* Thompson *Is Wrong: Misuse of the False Claims Act to Enforce the Anti-Kickback Act*, 51 Ala. L. Rev. 1, 18 (1999).[2]

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[2] The pressure to settle is particularly robust in the health care context given the FCA's draconian "per-claim" civil penalties provision and the potential for exclusion from participation in federal healthcare programs. *See* 31 U.S.C. § 3729(a); 28 C.F.R. § 85.3(a)(9). Providers, including *amici*, frequently submit claims for reimbursement for as little as $10. The government, however, routinely seeks to impose civil penalties of up to $11,000 on each individual claim. Under such an approach, the potential exposure quickly dwarfs the amount of reimbursement at issue and the incentive to settle increases.

III. THE FCA'S "MATERIALITY" AND "SCIENTER" REQUIREMENTS DO NOT ADEQUATELY PROTECT PROVIDERS FROM IMPLIED CERTIFICATION'S EXCESSIVELY BROAD REACH.

Given the high costs of complex litigation and the FCA's otherwise overbroad scope, it is not sufficient to rely on the statute's "materiality" and "scienter" requirements to protect healthcare providers and other government contractors from the overbreadth of the implied certification theory. Although the theory's defenders often insist that these requirements can be used to screen out meritless claims,[3] experience demonstrates that this retort is badly misguided and just plain wrong at a practical level.

1. Fundamentally, the "materiality" and "scienter" requirements cannot provide any real limits on the FCA if the statute is not interpreted to apply a common sense notion of what makes a claim "false or fraudulent" in the first instance. If a claim can be deemed "false or fraudulent" by virtue of a provider's non-compliance with any of the thousands of requirements buried in a "morass" of regulation, *Herweg*, 455 U.S. at 279, (Burger, J., dissenting), the notion that a defendant's conduct must be "material" is rendered meaningless. Likewise, if a claim can be "false or fraudulent" because FCA liability may arise from thousands of pages of federal regulations, federal sub-regulatory materials, state requirements, and local regulations, the notion that a defendant must be

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[3] *See, e.g.*, *United States* v. *Triple Canopy, Inc.*, 775 F.3d 628, 637 (4th Cir. 2015) ("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.'"), *petition for cert. filed*, 83 U.S.L.W. 3905 (U.S. June 8, 2015) (No. 14-1440).

shown to have acted knowingly or recklessly is illusory.

Moreover, the fact that an implied certification allegation *may* not satisfy these separate, independent elements of an FCA violation is no reason to loosen the Act's requirements for the element at issue here—namely, what qualifies as a "false or fraudulent claim." See, *e.g.*, *Mikes*, 274 F.3d at 696–97. It is difficult to imagine Congress had such a counterintuitive and backwards approach in mind when it enacted a statute whose title begins with the word "*False* Claims." 31 U.S.C. § 3729(a)(1)(A) (emphasis added).

2. Setting aside the flawed premise of the argument that "materiality" and "scienter" should be relied upon to cabin abuses of the implied certification theory, these elements do not in fact serve that function. Assessing either element frequently necessitates an in-depth, subjective, and fact-bound inquiry that is both difficult to forecast and costly to litigate. In the heavily regulated healthcare sphere, the resulting uncertainty imposes immense costs, while depriving *amici* and their members (and others) of the notice needed to tailor compliance to the Government's priorities. The FCA should be interpreted in a fashion that allows providers clearly to prioritize compliance issues, target limited resources appropriately, and meaningfully reduce liability risk by doing so. Without that, failure is inevitable and the incentive to commit to a compliance program is actually undermined.

a. Materiality, in particular, is a malleable, broad, and amorphous concept that evades consistent or predictable treatment. This makes it an ineffective limitation on the breadth of implied certification for at least two reasons.

First, whether a particular legal obligation is considered "material" to the Government's payment decisions typically is decided retroactively. The FCA defines the term "material" broadly to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). Unless Congress or an agency states so expressly, providers are left to guess *ex ante* what regulatory standards have a "natural tendency" or "capab[ility] of influencing" Government payment decisions on any given claim.[4]

Thus, far from resolving anything, the materiality standard just compounds one of the main problems with the implied certification theory: the lack of advance notice about which violations of the litany of

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[4] This definition was added to the FCA in 2009 via amendments passed by Congress as part of the Fraud Enforcement and Recovery Act of 2009 ("FERA"). Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1621–25 (2009). Prior to the FERA amendments, however, many courts had read into the FCA an implicit materiality requirement, but had split on how to define it. *See* John T. Boese, *The Past, Present, and Future of "Materiality" Under the False Claims Act*, 3 S.L. Univ. J. Health Law & Pol'y 291, 294 & n.17 (2010) (collecting cases). DOJ initially advanced the notion that a materially false claim is one that is "'capable of influencing' or [that] 'has a natural tendency to influence' the government's decision to pay," in response to a narrower "prerequisite for payment" standard emerging from some courts. *Id.* at 299–301. These Government efforts to expand the definition of materiality were generally successful, *id.* at 300–01, and ultimately were codified in the FERA amendments. The result is a statute that "defin[es] 'material' such that a falsity might be considered material even if it had no actual impact on the government's payment decision." Robert Fabrikant, Paul E. Kalb, M.D., Mark D. Hopson, Pamela H. Bucy & James C. Stansel, *Health Care Fraud: Enforcement and Compliance* § 4.01[3][d][ii] (2016).

statutes, regulations, and sub-regulatory guidance documents are actionable under the FCA.

All providers can do under these circumstances is hazard an educated guess, but educated guesses are just that—guesses. A guess, by definition, does not provide the certainty that a law subjecting providers to punitive sanctions demands. See *Fox Television Stations*, 132 S. Ct. at 2317 ("[R]egulated parties should know what is required of them so they may act accordingly."). In other words, rather than fixing the implied certification theory's fair notice problem, the materiality standard magnifies it.

The impact is profound. Healthcare providers spend enormous sums on compliance programs every year. But even the most robust compliance program cannot prevent every violation of every regulatory requirement, and limited resources may be misallocated when there is no guidance available to distinguish meaningfully between issues that can and cannot give rise to FCA violations. Effective compliance programs require clear direction, but the broad and ambiguous materiality standard does not provide it.

Greater clarity—which is offered by the proposal we outline below, *infra* Part IV—would allow providers to direct compliance resources towards rules that are truly material to the Government—i.e., rules that the Government deems important enough to expressly, specifically, and unambiguously reference in a claim form, or statutes Congress has expressly, specifically, and unambiguously identified as predicates for a violation of the FCA.

Second, healthcare providers cannot effectively rely on lack of materiality as a defense early in litigation when meritless FCA complaints should be dismissed. The reason for this is that the materiality inquiry

typically is so fact-bound that healthcare providers rarely prevail on the issue at the motion-to-dismiss stage. See, *e.g.*, *New York* v. *Amgen Inc.*, 652 F.3d 103, 110–11 (1st Cir. 2011) ("[W]hether the claims at issue misrepresented compliance with a material precondition of payment … is a fact-intensive and context-specific inquiry."). Defending even meritless implied certification suits, therefore, often requires proceeding through expensive discovery, then to summary judgment or even trial.[5]

b. The FCA's "scienter" requirement serves no better as a firewall against meritless claims and unnecessarily expensive *qui tam* litigation. It too requires a fact-intensive analysis that frequently is ill-suited for resolution in the early stages of a case and costly to litigate. Although FCA liability attaches only if the provider has "actual knowledge" that the claim is false or fraudulent, or acts in "deliberate ignorance" or "reckless disregard" of its truth or falsity, 31 U.S.C. § 3729(b)(1)(A), pleading such knowledge is virtually pro forma in FCA complaints. This often propels even meritless cases to summary judgment or

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[5] By way of example, in *United States ex rel. Williams* v. *Renal Care Group, Inc.*, 696 F.3d 518, 531 (6th Cir. 2012), the court of appeals reversed a grant of summary judgment against *amicus* Fresenius for alleged FCA violations based on alleged noncompliance with a series of minor, technical regulatory standards, "including honoring warranties, filling orders from its own inventory or via contract, and maintaining an appropriate place of business." The Sixth Circuit ultimately concluded that "defendants are correct, irrespective of whether they in fact violated the regulations," because "[t]he False Claims Act is not a vehicle to police technical compliance with complex federal regulations." *Id.* at 532. This victory was somewhat pyrrhic in the end, however, as *amicus* spent vast sums defending the suit after both the motion to dismiss and summary judgment stages failed to screen out the meritless claims.

trial, where costs multiply exponentially before providers have any meaningful opportunity to defeat the claims.[6]

This is particularly true in healthcare cases. Assessing a provider's "knowledge" of the regulatory standard that supposedly served as the basis for the implied certification can, depending on the circumstances, require courts to consider a broad "variety of evidence," including, but often not limited to, "whether the defendant sought, received and followed legal advice, whether the defendant acted in conformity with others in the industry, and whether the defendant reasonably believed that its interpretation was consistent with the government's." *United States ex rel. Saldivar* v. *Fresenius Med. Care Holdings, Inc.*, No. 1:10-CV-1614-AT, 2015 WL 7293156, at *32 (N.D. Ga. Oct. 30, 2015), *appeal docketed*, No. 15-15497 (11th Cir. Dec. 8, 2015).

As with materiality, these scienter questions are expensive and time-consuming to litigate. Indeed, by way of example, it took *five-and-a-half years* after a complaint was filed against *amicus* Fresenius for a district court to grant summary judgment and hold that Fresenius had *not* knowingly made false certifi-

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[6] The FCA allows defendants who prevail in litigation to seek attorney's fees from the relator in limited circumstances, but, in practice, this is rarely an effective tool in implied certification cases. The FCA provides that, if the Government declines to intervene and the relator proceeds with the action, the court may award a prevailing defendant "reasonable attorneys' fees and expenses," but only if the relator's claims were "clearly frivolous, clearly vexatious, or brought primarily for the purposes of harassment." 31 U.S.C. § 3730(d)(4). In light of all the regulatory ambiguity just described, it typically is quite challenging for a healthcare provider to show that an implied certification allegation meets this standard even in the most meritless of cases.

cations. *Id.* at *30. Scienter was hardly an effective gatekeeper against this allegation.

Quite apart from cost, the scienter analysis also requires providers to answer many of the questions that a proper reading of the "falsity" requirement should require the Government to answer in the first instance. In particular, healthcare providers defending against a scienter allegation often contend that their view of the relevant law, even if "erroneous, was not objectively unreasonable." *Safeco Ins. Co. of Am.* v. *Burr*, 551 U.S. 47, 69 (2007). But that defense—even when it is available[7]—transfers onto providers both the responsibility to clarify ambiguous and often obscure federal program requirements and the burden to defend their interpretations as objectively reasonable. That is unreasonable; it is it is the responsibility of agencies to produce a coherent, transparent set of expectations and obligations after notice to and comment from providers. It makes little sense to tarnish healthcare providers as "fraudsters" based on an interpretation of an ambiguous regulation that may be announced for the first time by a court in the context of litigation.

In sum, neither the materiality nor knowledge elements of the FCA cure the problems raised by the implied certification theory of falsity. The only solution is to restore the FCA to its intended scope as a statute designed to sanction the submission of *false claims*.

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[7] Notably, DOJ has argued that a healthcare provider's "objectively reasonable" interpretation of a regulation is *not* alone sufficient to defeat liability. *See*, *e.g.*, U.S. Opp. to Wyeth's Mot. for Summary Judgment at 30–45, *United States ex rel. Kieff* v. *Wyeth*, No. 03-cv-12366 (D. Mass. Dec. 16, 2011) (Dkt. No. 286).

IV. THE FCA SHOULD BE INTERPRETED AS INTENDED—*i.e.*, TO REQUIRE A CLAIM THAT IS ACTUALLY FALSE OR FRAUDULENT.

As the foregoing makes clear, the implied certification theory has enabled *qui tam* relators and prosecutors to assert alleged violations of the FCA well outside the boundaries of what the FCA permits. The solution to this problem is to reject the theory and to interpret the Act as it was intended to be applied.

1. The FCA prohibits the knowing submission of "a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). The trigger for liability is front-and-center in the statute: there must be, among other elements, a "claim for payment" that is "false or fraudulent." *Id.* The Act does not silently grant relators or the Government license to infer from a claim for payment that the submitter has certified compliance with any and all regulatory standards and contractual provisions that conceivably might apply to its business.

Thus, a proper reading of the FCA carefully cabins what constitutes a "false or fraudulent claim." A claim can be "false or fraudulent" in three scenarios. First, a claim may be false or fraudulent if it misrepresents the goods or services provided. That is, a claim may be "false" if it falsely states the facts (for example, that medical care was provided or that a clinical laboratory service was performed when it was not). Such a circumstance is, indeed, the classic scenario the FCA was designed to target. See, *e.g.*, Cong. Globe, 37th Cong., 3d Sess. 952, 955 (1863) (describing delivery of ammunition "filled not with the proper explosive materials for use, but with sawdust" as a false or fraudulent claim under the FCA).

Second, a claim may be false or fraudulent if it contains a false certification of compliance with a rule that is ***expressly, specifically, and unambiguously*** referenced on the claims form and which itself is unambiguous.

Third, a claim may be false or fraudulent if the underlying services were performed in violation of a statute that Congress itself has expressly, specifically, and unambiguously declared renders claims for those services false within the meaning of the FCA. Congress knows precisely how to do this, having amended the Anti-Kickback Statute explicitly to define a claim submitted in violation of that statute as a "false or fraudulent claim" under the FCA. See 42 U.S.C. § 1320a-7b(g) ("[A] claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA].").

This three-part test is simple for courts to apply and easy for providers to understand. Moreover, unlike the endlessly pliable implied certification theory, it provides clear notice of what the FCA prohibits, and therefore avoids the Due Process concerns raised by the implied certification theory. *Fox Television Stations*, 132 S. Ct. at 2317.

2. To ensure clarity and proper notice under the FCA, it is necessary also to ensure that *express* certifications are truly express, otherwise government contractors will continue to face the threat of improperly broad liability under the Act. This is critically important in the healthcare sphere, where providers routinely are required to make hopelessly broad and inherently ambiguous (even meaningless) representations in some existing claim forms. These certifications are far too vague and ambiguous to avoid the

Due Process issue, or the threat to the proper functioning of a regulatory regime.

Consider CMS Form 1500, which is the standard claims form that physicians and many other healthcare providers use to submit claims to Medicare, Medicaid, and other federal healthcare programs. *United States ex rel. Cieszyski* v. *LifeWatch Servs., Inc.*, No. 13-cv-4052, 2015 WL 6153937, at *2 (N.D. Ill. Oct. 19, 2015). It states:

> In submitting this claim for payment from federal funds, I certify that: … this claim, whether submitted by me or on my behalf by my designated billing company, complies with *all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment* including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law).

CMS, Health Insurance Claim Form (Form 1500), https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf (emphasis added). Although this statement appears on a claims form, because it fails to expressly, specifically, and unambiguously identify relevant prerequisites to payment, it fails to offer providers fair notice. Nonetheless, relators frequently leverage this catch-all provision to transform alleged violations of obscure, ambiguous regulations into alleged acts of fraud. And unfortunately, they have had significant success in convincing courts to adopt this sort of untethered application of the FCA. See, *e.g.*, *Cieszyski*, 2015 WL 6153937 (denying motion to dismiss complaint alleging that defendant defrauded Medicare by submitting Form 1500 when in violation of a Medicare regulation prohibiting technicians located outside the United States

from remotely conducting cardiac monitoring tests on patients in U.S. healthcare facilities).

Various iterations of CMS Form 855, which providers complete when applying to participate in the Medicare program, pose related problems. They too contain catch-all provisions that state as follows: "I agree to abide by the Medicare laws, regulations and program instructions that apply," and "I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions." See CMS, Medicare Enrollment Application, Physicians and Non-Physician Practitioners (Form 855I), https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855i.pdf. Relators routinely latch onto these utterly unbounded, limitless statements in Medicare enrollment forms as the basis for implied certification FCA suits. See*, e.g.*, *United States* v. *Amsurg Corp.*, No. 2:12-CV-02218-TLN, 2014 WL 7336671, *7 (E.D. Cal. Dec. 24, 2014). Unfortunately, some courts have endorsed this approach. *Id.* ("Although Defendants were not required to submit an explicit certification of compliance along with each claim for payment, the certification is implied in the language of Form 855–B.").

Attaching FCA liability to such a statement is inappropriate for three reasons. First, the statement in the enrollment form is *not* connected to any certification on a claim for payment. Second, the "laws, regulations, and program instructions" language is nonspecific. Third, any theory that holds healthcare providers liable for fraud based on forward-looking promises to comply with *all* applicable Medicare laws and regulations is not express, clear, and unambiguous, and thus "lacks a discerning limiting principle." *Sanford-Brown*, 788 F.3d at 711. As noted, it is im-

possible under this kind of "certification" for a provider to know *ex ante* which of the countless laws and regulations in this broad universe are conditions to payment under the FCA, and which are not.[8]

* * *

The implied certification regime transforms the FCA into a mechanism for attacking healthcare providers at will, without meaningful notice. Neither the FCA's text nor its purpose supports this interpretation of the Act or Congressional intent. The theory should thus be rejected in favor of an interpretation of the Act such as the one *amici* propose, which steadfastly adheres to the Act's central requirement of a false claim as the cornerstone of liability. Adoption of this interpretation would provide adequate notice, dramatically reduce wasteful and unproductive *qui tam* litigation, allow healthcare providers appropriately to focus their compliance efforts, and ultimately strengthen the federal healthcare system for the benefit of the beneficiaries of that system.

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[8] Importantly, under our proposed rule, the statute does not permit providers who lie upon enrolling in federal healthcare programs to avoid liability so long as their subsequent claims for payment are factually accurate. As this Court recognized in *United States* v. *Neifert-White Co.*, 390 U.S. 228 (1968), the FCA permits liability on promissory-estoppel grounds. *Id.* at 232. That subjects a provider to punishment if it makes an express, specific, and unambiguous misrepresentation in an enrollment application, not intending to comply with that certification at the time it makes it, and later submits a claim for payment attempting to benefit from that fraud. Our formulation—like the Act—simply requires that the provider engage in actual "*fraud*[]." *Id.* (emphasis added).

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

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