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 THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION AS AMICI CURIAE IN SUPPORT OF PETITIONER

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INTEREST OF AMICI CURIAE[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the nation's leading biopharmaceutical and biotechnology companies. PhRMA's members are dedicated to discovering medicines that enable patients to lead longer, healthier, and more productive lives. To that end, its members invest billions of dollars every year in drug research and development, including an estimated $51 billion in 2014 alone. Since 2000, these efforts have yielded more than 500 new medicines approved by the Food and Drug Administration, with thousands more in development.

The Advanced Medical Technology Association ("AdvaMed") is the world's largest medical technology association, with approximately 300 member companies that develop medical devices, diagnostic tools, and health information systems. Its members span every field of medical science and range from cutting-edge startups to multinational manufacturers, all dedicated to advancing clinician and patient access to safe, effective medical technologies in accordance with the highest ethical standards. The innovative products they develop and sell account for a substantial portion of the more than $170 billion spent annually in the United States on medical devices and in vitro diagnostics.

The products developed, manufactured, and sold by amici's members are an integral part of the nation's healthcare system. Each year, healthcare providers

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[1] No counsel for a party authored this brief in whole or in part, and no persons or entities other than amici and their counsel made a monetary contribution to the preparation or submission of this brief. Letters consenting to the filing of this brief are on file with the Clerk.

submit billions of dollars of claims for reimbursement to the federal government for the cost of providing prescription drugs and medical devices to patients covered by federal healthcare programs, such as Medicare. Amici and their members therefore have a substantial interest in the interpretation of the False Claims Act ("FCA"), which may apply to the submission of such claims. Amici closely monitor developments regarding the law and have routinely participated as amici curiae in FCA cases before this Court. *E.g.*, *Kellogg Brown & Root Servs., Inc.* v. *United States ex rel. Carter*, 135 S. Ct. 1970 (2015); *Schindler Elevator Corp.* v. *United States ex rel. Kirk*, 563 U.S. 401 (2011); *Graham County Soil & Water Conservation Dist.* v. *United States ex rel. Wilson*, 559 U.S. 280 (2010).

SUMMARY OF ARGUMENT

The expansive theory of implied certification reflected in the decision below and adopted by a handful of other courts fails to comport with elementary notions of due process, because it exposes defendants to treble damages and severe penalties without fair notice of what conduct constitutes a violation of the FCA. That problem is acute for amici's members, who must comply with exceedingly complex statutory and regulatory regimes governing the manufacture, marketing, sale, and reimbursement of pharmaceuticals and medical devices. As applied by courts that allow it, the implied-certification theory permits a relator—or the government—to transmute any technical noncompliance with those regulations into a claim for fraud under the FCA.

Petitioner has shown that there is no basis in the text or purposes of the FCA for transforming it into a tool to police, on pain of treble damages and massive penalties, regulatory noncompliance. Pet. Br. 29-41.

Noncompliance is not fraud, would not have been regarded as fraud at common law, and should not be treated as fraud under the FCA. Government agencies already have, and frequently use, many other administrative tools to ensure regulatory compliance, and these tools are both more effective and more efficient to address regulatory concerns, especially in the healthcare industry.

Amici's concern that implied-certification claims are unfair and unpredictable is not academic. To the contrary, pharmaceutical and medical device companies have already been subject to voluminous litigation, premised on expansive implied-certification theories, for alleged regulatory violations with little or no bearing on the accuracy of the actual claims submitted to the government, or on the public fisc. While many of these suits have ultimately failed, such failures underscore the mischief that the implied-certification theory invites. Moreover, those that have failed have typically done so because the regulation at issue was not expressly designated as a condition of payment. Those cases would likely have been decided differently under the First Circuit's limitless approach, which amici urge the Court to reject.

The implied-certification theory should be rejected or sharply circumscribed to afford reasonable notice consistent with the imposition of treble damages and massive penalties.

ARGUMENT

I. THE IMPLIED-CERTIFICATION THEORY FAILS TO PROVIDE FAIR NOTICE OF WHAT CONSTITUTES A FALSE OR FRAUDULENT CLAIM OR STATEMENT UNDER THE FCA

A. Implied Certification Makes FCA Liability Unknowable And Unpredictable

1. Determining the scope of FCA liability must begin "'as always, with the language of the statute'" to ensure that the statute is not "expand[ed] … beyond its intended role." *Allison Engine Co.* v. *United States ex rel. Sanders*, 553 U.S. 662, 668, 669 (2008). The quintessential element of an FCA violation, by the plain terms of the statute, is a "false or fraudulent claim" presented to the government, or a "false record or statement" in support of such a claim. 31 U.S.C. § 3729(a)(1)(A), (B).

The implied-certification theory dispenses with that textual requirement and thus expands the FCA far beyond its intended scope. The theory rests on the legal fiction that mere submission of a claim constitutes an implicit representation that the submitting party has complied with all of the contractual, regulatory, and statutory conditions to which it is subject, whether related to payment of the claim or participation in the relevant federal program. *See, e.g.*, *United States* v. *Science Applications Int'l Corp.* (*SAIC*), 626 F.3d 1257, 1261, 1266 (D.C. Cir. 2010) (a claim can be "'false or fraudulent' under the FCA" whenever "a contractor … has violated contractual requirements," because certification of compliance with those requirements can be "infer[red] … from silence" when the contractor submits a claim); *United States* v. *Triple Canopy, Inc.*, 775 F.3d 628, 636 (4th Cir. 2015) (a claim can be "false or fraudulent" whenever the submitting party "'withheld information about its noncompliance'").

Courts embracing this expansive theory freely concede that, "[u]nder an implied false certification theory, … courts do not look to the contractor's actual statements," *United States ex rel. Conner* v. *Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1218 (10th Cir. 2008), but rather to the contractual or regulatory requirements the contractor allegedly failed to comply with, which may have little or nothing to do with the substance of the claims. The theory thus "has the effect of putting words—false ones, at that—into the defendant's mouth, and then penalizing the defendant for those alleged falsities." 1 Boese, *Civil False Claims and* Qui Tam *Actions* § 2.03[G][2], at 2-206 (4th ed. 2014). In practice, courts applying the implied-certification theory have ceased to examine the putative falsity of the claims the defendant presented to the government for payment. The focus has shifted instead to a post hoc analysis of the defendant's general conduct and of whether particular contractual or regulatory provisions are sufficiently important that the act of submitting a claim should be deemed to imply a representation of compliance with them.

2. "A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required." *FCC* v. *Fox Television Stations, Inc.*, 132 S. Ct. 2307, 2317 (2012); *see also Johnson* v. *United States*, 135 S. Ct. 2551, 2556 (2015) (due process requires that the law "give ordinary people fair notice of the conduct it punishes"). A punitive statute cannot leave regulated parties to "guess at its meaning," *Connally* v. *General Constr. Co.*, 269 U.S. 385, 391 (1926), unable to "know where … [to] draw the line between the allowable and the forbidden," *Winters* v. *New York*, 333 U.S. 507, 519 (1948).

The implied-certification theory violates those basic precepts of due process because it makes the contours of FCA liability inherently unpredictable and unknowable in advance. In submitting claims and attempting in good faith to comply with the FCA, businesses cannot know with any reasonable degree of confidence what they may later be held to have impliedly certified. Because the theory "potentially transforms any undisclosed contractual, statutory, or regulatory violation into fraud," even failure to comply with "[r]elatively insignificant contract provisions and regulations" may give rise to liability. Martin, *Reining in Lincoln's Law*, 101 Cal. L. Rev. 227, 260 (2013). Any otherwise accurate claim submitted while in technical noncompliance with any portion of the contract or governing regulatory scheme could be deemed fraudulent after the fact.

In *Shaw* v. *AAA Engineering & Drafting Co.*, 213 F.3d 519, 523-524 (10th Cir. 2000), for example, the relator alleged that the defendant had submitted false claims for reimbursement for photography services the defendant provided to the Air Force. The complaint alleged no defects in the photographs supplied. But the defendant's contract with the Air Force provided that the defendant "shall dispose of" certain chemicals from the photography development process "in accordance with EPA guidelines and standards," and the defendant failed to do so. *Id.* at 527-528 & n.7. At the government's urging, the court of appeals treated the defendant's failure not as a run-of-the-mill breach of contract, but rather as a fraud perpetrated on the Air Force, on the theory that every time the defendant submitted a claim for payment, it "false[ly] implied certification of compliance with the contract's" disposal requirements. *Id.* at 531. The contract itself contained nothing to indi-

cate that seeking reimbursement would constitute an implied representation of having complied with the disposal provision, and the court of appeals offered no reason to distinguish that provision from any of the other numerous requirements in the parties' contract.

Shaw is no outlier. In implied-certification decisions, FCA liability is routinely sprung on a defendant without warning after the fact, as noncompliance (and silence) are equated with fraud. *See, e.g.*, *SAIC*, 626 F.3d at 1267-1270 (defendant held liable for "accurate reports of services rendered," on the theory that submitting those claims falsely implied compliance with "organizational conflict of interest requirements" in the parties' contract); *United States ex rel. Quinn* v. *Omnicare Inc.*, 382 F.3d 432, 435, 442-443 (3d Cir. 2004) (defendant's submission of Medicaid claims for recycled medications implied certification of compliance with state pharmacy regulation regarding storage and sealing of recycled medications); *United States ex rel. Augustine* v. *Century Health Servs., Inc.*, 289 F.3d 409, 414-415 (6th Cir. 2002) (defendants held liable under the FCA for violating Medicare regulations *after* submitting otherwise accurate claims, on the theory that prior claims impliedly certified that defendants "'would continue to comply with'" the regulations); *see also* 1 Boese § 2.03[G][2], at 2-204 n.704 (collecting cases).

The dangers of that approach are especially acute for amici's members and other firms in heavily regulated industries, such as healthcare. Thousands of pages of complex statutes and regulations govern even routine claims for reimbursement in those industries. As this Court once observed, for example, the Medicaid statute "is among the most intricate ever drafted by Congress," and its "Byzantine construction … makes the Act 'almost unintelligible to the uninitiated.'"

Schweiker v. *Gray Panthers*, 453 U.S. 34, 43 (1981) (quoting *Friedman* v. *Berger*, 547 F.2d 724, 727 n.7 (2d Cir. 1976) (Friendly, J.)); *cf. National Fed'n of Indep. Bus.* v. *Sebelius*, 132 S. Ct. 2566, 2580 (2012) (noting that the Patient Protection and Affordable Care Act's "10 titles stretch over 900 pages and contain hundreds of provisions" of statutory requirements alone). The "sheer volume of the laws and regulations" with which healthcare companies must comply provides significant practical challenges to what might be considered "total" or perfect compliance. Krause, "*Promises to Keep*," 23 Cardozo L. Rev. 1363, 1398, 1399 (2002); *see also* Krause, *Regulating, Guiding, and Enforcing Health Care Fraud*, 60 N.Y.U. Ann. Surv. Am. L. 241, 242 n.5 (2004) (reporting that Mayo Clinic staff "counted 132,720 pages of Medicare laws and regulations"). Noncompliance with any single regulation could form the basis for an alleged FCA claim premised on implied certification. Many of those regulations are subject to interpretation and in fact were drafted to be interpreted by regulators and subject-matter experts, under established administrative law doctrines, rather than by private plaintiffs. Further, in the healthcare industry much of this regulatory interpretation is in the form of informal guidance, frequently asked questions, manuals, and other agency documentation, much of which can change frequently in nuanced, complicated ways.

Petitioner has shown that the implied-certification theory cannot be reconciled with the text or purposes of the FCA, or the common law concepts of fraud on which it was built. Pet. Br. 29-41. A claim for payment that accurately describes the goods and services provided to the government is neither "false" nor "fraudulent." There is no basis in the statute for the legal fiction that submitting such a claim constitutes an unspo-

ken representation of compliance with all the contractual and regulatory provisions potentially bearing on payment of the claim.

Amici thus fully agree with petitioner that the implied-certification theory should be rejected. As the remainder of this brief demonstrates, the theory creates an intolerable degree of uncertainty for amici's members. It deprives them of fair notice of when or how the FCA will be violated, triggering treble damages and substantial penalties. It invites costly litigation and adds to the already considerable pressure to settle even meritless cases, essentially relieving plaintiffs of the burden to plead and prove actual fraud. And it is fundamentally unnecessary to police compliance with healthcare regulations (or any other regulations) because numerous administrative mechanisms already exist that better serve that function, without the threat of mandatory penalties and treble damages.

B. Implied Certification Exposes Defendants To Severe Penalties Without Fair Warning

1. Providing fair notice to defendants is critical in the FCA context because the statute imposes treble damages and severe penalties that are "essentially punitive in nature." *Vermont Agency of Natural Res.* v. *United States ex rel. Stevens*, 529 U.S. 765, 784 (2000). For each violation, the FCA mandates "a civil penalty of not less than [$5,500] and not more than [$11,000]," plus "3 times the amount of damages which the Government sustains." 31 U.S.C. § 3729(a)(1); *see also id.* § 3730(d)(1) (a prevailing relator is also entitled to an award of "expenses, fees, and costs").[2] The penalties

[2] The statutory text refers to penalties of $5,000 to $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act

are mandatory for any violation; a court does not have discretion to decline to award them, even when they bear no relation to the government's injury, the defendant's benefit, or the wrongfulness of the conduct.

These statutory penalties apply "per claim," *Graham County Soil & Water Conservation Dist.* v. *United States ex rel. Wilson*, 545 U.S. 409, 411 (2005), even if the defendant made only a single false statement (or impliedly false statement). Healthcare providers typically submit "enormous volumes of claims," and the statutory penalties can therefore quickly reach "astronomical sums." Jost & Davies, *The Empire Strikes Back*, 51 Ala. L. Rev. 239, 259, 260 (1999). For drugs or devices prescribed to patients thousands or millions of times each year, the statutory penalties theoretically available under the implied-certification theory for a *single* undisclosed regulatory violation are easily ruinous.[3] One cholesterol drug was prescribed a reported

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of 1990, Pub. L. No. 101-410, § 5, 104 Stat. 890, 891 (codified as amended at 28 U.S.C. § 2461 note). The current penalties, last increased in 1999, are set out at 28 C.F.R. § 85.3(a)(9). Recently, however, Congress enacted legislation to require additional increases, which must take effect by August 2016. Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Pub. L. No. 114-74, § 701, 129 Stat. 599, 599-600. As a result, FCA penalties will soon rise to as much as $7,700 to $15,400.

[3] Drug and device companies typically "do not submit bills directly to the federal health care programs, but rather sell their products to health care providers and patients," who may in turn seek reimbursement (*e.g.*, under Medicare Part D). Krause, 23 Cardozo L. Rev. at 1390. FCA litigation against such companies is premised on the theory—debatable in its own right—that the companies have "knowingly … cause[d]" false claims to be presented by the intermediaries who actually submit the claims. 31 U.S.C. § 3729(a)(1)(A); *e.g.*, *United States ex rel. Franklin* v. *Parke-Davis*, 147 F. Supp. 2d 39, 52-53 (D. Mass. 2001).

75 million times in 2005. Lansdale, *Used as Directed?*, 41 New Eng. L. Rev. 159, 178 (2006). Contemplating the minimum $5,500 penalty attached to just a fraction of reimbursement claims for such a popular drug "vividly illustrates just how quickly fines can amass under the FCA." *Id.*

Indeed, FCA penalties can approach a level that so dwarfs any actual loss to the government or gain to the defendant as to violate the Excessive Fines Clause of the Eighth Amendment, which forbids monetary penalties "grossly disproportional to the gravity of a defendant's offense." *United States* v. *Bajakajian*, 524 U.S. 321, 334 (1998) (criminal forfeiture); *see also Hudson* v. *United States*, 522 U.S. 93, 103 (1997) (Eighth Amendment "protects against excessive civil fines"); *United States* v. *Aleff*, 772 F.3d 508, 512 (8th Cir. 2014) (applying Excessive Fines Clause to FCA penalties); *United States* v. *Mackby*, 261 F.3d 821, 830 (9th Cir. 2001) (same). For that reason, the Justice Department has in some cases voluntarily sought judgment in amounts less than the statutory minimum in an apparent effort to avoid constitutional challenges. *See, e.g.*, *United States ex rel. Bunk* v. *Gosselin World Wide Moving, N.V.*, 741 F.3d 390, 400-401 (4th Cir. 2013) (government and relator proposed to accept less than half the statutory minimum penalty award after constitutional challenge); *United States* v. *Bickel*, 2006 WL 1120439, at *3 (C.D. Ill. Feb. 22, 2006) (government sought "civil penalties of $11,000" where "minimum statutory civil penalty would total $181,219,500").

Individuals and businesses cannot, consistent with due process, be subjected to the threat of such massive penalties without fair notice. The implied-certification theory wholly fails to provide such notice because the alleged violation of any contractual or regulatory provi-

sion might be the basis for an FCA claim. *See supra* pp. 5-9. It is anyone's guess what exactly is being impliedly certified upon submission of a claim to the government under the First Circuit's approach.

At a minimum, the uncertainty created by the implied-certification theory invites costly litigation and adds to the already "great pressure on defendants to settle even meritless suits." Boese & McClain, *Why* Thompson *is Wrong*, 51 Ala. L. Rev. 1, 18 (1999). Given the "potential for astronomical liability," even defendants who may have "'innocently misconstrue[d] a complex regulation'" are forced to settle. Krause, 60 N.Y.U. Ann. Surv. Am. L. at 275; *see also* Blanchard, *Medicare Medical Necessity Determinations Revisited*, 43 St. Louis. U. L.J. 91, 114 (1999) (healthcare providers are coerced to settle FCA cases involving regulatory compliance issues even when they "would likely prevail in the administrative process that was designed to hear and resolve such matters"). And that settlement pressure in turn fuels the expansion of the implied-certification theory, as the theory is only rarely put to the test through the full crucible of trial and appellate review, further exacerbating its unpredictability.

It is thus no accident that the "dramatic expansion of liability" brought about by the implied-certification theory, Martin, 101 Cal. L. Rev. at 231, has coincided with a sharp rise in *qui tam* litigation and settlement, particularly in the healthcare industry. In 2014, defendants paid a record-setting $5.7 billion in settlements and judgments in FCA litigation, $2.3 billion of which came from the healthcare industry. DOJ, *Press Release*, *Justice Department Recovers Nearly $6 Billion from False Claims Act Cases in Fiscal Year 2014* (Nov. 20, 2014). In other recent years, more than two-thirds of all FCA recoveries have come from the

healthcare industry. Ogden & Cook, *The Exclusion Illusion* 24 (Oct. 2012); *see also id.* at 1 (annual FCA fines imposed on pharmaceutical companies rose 813% from 2002 to 2012). And the pace of litigation shows no sign of abating: More than 700 *qui tam* suits were filed last year, for the second consecutive year—up from "30 in 1987" and "300 to 400 a year from 2000 to 2009." DOJ, *Press Release*. That explosive growth in litigation and penalties is not a sign that the system is working or that actual fraud is on the rise; it is a symptom of an expansive theory of liability that this Court should reject.

2. Amici's concerns for receiving fair notice before facing the threat of severe penalties cannot be addressed through the requirements that a defendant must have "acted knowingly" or that "the claim's defect is material," as the First Circuit has asserted. *United States ex rel. Hutcheson* v. *Blackstone Med., Inc.*, 647 F.3d 377, 388 (1st Cir. 2011); *cf. SAIC*, 626 F.3d at 1270 (rejecting what the court described as an "effort to cabin in the implied certification theory," and instead urging "strict enforcement of the Act's materiality and scienter requirements"). Those other elements do not effectively limit the scope of the implied-certification theory and thus do not supply the fair notice that the theory otherwise lacks.

First, the requirement that a false statement or claim be "material" to the government's decision to pay the claim is itself far from clear. Many courts historically interpreted the FCA to require a "material" false or fraudulent statement, although that term did not appear in the statute, and definitions of it varied. *See, e.g.*, *United States ex rel. A+ Homecare, Inc.* v. *Medshares Mgmt. Group, Inc.*, 400 F.3d 428, 442 (6th Cir. 2005) (collecting cases); *cf. Allison Engine Co.*, 553 U.S.

at 665 (false statement must "be material to the Government's decision to pay"). In the Fraud Enforcement Recovery Act of 2009 (FERA), Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1621-1622, 1623, Congress added a definition of "material" to the FCA but expressly incorporated that term into only two of the FCA's operative provisions. 31 U.S.C. § 3729(a)(1)(B), (G) (requiring a "material" false statement); *id.* § 3729(b)(4) (defining "material" as "having a natural tendency to influence, or be capable of influencing," the government's decision). The result is considerable post-FERA confusion.

The materiality element can also be exceedingly uncertain in practice. Courts must determine, after the fact, whether the government would have refused to pay a claim had it known of the contractor's alleged noncompliance with a given regulatory or contractual condition. The inquiry is necessarily subject to hindsight bias, turning in some cases on post hoc agency statements in litigation. *E.g.*, *United States ex rel. Thompson* v. *Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017, 1046 (S.D. Tex. 1998) (crediting declaration from government official that agency "relied on" certain certifications "in determining the issues of payment and retention of payment"); *see also* Pet. Br. 46-47. Given that backwards-looking character, it has unsurprisingly produced "inconsistent, lopsided, and irrational results." 1 Boese § 2.04[B][2], at 2-250. For example, the fact that the government continued to pay a contractor's claims even after learning of a contractual or regulatory violation would seem to be dispositive of the question whether the violation was material, but the results in actual cases vary widely. *Compare United States ex rel. Harrison* v. *Westinghouse Savannah River Co.*, 352 F.3d 908, 915 (4th Cir. 2003) (false conflict-of-interest certification held material to payment

decision even though government paid claims after learning of the problem), *with United States ex rel. Costner* v. *United States*, 317 F.3d 883, 887 (8th Cir. 2003) (contractual noncompliance held not material where agency "continued to approve monthly payments" after learning of problems). Materiality is thus no substitute for actual falsity.

Second, scienter and materiality are often difficult to address on a motion to dismiss because some courts regard them as "fact-intensive." *United States ex rel. Onnen* v. *Sioux Falls Indep. Sch. Dist. No. 49-5*, 688 F.3d 410, 414-415 (8th Cir. 2012); *see also Basic Inc.* v. *Levinson*, 485 U.S. 224, 236 (1988) (materiality is "inherently fact-specific"); Pet. Br. 54. Relying on these other elements to cabin the implied-certification theory thus "lowers the pleading bar" and makes it far "easier for a frivolous *qui tam* lawsuit to survive a motion to dismiss." Holt & Klass, *Implied Certification Under the False Claims Act*, 41 Pub. Cont. L.J. 1, 3 (2011); *see also* Martin, 101 Cal. L. Rev. at 260 (First Circuit's approach creates a "staggeringly low bar" to plead falsity). The result will be additional, costly discovery and settlement pressure.

C. Regulatory Noncompliance Is Not Fraud And Should Not Be Treated As Such

The implied-certification theory and the uncertainty and unfairness it creates are unnecessary to achieve any legitimate purpose of the FCA. Courts sympathetic to the theory have stressed Congress's broad goal in the Act to "reach all fraudulent attempts to cause the Government to pay out sums of money." S. Rep. No. 99-345, at 9 (1986). But the implied-certification theory reaches far beyond the conduct Congress intended to target, sweeping in conduct that is not fraud. Pet. Br.

35-41. The theory wrongly sanctions efforts by the government or a relator to transform noncompliance with a complex regulations into actionable fraud. Indeed, even courts that have adopted the theory have recognized that it 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." *SAIC*, 626 F.3d at 1270.

The FCA is "not the proper mechanism for government to enforce violations" of regulations or administrative program conditions, divorced from any affirmatively false claim or expressly false certification. *United States* v. *Sanford-Brown, Ltd.*, 788 F.3d 696, 712 (7th Cir. 2015). It was never intended to be "a general 'enforcement device' for federal statutes, regulations, and contracts." *United States ex rel. Steury* v. *Cardinal Health, Inc.*, 625 F.3d 262, 268 (5th Cir. 2010); *cf. Mikes* v. *Straus*, 274 F.3d 687, 699 (2d Cir. 2001) (FCA "not designed for use as a blunt instrument to enforce compliance with all medical regulations"). Noncompliance with regulatory or contractual provisions should instead generally be addressed administratively or through the dispute-resolution mechanisms specified in a contract. These measures provide the government with ample authority to remedy any violations, as well as significant discretion not to pursue minor technical violations. There is thus no need for any judicial expansion of the FCA.

This is certainly true of the healthcare area, in which amici's members operate. The state and federal agencies responsible for regulating the development, sale, and reimbursement of medical devices and biopharmaceuticals already have—and make extensive use of—a panoply of administrative and judicial enforce-

ment mechanisms specifically tailored to address perceived regulatory violations.

The Food and Drug Administration, for example, has a "variety of enforcement options that allow it to make a measured response to" perceived violations of the complex regulatory regime governing pharmaceuticals and medical devices. *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 (2001). Congress provided specific statutory authority for the agency to address the most serious violations by imposing civil monetary penalties and by suits for injunctive relief and seizure of the offending products. 21 U.S.C. §§ 332-334. The agency may also revoke marketing authorization if warranted, after notice to the application holder and an opportunity for a hearing. *Id.* § 355(e). And it may refer violators to the Justice Department for criminal prosecution—under strict liability, even for first-time offenders. *See id.* § 333(a)(1)-(2); *United States* v. *Dotterweich*, 320 U.S. 277, 280-281 (1943).

The agency also has at its disposal myriad administrative mechanisms to monitor and encourage regulatory compliance, and to sanction noncompliance, without the inappropriate threat of devastating FCA liability. When the FDA inspects a manufacturing facility, for instance, it typically details any perceived noncompliance in formal Inspectional Observations. 1 Levine, *FDA Enforcement Manual* ¶ 339 (2008); *see* 21 U.S.C. § 374(b) (inspection report). For "violations of regulatory significance," the agency issues warning letters "to achieve voluntary compliance" and to provide "prior notice" to the regulated party of the compliance issue. FDA, *Regulatory Procedures Manual* § 4-1-1 (July 2012). For lesser infractions, not deemed by the agency to be "of regulatory significance," the FDA also issues so-called "untitled letters" (*i.e.*, letters not designated

as formal warning letters). *Id.* § 4-2-1. Uncorrected regulatory violations can result in a number of administrative sanctions in addition to the remedies described above—including mandatory product recalls, *e.g.*, 21 U.S.C. § 360h(e) (medical devices); withdrawal or suspension of the agency's approval to sell the product, *e.g.*, *id.* § 360e(e) (same); and import bans or manufacturing facility shutdowns, *e.g.*, FDA, *Manual* § 9-1 (listing statutory authorities). Under 21 U.S.C. § 335a, in some circumstances the agency may also "debar"—ban from the industry—"individuals found to have participated in or countenanced fraud respecting any 'drug product.'" 1 Levine ¶ 740.

The Office of Inspector General at the Department of Health and Human Services also has an array of enforcement tools, such as civil monetary penalties and the authority to exclude individuals and companies from participation in federally-funded healthcare programs; unlike the FCA, these tools are specifically targeted at healthcare fraud. *See*, *e.g.*, HHS OIG, *Civil Monetary Penalty Authorities*, http://oig.hhs.gov/fraud/enforcement/cmp/cmpa.asp (last visited Jan. 26, 2016) (listing 25 separate statutory authorities for civil monetary penalties); 42 U.S.C. § 1320a-7 (exclusion).

Both agencies make effective and broad use of these tailored enforcement mechanisms, which Congress intended to be employed to combat regulatory noncompliance. *See*, *e.g.*, 1 Levine ¶ 141 ("more than 40,000" FDA enforcement actions annually); FDA, *FDA Enforcement Statistics Summary: Fiscal Year 2014*, at 1 (8,000 warning letters in 2014); DOJ & HHS, *Annual Report of the Departments of Health and Human Services and Justice: Health Care Fraud and Abuse Control Program FY 2014*, at 1-2 (Mar. 19, 2015) (4,000 exclusion orders).

Set against these tailored administrative tools, the blunt instrument of the FCA is particularly ill-suited for pursuing the sorts of undisclosed regulatory violations often asserted in implied-certification cases. The FCA's *qui tam* provisions and massive penalties create financial incentives for private relators to target regulatory violations that the government itself does not deem significant. *See Hughes Aircraft Co.* v. *United States ex rel. Schumer*, 520 U.S. 939, 949 (1997) ("[R]elators are … less likely than is the Government to forgo an action arguably based on a mere technical noncompliance with reporting requirements that involved no harm to the public fisc."). In fact, private FCA suits may affirmatively frustrate agencies' exercise of their administrative enforcement discretion, effectively "'short-circuit[ing] the very remedial process the Government has established to address non-compliance with those regulations.'" *United States ex rel. Rostholder* v. *Omnicare, Inc.*, 745 F.3d 694, 702 (4th Cir.), *cert. denied*, 135 S. Ct. 85 (2014); *see, e.g.*, *United States ex rel. Johnson* v. *Shell Oil Co.*, 34 F. Supp. 2d 429, 432-433 (E.D. Tex. 1998) (permitting FCA litigation to proceed even though Interior Department had not yet completed its internal audit process into the same alleged violations).

The implied-certification theory is not needed to vindicate the FCA's important function in combating fraud against the government. Until recently, it had not been employed to punish regulatory noncompliance. Rejecting the implied-certification theory thus would *return* the statute to playing its traditional role: punishing fraud.

D. The Experiences Of Amici's Members Confirm The Dangers Of Implied Certification

The fundamental uncertainty of the implied-certification theory invites baseless and costly litigation premised on a wide range of alleged regulatory compliance issues in the healthcare industry—issues that are properly the domain of the administrative remedies available to the FDA, HHS, and other agencies. Several representative examples are described below. The alleged noncompliance at the heart of these cases falls far short of the sort of fraud for which the FCA should be reserved, and many of these suits have properly been rejected by the courts. But the deluge of litigation underscores how the implied-certification theory invites private relators to seek to transform any undisclosed failure to comply with a regulation or program condition into fraud. Moreover, many of the suits described below have failed only because the regulation at issue was not expressly designated as a condition of payment; those cases likely would have been decided differently under the First Circuit's approach. And, even when defendants ultimately prevail in these cases, the cost of defending litigation premised on the implied-certification theory is ultimately borne by all industry participants—manufacturers, providers, and patients alike.

1. Promotion And Marketing

The marketing of medical drugs and devices is subject to intricate statutory and regulatory regimes, and the FDA has authority to address violations of those regimes in a variety of ways, including by imposing civil monetary penalties. *See supra* pp. 17-18. Prosecutors and private relators have nevertheless aggressively pursued various alleged unlawful marketing practic-

es with the blunt instrument of the FCA, subjecting companies to the threat of massive penalties and treble damages under the implied-certification theory—even when there is no dispute that the claims submitted to the government were entirely accurate on their face, for medications and devices patients actually received and from which they actually benefitted.

As relevant here, when the FDA grants approval to sell a new drug or certain medical devices, the agency also approves labeling that the manufacturer must include with the product, detailing the conditions for which the drug or device is indicated and the manner of use. *See, e.g.*, *United States* v. *Caronia*, 703 F.3d 149, 152-153 (2d Cir. 2012) (overview). After approval, physicians may exercise their medical judgment to use a device or drug for a purpose or in a manner other than as specified in the labeling. Such "off-label" use is "generally accepted" by the medical community, *Buckman Co.*, 531 U.S. at 351, and is expressly contemplated by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 396. Nonetheless, the FDA considers a manufacturer's "promotion" of a physician's legal off-label prescription to be contrary to the labeling regime and evidence that the products are misbranded in violation of federal law. *E.g.*, *Final Guidance on Industry-Supported Scientific and Educational Activities*, 62 Fed. Reg. 64,074, 64,075 (Dec. 3, 1997).

Allegations of off-label promotion have fueled numerous FCA suits (and enormous settlements) under an expansive implied-certification theory. The central claim in these cases is, typically, that a drug or device manufacturer engaged in off-label promotion, did not disclose that activity, and caused healthcare providers to submit claims for reimbursement to the government that impliedly—and falsely—certified regulatory com-

pliance. *See* Hall & Berlin, *When You Have a Hammer Everything Looks Like a Nail*, 61 Food & Drug L.J. 653, 658 (2006); *e.g.*, *United States ex rel. Simpson* v. *Bayer Corp.*, 2014 WL 1418293, at *8-10 (D.N.J. Apr. 11, 2014) (dismissing claims where off-label use would have been reimbursed in any event); *United States ex rel. Bennett* v. *Medtronic, Inc.*, 747 F. Supp. 2d 745, 777-778 (S.D. Tex. 2010) (same, explaining that "off-label use of a drug or medical device is distinct from medically unnecessary use"); *United States ex rel. Galmines* v. *Novartis Pharm. Corp.*, 2013 WL 2649704, at *11 (E.D. Pa. June 13, 2013) (declining to dismiss). Nothing in the labeling regulations provides any notice that off-label promotion, which may well be entirely truthful in its own right, might result under the FCA in treble damages and statutory penalties of up to $11,000 per *claim—i.e.*, per request for reimbursement by providers.[4] Yet the implied-certification theory practically invites such suits, by allowing plaintiffs to craft expansive theories of liability even in the absence of any actual misstatements.

Other recent suits have involved alleged inaccuracies in promoting drugs or devices for their indicated conditions, again predicated entirely on the legal fiction of implied certification. For example, in one such case—stayed pending the Court's decision in this matter—the plaintiff alleges that the defendants misrepresented the relative efficacy of the drug in question over other less expensive treatment options, thus allegedly rendering virtually every claim for reimbursement for

[4] Indeed, nothing in the labeling regulations even "expressly prohibit[s] the 'promotion' or 'marketing' of drugs for off-label use," *Caronia*, 703 F.3d at 154, let alone provides fair warning of potential FCA liability.

the drug "fraudulent" under the FCA. *In re Plavix Mktg., Sales Practices & Prods. Liab. Litig. (No. II)*, 2015 WL 4997077, at *2 (D.N.J. Aug. 20, 2015). The district court has to date rejected that theory, but only after considerable and expensive litigation over whether the federal healthcare programs were obligated to pay claims for "on-label" use of the drug regardless of any alleged inaccurate marketing. If the Court does not eliminate or curtail the implied-certification theory, similar suits will surely follow.

2. Adverse-Event Reporting

The implied-certification theory has fueled a number of suits alleging, at bottom, technical noncompliance with the regulations governing a drug manufacturer's reporting duties to the FDA. Manufacturers must inform the FDA if they learn of an "adverse event" caused by a drug or medical device. *See* 21 C.F.R. §§ 310.305(c), 314.80(c), 314.98 (drugs); *id.* § 600.80(c) (biological products); *id.* § 803.50(a) (medical devices). Persistent failure to comply with those regulations can result in the FDA's withdrawing its approval for the product or in other administrative sanctions. *E.g.*, 21 U.S.C. § 360e(e)(1)(D)(i) (withdrawal of premarket approval of medical device).

In FCA litigation, however, relators have asserted that a manufacturer's alleged failure to file adverse-event reports is not merely a regulatory infraction but a fraud on the government under the implied-certification theory. *See, e.g.*, *United States ex rel. Roop* v. *Hypoguard USA, Inc.*, 559 F.3d 818, 824 (8th Cir. 2009) (affirming dismissal of FCA claims premised on alleged failure to file required device reports); *United States ex rel. Ge* v. *Takeda Pharm. Co.*, 2012 WL 5398564, at *5-6 (D. Mass. Nov. 1, 2012) (dismissing

similar suit), *aff'd*, 737 F.3d 116 (1st Cir. 2013); *United States ex rel. Krahling* v. *Merck & Co.*, 44 F. Supp. 3d 581, 594-595 (E.D. Pa. 2014) (declining to dismiss). The theory of these suits is *not* that the claims for reimbursement submitted to federal healthcare programs were themselves facially inaccurate in any respect, but rather that drug or device manufacturers caused providers to submit claims for reimbursement that impliedly and falsely represented that all adverse events had been reported. Again, nothing in any of the FDA's regulations remotely suggests that failure to file adverse-event reports will result in liability for treble damages and mandatory penalties per claim for reimbursement submitted while in technical noncompliance with the reporting regulations.

3. Current Good Manufacturing Practices

Amici's members have also faced a number of suits, again predicated on implied certification, involving alleged noncompliance with the FDA's "Current Good Manufacturing Practices" (CGMPs), which are regulations and associated agency guidance intended to set out minimum standards "for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug" to assure the drug's safety, quality, and purity. 21 C.F.R. § 210.1(a). Failure to abide by the minimum standards may cause the resulting drug to be deemed "adulterated." *Id.* § 210.1(b). "The regulations are designed to be flexible … in order to cover a wide variety of manufacturing environments and evolving technical standards," and the result is necessarily a high degree of "ambiguity" about what exactly is required in any specific situation. Schulman et al., *Manufacturing Trouble*, 12 Pharm. L. & Indus. Report 1464, 1465 (Oct. 17, 2014).

That has not prevented relators—and the government—from seeking to transform undisclosed violations of the CGMPs into fraud under the FCA.

For example, in *Rostholder*, 745 F.3d at 698, the relator alleged that the defendant manufacturers had violated the CGMPs by repackaging penicillin in the same building where other non-penicillin drugs were also packaged, thus causing a risk that the other drugs were contaminated with penicillin. The plaintiff's FCA theory was a paradigmatic example of implied certification. There was no suggestion that any provider's claim for reimbursement to the government had been inaccurate in any respect (nor, for that matter, any alleged effect on patients). Rather, the plaintiff argued that the manufacturer's alleged violation of the CGMPs rendered the drugs adulterated and ineligible for Medicare and Medicaid reimbursement, and therefore that any claim for reimbursement for those drugs was impliedly false. *Id.* at 701-702.

That theory was rejected by the Fourth Circuit, but only after costly and uncertain litigation about whether federal healthcare programs were required to pay the claims notwithstanding any undisclosed failure to follow the CGMPs. *Rostholder*, 745 F.3d at 701-702. Moreover, the court's holding was premised on its conclusion that the Medicare and Medicaid statutes do not expressly require "compliance with the CGMPs" as a condition of payment. *Id.*; *see also United States ex rel. Campie* v. *Gilead Scis., Inc.*, 2015 WL 106255, at *12 (N.D. Cal. Jan. 7, 2015) (similar, noting that "[v]iolations of … cGMPs would seem better addressed by the FDA regulatory process than by the blunt tool of FCA litigation"). It would be far more consistent with the text and purposes of the FCA to recognize, instead, that claims like the ones at issue in *Rostholder*

are not "false or fraudulent" in any respect because a request for reimbursement carries with it no implication at all about the manufacturing practices used in making the drug.

II. THE COURT SHOULD REJECT OR SHARPLY LIMIT IMPLIED CERTIFICATION

Amici fully agree with petitioner that the Court should reject the implied-certification theory of liability entirely, as the Seventh Circuit has done. *Sanford-Brown, Ltd.*, 788 F.3d at 708-712. The theory is contrary to the statutory text; to the purposes of the FCA; and to common law principles, which Congress presumptively intended to incorporate and which would require more than undisclosed violations of a contract or regulation to constitute fraud. Pet. Br. 29-41.

A number of courts that have nevertheless adopted the implied-certification theory have struggled to "maintain a 'crucial distinction' between punitive FCA liability and ordinary breaches of contract," *Steury*, 625 F.3d at 268, by imposing various atextual limitations on the theory. In amici's view, the fact that courts have been compelled to invent limitations to cabin the theory primarily illustrates why it should be rejected in the first instance as vastly overbroad. But if the implied-certification theory is not rejected outright, amici urge the Court to impose clear and workable limits on it, in order to provide at least some notice to defendants of exactly what is being impliedly certified when a contractor submits a claim to the government.

Amici are concerned, in particular, that the "condition of payment" limitation adopted by several courts suffers from many of the same failings as the implied-certification theory more broadly. Under that ap-

proach, the submission of a claim for payment constitutes an implied representation that the contractor has complied with all of the "prerequisite[s] to obtaining payment." *Chesbrough* v. *VPA, P.C.*, 655 F.3d 461, 468 (6th Cir. 2011); *see, e.g.*, *United States ex rel. Wilkins* v. *United Health Group, Inc.*, 659 F.3d 295, 305 (3d Cir. 2011) (submission of a claim constitutes an implied certification of compliance with any "statute or regulation the compliance with which is a condition for Government payment"). Like the materiality inquiry (*supra* pp. 13-15), determining after the fact whether any of the various "underlying contracts, statutes, or regulations" potentially bearing on a claim for reimbursement imposed what could be described as "prerequisite[s] to the government's payment" of the claim, *Conner*, 543 F.3d at 1218, is an uncertain task at best.[5]

The decision below is illustrative. The court of appeals asserted that the regulations petitioner allegedly violated "clearly impose conditions of payment." Pet. App. 15. But, as the district court recognized, there was "'no indication' in the text of any of the pertinent regulations that they were intended as conditions of payment." *Id.* at 10; *see id.* at 40, 42. At the relevant time, neither the general regulation governing staff supervision, 130 Mass. Code Regs. § 429.438, nor the specific regulation governing oversight of unlicensed staff members, *id.* § 429.424, so much as mentioned payment or reimbursement. Pet. Br. 7-8 & n.2. The court of appeals relied instead on yet another section of the regu-

[5] Indeed, several courts have confusingly stated that the "condition of payment" limitation adopted to cabin the implied-certification theory is itself an aspect of materiality—further underscoring the pervasive uncertainty in this area. *E.g.*, *Conner*, 543 F.3d at 1219 n.6; *see also* 1 Boese § 2.04[B][1], at 2-242.7.

lations, § 429.439, which states that certain services "are reimbursable only if" conditions set out in that section are met, including that the satellite clinic for which reimbursement is sought employ a full-time director, *id.* § 429.439(C), who in turn is responsible for "overall supervision of staff performance," *id.* § 429.423(B)(2)(c). *See* Pet. App. 16. Read together, the court concluded, the regulations "explicitly condition the reimbursement of satellites' claims on the clinical director's fulfillment of his or her regulatory duties," including (apparently) every other regulatory requirement pertaining to supervision. *Id.*

Potentially massive FCA penalties should not turn on such a tortured chain of inferences and cross-references. If the regulations that petitioner allegedly violated are "conditions of payment" for FCA purposes, then that limitation is meaningless. For that reason, if the Court does not reject implied certification outright, it should at a minimum limit the theory along the lines of the Second Circuit's decision in *Mikes*, 274 F.3d 687. Under that approach, submission of a claim for payment constitutes at most an implied representation that the contractor has complied with all of the *express* conditions of payment set forth in the contract or applicable statutes and regulations. *Id.* at 700; Pet. Br. 42-47.[6]

[6] If compliance with particular provisions is actually central to the government's willingness to pay a claim, the government can require—either by contract or regulation—that contractors *expressly* certify compliance. *E.g.*, 42 C.F.R. § 423.505(k)(1) (mandatory certification in Medicare Part D program). Congress may also specify that failure to comply with particular provisions will give rise to FCA liability for any resulting claims. *E.g.*, 42 U.S.C. § 1320a-7b(g) (Anti-Kickback Statute). The ability to require express statements of compliance is yet another reason to reject the implied-certification theory as unnecessary and unwise.

That limitation does not fully address amici's concerns for fair notice because it still rests, at bottom, on imposing potentially massive liability by implication, for things the defendant never actually said in presenting a claim to the government, but it at least provides some inkling to those who do business with the government of "what certifications, if any, are implied by the submission of a claim for payment." Martin, 101 Cal. L. Rev. at 231.

* * *

The implied-certification theory fails to provide defendants with fair notice of what conduct violates the law because defendants cannot predict with any confidence what they may later be held to have impliedly certified in submitting a claim. It subjects defendants to massive penalties and treble damages for regulatory noncompliance, which is not fraud and should not be treated as such. Regulatory noncompliance is better addressed through the many other tools already available to regulators. That problem is especially acute in the healthcare industry, where the governing statutes and regulations are complex, and where numerous administrative mechanisms already exist that are better tailored to address noncompliance. Amici urge the Court to reject the implied-certification theory or to limit it sharply in order to provide clear notice in advance of the scope of potential FCA liability.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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