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 AMERICAN HOSPITAL ASSOCIATION, FEDERATION OF AMERICAN HOSPTIALS, AND ASSOCIATION OF AMERICAN MEDICAL COLLEGES AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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TABLE OF CONTENTS

TABLE OF CONTENTS—Continued

TABLE OF AUTHORITIES

Page

CASES:

TABLE OF AUTHORITIES—Continued

Page

TABLE OF AUTHORITIES—Continued

Page

TABLE OF AUTHORITIES—Continued

Page

TABLE OF AUTHORITIES—Continued

Page

TABLE OF AUTHORITIES—Continued

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STATEMENT OF INTEREST[1]

The American Hospital Association, Federation of American Hospitals, and Association of American

[1] No party or counsel for a party authored or paid for this brief in whole or in part, or made a monetary contribution to fund the brief's preparation or submission. No one other than *amici* or their members or counsel made a monetary contribution to the brief. A consent letter from Petitioner was submitted with this brief; Respondent filed a blanket *amicus* consent letter.

Medical Colleges respectfully submit this brief as *amici curiae*.

The American Hospital Association (AHA) represents more than 5,000 hospitals, healthcare systems, and other healthcare organizations, plus 43,000 individual members. AHA members are committed to improving the health of communities they serve and to helping ensure that care is available to and affordable for all Americans. The AHA educates its members on healthcare issues and advocates to ensure that their perspectives are considered in formulating health policy.

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Its members include teaching and non-teaching, short-stay acute, rehabilitation, and long-term acute care, psychiatric and cancer hospitals in urban and rural America, and provide a wide range of acute, post-acute and ambulatory services. Dedicated to a market-based philosophy, the FAH provides representation and advocacy on behalf of its members to Congress, the Executive Branch, the judiciary, media, academia, accrediting organizations, and the public.

The Association of American Medical Colleges (AAMC) is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members comprise all 145 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and

organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their 148,000 faculty members, 83,000 medical students, and 115,000 resident physicians.

The questions presented here are of tremendous importance to *amici*'s members. The majority of the services *amici*'s members provide are reimbursed by government healthcare programs. The requirements for those programs have been described by this Court as "Byzantine" and "among the most intricate ever drafted by Congress." *Schweiker* v. *Gray Panthers*, 453 U.S. 34, 43 (1981). Given that complexity, "implied certification" False Claims Act (FCA) liability is of obvious concern. Because the FCA makes lucrative bounties available to private citizens, the relators' bar has—with increasing frequency and an ever-widening reach—embraced this theory. The United States declines to pursue most relator-filed FCA cases after investigating the relator's allegations. Yet as endorsed by the court below, the theory can result in crippling liability for healthcare providers accused of regulatory non-compliance—even if no false statement was made in connection with a payment request.

Amici have participated as *amicus curiae* in numerous cases before this Court that, like this one, involve the proper interpretation of the FCA. *See, e.g.*, *Kellogg Brown & Root Servs., Inc.* v. *U.S. ex rel. Carter*, 135 S. Ct. 1970 (2015); *Schindler Elevator Corp.* v. *U.S. ex rel. Kirk*, 563 U.S. 401 (2011); *Graham Cnty. Soil & Water Conservation Dist.* v. *U.S. ex rel. Wilson*, 559 U.S. 280 (2010); *Allison Engine Co.* v. *U.S. ex rel. Sanders*, 553 U.S. 662 (2008); *Rockwell Int'l Corp.* v. *United States*, 549 U.S. 457 (2007). Given the enormous complexity of the statu-

tory and regulatory regime governing healthcare, *amici* have a strong interest in ensuring that FCA liability extends only to claims that are truly false or fraudulent. Hospitals, physicians, and other providers need clear notice of the precise circumstances that render factually accurate claims for necessary, appropriate medical services nevertheless actionable under the FCA.

SUMMARY OF ARGUMENT

The First Circuit's interpretation of the FCA permits relators to shoehorn regulatory violations into FCA liability and raises clear issues of fundamental fairness. The implied certification theory of FCA liability permits the imposition of damages and penalties "that are essentially punitive in nature" for submitting factually accurate claims containing only truthful information. *Vt. Agency of Nat. Res.* v. *U.S. ex rel. Stevens*, 529 U.S. 765, 784 (2000). This theory has been advanced by the relators' bar and, to some extent, the Department of Justice, as a means to transform the FCA's lucrative damages and penalties provisions into a one-size-fits-all remedy for alleged non-compliance with a federal program requirement or a contractual provision. As the decision below shows, a defendant can be found to have "defrauded" the government by committing a regulatory misstep never previously identified as disqualifying a claim for payment for services provided to a patient, and a relator can use the FCA to supplant the administrative remedies an agency has established as appropriate for the sort of misstep at issue.

The FCA is too blunt an instrument to be used in this way. It is simply not an appropriate tool for enforcing regulatory compliance with requirements

not explicitly linked to payment of a claim. The overly broad conception of FCA liability endorsed below deprives providers in the exceedingly complex and technical federal healthcare programs of fair notice as to what conduct could trigger FCA liability. It allows relators to pursue FCA liability even where a carefully calibrated administrative mechanism provides for a different response to non-compliance and even when the United States takes no action in response to a relator's allegations. It lowers the bar as to what constitutes "fraud" to include payment requests that contain no false information.

The plain language of the statute does not permit these outcomes. FCA liability should only attach when a defendant submits a claim that it knows is ineligible for payment because some expressly designated condition for payment of that claim has not been satisfied. And whether such a condition exists should be objectively and unambiguously ascertainable from the statute, regulation, or contract involved. Any rule short of that will fail to ensure that hospitals have concrete guidance concerning the legal requirements for submitting a claim and will result in an unfair risk that ad hoc, after-the-fact conjecture about the materiality of a particular regulatory infraction could result in FCA liability.

ARGUMENT

I. THE FALSE CLAIMS ACT IS TOO BLUNT AN INSTRUMENT TO BE A GENERAL ENFORCEMENT MECHANISM FOR REGULATORY COMPLIANCE.

A. Government Healthcare Programs Impose A Breathtaking Number Of Requirements And Obligations On Hospitals And Providers.

Hospitals and healthcare systems like *amici*'s members submit hundreds of thousands of claims a day to the government for providing care to Medicare and Medicaid beneficiaries. Based on data from *2014 CMS Statistics*, hospitals submitted an average of 390,000 claims per day in 2013 for inpatient and outpatient services provided to Medicare beneficiaries alone. *See* U.S. Dep't of Health & Human Services, *2014 CMS Statistics* at 46, Table V.6 (Aug. 2014).[2] As participating providers in Medicare and Medicaid, *amici*'s members must navigate program requirements spread across Titles XVIII and XIX of the Social Security Act, many volumes of Title 42 of the Code of Federal Regulations, enormous amounts of subregulatory guidance—such as the thirty-eight chapter Medicare Claims Processing Manual, the sixteen-chapter Medicare Benefit Policy Manual, the fifteen-chapter Medicare Program Integrity Manual, four hundred-plus pages of Medicare National Coverage Determinations, and thirteen Medicare Administrative Contractors' Local Coverage Determina-

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[2] *Available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Statistics-Reference-Booklet/Downloads/CMS_Stats_2014_final.pdf.

tions—and the specific rules and requirements of each State's Medicaid plan.

To acknowledge that the Medicare and Medicaid programs are complex and technical is an understatement. Courts consistently recognize the inordinate challenge posed to hospitals, physicians, and other providers trying to understand and provide care for beneficiaries in these programs. This Court has referred to the statutes governing these programs as "among the most intricate ever drafted by Congress," having a "Byzantine construction" that renders it "almost unintelligible to the uninitiated." *Schweiker*, 453 U.S. at 43 (citation omitted). Courts of appeals, in similar fashion, describe Medicare and Medicaid rules as "among the most completely impenetrable texts within human experience,"[3] "baffling,"[4] and "dense reading of the most tortuous kind" for which "any solid grasp of the matters addressed [is] merely a passing phase."[5] By one count, 130,000 pages of rules govern healthcare providers, with Medicare rules comprising over 100,000 of those pages. Victor E. Schwartz & Phil Goldberg, *Carrots and Sticks: Placing Rewards As Well As Punishment in Regulatory and Tort Law*, 51 Harv. J. on Legis. 315, 350 (2014).

Few, if any, regulatory regimes rival this complexity. Literally everything from where a hospital places emergency power and lighting, 42 C.F.R.

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[3] *Abraham Lincoln Mem'l Hosp.* v. *Sebelius*, 698 F.3d 536, 541 (7th Cir. 2012) (citation omitted).

[4] *Beverly Cmty. Hosp. Ass'n* v. *Belshe*, 132 F.3d 1259, 1266 (9th Cir. 1997).

[5] *Rehab. Ass'n of Va. Inc.* v. *Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994).

§ 482.41(a)(1), to whether a hospital has a full-time employee serving as a director of the food and dietetic service, *id.* § 482.28(a)(1)(i), to who supervises an operating room and how far in advance of surgery a patient's medical history must be taken, *id.* § 482.51(a)(1), (b)(1)(i), to what must be included in a discharge planning evaluation, *id.* § 482.43, are all covered by Medicare regulations. Being a provider in these healthcare programs involves analyzing, understanding, and implementing a truly massive number of technical, intricate, and often obscure requirements every day.

B. Government Healthcare Programs Have Numerous Regulatory Mechanisms To Police Compliance With Program Requirements.

While the primary focus of hospitals is caring for the sick and injured, hospitals take very seriously their obligation to bill properly for the services they provide. Hospitals invest significant resources in compliance programs and ongoing efforts to make their procedures and practices meet the requirements. They employ staff devoted to ensuring compliance with the daunting range of program requirements and have internal audit departments that regularly audit and monitor bills submitted to the federal government. Hospitals also are subject to external review of claims they submit by various government oversight entities, including Medicare recovery audit contractors (RACs), Medicare administrative contractors (MACs), Medicaid RACs, the Supplemental Medicare Review Contractor, and the Comprehensive Error Rate Testing contractor. *See* AHA, *Reforming Program Integrity Efforts to Im-*

prove Accuracy, Fairness and Transparency (Apr. 23, 2015);[6] *see also, e.g.*, *Medicare Program Integrity Manual*, Chapter 3 (outlining the prepayment and postpayment review process and available corrective actions for MACs and RACs).[7]

In addition, the federal healthcare programs contain administrative mechanisms for investigating and resolving circumstances in which a provider has fallen short of compliance with a program requirement. For instance, Medicare can impose administrative sanctions, *see generally Medicare Program Integrity Manual*, Chapter 4, § 4.19, and the Secretary of the Department of Health and Human Services can seek civil monetary penalties (CMPs) for a variety of missteps, *see generally id.* § 4.20.[8] "The central purpose of the CMP process is to promote compliance with the program rules and regulations." *Id.* § 4.20.1.2. On top of CMPs, "CMS may revoke a currently enrolled provider or supplier's Medicare billing privileges" in certain circumstances, including if "[t]he provider or supplier is determined to not be in compliance with the enrollment requirements described in [42 C.F.R. Part 424, subpart P] or in the enrollment application applicable for its provider or supplier type, and has not submitted a plan of corrective action." 42 C.F.R. § 424.535(a)(1).

Each State's Medicaid program has similar discretion to investigate and determine the appropriate

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[6] *Available at* http://www.aha.org/advocacy-issues/issuepapers/ip-programinteg.pdf.

[7] *Available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c03.pdf.

[8] *Available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c04.pdf.

remedy for instances of regulatory non-compliance. Massachusetts' Department of Public Health did just that in this case. It concluded that the Lawrence clinic had some deficiencies in its operations, including that the clinic had violated state regulations governing the credentials required for clinic staff and the supervision of staff members. But Massachusetts Medicaid never sought to withhold or recover amounts that had been paid to the clinic for treating patients based on these deficiencies. Pet. Br. 12-13, 51-52.

Medicare and Medicaid's administrative mechanisms ensure that CMS and state agencies have discretion to investigate and resolve allegations of noncompliance. In doing so, CMS and these state agencies make individualized assessments of culpability, assess the seriousness of a violation, and fashion an appropriate remedy, balancing those factors against the program's interest in continuous delivery of care.

C. The False Claims Act Is Not A General Enforcement Mechanism For Regulatory Compliance.

Many courts of appeals have recognized that the FCA does not create a private right of action to enforce regulatory compliance. As the Fourth Circuit recently explained:

> Were we to accept relator's theory of liability based merely on a regulatory violation, we would sanction use of the FCA as a sweeping mechanism to promote regulatory compliance, rather than a set of statutes aimed at protecting the financial resources of the government from the consequences of fraudulent conduct.

U.S. ex rel. Rostholder v. *Omnicare, Inc.*, 745 F.3d 694, 702 (4th Cir.), *cert. denied*, 135 S. Ct. 85 (2014). The *Rostholder* court thus rejected a relator's argument that he could enforce the Food and Drug Administration's (FDA's) Current Good Manufacturing Practice regulations through the FCA. Rostholder alleged that the defendant (1) packaged penicillin and non-penicillin drugs in separate sections of a building connected by rolling garage doors and utilizing a shared break area for employees, and (2) submitted claims for payment of those drugs to Medicare and Medicaid.

The Fourth Circuit emphasized that "the correction of regulatory problems is a worthy goal, but is 'not actionable under the FCA *in the absence of actual fraudulent conduct.*' " *Id.* (citation omitted; emphasis added). Actionable *fraudulent* conduct affects "the funds and property of the government." *Id.* at 700 (citation omitted). The court emphasized that "[w]hen an agency has broad powers to enforce its own regulations, as the FDA does in this case, allowing FCA liability based on regulatory non-compliance could 'short-circuit the very remedial process the Government has established to address non-compliance with those regulations.' " *Id.* at 702 (quoting *U.S. ex rel. Wilkins* v. *United Health Grp., Inc.*, 659 F.3d 295, 310 (3d Cir. 2011)).

Other courts have reached the same conclusion. Even before it rejected the implied certification theory entirely in *United States* v. *Sanford-Brown, Ltd.*, 788 F.3d 696, 712 (7th Cir. 2015), the Seventh Circuit had held that "technical violations of a federal regulation on which a claim is based do not make the claim 'false,' " *Luckey* v. *Baxter Healthcare Corp.*, 183 F.3d 730, 733 (7th Cir. 1999), and that the

FCA is not a "vehicle for policing technical compliance with administrative regulations." *U.S. ex rel. Lamers* v. *City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999). The Ninth Circuit similarly has underscored that "[v]iolations of laws, rules, or regulations alone do not create a cause of action under the FCA." *U.S. ex rel. Hopper* v. *Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996); *see also U.S. ex rel. Siewick* v. *Jamieson Sci. & Eng'g, Inc.*, 214 F.3d 1372, 1376 (D.C. Cir. 2000) (same, quoting *Hopper*). And the Tenth Circuit has concluded that there is "no basis in either law or logic" to accept a theory of FCA liability "that turns every violation of a Medicare regulation into the subject of an FCA *qui tam* suit." *U.S. ex rel. Conner* v. *Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1221 (10th Cir. 2008) (emphasis omitted).

These cases recognize a basic limiting principle of FCA liability: "The False Claims Act does not create liability merely for a healthcare provider's disregard of Government regulations * * * unless, as a result of such acts, the provider knowingly asks the Government to pay amounts it does not owe." *McNutt ex rel. United States* v. *Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005) (citation omitted). This principle should lead the Court to reverse the decision below.

D. There Is A Crucial Distinction For Purposes Of The FCA Between Conditions Of Participation In A Federal Program And Conditions Of Payment.

Although Medicare and Medicaid set out extensive requirements for providers and suppliers to participate in the programs, nothing in the statutes or regulations governing those programs indicates that

payment to providers for items or services turns on perfect compliance with all program requirements. To the contrary, the vast majority of these requirements for participation are just that: requirements to be a participating provider or supplier without any express connection between compliance and payment of a claim for treating an individual patient. The FCA is a statute designed to protect the public fisc; it does not endorse liability theories based on conduct that the government has not declared in advance affect payment.

The fact that government payment in healthcare programs is not conditioned on "perfect compliance with all underlying statutes and regulations" means that there is a crucial distinction between those program requirements that are a condition of payment of a claim and those that are not. *U.S. ex rel. Conner*, 543 F.3d at 1220. "The FCA is simply not the proper mechanism for government to enforce violations of conditions of participation contained in—or incorporated by reference into—a [provider participation agreement]." *Sanford-Brown*, 788 F.3d at 712; *see also Mikes* v. *Straus,* 274 F.3d 687, 701-702 (2d. Cir. 2001) (discussing conditions of participation versus payment in an implied certification context).

Requirements for *participation*, as opposed to *payment*, are generally "enforced through administrative mechanisms, and the ultimate sanction for violation of such conditions is removal from the government program." *U.S. ex rel. Conner*, 543 F.3d at 1220 (citing *Mikes*, 274 F.3d at 701-702); 42 C.F.R. § 424.535(a)(1) (providing for revocation of Medicare billing privileges based on provider noncompliance). *See also Sanford-Brown*, 788 F.3d at

712 ("under the FCA, evidence that an entity has violated conditions of participation after good-faith entry into its agreement with the agency is for the agency—not a court—to evaluate and adjudicate"); *U.S. ex rel. Hobbs* v. *MedQuest Assocs., Inc.*, 711 F.3d 707, 714 (6th Cir. 2013) (distinguishing conditions of payment from conditions of participation and holding only a violation of the former can trigger FCA liability); *U.S. ex rel. Wilkins*, 659 F.3d at 310-311 (same).

Payment conditions, in contrast, are those requirements that the government has declared will result in a denial of payment for treating a patient if not followed. As one example, the Anti-Kickback Statute specifies that "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]." 42 U.S.C. § 1320a-7b(g). This statutory language provides clear notice that knowingly submitting a claim that has resulted from an Anti-Kickback Statute violation is effectively seeking payment on a claim that is ineligible for payment.

E. For FCA Liability To Attach, A Provider Must Have Clear Notice That A Claim Is Ineligible For Payment And Knowingly Submit It Anyway.

Hospitals operate within an exceedingly complex regulatory scheme—which means that they cannot be left guessing which of the tens of thousands of program requirements are conditions of payment that can subject them to crushing FCA liability. Just the opposite: fundamental fairness requires that hospitals and other healthcare providers receive clear notice of what specific statutory and regulatory requirements, if not met, render a claim ineligible for

payment and can result in the FCA's punitive treble damages and per-claim penalties.

It is deeply unfair for healthcare providers to face FCA liability for a regulatory violation simply because a court's or jury's after-the-fact view is that the government would consider it to be material, when the government itself never said so. *Sanford-Brown*, 788 F.3d at 711 (explaining that it would be "unreasonable" to hold that an entity's "continued compliance with the thousands of pages of federal statutes and regulations" referenced in a provider participation agreement is a condition of payment for purposes of FCA liability).

It simply defies logic to treat a healthcare provider's submission of a claim as an implicit certification that the provider is in perfect compliance with every single requirement applicable to the healthcare programs. Not only would such a holding "import[ ] boundless FCA jurisdiction on any recipient of government subsidies," it would "simultaneously undermine [the government's] existing administrative enforcement powers." *Id.* at 711 n.6. Many of the statutes and regulations on which relators base false certification allegations include carefully calibrated administrative remedies, not subject to private enforcement, to address allegations of noncompliance.

Allowing FCA suits to proceed where the legislature or an executive agency has designed specific administrative remedies appropriate to redress specific kinds of regulatory noncompliance improperly permits *qui tam* plaintiffs to supersede the appropriate administrative mechanisms, second-guess the agency's determination, rewrite the mechanisms for dealing with noncompliance, and override the discre-

tion vested in executive agencies. *See, e.g.*, *U.S. ex rel. Hendow* v. *Univ. of Phoenix*, 461 F.3d 1166, 1169-1170 (9th Cir. 2006) (permitting relator to pursue FCA theory based on alleged noncompliance with a condition of participation in student loan program even though the federal Department of Education treated the alleged noncompliance of condition as an administrative enforcement matter, not fraud). In contrast, concluding that the FCA does not authorize liability under an implied certification theory is consistent with the principle recognized by many courts of appeals that the FCA is too blunt an instrument to be an appropriate tool for enforcing compliance with regulatory requirements not explicitly linked to payment of a claim.

The extremely complicated Medicare and Medicaid program rules described above, coupled with the FCA's potentially crippling liability provisions and litigation costs, underscore how untenable—and unfair—the decision below is for hospitals participating in these programs. Under the statute's six-year statute of limitations, hundreds of thousands of claims can be at issue; under its treble damages provision, a healthcare provider could be held liable for three times the claimed amount (without regard to the costs the provider actually incurred to provide the services); and under the per-claim penalties of up to $11,000 per claim, even small value claims quickly amount to monumental liabilities.

To demonstrate exactly how crippling that liability can be, assume a provider submitted a single $50 claim every day while in violation of a regulatory requirement as to which a relator alleges the provider made a false implied certification of compliance. The provider faces potential liability in this situation

of *over $25 million*, consisting of $328,500 in treble damages ($50 claim times 365 days times 6 years times three) and $24,090,000 in penalties (1 claim/day times 365 days times 6 years times $11,000 penalty per claim). This, for claims that totaled only $109,500.[9]

The astronomical potential liability, coupled with a relator's right to claim a bounty of up to 30 percent of any judgment or settlement and their attorneys' right to fees even in the event of settlement, make the statute irresistible to relators and their counsel. But nothing in the terms of the statute creates liability "merely" for not following a regulation or having an insufficient internal policy; the proper question is whether a "provider knowingly ask[ed] the Government to pay amounts it does not owe." *U.S. ex rel. Clausen* v. *Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002). And the only way a provider can knowingly do so is if the government has made clear—in advance and unambiguously—precisely which subset of statutory and regulatory requirements, if not met, will produce a claim for

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[9] Similar math has played out in real life. The government sought between $1,032,960 and $1,887,960 in damages and penalties against a home healthcare provider whose employee allegedly submitted 171 claims to Medicare for "worthless" physical therapy services, totaling only $59,320. *United States* v. *S. Md. Home Health Servs., Inc.*, 95 F. Supp. 2d. 465, 466-467, 473 (D. Md. 2000). And a district court, before reversal, assessed damages and penalties of $11,110,662 based on 1,288 Medicare claims totaling $713,387.57 in *U.S. ex rel. Hobbs* v. *MedQuest Associates, Inc.*, No. 3:06-01169, 2011 WL 5027504, at *5 (M.D. Tenn. Oct. 21, 2011), *rev'd*, 711 F.3d 707, 709-710 (6th Cir. 2013) (rejecting relator's implied certification theory as based on a condition of participation, not payment).

payment that the government does not owe. *See Mikes*, 274 F.3d at 700 (a mere claim for payment cannot be fraudulent unless the defendant submitted the claim "while knowing * * * that payment expressly is precluded because of some noncompliance by the defendant").

II. THE HEALTHCARE FIELD IS HEAVILY TARGETED BY RELATORS SEEKING A BOUNTY IN *QUI TAM* CASES.

A. The Implied Certification Theory Has Exacerbated Meritless Suits Filed By Relators Targeting The Healthcare Field.

There is no real debate that relators file and pursue *qui tam* actions based on different motivations than government prosecutors or federal agencies evaluating a regulated entity's conduct. *See Hughes Aircraft Co.* v. *U.S. ex rel. Schumer*, 520 U.S. 939, 949 (1997) ("*qui tam* relators are * * * motivated primarily by prospects of monetary reward rather than the public good"); *see also* Jody Freeman, *The Private Role in Public Governance*, 75 N.Y.U. L. Rev. 543, 574 (2000) (explaining that relators "pursue different goals and respond to different incentives than do public agencies" and have no "direct accountability to the electorate"). Permitting FCA liability to turn on after-the-fact speculation by these financially motivated actors threatens endless litigation for *amici*'s members and others in the healthcare field.

Over the last two decades, relator-filed FCA suits have dramatically increased—particularly in the healthcare field. Of the 373 FCA cases in 1987, only 15 involved healthcare entities. *See* U.S. Dep't of Justice, Civil Div., *Fraud Statistics—Overview, Oct.*

1, 1987–Sept. 30, 2015, 1–4 (DOJ Fraud Statistics) (identifying number of FCA cases involving the Department of Health and Human Services as the primary client agency).[10] In sharp contrast to the *four percent* of those cases involving healthcare defendants, 447 of the 737 FCA cases filed in 2015 involved healthcare entities. *Id.* That is over *sixty percent* of cases filed. And the numbers are even sharper if the Court looks just to relator-filed cases. In 2015, *over seventy percent* of those were against healthcare entities. *Id.* (423 of 632 cases).

The implied certification theory has been a driving force behind this trend. It renders the complexity of the Medicare and Medicaid programs a potential gold mine for opportunistic relators. To give just a flavor of how relators have targeted healthcare providers with meritless litigation using the implied certification theory: In *U.S. ex rel. Conner*, 543 F.3d at 1216 n.5, a relator alleged that a hospital was liable under the FCA because it impliedly certified compliance with the prohibition against discrimination in federally assisted programs and with requirements for examining and treating emergency medical conditions; in *U.S. ex rel. Steury* v. *Cardinal Health, Inc.*, 625 F.3d 262, 267 (5th Cir. 2010), a relator alleged that a device manufacturer was liable under the FCA because it impliedly certified that medical pumps complied with a warranty of merchantability; in *U.S. ex rel. Wilkins*, 659 F.3d at 307, a relator alleged that healthcare service companies were liable under the FCA because they impliedly certified compliance with Medicare regulations

[10] *Available at* http://www.justice.gov/civil/file/801676/download.

concerning the content of marketing flyers and limiting marketing efforts in a doctor's office waiting room; and in *Foglia* v. *Renal Ventures Management, LLC*, 754 F.3d 153, 154-155 (3d Cir. 2014), the relator alleged that a dialysis care services company was liable under the FCA because it falsely implied compliance with state quality-of-care regulations by submitting claims for a drug.[11]

The proliferation of vexatious or otherwise non-meritorious *qui tam* actions for hospitals and health care providers is very real. "Implied certification" resulted from relators' zeal to stretch the FCA into a broad private enforcement for healthcare regulatory regimes and to supplant the enforcement authority expressly delegated to the oversight agencies. Relators in healthcare *qui tam* cases often concoct highly creative theories of liability, and often bring claims in cases where healthcare providers unwittingly ran afoul of complex federal requirements. *See, e.g.*, Joan H. Krause, *"Promises to Keep": Health Care Providers and the Civil False*

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[11] *See also U.S. ex rel., Prather* v. *Brookdale Senior Living Communities, Inc.*, No. 3:12-CV-00764, 2015 WL 6812581, at *19 (M.D. Tenn. Nov. 5, 2015) (relator alleged that defendant's submission of claims made false implied certification of compliance with physician documentation requirement); *U.S. ex rel. Modglin* v. *DJO Global Inc.*, No. CV-12-07152, 2015 WL 4111709, at *19-20 (C.D. Cal. May 8, 2015) (relator alleged that defendants' submission of Medicare claims made false implied certification of compliance with FDA regulation); *U.S. ex rel. Ortolano* v. *Amin Radiology*, No. 5:10-cv-583, 2015 WL 403221, at *7 (M.D. Fla. Jan. 28, 2015) (relator alleged that radiology practice's submission of claims falsely implied certification of compliance with Florida's licensing and certification laws for PET/CT scans).

Claims Act, 23 Cardozo L. Rev. 1363, 1368 (Mar. 2002) (explaining this phenomenon).

The United States government declines to participate in the vast majority of these cases. *See* Letter from DOJ & HHS to Hon. Charles E. Grassley 15 (Jan. 24, 2011) (United States intervened in only 22 percent of cases from 2006 to 2011)[12]; *see also* U.S. Dep't of Justice, *False Claims Act Cases: Government Intervention in Qui Tam (Whistleblower) Suits*, 2 (Apr. 18, 2011) ("Fewer than 25% of filed qui tam actions result in an intervention on any count by the Department of Justice.");[13] Letter from GAO to Hon. F. James Sensenbrenner, Jr., Hon. Chris Cannon, and Hon. Charles E. Grassley, *Information on False Claims Act Litigation* 29 (Jan. 31, 2006) (noting 754 of the 1770 cases the government had declined since 1987 were in the healthcare field) ("GAO Report")[14]. Relators thus are left to pursue their claims—and their own pecuniary interests—in the name of the United States, but unbridled by government oversight, direction, or prosecutorial discretion. *Cf. Hughes Aircraft Co.*, 520 U.S. at 949 ("*Qui tam* relators 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.").

The overwhelming majority of declined healthcare *qui tam* cases are meritless. They lead to no

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[12] *Available at* http://www.taf.org/DOJ-HHS-joint-letter-to-Grassley.pdf.

[13] *Available at* http://www.justice.gov/sites/default/files/usao-edpa/legacy/2011/04/18/fcaprocess2_0.pdf.

[14] *Available at* http://www.gao.gov/new.items/d06320r.pdf.

recovery for the United States (or the relator). A substantial number of them are dismissed or resolved pre-trial, but often only after burdensome and expensive dispositive motion litigation and discovery. *See* Christina O. Broderick, *Qui Tam Provisions and the Public Interest: An Empirical Analysis*, 107 Colum. L. Rev. 949, 975 (2007) (study shows from 1987 to 2004, 92% of declined *qui tam* cases were ultimately dismissed); *see also Riley* v. *St. Luke's Episcopal Hosp.*, 252 F.3d 749, 767 n.24 (5th Cir. 2001) (Smith, J., dissenting) (noting that "[o]f the 1,966 [of all *qui tam*] cases that the government has refused to join, only 100 have resulted in recoveries (5%)"). And even when declined *qui tam* cases are successful, historically the government recovers very little. *See* GAO Report at 36 (noting that the median recovery in declined *qui tam* cases is just over $22,000). Since 1987, only six and a half percent of the total amount of recovery from *qui tam* settlements and judgments have come from cases where the government declined to intervene. *See* DOJ Fraud Statistics, 2 (calculated by dividing the total recovery in declined *qui tam* cases by the total recovery in all *qui tam* cases). In healthcare *qui tam* suits, declined cases account for only four percent of the amount of recoveries. *Id.* at 4.

B. Defending *Qui Tam* Actions Is Expensive And Diverts Resources From Healthcare Providers' Core Responsibilities.

Although some FCA recoveries are unquestionably legitimate, others are the result of healthcare companies making the rational business decision not to challenge tenuous claims that would require long and expensive litigation to defeat. Defending declined *qui tam* cases is extraordinarily expensive and

burdensome, even when the relators' claims are meritless. Many defendants are pressured to settle cases, given the costs of defense, the magnitude of potential liability, *supra* pp. 16-18, and potential that an adverse decision would result exclusion from participation in federal healthcare programs. *See, e.g.*, 31 U.S.C. §§ 3729(a)(1), 3730(d); 42 U.S.C. §§ 1320a-7, 1396a(a)(39).[15]

The broad rule advanced by the court of appeals all but guarantees that providers will face dramatically increased litigation costs and prolonged, meritless lawsuits. By equating whether a regulatory breach renders a claim fraudulent with the fact-intensive materiality and scienter analysis, the court of appeals has offered relators a free pass beyond the pleading stage to the costly realm of discovery. *See U.S. ex rel. Escobar* v. *Universal Health Servs., Inc.*, 780 F.3d 504, 512-513 (1st Cir. 2015). Not only is the First Circuit's standard inconsistent with the purpose of the FCA—which is designed to prevent fraud on the government, not punish misinterpretations of complex federal law—it is harmful to the interests of patients and the communities healthcare providers serve.

Whether settled early or litigated to a conclusion, questionable and meritless FCA cases divert enormous resources away from providers' core responsibility: caring for patients. *See* Keith D. Barber et al., *Prolific Plaintiffs or Rabid Relators? Recent Developments in False Claims Act Litigation*,

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[15] Once excluded, entities may not submit claims for items or services and will not be reimbursed for any item or service furnished. 42 C.F.R. § 1001.1901.

1 Ind. Health L. Rev. 131, 172 (2004) ("unjust settlements * * * often include payment of penalties that further divert resources from the provision of health care"). Two hospitals' stories stand as illuminating examples. In 1998, four certified registered nurse anesthetists sued George Washington University, alleging the university's medical center submitted false claims for reimbursement because certain anesthesiologists had not personally performed specific steps of the anesthesia procedure. *U.S. ex rel. El-Amin* v. *George Washington Univ.*, 4 F. Supp. 3d 30, 31-33 (D.D.C. 2013). The case was ultimately resolved entirely in the defendant's favor—but not until after *eighteen years* of litigation before three district judges and two magistrate judges, including massive discovery, *id.* at 31, 39-40, that no doubt cost the university many millions of dollars in fees and costs.

As another example, in early 2003, Good Shepherd Medical Center in Hermiston, Oregon, was the subject of an FBI raid after a relator filed a sealed *qui tam* complaint alleging vast irregularities in the hospital's billing practices. *See* Letter from Dennis E. Burke, President, Good Shepherd Health Care System, to Senator Ron Wyden (Aug. 23, 2006).[16] During an arduous three-year investigation of the claims, the alleged irregularities—"unbundling," kickbacks, over-coding, billing for services not provided, among others—dropped away one by one until so little of substance remained that the federal government discontinued its investigation. *Id.* at 1-

[16] *Available at* http://www.aha.org/ content/00-10/wydenltr.pdf.

2.[17] The hospital incurred over one million dollars in fees and costs relating to the investigation. *Id.* at 2.

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Compliance with statutes, regulations, contracting requirements and other laws is critically important, which is precisely why hospitals dedicate extensive resources to compliance activities. *Amici* support appropriate enforcement of the FCA. But the implied certification theory—and in particular, the standard for FCA liability endorsed by the court of appeals below—is an instance of statutory overreach created by a relators' bar intent on expanding the FCA into an all-purpose statute to privately enforce statutory, regulatory, and contractual requirements. The proliferation of meritless *qui tam* suits targeting hospitals and other providers threatens the legitimate business activities of all who provide services to federal health care program beneficiaries.

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[17] An audit of the hospital's emergency billing records revealed that a computer programming error had resulted in the names of the treating ER physician and the hospital's former ER medical director being entered incorrectly on electronic claims form. That revelation triggered a third-party audit, which showed that all ER services had been provided by qualified physicians and appropriately coded—indeed, sometimes undercoded. *Id.*

CONCLUSION

For the foregoing reasons, as well as those in Petitioner's brief, the judgment of the First Circuit should be reversed.

Respectfully submitted,

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