Case No.
18-10500-AA

In the United States Court of Appeals for the Eleventh Circuit

United States of America, *et al.*,
ex rel. Angela Ruckh,
Plaintiff-Appellant,

v.

CMC II, LLC, *et al.*,
Defendants-Appellees

Appeal from the United States District Court
for the Middle District of Florida,
No. 8:11-cv-01303-SDM-CPT

The Honorable Steven D. Merryday, United States District Judge

BRIEF OF AMICI CURIAE COALITION OF INTERESTED HEALTHCARE COMPANIES AND THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA IN SUPPORT OF DEFENDANTS-APPELLEES

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CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Eleventh Circuit Rules 26.1-1 and 26.1-2(b), *amici curiae* Coalition of Interested Healthcare Companies and the Chamber of Commerce of the United States of America submit this Certificate of Interested Persons and Corporate Disclosure Statement. *Amici Curiae* state that the certificates submitted by Relator-Appellant, Defendants-Appellees, and *amici curiae* in support of Relator-Appellant correctly list trial judges, attorneys, persons, associations of persons, firms, partnerships, and corporations with an interest in the outcome of the instant appeal, and add the following Coalition of Interested Healthcare Companies members, the Chamber of Commerce of the United States of America, and their counsel to that list:

Ardent Health Partners, LLC

Ardent Health Partners, LLC is a privately held company. It has no parent corporation, nor has it issued any shares or securities.

DaVita HealthCare Partners, Inc.

DaVita HealthCare Partners, Inc. is a subsidiary of DaVita Inc., which is a publicly traded company. More than 10% of DaVita Inc.'s stock is owned by Berkshire Hathaway Inc., which is a publicly held company whose stock is traded on the New York Stock Exchange.

Eli Lilly and Company

Eli Lilly and Company is a publicly traded company. Its stock ticker symbol is LLY. Eli Lilly and Company has no parent corporation and no publicly held corporation owns 10% or more of its stock.

GlaxoSmithKline, LLC

GlaxoSmithKline, LLC is a Delaware limited liability company. Its sole member is GlaxoSmithKline Holdings (Americas) Inc., a Delaware corporation with its principal place of business in Delaware. *See Johnson v. SmithKline Beecham Corp.*, 724 F.3d 337, 341 (3d Cir. 2013).

Medtronic PLC

Medtronic PLC is a publicly traded company. Its stock ticker symbol is MDT. Medtronic has no parent corporation and no publicly held company owns 10% or more of its stock.

Pfizer, Inc.

Pfizer, Inc. is a publicly traded company. Its stock ticker symbol is PFE. Pfizer has no parent corporation and no publicly held corporation owns 10% or more of its stock.

The Chamber of Commerce of the United States of America

The Chamber of Commerce of the United States of America is a business federation. It is not a subsidiary of any corporation, and no publicly held corporation owns 10% or more of its stock.

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Kalb, Paul E., M.D. – an attorney with Sidley Austin LLP, representing *amici curiae* Coalition of Interested Healthcare Companies and the Chamber of Commerce of the United States of America. (*Amici* list Dr. Kalb solely for his role in this litigation and are unaware of any financial interest he possesses in this matter.)

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INTRODUCTION AND STATEMENT OF INTEREST OF *AMICI CURIAE* COALITION OF INTERESTED HEALTHCARE COMPANIES AND THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA

Pursuant to Federal Rule of Appellate Procedure 29, *Amici Curiae* Coalition of Interested Healthcare Companies (the "Coalition") and the Chamber of Commerce of the United States of America (the "Chamber") (collectively, "*Amici*") respectfully submit this brief in support of Defendants-Appellees.[1]

The Coalition consists of healthcare providers, pharmaceutical companies, and medical device manufacturers providing healthcare and pharmaceuticals to tens of millions of patients throughout the United States, including millions of beneficiaries of federal healthcare programs.

Coalition member Ardent Health Partners, LLC is the third largest privately held, for profit operator of acute care hospitals in the United States and a leading provider of comprehensive high-quality healthcare and related services in its 31 hospitals located in seven states. It has 25,000 employees including 1,100 employed physicians, nurse practitioners, physician assistants and other providers of health care services.

[1] *Amici* certify that no party or party's counsel authored this brief in whole or in part, or contributed money intended to fund its preparation or submission. *Amici* further certify that no person, other than their members and undersigned counsel, contributed money intended to prepare or submit this brief. Both the Appellant and the Appellees have consented to the filing of this brief.

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

Coalition member Eli Lilly and Company develops medicines that help people live longer, healthier and more active lives, including in the areas of oncology, bio-medicines, diabetes, and other medicines to address unmet needs of patients worldwide.

Coalition member GlaxoSmithKline, LLC is a pharmaceutical company that researches and develops vaccines, medicines, and other healthcare products.

Coalition member Medtronic PLC is a global healthcare solutions company that improves lives through medical technologies, services and solutions, which it provides through its Cardiac and Vascular Group, Restorative Therapies Group, Minimally Invasive Therapies Group, and Diabetes Group.

Coalition member Pfizer, Inc. is a pharmaceutical company whose mission is to fund programs that provide public benefit, advance medical care and improve

patient outcomes by providing access to medicines that are safe, effective and affordable.

The Chamber of Commerce of the United States of America is the world's largest business federation. It represents 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry, from every region of the country. The Chamber regularly files *amicus curiae* briefs in cases raising issues of concern to the nation's business community, including FCA cases.

As participants in government healthcare programs and other government programs, *amici*'s members are subject to an expansive web of statutes, regulations, and contractual provisions governing their participation in those federal programs. *See Universal Health Services, Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 2002 (2016) ("billing parties are often subject to thousands of complex statutory and regulatory provisions"); *see also Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000) (characterizing Medicare as "a massive, complex health and safety program…embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations"). Regulations applicable to Coalition and Chamber members from the healthcare industry include, for example, Medicare conditions of coverage, which consume thousands of pages in the *Federal Register*. Indeed, regulations applicable to renal care providers such as

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

Similarly, pharmaceutical manufacturers such as Coalition members Eli Lilly, GlaxoSmithKline, and Pfizer are subject to an extensive regulatory regime under the Food, Drug, and Cosmetic Act ("FDCA"). This includes numerous regulations addressing current Good Manufacturing Practices ("cGMPs"), which govern all aspects of the manufacturing process. *See* 21 C.F.R. § 211. These regulations include ten subparts with 58 sections, each addressing a type of cGMP requirement, which in turn incorporate numerous specific provisions.

As the Supreme Court recognized in *Escobar*, not every one of the numerous legal obligations imposed on participants in government programs is material to payment under the False Claims Act ("FCA"). 136 S.Ct. at 1996 ("What matters is not the label the Government attaches to a requirement, but whether the defendant

knowingly violated a requirement that the defendant knows is material to the Government's payment decision."). Because of their participation in heavily regulated industries subject to frequent lawsuits under the FCA, *Amici* have a strong interest in the proper application of the FCA's materiality and scienter requirements. As the Supreme Court cautioned in *Escobar*, vigorous application of those requirements is particularly important for implied certification claims; otherwise, the FCA will unfairly become a vehicle for imposing massive damages and penalties for violations that have not caused the improper expenditure of government funds.

SUMMARY OF ARGUMENT

In *Universal Health Services, Inc. v. U.S. ex rel. Escobar*, the Supreme Court upheld the validity of the "implied certification" theory of FCA liability but delineated critical doctrinal limitations on its scope. Specifically, the Court held that: (1) the FCA's "materiality standard" is "rigorous" and "demanding"; (2) the government's payment of claims is uniquely probative and "very strong evidence" of non-materiality to payment; and (3) materiality to payment can be decided by a court as a matter of law.[2] Relator-Appellant and the *amici* supporting her attempt

[2] This brief focuses on the rationale for a rigorous materiality standard in implied certification cases, but in *Escobar*, the Court interpreted the statutory language regarding materiality that governs *all* FCA claims. Thus, there is no basis under the Supreme Court's holding to apply a different or less demanding analysis in

to undermine or minimize each of these key doctrinal limitations. They argue instead that (1) the FCA's standard for "materiality" is easy to meet; (2) the government's payment of claims despite knowing of alleged noncompliance with an underlying legal requirement is just one of many factors to weigh in determining materiality to payment; and (3) whether the materiality standard has been met is a question almost always to be decided by the trier of fact. None of these contentions is correct. Indeed, many courts of appeals have held, as the district court held here, that materiality is a meaningful and rigorous requirement; that failure to show that the government discontinued payment after learning of an alleged violation (or had a history of denying payment for similar infractions) is powerful evidence, and indeed a deciding factor, in establishing a lack of materiality; and that materiality can, and frequently should, be decided as a matter of law. Courts' application of *Escobar's* heightened materiality requirement to decide this issue as a matter of law helps ensure earlier resolution of FCA claims and thus protects companies, particularly ones that do a large volume of business with the government, against having to spend large sums responding to FCA claims that are meritless because they are based on alleged violations that did not influence the government's payment decision. For the same reason, faithful

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other cases. *See, e.g., D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016) (applying *Escobar's* materiality standard in fraudulent inducement case).

adherence to *Escobar*'s "rigorous" materiality standard also avoids needless expenditures of government and judicial resources.

ARGUMENT

I. The Supreme Court Established A "Rigorous" Standard For Materiality That Focuses On The Government's Conduct.

In *Escobar*, the Supreme Court recognized the potentially expansive scope of the implied certification theory of FCA liability, which exposes defendants to treble damages and penalties that are "essentially punitive in nature." Accordingly, the Supreme Court emphasized that the scope of the implied certification theory was limited by two important substantive bulwarks: the FCA's materiality and scienter requirements. *See Escobar*, 136 S. Ct. at 1996, 2002. The Court characterized these requirements as "demanding" and "rigorous." *Id.* at 2002-03.

With regard to materiality, the Court made clear that designation of a legal obligation as a condition of payment by Congress or an agency, by itself, is not a sufficient basis to determine that compliance is material to payment. *Id.* at 2003. "Nor is it sufficient for a finding of materiality that the Government would have the *option* to decline to pay if it knew of the defendant's noncompliance." *Id.* (emphasis added). Furthermore, where noncompliance is "minor" or "insubstantial," the Court held that "[m]ateriality cannot be found." *Id.* Instead, the Court emphasized, what is most critical is how the government has *in fact* responded when faced with evidence of non-compliance with statutory, regulatory,

or contractual obligations. *Id.* at 2003-04. On the one hand, proof that the "Government consistently refuses to pay claims in the mine run of cases" involving a given category of non-compliance is evidence of materiality; on the other hand, government payment of "a particular claim in full despite its actual knowledge that certain requirements were violated" is "very strong evidence those requirements are not material." *Id.* The Court's emphasis on factors relating to the government's *payment* activity appropriately is grounded in the fact that the essence of an FCA violation is the submission of claims *for payment*—which are the "*sine qua non*" of an FCA violation. *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1308 (11th Cir. 2002).

The FCA defines materiality as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). *Amici* supporting Relator-Appellant appear to be asking this Court to disregard the Supreme Court's rules for determining materiality and reinterpret the term "natural tendency" under the FCA to mean that the mere possibility the government might deny payment is all that is required. *See* DOJ Br. 1; TAFEF Br. 12.

Escobar rejected that reading of the FCA. In *Escobar*, the Court explained that "[u]nder any understanding of the concept, materiality 'look[s] to the effect on the *likely or actual*'"—not potential—"behavior of the recipient of the alleged

misrepresentation," 136 S. Ct. at 2003 (emphasis added), specifically the actual impact on government *payment*.[3] It is the government's actual conduct—has it paid or not?—not the mere possibility that the government might choose not to pay, that is most probative.

The Supreme Court adopted a high bar for materiality that focuses on the government's actual conduct for an important reason: a high bar is necessary to cabin the potentially expansive scope of the implied certification theory of liability. Under the implied certification theory, claims may be deemed "false" based on an underlying violation of any of hundreds or perhaps thousands of statutes, regulations, or contractual provisions. Prior to *Escobar*, relators relied on a wide array of regulatory violations to ground implied certification claims. For example, relators filed suits alleging that healthcare providers committed fraud under the FCA by supposedly failing to comply with regulations that had no clear (or even apparent) connection to the Government's payment decision. *See, e.g., Compl., United States ex rel. Troxler v. Warren Clinic, Inc.*, No. 11-CV-808-TCKFHM,

[3] Not all provisions of the FCA contain the word "material," (*e.g.*, 31 U.S.C. § 3729(a)(1)(A), which was analyzed by the Court in *Escobar*), but materiality is a requirement for any FCA claim, including for implied certification claims. *Escobar*, 136 S. Ct. at 2002 ("[M]isrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act").

(N.D. Okla. Dec. 30, 2011) (alleging violation of rule prohibiting medical assistants from collecting illness information during office visits); Compl., *United States ex rel. Williams v. Renal Care Group, Inc*., No. 09-0738 (M.D. Tenn. June 21, 2005) (alleging violation of FCA based in part on failure to provide product warranties). Indeed, at least one court has held that a healthcare provider's alleged non-compliance with interpretive guidance from a federal agency was a valid basis for an FCA claim. *See In re Cardiac Devices Qui Tam Litig*., 221 F.R.D. 318, 354 (D. Conn. 2004) (alleged failure to comply with the 1986 Medicare Hospital Manual).

The defendant in *Escobar* challenged the validity of the implied certification theory, arguing that liability under this theory was potentially open-ended. The Supreme Court disagreed, but held that "'[i]nstead of adopting a circumscribed view of what it means for a claim to be false or fraudulent,' concerns about fair notice and open-ended liability 'can be effectively addressed through *strict enforcement* of the Act's materiality and scienter requirements.' *Those requirements are rigorous.*" *Id.* at 2002 (internal citations omitted) (emphasis added). Numerous federal courts of appeals have followed the Supreme Court's guidance on this score. *See United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 489 (3d Cir. 2017) (affirming grant of motion to dismiss under "rigorous" materiality standard); *Abbott v. BP Expl. & Prod., Inc.*, 851 F.3d 384,

387, 389 (5th Cir. 2017) (affirming grant of summary judgment to defendants because relator failed to meet "demanding" materiality standard); *United States ex rel. Harman v. Trinity Indus., Inc.*, 872 F.3d 645, 660, 670 (5th Cir. 2017) (granting post-trial judgment as a matter of law to defendant for relator's failure to meet "demanding" materiality requirement). And, of course, the requirement of materiality is fair and appropriate, because without it huge penalties could be imposed for violations the government would not deem material to payment.

In sum, by repeatedly emphasizing the "natural tendency" language in the statutory definition, Relator-Appellant and the *amici* supporting her essentially ask this Court to find that all that a trier of fact must do to assess materiality is determine whether the alleged violation might possibly have affected payment—a broad and lax standard. This is emphatically *not* what the Supreme Court held in *Escobar*.

II. The Government's Knowing Payment Is "Very Strong Evidence" Of Non-Materiality, Not Simply One Of Many Factors That Is Entitled To Equal Or Lesser Weight Than Others.

Escobar established a number of guideposts for determining materiality, all of which focus on the government's *conduct* when presented with evidence of wrongdoing, not on labels. Most importantly, evidence concerning the government's decision to pay or not is the only evidence that the Supreme Court characterized as "very strong." *Escobar*, 136 S. Ct. at 2003.

The Court stated that the key question is not whether the government could have or should have withheld payment, but—in cases where there is a history of government conduct to consider—whether it in fact *did* withhold payment when faced with evidence of the underlying legal violation. The Court expressly rejected the argument that the mere fact that a statute or regulation is designated as a "condition of payment" is dispositive of whether compliance with the statute or regulation is material to payment. *Escobar*, 136 S. Ct. at 2003 ("[W]hen evaluating materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive"). Instead, the Court instructed:

> "[P]roof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, *if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material.* Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material." *Id.* at 2003-04 (emphasis added).

Other courts of appeals (and district courts) have recognized *Escobar's* emphasis on the government's continued payment in the face of knowledge of noncompliance as the most important factor indicating lack of materiality. *See United States ex rel. Nargol v. DePuy Orthopaedics*, Inc., 865 F.3d 29, 35 (1st Cir.

2017) (dismissing, on materiality grounds, an FCA claim based on alleged false statements that led to FDA approval of a medical device when "the complaint allege[d] that Relators told the FDA about every aspect of the design . . . that they felt was substandard, yet the FDA allowed the device to remain on the market"); *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 764 (3d Cir. 2017) (granting summary judgment on materiality grounds when "CMS knew that dummy prescriber IDs were being used by PBMs, that it routinely paid PBMs despite the use of these dummy Prescriber IDs"); *Petratos*, 855 F.3d at 490 (dismissing, on materiality grounds, an FCA claim in which the relator "essentially conceded that [the government] would consistently reimburse these claims with full knowledge of the purported noncompliance" with the reporting requirement); *Harman*, 872 F.3d at 667 (overturning jury verdict for relator on materiality grounds because government investigated relator's allegations, found them wanting, and kept paying defendant).

As part of their attempt to set a low bar for materiality post-*Escobar*, Relator-Appellant and the *amici* supporting her argue that this Court should adopt a "holistic" approach to determining materiality that gives little, if any, weight to evidence that the government continued to pay claims in the face of knowledge of the underlying violations. For example, *amicus* Department of Justice ("DOJ") asserts that the government's decision to continue payment despite knowing of

underlying violations should be given little weight because "the government may have good reasons" for not stopping or recouping payment, such as "substantial costs associated with recoupment or enforcement," "collateral effects on third parties," or lack of "available alternatives to protect its interests." DOJ Br. at 24-25. Similarly, *amicus* TAFEF asserts that "[t]he Government's failure to deny payment in the face of noncompliance will often be a poor indicator of materiality." TAFEF Br. at 14. According to TAFEF, the government effectively is incapable of stopping payment despite knowledge of underlying violations. *Id.* at 9.[4] *Amici* AARP, *et al.*, also urge the Court to give little significance to whether the government continues to pay upon learning of the alleged noncompliance. *See* AARP Br. at 20-21. None of these arguments is consistent with *Escobar's* instruction that the government's continued payment despite knowing of noncompliance is "very strong evidence that those requirements are not material." *Escobar*, 136 S. Ct. at 2003.[5]

[4] TAFEF's brief includes a discussion of several cases, which it characterizes as demonstrating materiality despite the fact that the government paid the claims. However, those cases either predate *Escobar* (*see, e.g.*, *United States ex rel. Tyson v. Amerigroup Illinois, Inc.*, 488 F. Supp. 2d 719 (N.D. Ill. 2007), TAFEF Br. at 13-15 *)* or did not expressly adjudicate the issue of materiality (*see, e.g., United States ex rel. Kennedy v. Novo Nordisk et al*. settlement, TAFEF Br. at 16-18).

[5] This does not mean that in a particular case the government may not introduce evidence of these kinds in an effort to rebut the inference of immateriality that arises from continued payment in the face of knowledge of alleged noncompliance.

Escobar's directive that courts give principal weight to whether the government *in fact* alters its reimbursement practices upon learning of alleged noncompliance is consistent with the common law materiality standard described in the opinion, which looks to the impact of non-compliance on the "likely or actual behavior" of the government with respect to payment. Focusing on this evidence also makes logical sense. Indeed, if materiality is defined as whether the conduct had an effect on the "likely or actual behavior" of the government with respect to payment, it follows that—absent some extraordinary situation—actual payment by the government with knowledge of the relevant facts is dispositive proof of non-materiality. It also follows that the government's continued payment despite knowledge of the alleged noncompliance is highly relevant to scienter, as it is logically impossible for the submitter of a claim to "know" that the government will not pay when it in fact has paid and continues to do so. *See* Dist. Ct. Opinion at 6 (FCA requires proof that defendant knew when seeking payment that noncompliance was material to the government's decision to pay).

Moreover, it is appropriate and equitable to find that a claim is not material to payment when the government does not alter its payment practice in response to

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But the possibility that in (likely rare) cases these factors may have affected the government's conduct is no reason to undercut the general rule that continued payment gives rise to a strong presumption of immateriality.

learning of the alleged misconduct. *See* Dist. Ct. Opinion at 4 (Medicare and Medicaid consistently paid claims to Defendants-Appellees despite routine Medicare audits and knowledge by Medicaid of alleged documentation and billing deficiencies). To hold otherwise would deprive *Amici's* members and similarly situated companies of notice as to which requirements are sufficiently important that noncompliance can form the basis of FCA liability with its attendant treble damages and civil penalties.

Amici supporting Relator-Appellant make a number of policy arguments as to why lower courts should assign less weight to the government's continued payment of claims than the Supreme Court assigned to that fact. *First*, they argue that there may be legitimate reasons why the government chooses to pay claims despite being aware of noncompliance with some underlying statute or regulation. In particular, *amicus* TAFEF argues that the government follows a "pay and chase" model, and thus a finding of a lack of "materiality" cannot turn on whether the government paid. TAFEF Br. at 9-10. But that argument is backwards. The statutory standard should not be reinterpreted to accommodate the government's practices; the government's practices must be altered to satisfy the binding legal standard articulated by the Supreme Court. Moreover, contrary to TAFEF's argument, CMS already requires that when there are "credible allegations of

fraud," a state Medicaid agency must suspend payment and make a law enforcement referral.[6]

Indeed, that the government continues to pay in the face of *some* violations confirms that not every violation of a rule can establish liability under the FCA. But that does not leave the government without other remedies in those other situations; if the government concludes that there has been a violation of a rule, which, for whatever reason, does not justify non-payment, then it is free to pursue alternative remedies. In the healthcare context specifically, agencies have a wide array of remedies *other than* non-payment available. *See United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d. 694, 702 (4th Cir. 2014) (where an "agency has broad powers to enforce its own regulations, as the FDA does … 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.'"); *see also Nargol*, 865 F.3d at 34 (FDA's decision not to employ its "full array of tools" [*e.g.*, facility inspections, oral observations, establishment inspection reports, untitled letters, warning letters, GMP holds, or

[6] Centers for Medicare & Medicaid Services, *E-Bulletin: Payment Suspensions Snapshot*, available online at https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/ebulletins-payment-suspensions.pdf (last visited September 17, 2018).

seizing or withholding approval of products] for enforcing its rules against fraud "in the wake of Relators' *allegations*" was sufficient to "render[] a claim of materiality implausible") (emphasis added).

Second, *amicus* DOJ argues that highly probative evidence—whether the government later discontinued or attempted to recoup payment upon learning of alleged noncompliance with another requirement—should be disregarded because courts' materiality analysis should be limited to "the government's behavior at the time of the transaction in question." DOJ Br. 9. That makes little sense. Evidence of ongoing payment and non-recoupment over a period of time is highly relevant to the question of whether the government views the claimant's course of action to be material to payment. Indeed, later in its brief DOJ itself acknowledges this. *See* DOJ Br. at 13 ("The government's subsequent actions once it learns the truth (which could be many years later) may also have probative value…"). And multiple federal courts of appeals have found such evidence strongly probative of materiality. *See, e.g.*, *Petratos*, 855 F.3d 481 (finding no materiality where multiple government agencies took no action upon learning of the relator's allegations); *Abbott*, 851 F.3d 384 (same*); D'Agostino*, 845 F.3d 1 (finding no materiality where CMS did not deny payment in the wake of the relator's allegations).

Finally, *amici* AARP *et al*. suggest that a regulatory requirement (such as the care plan requirement here) is material to payment if "goes to the 'very essence of the bargain' between the government and the defendants." AARP Br. at 8. As a doctrinal matter, however, the abstract labeling of a requirement as the "essence of the bargain" (particularly if done *post hoc*) is manifestly not *more* probative of materiality *to payment* than whether the government, as here, knew of alleged noncompliance with the requirement and continued to pay.[7]

[7] As noted in Defendants-Appellees' brief, "the record is devoid of evidence of what Medicaid *actually does* regarding claims lacking a care plan." Def. Br. at 26. Because *Escobar* indicates that the government's conduct with respect to payment is key, Relator-Appellant's failure to provide *any* evidence regarding government conduct means she failed to carry her burden to prove materiality. Moreover, the only evidence in the record demonstrates *lack* of materiality. Though not relied upon by Relator-Appellant, the HHS OIG study on which AARP, *et al*. rely to show that care plans are the "essence of the bargain" actually cuts against a finding of materiality, demonstrating that absence of a care plan frequently does not lead to non-payment. Indeed, the study noted that skilled nursing facilities ("SNFs") failed to meet care plan requirements 37 percent of the time, and suggested that CMS or state surveyors could "impose a number of different enforcement actions [in response] depending upon the scope and severity of the deficiencies found. These actions include requiring a plan of correction, denying future payment, or terminating the provider agreement," as well as "increased State monitoring…or civil monetary penalties." *See* Office of Inspector Gen., Dep't of Health & Human Servs., *Skilled Nursing Facilities Often Fail to Meet Care Planning and Discharge Planning Requirements*, (Feb. 2013) (No. OEI- 02-09-0021) at 5, 17, available online at https://oig.hhs.gov/oei/reports/oei-02-09-00201.pdf (last visited September 17, 2018). The array of possible responses suggested by the HHS OIG shows that while a care plan may well be important to *care*, the absence of a care plan need not affect payment and thus is not sufficient to ground an FCA claim.

III. Courts May Decide Materiality As A Matter Of Law.

The Supreme Court expressly held that materiality could be decided as a matter of law. *Escobar*, 136 S. Ct. at 2004 n.6 ("We reject Universal Health's assertion that materiality is too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss or at summary judgment"). Yet Relator-Appellant and the *amici* supporting her incorrectly argue not only that materiality requires a "holistic" analysis of various factors but, according to *amicus* DOJ, that "because materiality depends on a holistic assessment, in many cases it is likely to be a determination for a jury." DOJ Br. at 20.

Although it is certainly true that materiality may in some cases be appropriate for resolution by a jury, the suggestion that materiality is almost always an issue for the jury is contrary to *Escobar's* express holding that materiality could be decided as a matter of law. That holding is of a piece with the Court's holding that the materiality standard must be "rigorous" in order to limit the scope of the implied certification theory. The Supreme Court wanted the lower courts to play an important gatekeeping role in limiting the scope of this theory and in minimizing the burden to defendants exposed to liability under the implied certification theory where there is little evidence of materiality. *See, e.g*, *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1031 (D.C. Cir. 2017) (insufficient evidence of materiality to survive summary judgment, stating "[t]he

Court [in *Escobar*] made clear that courts should continue to police expansive implied certification theories "through strict enforcement of the Act's materiality and scienter requirements"). Where, as here, a district court finds that the government, despite knowledge of the underlying violation, had neither a practice of denying payment of similar claims nor in fact declined to pay the claim at issue, it is entirely appropriate to conclude as a matter of law that the materiality standard was not satisfied. Indeed, as discussed below, a failure to do so would allow a matter to proceed at great expense to the parties—and potentially exerting significant pressure on a defendant to settle a matter for substantial sums—despite it having become clear that the correct disposition is judgment for the defendant.

Many courts of appeals since *Escobar* have correctly held that continued government payment in the face of knowledge of noncompliance is strong evidence, and generally a deciding factor, that compliance with that obligation was not material to payment. The First, Second and Third Circuits have found relators' FCA claims insufficient as a matter of law, and thus inadequate to survive a motion to dismiss, where their complaints indicated that the government knew of the alleged misconduct but continued to pay. *See Nargol*, 865 F.3d 29 (alleged false statements to FDA immaterial where FDA knew of relator's allegations and allowed medical device to stay on the market); *D'Agostino,* 845 F.3d 1 (no materiality where CMS did not deny payment in the wake of relator's allegations

regarding defendant's allegedly fraudulent representation to FDA, even though representation "could have" influenced its approval decision, which was a precondition of payment by CMS); *Coyne v. Amgen, Inc.*, No. 17-1522-cv, 2017 WL 6459267 (2d Cir. Dec. 18, 2017) (non-precedential) (no materiality where defendant introduced changes to its labeling that relator alleged should have been disclosed previously and CMS did not alter payment); *Petratos*, 855 F.3d 481 (no materiality where relator disclosed allegations to FDA and DOJ, and neither took any action).

Likewise, the Third, Seventh, Ninth and D.C. Circuits have held that relators' claims were insufficient to survive summary judgment when the government knew of the alleged noncompliance and continued to pay. *See Spay*, 875 F.3d 746 (no materiality where undisputed testimony showed that CMS knew of alleged misconduct and continued to pay); *U.S. v. Sanford-Brown, Ltd.*, 840 F.3d 445 (7th Cir. 2016) (no materiality where relevant agencies examined defendant "multiple times" and concluded agency action or termination was not warranted); *United States ex rel. Kelly v. Serco*, 846 F.3d 325 (9th Cir. 2017) (no materiality where government knowingly accepted noncompliant reports and continued to pay defendant); *McBride*, 848 F.3d 1027 (no materiality where Army witnesses testified that alleged non-compliance "had no bearing on costs billed to the Government" or related award decisions, Defense Contract Audit Agency

investigated allegations and "did not disallow any charged costs," and defendant continued to receive "award fee for exceptional performance" after government learned of allegations). Furthermore, as the District Court did here, the Fifth Circuit has granted judgment as a matter of law post-trial on materiality grounds where the government knew of the alleged misconduct and continued to pay. *See Harman*, 872 F.3d 645 (overturning jury verdict where relevant agency issued memorandum stating that allegedly non-conforming modifications were always, and continued to be, approved for payment).[8]

This Court should follow its many sibling Circuits in holding that the government's response upon learning of allegations of noncompliance, and particularly its continued payment of claims, may and frequently will suffice to negate a finding of materiality.

[8] In *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 906-07 (9th Cir. 2017), *pet'n for cert. filed*, No. 17-936, 2017 WL 6812110, the Ninth Circuit found a relator's allegations sufficient to survive a motion to dismiss, but only because the extent of the government's knowledge regarding the alleged noncompliance was disputed. In *United States ex rel. Rose v. Stephens Institute*, No. 17-15111, 2018 WL 4038194 (9th Cir. Aug. 24, 2018), the Ninth Circuit affirmed a denial of the defendant's summary judgment despite continued government payment of claims, but only after concluding that the record contained no evidence concerning the government's knowledge of the alleged misconduct and significant evidence that the government had in fact refused payment in similar circumstances in other cases. Judge Smith, in partial dissent, cogently explained why the majority's approach was not sufficiently faithful to *Escobar's* command that the test for materiality must be demanding in order to properly limit implied false certification claims. *Id.* at *9-*12.

IV. Application of *Escobar's* Heightened Materiality Standard Protects Companies That Do Business With The Government Against Unreasonable Financial Risk.

Members of the Coalition, the Chamber, and other similarly situated companies conduct a large volume of business through government programs. Particularly in the healthcare industry, that activity subjects them to vast numbers of regulatory requirements. Though *Amici's* members spend considerable resources on robust compliance programs, they cannot ensure that every "i" is always dotted and "t" is always crossed. But that should not readily subject them or other companies to treble damages and large penalties under the FCA. In many circumstances, the government is willing to continue to pay despite regulatory noncompliance. That need not reflect a judgment that the noncompliance should not be addressed through available administrative remedies. What it does demonstrate is that the alleged misconduct should not be actionable under the FCA. Application of *Escobar's* heightened materiality standard thus is crucial to companies' ability to avoid having to spend large sums responding to meritless FCA claims.

Indeed, the possible windfall resulting from a share of the recovery of FCA treble damages and civil penalties motivates enterprising relators to try to capitalize on any perceived regulatory or contractual infractions by filing *qui tam* lawsuits. The government declines to intervene in approximately 80 percent of

those cases each year,[9] yet even declined cases can subject companies such as the Coalition's and Chamber's members to enormous litigation costs and substantial pressure to settle even meritless claims.

Resources that companies such as the Coalition's and Chamber's members spend on responding to FCA suits could be put to better use. Healthcare companies, for example, could spend that money investing in further research or treatment for patients. *Qui tam* cases alleging violations that are not material to payment waste not only defendants' resources, but the government's and courts' as well. The government needs to investigate and monitor such cases, even when it declines to intervene, and judges must spend time and effort resolving the many legal and factual issues that may be presented.

For all of these reasons, rigorous enforcement of *Escobar's* materiality standard is particularly important.

[9]U.S. Dep't of Justice, *Acting Assistant Attorney General Stuart F. Delery Speaks at the American Bar Association's Ninth National Institute on the Civil False Claims Act and Qui Tam Enforcement*, (June 7, 2012) (available at https://www.justice.gov/opa/speech/acting-assistant-attorney-general-stuart-f-delery-speaks-american-bar-association-s-ninth) (last visited September 17, 2018).

CONCLUSION

For the reasons described above, the Coalition and the Chamber submit this brief in support of Defendants-Appellees' request for affirmation of the District Court's grant of judgment as a matter of law.

Respectfully submitted,

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Dated: September 18, 2018

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on September 18, 2018, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system, which will send a notice of electronic filing to counsel of record for all parties to this appeal.

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