23-2553

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

UNITED STATES OF AMERICA EX REL.
STEPHEN A. KRAHLING; JOAN A. WLOCHOWSKI,
Plaintiffs-Appellants

v.

MERCK & CO, INC.,
Defendant-Appellee

On Appeal from the United States District Court
for the Eastern of District of Pennsylvania,
The Honorable Chad F. Kenney, Case No. 2:10-04374-CFK

BRIEF OF AMICUS CURAIE THE ANTI-FRAUD COALITION IN SUPPORT OF PLAINTIFFS-APPELLANTS

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DISCLOSURE OF CORPORATE AFFILIATIONS AND FINANCIAL INTEREST

Pursuant to Federal Rule of Appellate Procedure 26.1, The Anti-Fraud Coalition (TAF Coalition, formerly Taxpayers Against Fraud Education Fund) states that it is a corporation organized under § 501(c)(3) of the Internal Revenue Code. It has no parent corporation and no stock owned by a publicly owned company. TAF Coalition represents no parties in the matter and has no pecuniary interest in its outcome. However, TAF Coalition has an institutional interest in the effectiveness and correct interpretation of the False Claims Act.

Respectfully Submitted,

Dated: November 8, 2023

By: /s/Jacklyn DeMar

Jacklyn DeMar
Attorney for *Amicus Curiae*

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To the Honorable United States Court of Appeals:

Pursuant to Rule 29 of the Federal Rules of Appellate Procedure, TAF Coalition respectfully submits this brief as AMICUS CURIAE in support of Appellants. All parties have consented to the filing of this brief.

STATEMENT OF INTEREST[1]

TAF Coalition is a nonprofit, public interest organization dedicated to combating fraud against the Government and protecting public resources through public-private partnerships. TAF Coalition is committed to preserving effective anti-fraud legislation at the federal and state levels. The organization has worked to publicize the *qui tam* provisions of the federal False Claims Act ("FCA"), has participated in litigation as a *qui tam* relator and as an *amicus curiae*, and has provided testimony to Congress about ways to improve the FCA. TAF Coalition is supported by whistleblowers and their counsel, by membership dues and fees, and by private donations. TAF Coalition is the 501(c)(3) arm of Taxpayers Against Fraud, which was founded in 1986. TAF Coalition has a strong interest in ensuring proper interpretation and application of the FCA.

[1] No party's counsel authored this brief, in whole or in part, and no person other than Amicus Curiae TAF Coalition, its members, or its counsel made a monetary contribution that was intended to fund preparing or submitting this brief.

TAF Coalition's interest in this case is ensuring that the Supreme Court's broad dicta in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016) (*Escobar*) on materiality is not misinterpreted to impose a standard the Supreme Court did not adopt and Congress did not intend, and that is contrary to this Court's decision in *United States ex rel. Druding v. Care Alternatives*, 81 F.4th 361 (3d Cir. 2023), which emphasized a "holistic" approach to materiality. The district court granted summary judgment on the element of materiality because it found that the government's continued payment after it learned of the allegations of fraud negated a finding of materiality. *United States ex rel. Krahling v. Merck & Co., Inc.,* Memorandum, 10-cv-04374-CFK, Dkt. 350 (E.D. Pa). As numerous courts have recognized, in many circumstances the government's continued payment reflects the overriding needs of government operations and does not negate that the violation in question has "a natural tendency to influence" or is "capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

The district court also made several broad statements about materiality that, if misconstrued, could result in improper burdens being shifted to relators and the government in pleading and proving materiality that were not intended by Congress and are inconsistent with this Court's holdings. This brief specifically addresses

some such statements in order to ensure proper interpretation of the materiality element of the FCA.

ARGUMENT

In summarizing its decision, the district court stated that it was granting the defendant's motion for summary judgment on materiality grounds, because "the Government has had actual knowledge of the alleged false claims and has continued to purchase Merck's mumps vaccines." *Krahling,* Memorandum at 37. That statement encapsulates the district court's misunderstanding of how materiality should be analyzed under the FCA. Awareness of allegations is not the same as awareness of fraud and even when the government is aware of fraud it may have reasons to continue paying that do not indicate lack of materiality.

I. The FCA Materiality Analysis Is a Holistic One and No One Factor, Including Government Knowledge, is Dispositive.

As the Supreme Court opined in *Escobar* and this Court most recently held in *Druding*, no one factor is dispositive of materiality. *Escobar,* 579 U.S. at 194-95 (listing several relevant but nondispositive factors to consider when assessing materiality); *Druding,* 81 F.4th at 375 (explaining that the fact that the government had actual knowledge of the fraud was not dispositive). Although government knowledge may be *relevant* to the materiality analysis, the analysis is a "holistic, totality of the circumstances examination," and government knowledge is only relevant insofar as the government has actual knowledge of actual false claims, not

of allegations of false claims. *See United States ex rel. International Brotherhood of Electrical Workers Local Union No. 98 v. Farfield Company,* 5 F.4th 315, 342 (3rd Cir. 2021); *Druding,* 81 F.3d at 374 (rejecting the defendant's argument that the government had actual knowledge of false claims after the complaint had been filed and the investigation had been undertaken).

In this case, the district court continuously referred to the government's full knowledge of the "facts," but even after the discovery process, it should not be presumed that the government actually knows the facts regarding the alleged false claims. *See Druding*, 81 F.4th at 375 ("…we will not equate the government's awareness of allegations of fraud with 'actual knowledge' that fraud occurred."); *United States ex rel. USN4U, LLC v. Wolf Creek Fed. Servs.*, 34 F.4th 507, 517 (6th Cir. 2022) ("…there is a difference between alleged fraud and actual fraud, and the Government may not want to prematurely end a relationship with a contractor over unproven allegations.")

The district court rejected the relators' attempts to differentiate between actual knowledge and knowledge of allegations, as well as their attempts to show that the government finds the violations material based on their involvement in the case. *See Krahling,* Memorandum at 31 (rejecting the relators' arguments regarding the government's beliefs about whether it had all of the facts and their emphasis on the government's continued involvement in the case, opining that "DOJ's involvement

could indicate simply the DOJ's continuing advocacy in the interpretation of a statute which generates significant recovery for the Government."). However, the question at summary judgment is whether there is evidence from which a factfinder reasonably could conclude that a requirement is capable of influencing a payment decision. The burden is not on the relator to show what the government knew, rather, the burden is on the defendant to show that there is no dispute of material fact as to the element of materiality. *See Druding,* 81 F.4th at 375 (finding that it was not incumbent upon the relators to present evidence that the government's inaction was due to immateriality, rather it is the moving party that bears the burden of demonstrating the absence of a dispute of material fact)*; United States ex rel. Bibby v. Mortgage Investors Corporation,* 987 F.3d 1340, 1352 (D.Conn. 2021) (reversing grant of summary judgment where evidence to support materiality was presented and factfinder would have to weigh the factors favoring materiality against those favoring immateriality).

The district court suggested that because the relevant government agencies had been "given all of the evidence," there was no question as to whether they had "actual knowledge" (of what, the court does not specify), and that if that were in question, "courts could never consider materiality at summary judgment unless the defendant has conceded to violating a statute, regulation, or contract provision, or alternatively the Government concedes it has knowledge of all the facts. This would

create a perverse incentive for the Government to decline to intervene and then stick their heads in the sand and ignore the progression of the case." *Krahling,* Memorandum at 37. But the government's receipt of evidence, even extensive evidence, in a case does not mean that actual knowledge of fraud can be imputed to the government. For example, in *Druding*, the relators filed their complaint and HHS-OIG and the DOJ conducted a joint investigation, which included subpoenas of patient medical records, company policies, internal documents, and employee emails. *See Druding*, 81 F.4th at 374 (describing the government's potential knowledge of the fraud). There, this Court held that it was still "not clear" whether the government had "acquired actual knowledge."

Moreover, the court's policy observation is contrary to both the text and purposes of the FCA, which expressly contemplates that the relator may proceed, and the government may sit on the sidelines. The FCA is the "premier tool for recovering money lost to fraud against the Government," responsible for recovering almost $72 billion wrongfully taken from the federal Treasury, with over $2 billion recovered each year since 2010 under the *qui tam* provisions. *See* Sen. Chuck Grassley, Prepared Statement at the False Claims Act hearing, Feb. 27, 2008, *available at* https://www.grassley.senate.gov/news/news-releases/prepared-statement-senatorchuck-grassley-false-claims-act-hearing; *see* U.S. Dep't of Justice, Fraud Statistics, *available at* https://www.justice.gov/media/1273591/dl?inline. *Qui*

tam actions are responsible for $50 billion of the $72 billion recovered under the FCA. *Id.* Relators take on incredible risks to their livelihoods and personal relationships to come forward with information about fraud on the government. They will not be incentivized to come forward with that information if it will, in turn, be used to defeat their case.

The government's decision to allow a relator to proceed is a feature of the statute, not an indication that the government is shirking its responsibilities. The government has no incentive to decline to intervene and then actively ignore a case's progression. If a case moves forward in litigation after declination, it is the government's claims being pursued on its behalf and decisions in the case can affect its interests. For that reason, the statute expressly provides that the government is entitled to be served with pleadings and may move to intervene later for good cause. 31 U.S.C. § 3730(c)(3). The FCA also provides the Government broad powers to control the case even when it does not intervene, including seeking limits on discovery. 31 U.S.C. § 3730(c)(4). If the government determines that a violation is not material to an agency's decision making, it has broad authority to move to dismiss the claims. 31 U.S.C. §3730(c)(2)(A); *see also U.S. ex rel. Polansky v. Executive Health Resources, Inc.*, 599 U.S. 419, 437-38 (2023) (explaining that the government's motion to intervene for good cause to move to dismiss a qui tam action should be

granted in "all but the most exceptional circumstances," and that the government's views in this regard should be given "substantial deference.")

II. Even If the Government Has Actual Knowledge of Fraud, There Are Many Reasons the Government May Continue to Pay Claims.

The district court completely discounted relators' arguments regarding the reasons that the government may have continued to pay even if it did have actual knowledge of the fraud, including the fact that vaccine at issue was the only stand-alone mumps vaccine on the market. *See Krahling,* Memorandum at 35-36. (citing the CDC's "prefer[ence for] vaccines that protect against multiple diseases."). Together with the district court's broad statements about materiality, it thus ignored that the government often has myriad reasons to continue to pay claims and continue to contract with FCA defendants even where the government has actual knowledge of the fraud.

Because Government payment systems often have to deal with many competing issues of importance, courts have consistently recognized that the Government may have many reasons to continue paying even upon learning of possible wrongdoing. One of those reasons is that stopping the payment of claims could potentially jeopardize the public health, safety and welfare, or interfere with contractual rights. *United States ex rel. Am. Sys. Consulting v. ManTech Advanced Sys. Int'l*, 600 Fed. Appx. 969, 977 (6th Cir. 2015) (termination could cause incremental losses that exceed the benefits, making a decision not to terminate a poor

indicator of materiality at the outset); *United States ex rel. USN4U, LLC v. Wolf Creek Fed. Servs.*, 34 F.4th 507, 517 (6th Cir. 2022) ("There are a variety of factors unrelated to the materiality of the allegations that could cause the Government to continue contracting with a party after the Government becomes aware of alleged fraud").[2] This is particularly true in the context of healthcare recipients, where the Government's decision also significantly affects Medicare and Medicaid beneficiaries. *United States v. Rite Aid Corp.*, No. 2:11-cv-11940, 2019 U.S. Dist. LEXIS 54854, at *20-21 (E.D. Mich. Mar. 30, 2019) ("Even if the government decided to pay Rite Aid's prescription charges despite knowledge of violations, the payment decision would not necessarily reflect a lack of materiality. For example, the Government may have continued to pay to avoid 'adversely affecting[ing] (sic) the millions of Medicaid beneficiaries who rely on Rite Aid to meet their prescription

[2] *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 917 (4th Cir. 2003) ("we can foresee instances in which a government entity might choose to continue funding the contract despite earlier wrongdoing by the contractor. For example, … to avoid further costs the government might want the subcontractor to continue the project rather than terminate the contract and start over."); *United States v. President & Fellows of Harvard College*, 323 F. Supp. 2d 151, 182 (D. Mass. 2004) (government agency's attempts to continue a project to aid in reform of the Russian market system after discovering the fraud of federal grantee "might simply mean that USAID decided that its first priority would be to salvage some of the work to reform the Russian economy, and then deal with its miscreant grantee later"); *United States v. Incorporated Village of Island Park*, 888 F. Supp. 419, 442 (E.D.N.Y. 1995) (government continued to pay claims after learning of falsity because it was contractually bound to make the payments).

needs.'"); *United States ex rel. Prose v. Molina Healthcare of Illinois, Inc.*, 17 F.4th 733, 744 (7th Cir. 2021) (The government "may have needed time to work out a way not to prejudice Medicaid recipients who had nothing to do with this problem.").[3] Thus, the critical importance of the Government's *continued* payment on federal healthcare beneficiaries militates against its weight in the materiality analysis. *United States ex rel. Al-Sultan v. Public Warehousing Co.,* No. 1:05-cv-2968-TWT, 2017 WL 1021745, at *16-18 (N.D. Ga. Mar. 16, 2017) (internal quotations and citations omitted). Indeed, "the more dependent the government became on a fraudulent contractor, the less likely it would be to terminate the contract." *Id.* at *6. In light of the heightened public interest in the payment of healthcare claims, the Government may determine that collecting the wrongfully obtained payments later as damages is often the most prudent, and sometimes the only, way to proceed. Plainly put, a "defendant's false statement or omission that is capable of influencing the agency's action can give rise to FCA liability—regardless of whether the government pays for the claims or pursues some other course of action." United

[3] As another court has explained, "the Government does not enjoy the luxury of refusing to reimburse health care claims the moment it suspects there may be wrongdoing," and "years of investigation" cuts for not against materiality. *United States ex rel. Lutz v. Berkeley HeartLab, Inc.*, Civil Action No. 9:14-230-RMG, 2017 U.S. Dist. LEXIS 174733, at *21-23 (D.S.C. Oct. 23, 2017), *aff'd United States v. Mallory*, 988 F.3d 730 (4th Cir. 2021).

States Statement of Interest, *Petratos et al v. Genentech, Inc. et al*, 2:11-cv-03691, ECF No. 35-1 (D.N.J. Oct. 07, 2013), at 6-7.[4]

Materiality is shown by establishing that the underlying violation has the "natural tendency to influence, or be capable of influencing, the payment of money" by the Government. 31 U.S.C. § 3729(b)(4). "Under any understanding of the concept, materiality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'" *Escobar*, 579 U.S. at 193. Materiality for FCA purposes means "either (1) a reasonable person would likely attach importance to it or (2) the defendant knew or should have known that the government would attach importance to it." *United States ex rel. Miller v. Weston Educ., Inc*, 840

[4] The United States has filed numerous statements of interest explaining that "even where the government has actual knowledge of the defendant's wrongful conduct and continues to pay claims, such action does not necessarily undermine a materiality finding because there are many good reasons, including important public health and safety considerations, why the government might continue to pay claims in such circumstances." *Escobar I*, Case No. 14-1423, Brief of the United States as Amicus Curiae at 24 (1st Cir. Aug. 22, 2016) (citing *Harrison II*). *See, e.g.*, *U.S. ex rel. Miller and Sillman v. Weston Educational*, Case No. 14-1760, Brief of the United States as Amicus Curiae at 24 (8th Cir. Sept. 14, 2016) (same); *U.S. ex rel. Bibby and Donnelly v. Mortgage Investors Corp.,* Case No. 19-12736, Brief of the United States as Amicus Curiae at 22 (11th Cir. Sept. 24, 2019); (same); *U.S. ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, Case No. 17-5826, Brief of the United States as Amicus Curiae at 3 (6th Cir. Oct. 18, 2017) (same); *U.S. ex rel. A1 Procurement, LLC v. Thermcor, Inc.*, Case No. 15-cv-0015 RBS-DEM, ECF No. 188, Statement of Interest at 11 (E.D. Va. Apr. 26, 2017) (same); *U.S. ex rel. Beauchamp v. Academi Training Center, LLC*, Case No. 11-cv-00371 TSE-MSN, ECF No. 204, Statement of Interest at 6 (E.D. Va. Oct. 28, 2016) (same); *U.S. ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, Case No. 12-cv-00764, ECF No. 107, Statement of Interest at 7 (M.D. Tenn. May 3, 2017) (same).

F.3d 494, 503 (8th Cir. 2016), quoting *Escobar*, 579 U.S. 176, 193. The relator's ultimate burden is not to show that the Government would have rejected every claim after it had knowledge of the allegations (or evidence) in this matter, but to demonstrate that compliance with the underlying statutes and regulations at issue were important to Government payment decisions.

Because the government's awareness of fraud is not dispositive, the jury should be permitted to weigh the importance of the requirements at issue against the reasons why the government may continue to pay federal healthcare claims while FCA cases are litigated. *Druding*, 81 F.4th at 376 (3d Cir. 2023) ("jury must be permitted to weigh the government's inaction alongside *Escobar*'s other factors."). This is consistent with the purpose of the FCA itself, which contemplates that FCA matters, both intervened and declined, will proceed into litigation. 31 U.S.C. §3730(b)(4). If FCA proceedings resulted in preemptive actions to cut-off healthcare beneficiaries from care, or stop contracting with a defendant, in order to demonstrate materiality, such a requirement would result in a massive disincentive to use the statute, contrary to Congress's purposes. TAF Coalition urges the Court to read the statute in a manner consistent with its purpose, which is to effectively detect and deter fraud upon the federal Treasury through a "coordinated effort of both the Government and the citizenry" S.Rep. No. 99-345, 2-3 (1986).

CONCLUSION

For the reasons stated above, the district court's holdings on materiality should be reversed.

Respectfully Submitted,

November 8, 2023

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CERTIFICATE OF COMPLIANCE
(Fed. R. App. P. 32(a); Local Appellate Rule 113.3)

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because this brief contains 3.069 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5), and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2019 word processing program, a 14-point font size, and the Times New Roman type style.

The text of this electronic version of the brief is the same as the text of the paper copies of the brief. A virus check using the software Symantec Endpoint Protection Small Business Edition has been run on the electronic version and no virus was detected.

The undersigned is a member of the bar of this Court.

Respectfully submitted,
Dated: November 8, 2023
By: */s/Jacklyn DeMar*

CERTIFICATE OF SERVICE

I, Jacklyn N. DeMar, certify that November 8, 2023, I caused a true and correct copy of the Brief of *Amicus Curiae* The Anti-Fraud Coalition to be served via the Court's ECF Filing System Notification and that service will be accomplished by the CM/ECF system. I further certify that upon filing, I will send ten (ten) paper copies of the foregoing to the Clerk of the Court

Dated: November 8, 2023

By: *s/ Jacklyn N. DeMar*