Case No.18-10500-AA

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

ANGELA RUCKH, Relator,
Plaintiff-Appellant,

v.

SALUS REHABILITATION, LLC,
d.b.a. La Vie Rehab, *et al.*,
Defendants-Appellees.

On Appeal from the United States District Court for the Middle District of Florida (Case No. 8:11-CV-01303-SDM-TBM)

BRIEF OF AMICUS CURIAE TAXPAYERS AGAINST FRAUD EDUCATION FUND IN SUPPORT OF APPELLANT ANGELA RUCKH AND IN SUPPORT OF REVERSAL

Colette G. Matzzie
PHILLIPS & COHEN LLP
2000 Massachusetts Ave., NW
Washington, DC 20036
Telephone: (202) 833-4567

David Chizewer
GOLDBERG KOHN LTD
55 East Monroe, Suite 3300
Chicago, IL 60603
Telephone: (312) 201-4000

Jacklyn DeMar
TAXPAYERS AGAINST FRAUD
EDUCATION FUND
1220 19th Street, N.W., Suite 501
Washington, DC 20036
Telephone: (202) 296-4826

Jennifer Verkamp
MORGAN VERKAMP LLC
35 E. 7th St., Suite 600
Cincinnati, OH 45202
Telephone: (513) 651-4400

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to FRAP 26.1 and 11th Circuit Rules 26.1, 28-1(b), and 29-1, Amicus Curiae Taxpayers Against Fraud Education Fund through the undersigned counsel of record certifies that in addition to the individuals and entities identified in Appellant's opening brief and Appellee's Certificate of Interested Parties, the following listed individuals and entities have an interest in the outcome of this case:

1. **Chizewer, David** (counsel for Amicus Curiae)
2. **DeMar, Jacklyn** (counsel for Amicus Curiae)
3. **Matzzie, Colette G.** (counsel for Amicus Curiae)
4. **Taxpayers Against Fraud Education Fund** (Amicus Curiae)

Taxpayers Against Fraud Education Fund is a non-profit entity that does not have parent corporations. No publicly held corporation owns 10 percent or more of any stake or stock in Amicus Curiae.

5. **Verkamp, Jennifer M.** (counsel for Amicus Curiae)

Respectfully submitted,

Dated: July 20, 2018

PHILLIPS & COHEN LLP

By: */s/ Colette G. Matzzie*
Colette G. Matzzie

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

Rules

To the Honorable United States Court of Appeals:

Pursuant to Rule 29 of the Federal Rules of Appellate Procedure, the Taxpayers Against Fraud Education Fund respectfully submits this brief as AMICUS CURIAE in support of Appellant-Relator Angela Ruckh ("Relator"). A Motion for Leave to File has been filed contemporaneously herewith, and this brief is subject to that Motion. The Taxpayers Against Fraud Education Fund supports Relator for the reasons set forth below.

STATEMENT OF INTEREST

Taxpayers Against Fraud Education Fund ("TAFEF") is a nonprofit, public interest organization dedicated to combating fraud against the Government and protecting public resources through public-private partnerships. TAFEF 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 False Claims Act ("FCA"), has participated in litigation as amicus curiae, and has provided testimony to Congress about ways to improve the FCA. TAFEF is supported by whistleblowers and their counsel and funded by membership dues and foundation grants. TAFEF is the 501(c)(3) arm of Taxpayers Against Fraud, which was founded in 1986. TAFEF has a strong interest in ensuring proper

interpretation and application of the FCA.[1]

TAFEF previously filed amicus briefs in *United States ex rel. Escobar v. Universal Health Services* in the First Circuit and in the Supreme Court, and on remand in the First Circuit. TAFEF files this brief to address the interpretation of the Supreme Court's decision in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016) . TAFEF has filed briefs on the interpretation of *Escobar* on remand of the case to the First Circuit, *United States ex rel. Escobar v. Universal Health Services, Inc.*, 842 F.3d 103(1st Cir. 2016) , in the Second Circuit in *United States ex rel. Bishop v. Wells Fargo & Co.*, 870 F.3d 104 (2d Cir. 2017) , and in the Ninth Circuit in *United States ex rel. Scott Rose, v. Stephens Institute*, No. 17-15111 (9th Circuit) (pending).

TAFEF's interest in this case is ensuring that the Supreme Court's broad statements in *Escobar* on materiality are not misinterpreted to impose a standard that the Court did not adopt. The district court's suggestion in this case that the Government must stop payment upon knowledge of noncompliance is contrary to the Supreme Court's decision, inconsistent with how Government payment systems function and if adopted would dramatically undermine the federal False

[1] Pursuant to Rule 29(a)(4)(E) of the Federal Rules of Appellate Procedure, *Amicus Curiae* represents that no party's counsel has authored this brief in whole or in part, no party or party's counsel has contributed money that was intended to fund preparing or submitting the brief; and no person other than *Amicus Curiae*, its members, or its counsel has contributed money that was intended to fund preparing or submitting the brief.

Claims Act.

STATEMENT OF ISSUES

Amicus hereby adopts by reference the Statement of the Issues set forth at page 3 of the Brief for Appellant Angela Ruckh, filed July 13, 2018.

SUMMARY OF THE ARGUMENT

The Supreme Court's decision in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016) endorsed well-understood standards of materiality grounded in the common law. *Id.* at 2003. Although the Supreme Court, in dicta, identified several factors that may be considered in evaluating materiality, lower courts have both misconstrued and wrongly placed emphasis on the Supreme Court's observation that Government payment with actual knowledge of noncompliance is evidence to consider when weighing whether the noncompliance is material. In this brief, TAFEF demonstrates through examples from litigated and settled False Claims Act cases that the Government frequently pays claims while on notice of actual noncompliance and payment of those claims is not evidence that the noncompliance did not meet settled standards of materiality that were not altered by *Escobar*. Rather, the Government has many reasons to continue paying in the face of noncompliance and to later recover those wrongfully induced payments through damages under the False Claims Act.

ARGUMENT

In its decision in *Universal Health Services, Inc. v. United States ex rel. Escobar,* 136 S. Ct. 1989 (2016), the United States Supreme Court "clarif[ied] some of the circumstances in which the False Claims Act imposes liability," *id.* at 1995, by holding that implied false certification is a valid theory of liability when the underlying misrepresentation or omission is materially misleading.[2] The Court rejected efforts to apply non-statutory limits on falsity, and explained that the statutory requirements of knowledge and materiality adequately bounded liability. *Id*. at 2002.

The Court did not change the definition of materiality that Congress enacted in the False Claims Act ("FCA"), which provides that a violation is material if it has "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)) . Indeed, the Court specifically observed that the FCA's materiality requirement is no different whether using the language of the statute or the common law, because "[u]nder any understanding of the concept, materiality 'look[s] to the effect on the likely or

[2] *Id*. at 1999. The Court stated: "we hold that the implied certification theory can be a basis for liability, at least where two conditions are satisfied: first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Id.* at 2001.

actual behavior of the recipient of the alleged misrepresentation.'" *Id.* (quoting 26 R. Lord, Williston on Contracts § 69:12, p. 549 (4th ed. 2003)). Rather, the Court clarified "how that materiality requirement should be enforced." *Id.* at 2002.

In so doing, the Supreme Court made clear that materiality can be established from the perspective of a "reasonable person" or the particular defendant. Specifically, a matter is material under the FCA if: (1) a reasonable person would attach importance to it in determining his choice of action; or (2) if the defendant knew or had reason to know that the recipient of the representation would attach importance to it in determining his choice of action even if a reasonable person would not. *Id*. at 2003 (citing Restatement (Second) of Torts §538, at 80). The Supreme Court then noted a number of non-dispositive factors relevant to the materiality determination. *Id.* at 2003-04. These factors included consideration of the underlying statutory, regulatory or contractual system, and whether the compliance was "central" or imperative" to the items or services provided or "minor or insubstantial." *Id.* at 2001-04.

However, like the district court below, several post-*Escobar* decisions have emphasized the Court's statement relating to one factor above others -- that "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. *See, e.g., United States ex rel. Ruckh v. Salus Rehab., LLC*, 304 F. Supp. 3d 1258, 1263-68 (M.D. Fla. 2018); *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1034 (D.C. Cir. 2017); *United States ex rel. Schimelpfenig v. Dr. Reddy's Labs., Ltd.*, No. 11-4607, 2017 WL 1133956, *6-7 (E.D. Pa. Mar. 27, 2017). In the case below, the district court interpreted *Escobar* as requiring a relator or the Government to prove that the Government would have refused to pay if it had known the facts. 304 F. Supp. 3d at 1269-70 (observing that if the Government continued to pay after being on notice of noncompliance it would face the "insurmountable burden of proving that the government would not do exactly what history demonstrates the government in fact did"). The district court's standard – that the Government would have refused to pay -- is not the standard *Escobar* adopted. Nor is it the standard Congress adopted when it amended the FCA in 2009 to include a definition of materiality. *See* Fraud Enforcement and Recovery Act of 2009, S.Rep. No. 111-10, at 12, n.6 (2009) (citing *Neder v. United States*, 527 U.S. 1, 16 (1999)).

At most, the Court in *Escobar* observed that Government payment after actual notice of noncompliance was strong evidence relevant to materiality, but was not dispositive of materiality. While the factors that the Court listed in dicta may be the types of factors to consider when assessing materiality, as the Court itself explained, the list was not exhaustive and the materiality determination

requires an analysis based on the facts of each case. 136 S. Ct. at 2001 (no "single fact or occurrence [is] always determinative") (quoting *Matrixx Initiatives, Inc. v. Siracusaro,* 563 U.S. 27, 39 (2011)); *see also United States ex rel. Escobar v. Universal Health Services, Inc*., 842 F.3d 103, 109 (1st Cir. 2016) (describing inquiry as "holistic"); *United States ex rel. Prather v. Brookdale Senior Living Communities, Inc*., 892 F.3d 822, 831 (6th Cir. 2018) (same). Other factors, not mentioned in *Escobar*, may be highly relevant to a materiality determination, such as the defendant's effort to cover up or lie about whether it complied with important requirements, which may indicate that the defendant was aware the noncompliance was material to payment. *See, e.g., United States v. Triple Canopy, Inc.*, 857 F.3d 174, 178-79 (4th Cir. 2017) (noting prior observation that defendant's own actions in covering up the noncompliance supported materiality and that that conclusion aligned with *Escobar*). An emphasis on this factor above others is a return to the type of rigid non- statutory requirements the *Escobar* Court rejected.

More fundamentally, however, the typical reasons for payment or nonpayment in Government programs was not before the Supreme Court in *Escobar* and the Court's statement about the type of evidence that is relevant to materiality was dicta. The question presented to the Court in *Escobar* did not involve a challenge to the materiality standard, but rather addressed falsity --

whether "the 'implied certification' theory of legal falsity under the FCA…. is viable" and, if it is, whether a claim can be false if the violated requirement does not expressly state that it is a condition of payment. *See* Petition for Writ of Certiorari, *Universal Health Services, Inc. v. United States et al*., No. 15-7, at ii (June 30, 2015). Moreover, *Escobar* was a case at the pleading stage, when no evidence had yet been presented. Thus, the Court's observation about what weight to give hypothetical evidence, devoid of any context, much less a developed factual record on the issue of whether and why the Government historically stops (or does not stop) payment, cannot provide a reliable guide for lower courts in assessing the weight of evidence before them.

The Government's failure to deny payment in the face of noncompliance will often be a poor indicator of materiality. The Government may have many reasons to continue paying even upon learning of possible wrongdoing, including that stopping the payment of claims could potentially jeopardize the public health, safety and welfare, or interfere with contractual rights. *See United States ex rel. Am. Sys. Consulting, Inc., 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. 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). Indeed, "the more dependent the government became on a fraudulent contractor, the less likely it would be to terminate the contract." *United States ex rel. Al-Sultan v. Public Warehousing Co.*, No. 1:05-cv-2968-TWT, 2017 WL 1021745, *6 (N.D. Ga. March 16, 2017) (internal quotations and citations omitted). That continued payment may be a poor indicator is particularly true in the healthcare context where the system is not set up to allow stopped payment. Rather, the Government has long followed a "pay and chase" model in the delivery of healthcare services, which ensures that patients do not experience delay in

receiving medical services and providers are not delayed payment.[3]

The Government's continued payment of claims often has no bearing on whether a reasonable government actor would have considered the requirement important to the Government's payment decision or whether the defendant knew or had reason to know that the Government's payment decision would have been affected by it, let alone present strong evidence that the noncompliance was not material. In fact, many FCA cases feature misrepresentations that clearly satisfy *Escobar's* materiality standard – in that they involve misrepresentations that a reasonable government actor would find important to the government's payment decision or that the defendant knows the government actor would find important to the government's payment decision – but also feature payment by the Government even after the alleged misrepresentations have been revealed. This type of continued payment occurs routinely, and for any number of reasons that signal nothing about the significance of the noncompliance to the Government's payment decision or the defendant's understanding of the significance of the nonconformance to the Government's payment decision. The Supreme Court's observation that continued payment is relevant is not, and could not be, a directive

[3]*See* Preventing Health Care Fraud: New Tools and Approaches to Combat Old Challenges, Hearing Bef. the Sen. Comm. on Finance, 112th Cong,(2011) (statement of Dr. Peter Budetti, Deputy Admin. and Dir. of CMS Center for Program Integrity), http://www.finance.senate.gov/imo/media/doc/030211PB71524.pdf.

to the Government regarding how the Government *should* act if it cares about a violation. Rather, the Supreme Court's observation assumes that the Government *does* stop paying if it is concerned. That assumption is factually incorrect.

To illustrate this point, this brief presents FCA cases that were litigated or settled and each of which featured overwhelming evidence or credible allegations of misrepresentations that would have disqualified a contractor from receiving full payment from the Government. Each of these cases ultimately led to FCA judgments, criminal fines, and/or enormous settlements. Yet in each of these cases, even after receiving the compelling evidence of the misrepresentation, the Government continued to pay the contractor on transactions tainted by the egregious conduct at issue and that continued payment did not demonstrate that the violation was not material under the well-understood meaning of that standard. *See, e.g.*, *United States v. Rogan*, 517 F.3d 449, 452 (7th Cir. 2008) (rejecting as "not a component of materiality" the argument that the Government must present testimony that the Government was sure to enforce a statute); *see also* Fraud Enforcement and Recovery Act of 2009, S. Rep. No. 111-10, at 12, n.6 (2009) (citing *Rogan* with approval). The cases discussed below are just a few of many real-world examples of why the Government's continued payment in a given case is not necessarily evidence, let alone strong evidence, that the noncompliance was not material as that concept has long been understood. Rather, they reflect that

even in the face of egregious conduct the Government may continue to pay claims for any number of legitimate reasons, including to aid beneficiaries, to provide needed goods for critical government services, or because government systems make it impossible to immediately cut off payment. Each of these examples of continued payment in the face of noncompliance are not inconsistent with the determination that the noncompliance was material, but rather, fully consistent with the FCA and its purposes.

CONTINUED GOVERNMENT PAYMENT MAY HAVE NO BEARING ON WHETHER NONCOMPLAINCE WAS MATERIAL

The case examples below illustrate the types of situations in which the Government, despite awareness of significant noncompliance with important statutory or contractual requirements, did not cease payment of affected claims. That the Government did not cease payment was not inconsistent with the position that the noncompliance was material – i.e., that the noncompliance would have a natural tendency to affect decision-making had the Government been told the truth at the time the claims were submitted. Once a contract or other program arrangement is underway, ceasing the payment of claims can be detrimental to the public interest, and collecting the wrongfully induced payments later as damages is often the best, and sometimes the only, way to proceed.[4] That the Government was

[4] This is precisely the framework the FCA provides. The Government is free to choose between

[Footnote Text Cont'd on Next Page]

put in the situation by the defendant's conduct should not immunize the defendant from liability. Nothing is *Escobar* requires that result.

Although in a number of the cases discussed below the Government intervened, intervention is also not a component of materiality. The Government had not intervened in the *Escobar* case and the Supreme Court did not identify that as a factor relevant to materiality. As the Sixth Circuit recently observed, if the Government's choice not to intervene affected the relator's ability to plead materiality, the purposes of the Act would be undermined. *Prather*, 892 F.3d at 836.

1. *United States ex rel. Tyson v. Amerigroup, No. 02 C 6074 (N.D. Ill.)*

In many FCA cases involving violations of important statutory, regulatory, or contractual requirements intended to ensure the provision of Government funded healthcare to individuals who are dependent upon it, the Government continues to fund the care, while pursuing enforcement against those who violate the law. *United States ex rel. Tyson v. Amerigroup*, No. 02 C 6074 (N.D. Ill.) was such a case.

On August 6, 2002, Cleveland Tyson sued his former employer,

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administrative remedies or the tools under the FCA. *See United States ex rel. Onnen v. Sioux Falls Indep. Sch. Dist. No. 49-5*, 688 F.3d 410, 415 (8th Cir. 2012) (agreeing with the Government that "Congress intended to allow the government to choose among a variety of remedies, both statutory and administrative, to combat fraud.").

Amerigroup, alleging that it was discouraging pregnant women and other people with expensive health needs from joining Amerigroup's HMO plan for Illinois Medicaid recipients. Illinois paid Amerigroup a set, capitated amount per member per month, varying only by the member's age and gender, and calculated based on actuarial tables of a representative Medicaid population. Federal law and Amerigroup's contract with the state prohibited Amerigroup from taking the health status of prospective members into account when deciding whom it should solicit and enroll. By engaging in the discrimination alleged, Amerigroup asked for and received inflated capitation payments intended to compensate Amerigroup for a representative and more expensive Medicaid population than the one Amerigroup enrolled.

The federal and state governments investigated the case and, on June 13, 2003, declined to intervene. Mr. Tyson, with his private counsel, pursued the case on his own as the FCA contemplates. On August 12, 2005, after being presented with overwhelming evidence of Amerigroup's illegal discrimination, the United States reconsidered its earlier position and moved to intervene. The United States attached to its motion emails detailing how Amerigroup avoided signing up pregnant women and substance abusers, and the financial motivation behind it. *See* United States' Memorandum of Law in Support of Its Motion to Intervene, *United States ex rel. Tyson v. Amerigroup Illinois, Inc.*, No. 1:02-cv-

06074, (N.D. Ill. Aug. 11, 2005).[5] Yet, even after the court granted the motion, and the United States became party to the case, the Governments did not fire Amerigroup, did not stop paying the claims for inflated capitation payments that Amerigroup continued to submit, and did not invoke any of the myriad of administrative remedies at the governments' disposal. Amerigroup argued these points to the court in opposing the plaintiffs' motion for summary judgment, and to the jury as a reason why its conduct was permissible. *United States ex rel. Tyson v. Amerigroup Illinois, Inc*., No. 02 C 6074, 2006 WL 4586279, at *7-8 (N.D. Ill. Sept. 13, 2006). Ultimately, the jury found Amerigroup liable under the FCA and, on March 21, 2007, the trial court denied all of Amerigroup's post-trial motions and entered a judgment, including treble damages and penalties, for $334 million. *United States ex rel. Tyson v. Amerigroup Illinois, Inc*., 488 F. Supp. 2d 719 (N.D. Ill. 2007). In this not uncommon scenario, where the Government relied on the FCA case as the sole enforcement mechanism against a bad actor, it is difficult to understand how its failure to take other action, including the failure to suspend payment, constitutes "strong evidence" that it did not consider the violation important.

[5] The State of Illinois also reconsidered its declination and joined the case a few months prior to the United States.

2. *United States ex rel. Kennedy v. Novo Nordisk et al.*, No. 13-cv-01529 (D.D.C.)

The Government imposes many critical safety requirements on entities that provide drugs to the American public, including requirements that drug manufacturers notify physicians of risks associated with the drugs, but may continue paying for the drug even while pursuing enforcement actions against entities that violate those requirements. A series of cases against Novo Nordisk are examples of how the Government's continued payment for a drug does not indicate that the Government considers noncompliance with safety requirements unimportant.

On October 15, 2000, the relator in *United States ex rel. Kennedy v. Novo A/S* filed her complaint against the drug manufacturer where she was formerly employed, alleging that Novo Nordisk and its affiliates failed to comply with the Risk Evaluation and Mitigation Strategy (REMS) mandated by the Food and Drug Administration (FDA) for its Type II diabetes medication, Victoza. Six additional *qui tam* actions followed alleging violations of the FCA for off-label and dangerous promotion of Victoza by Novo Nordisk. At the time of Victoza's approval in 2010, the FDA required a REMS to mitigate the potential risk in humans of a rare form of cancer called Medullary Thyroid Carcinoma (MTC) associated with the drug. The REMS required Novo Nordisk to provide information regarding Victoza's potential risk of MTC to physicians. The relator

alleged that Novo Nordisk sales representatives falsely promoted Victoza for off-label uses and gave information to physicians that created the false or misleading impression that the Victoza REMS-required message was erroneous, irrelevant, or unimportant. The relator also alleged that Novo Nordisk purposefully hid patient safety information from doctors, and that a survey in 2011 showed that half of primary care doctors polled were unaware of the potential risk of MTC associated with the drug. The FDA subsequently required a modification to the REMS to increase awareness of the potential risk. The relator alleged that Novo Nordisk, rather than appropriately implementing the modification, instructed its sales force to provide statements to doctors that obscured the risk information and failed to comply with the REMS modification.

The seven complaints included a slew of specific detailed allegations about who was involved in the alleged fraud, how it worked, and dates that individual fraudulent claims were submitted. Additionally, several of the complaints attached evidence in the form of emails and marketing materials showing that Novo Nordisk was knowingly violating the REMS requirements and paying illegal kickbacks to persuade physicians to prescribe Victoza for off-label uses. However, even after being apprised of the relators' allegations as early as 2010 when the first complaint was filed, the Government continued to pay for the drug, and in fact, continues to pay for the drug. The Government intervened and the parties entered

into a settlement agreement in which Novo Nordisk agreed to pay $58 million to resolve claims stemming from six different cases involving allegations against Novo Nordisk for improper marketing of Victoza. *See* Novo Nordisk Agrees to pay $58 Million for Failure to Comply with FDA-Mandated Risk Program (Sept. 5, 2017), *reprinted a*t https://www.justice.gov/opa/pr/novo-nordisk-agrees-pay-58-million-failure-comply-fda-mandated-risk-program.[6]

3. *United States ex rel. Delaney v. eClinicalWorks* No. 2:15-CV-00095 (D. Vt.)

The Government imposes requirements on software vendors to ensure the accuracy of those records used in a variety of contexts. Continued payment of the claims submitted by users of the software while enforcing requirements against software vendors does not reflect that the Government considers the requirements unimportant, as a case against eClinicalWorks illustrates.

In 2017, the Department of Justice intervened in a False Claims Act *qui tam* case brought against eClinicalWorks (ECW), a vendor of electronic health records software, and some of its employees for misrepresenting the capability of its software and paying kickbacks to promote its product. The defendants settled the

[6] The cases are *United States ex rel. Kennedy v. Novo A/S*, No. 13-cv-01529 (D.D.C.), *United States ex rel. Dastous, v. Novo Nordisk*, No. 11-cv-01662 (D.D.C), *United States ex rel. Ferrara and Kelling v. Novo Nordisk, Inc.* No. 1:11-cv-00074 (D.D.C.), *United States ex rel. Myers v. Novo Nordisk, Inc.*, No. 11-cv-1596 (D.D.C.), *United States ex rel. Stepe v. Novo Nordisk, Inc.*, No. 13-cv-221 (D.D.C.), *United States ex rel. Doe, v. Novo Nordisk, Inc.*, No. 1:17-00791 (D.D.C.), and *United States ex rel. Smith, v. Novo Nordisk, Inc.*, No. 16-1605 (D.D.C.).

case for $155 million, including payments by the individual defendants. Despite Acting Assistant Attorney General Chad Readler emphasizing the importance of accurate health records in the Department of Justice Press release regarding the settlement, stating that "[e]very day, millions of Americans rely on the accuracy of their electronic health records to record and transmit their vital health information…[t]his resolution is a testament to our deep commitment to public health and our determination to hold accountable those whose conduct results in improper payments by the federal government," the Government did not at any time stop the incentive payments that ECW caused to be paid or take steps to remove ECW products from the market. *See* https://www.justice.gov/opa/pr/electronic-health-records-vendor-pay-155-million-settle-false-claims-act-allegations. Rather, the Government used the power of the FCA enforcement remedy to demonstrate that integrity in electronic records was critical to patient safety and to the Government's efforts to improve the care provided to beneficiaries. *See id.*

4. *United States ex rel. Brown v. Amedisys Home Health, Inc.* No. 10-cv-2323 (E.D. Pa.)

One of the most common FCA violations is the upcoding of medical services. The Government has long pursued a "pay and chase" model, paying the claims for health care services to ensure delivery of care and pursuing wrongful payments later. *See supra*, n. 3. A case against Amedisys illustrates that this

model does not reflect that the Government does not consider upcoding unimportant because it enforces the law after payment is made.

On January 22, 2010, April Brown filed an FCA case against Amedisys Home Health Inc. ("Amedisys"). Shortly thereafter, and in rapid succession, CAF Partners filed an action on May 18, 2010 alleging facts demonstrating fraud relating to the upcoding of payment data, the manipulation of therapy visits to increase profits *vis a vis* "clinical tracks" designed to place patients on care plans to achieve therapy thresholds regardless of actual patient needs, and the fraudulent recertification of non-qualifying patients.

Until January 2008, Medicare paid a flat rate of $2,200 for up to nine (9) home therapy visits. When a tenth visit was made, an additional payment of $2,200 was issued to the provider. As a result, prior to January 2008, the number of home health visits billed for by Amedisys routinely clustered around 10-13. In 2008, CMS implemented new rules replacing the single therapy threshold with a three-tiered system of bonus payments at 6, 14, and 20 visits. When the new system was implemented, statistical analysis revealed that the cluster pattern shifted to correlate with the new thresholds.

Notably, also in the spring of 2010, the Wall Street Journal published an article stating that Amedisys' therapy visit reimbursement claims "cluster[ed]" around the reimbursement trigger points both before and after the 2008 revisions to

the payment rules. Almost immediately following the publishing of the Wall Street Journal article, in May 2010 the Senate Finance Committee requested documents from each home health care company identified in the Wall Street Journal article. Subsequently, in October 2011, the Committee released its report asserting that home health care companies, including Amedisys, had "gamed" the Medicare reimbursement system for therapy visits to the homes of eligible Medicare beneficiaries.

Following a nearly four and a half year investigation, on April 23, 2014, the Government entered into a settlement agreement with Amedisys, which agreed to pay the Government $150 million for, *inter alia*, "improperly billing and failing to refund overpayments for Medicare home health care services that Amedisys: (a) provided to non-homebound patients, (b) provided to patients lacking a need for skilled nursing and/or skilled therapy services, (c) provided to patients without regard to medical necessity, and (d) overbilled by upcoding patients' diagnoses, during the period from January 1, 2008 through December 31, 2010."[7]

Although enough facts were presented to the Government to show that the fraudulent conduct was taking place during the pendency of the case, the Government continued to make payments to Amedisys on the tainted claims. As

[7] Civil Settlement Agreement, p. 4, https://www.kenneymccaggerty.com/pdf/Amedisys/2014.04.22%Agreement.pdf.

in many cases, the Government's election to recover the funds through an FCA action rather than cutting off payment did not suggest that the violations were not important to the Government.

5. *United States ex rel. Hutcheson v. Blackstone Medical, Inc., et al.* No. 06-1171 (D. Mass)

The Government prohibits kickbacks to influence the recommendation or referral of government funded healthcare services. 42 U.S.C. § 1320a-7b(b). As a case against Blackstone Medical, Inc., illustrates, the Government's continued payment of claims for the underlying medical services does not indicate that it considers violation of this statute, for which there are criminal penalties, unimportant or irrelevant to its payment of claims.

Ms. Hutcheson filed an FCA suit in September 2006 against her former employer Blackstone Medical, a manufacturer of spine hardware, alleging that it violated the Anti-Kickback Statute by paying physicians across the country to use Blackstone hardware in spine surgeries, primarily by recruiting them as sham paid consultants. In addition, Ms. Hutcheson alleged that Blackstone offered many other incentives to physicians to use its products, such as royalties, unrestricted grants, cash payments, and lavish entertainment.

Ms. Hutcheson's suit uncovered a pernicious kickback scheme in which Blackstone pressured its sales force to do whatever it took to make a doctor happy enough to schedule more surgeries with its products. The Department of Justice

actively investigated the matter, including by opening criminal investigations around the country, but did not initially intervene when the district court unsealed the matter in September 2008. The case proceeded into litigation in a declined posture while the Government continued its investigation.

The district court dismissed the action under Rule 12(b)(6) on the grounds that the complaint failed to adequately allege that the claims were "false," which was overturned on appeal. *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377 (1st Cir.), *cert. denied*, 565 U.S. 1079 (2011). The matter was remanded to the district court. Although the Government declined to intervene, the Government worked with the Relator and Defendant to settle the matter in November 2012 in the amount of $30,000,000. *http://www.justice.gov/opa/pr/orthofix-subsidiary-blackstone-medical-pays-us-30-million-settle-false-claims-act-allegations*.

In the more than six years the matter was pending, the Government continued to pay the physicians who received kickbacks from Blackstone, and continued to pay the hospitals where the doctors performed the surgeries, and payment continued to implicated providers over the entire span of the litigation. As is generally the case with all FCA settlements, the amounts of claims paid for services tainted by kickbacks was recovered by the United States through FCA damages.

6. *United States ex rel. Gonter v. Hunt Valve, et al.*
No. 01-cv-634 (N.D. Ohio)

The Government's payment for materials necessary for the military, even if the materials are noncompliant, does not reflect that the Government considers noncompliance unimportant. Often, these materials are vital to troops in combat, and even if there are overpayments by the Government, or noncompliance with the underlying contractual or regulatory requirements, the Government must continue to make payments to the contractor. The case against Hunt Valve illustrates this reality.

Tina and Bill Gonter worked for Hunt Valve Company, an Ohio-based manufacturer of valves used in nuclear submarines, Navy ships, and containers for radioactive waste, and a subcontractor for the ship-building companies, General Dynamics and Northrop Grumman. As former Navy employees and quality personnel, they quickly discovered that Hunt was violating core quality requirements. They filed a *qui tam* suit in 2001, alleging that Hunt Valve, and the prime contractors, had violated material contractual requirements by failing to perform required testing and inspection, and then covering their tracks with fabricated paperwork and undocumented and potentially dangerous repairs to valve parts. The complaint alleged that these valves were falsely certified to be conforming to the contract and were then put into critical areas of the propulsion system on United States submarines.

Ms. Gonter wore a wire for the Defense Department for several months, collecting powerful evidence of fraud against the defendants as part of the Government's investigation. As one of the results of those efforts, the Department of Defense Criminal Investigative Service ("DCIS") executed a search warrant on Hunt Valve and two executives went to federal prison for fraud. *See* https://media.defense.gov/2005/Jun/02/2001711435/-1/-1/1/Aldrich_060206.pdf. In addition, hundreds of valves were inspected for safety, and, in some cases, repaired, and the Navy changed the way it supervises manufacturers like Hunt. The Government ultimately settled with Hunt Valve as part of a settlement which involved a complete restructuring of the company. The Government declined to intervene against the prime contractors, but was involved in a court-moderated mediation with those defendants which resulted in settlement of more than $13 million in 2006. *See* The False Claims Correction Act (S. 2041): Strengthening the Government's Most Effective Tool Against Fraud for the 21st Century, Hearing Before the Senate Committee on the Judiciary, 110th Cong. 167 (description of case history); *see also* The False Claims Act Correction Act of 2008, S.Rep. 110-507, at 10-11 (2008) (discussing the *Gonter* case).

Notwithstanding the obvious materiality of the allegations at issue, the United States did not stop payment to any of these contractors during the duration of its investigation, or the litigation. Moreover, the United States continues to

contract with each of these entities. As is generally true of most cases involving military defense, the United States does not have the luxury of halting operations, either in production or in theatre, in order to send messages on materiality to its contractors. Rather, the FCA is one of its primary tools for recovering the losses from false or fraudulent claims. *Avco Corp. v. United States Dep't of Justice*, 884 F.2d 621, 622 (D.C. Cir. 1989), *citing* S. Rep. No. 99-345, at 1, 2 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266.

CONCLUSION

For the reasons set forth herein, and in the Brief for Appellant-Relator, the district court's erroneous interpretation of the Supreme Court's decision in *Escobar* on the materiality standard should be rejected.

Respectfully submitted,

Dated: July 20, 2018

PHILLIPS & COHEN LLP

By: */s/ Colette G. Matzzie*
Colette G. Matzzie

PHILLIPS & COHEN LLP
2000 Massachusetts Ave., NW
Washington, DC 20036
Telephone: (202) 833-4567
Facsimile: (202) 833-1815
Email: cmatzzie@phillipsandcohen.com

Jacklyn DeMar
TAXPAYERS AGAINST FRAUD EDUCATION FUND
1220 19th Street, N.W., Suite 501
Washington, DC 20036
Telephone: (202) 296-4826

David Chizewer
GOLDBERG KOHN LTD
55 East Monroe, Suite 3300
Chicago, IL 60603
Telephone: (312) 201-4000

Jennifer Verkamp
MORGAN VERKAMP LLC
35 E. 7th St., Suite 600
Cincinnati, OH 45202
Telephone: (513) 651-4400

Counsel for Amicus Curiae Taxpayers Against Fraud Education Fund

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 5521 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

2. 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 2010 in Times New Roman 14-point typeface.

Respectfully submitted,

Dated: July 20, 2018

PHILLIPS & COHEN, LLP

By: */s/ Colette G. Matzzie*
Colette G. Matzzie

Phillips & Cohen LLP
2000 Massachusetts Ave., NW
Washington, DC 20036
Telephone: (202) 833-4567
Facsimile: (202) 833-1815
Email: cmatzzie@phillipsandcohen.com

Counsel for Amicus Curiae Taxpayers Against Fraud Education Fund

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on July 20, 2018, I electronically filed the foregoing Brief of Amicus Curiae Taxpayers Against Fraud Education Fund in Support of Appellant Angela Ruckh to be served via the Court's ECF Filing System Notification. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system. I further certify that upon filing, I will send seven (7) paper copies of the foregoing to Clerk of the Court using one of the methods outlined in Federal Rule of Appellate Procedure 25(a)(2)(B) and Eleventh Circuit Rule 25-3(a).

By: */s/ Colette G. Matzzie*
Colette G. Matzzie