No. 17-_____

In the Supreme Court of the United States

UNITED STATES OF AMERICA,
EX REL., JOSHUA HARMAN,

Petitioner,

–v–

TRINITY INDUSTRIES INC. &
TRINITY HIGHWAY PRODUCTS LLC.,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether continued payment by the Government is a factor that may be considered by the jury in an FCA claim, or whether it is a determinative factor that would cause the claim to be immaterial as a matter of law.

2. Whether the "Government" for the purpose of analyzing a payment decision under *Escobar*'s materiality standard is the state or federal government, when the false statement is made to the state, the state is the decision maker and makes the actual payment, but both federal and state funds are used for payment.

3. Whether the materiality standard laid out in *Universal Health Servs., Inc. v. United States* ("*Escobar*")[1] for implied certification cases also applies to express certification cases, despite the fact that, by their very nature, mandatory express certifications of compliance are material to a purchase decision.

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[1] 136 S.Ct. 1989, 2003-04, 195 L.Ed.2d 348 (2016).

PARTIES TO THE PETITION

Pursuant to Supreme Court Rule 14.1(b), the following list identifies all of the parties appearing here and before the United States Court of Appeals for the Fifth Circuit. The petitioner here, and appellee below, is Joshua Harman. The respondents here, and appellants below, are Trinity Industries, Inc. and Trinity Highway Products, LLC.

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The opinion of the court of appeals (App.1a-51a) is published at 872 F.3d 645. The district court's opinion (App.58a-109a) is published at 166 F.Supp.3d 737.

JURISDICTIONAL STATEMENT

The judgment of the court of appeals was entered on September 29, 2017. A timely petition for rehearing *en banc* was filed on October 27, 2017. The order denying the petition for rehearing was entered on November 14, 2017. App.110a-111a. The jurisdiction of this Court to review the court of appeal's judgment is conferred by 28 U.S.C. § 1254(1).

STATUTES INVOLVED

The relevant portions of the False Claims Act (FCA or Act), 31 U.S.C. § 3729 *et seq.*, are reproduced in the appendix to this brief. App., *infra*, 112a-127a.

INTRODUCTION [2]

This case presents three important issues—two of which are the subject of circuit splits—and all pertaining to the materiality standard that should be applied in False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.*, cases under this Court's decision in *Universal Health Servs., Inc. v. United State* ("*Escobar*")[3].

Escobar set out an evidence-based materiality standard requiring consideration of various factors, including whether the government has continued to pay and whether the false statements relate to an issue so central to the government program that the government would refuse to pay had it known of the false statement.

This petition uniquely presents the opportunity to clarify the materiality standard in a case that went to trial, where extensive evidence was presented related to the government's payment decision, where the jury returned a verdict in favor of Petitioner, and where, on appeal, the jury verdict was reversed because the Fifth Circuit found that, as a matter of law, Respondents' false statements could not be material because, in the court's reasoning, "[Respondents] alleged misstatements were not material to [the government's] payment decisions." App.47a.

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[2] The Record on Appeal in the Court of Appeals is cited as "ROA ___." The appendix to this petition is cited as "App.__."

[3] 136 S.Ct. 1989, 2003-04, 195 L.Ed.2d 348 (2016).

The circuits need clarity on these issues as demonstrated by another petition raising similar questions concerning the "continuing to pay" materiality standard. *See e.g.* Petition for Certiorari filed by defendants in *United States ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890, 906 (9th Cir. 2017) (S.C. # No. 17-936).

The Fifth Circuit's decision cannot be reconciled with decisions from three other circuits where multiple factors are considered by the circuits and the government's payment decision is not determinative.

The panel's decision also raises two other questions relating to materiality under the FCA, both of which warrant review in this Court.

First, the panel's analysis rests upon the assumption that when federal funds are at issue, a federal agency is the government payer even where state agencies—not the federal agency—actually make the payment decisions and the false statements of compliance are made to the state agencies. Amendments to the FCA statute in 2009 were enacted in direct response to this Court's decision in *Allison Engine Co. v. U.S. ex rel. Sanders*, 553 U.S. 662, 668 (2008) to expand the reach of the FCA to ensure that it covered federal money doled out by state agencies under federal benefit programs. *Escobar* presented a case where the defendants violated state rules and regulations (as they did here) and the false statements were made to state agencies (as they were here) and the analysis was limited to the decisions made by state agencies. In this case, however, a federal agency's "approval letter" issued nine years after the fraud began was considered by the Fifth Circuit to negate

the fraud. App.39a-40a. The Fifth Circuit's analysis is in conflict with two other circuits and raises the question of the reach of federal agency power in a False Claims Act case involving misstatements made to a state agency.

Second, the materiality standard articulated by this Court in *Escobar* was based upon implied certification claims. Implied certifications are given by contractors when claims are submitted for payment, implicitly certifying compliance with all rules, regulations and contract terms related to that claim. Due to concerns raised about open-ended liability, fair notice and converting garden-variety breaches of contract claims into fraud claims, this Court articulated a "rigorous" materiality standard that includes consideration of the government's decision to continue payment.

Unlike implied certifications, express certification claims, including the claims at issue in this case that were made to the states, rely upon actual, affirmative (and mandatory) representations of compliance made by defendants in order to obtain payment. Fair notice, open-ended liability and concerns of converting contract claims into fraud claims are not an issue with express certification claims.

Federal courts since *Escobar* have expressed continuing uncertainty about whether the materiality standard outlined by *Escobar* applies to all causes of action brought under § 3729(a)(1)(A) or only to causes of action brought specifically on an implied false certification theory.

This Court should grant this Petition to answer important, unsettled questions about the FCA materiality standard and to resolve the conflicts among the

circuits to ensure that the claims under the FCA are handled uniformly around the country.

STATEMENT OF THE CASE

The False Claims Act and, in particular, the *qui tam* provisions of that Act were originally adopted by Congress in 1863 and strengthened in 1986 and 2009 to protect the public fisc, not only from the fraud of government contractors, but also from the complicity, inaction or temerity of federal officials who fail or refuse to take action even after the fraud is discovered.

In making the 1986 changes, Congress relied on a study that found that fully 69 percent of government officials who had direct knowledge of illegalities failed to report that information to their superiors. Senate Report 99-345, 1986 WL 31937 (1986), at 5268-70. For this reason, among others, courts have long held that a particular agency's reaction to the fraud cannot be determinative of whether fraud was committed or whether the fraud was material. They have also held that, with the exception of the Department of Justice ("DOJ"), no federal agency, by its action or inaction, can cause the dismissal of a False Claims Act case. That has now changed as a result of the Fifth Circuit's decision.

Under the applicable regulatory scheme presented here, the states are reimbursed, in part, by the federal government through the Federal Highway Administration ("FHWA") for road improvements on major highways. ROA 16853-16855. Safety devices installed

on the highways will not receive federal reimbursement unless they are certified to the states as complying with certain safety standards and that they are identical to the products already approved by the FHWA and the states. ROA 17431; App.137a, 138a. The FHWA allows the states to test safety devices on their own to ensure compliance but it also provides that service itself. ROA 13440. Here, Respondents sought and obtained certification of their guardrail end terminal, the ET-Plus, from the FHWA in 1999 and each of the 50 states' Department of Transportation ("DOT") relied upon that certification in approving the ET-Plus for installation on the highways. ROA 16855; ROA 9196-9197; ROA 9359-9361. In order to continue to sell the ET-Plus to the states, Respondents were required to expressly certify to the states that the device they were selling had been approved by the FHWA and that the dimensions of the device had not changed since it was approved. ROA 17344-17351; ROA 17650-51. Respondents did this by sending letters to the states so certifying and by attaching a Certificate of Compliance with each invoice or shipping form. App.137a, 138a, 140a, 144a; ROA 17344-7351; 17368-71; 17244-17246; 9231; 9233; 9235-9247; 9249-9258.

In 2005, Respondents decided to make changes to the dimensions in the ET-Plus and specifically chose not to disclose those changes to either the states or the FHWA. ROA 16691-16695. Nonetheless, Respondents continued to falsely certify to the states that the device had been approved by the FHWA (which it had not) and that they had made no changes and that the ET-Plus that it was selling to the states was the same as that which was approved by the FHWA in

1999. App.137a, 138a, 140a, 144a; ROA 17344-7351; 17368-71; 17244-17246; 9231; 9233; 9235-9247; 9249 -9258.

Respondents admitted at trial that their certifications were false at the time they were made to the 50 state DOTs, and admitted that if they had told the truth from 2005 through 2012 (when Respondents' fraud was discovered by Relator[4]), not a single state DOT would have purchased their device. App.133a-137a. Respondents also could not explain why a product that had previously exhibited no serious failures, began to fail after 2005, turning the guardrail into a spear that pierced cars and killed or maimed people. ROA 9314; 9323; ROA 17329; ROA 16970.

Still, Respondents have claimed they are immune as a matter of law from FCA liability because in 2014, a week before trial in this case and nine years after their fraud commenced, Respondents were able to obtain a letter from the FHWA saying the FHWA approved the ET-Plus for use on highways. App.39a.

The FHWA letter was offered into evidence at trial, read aloud to the jury by Respondents, mentioned 482 times during testimony and presentations to the jury, and was used to cross-examine every witness. ROA 16483-17990. But Respondents claimed this was not enough. After the jury returned a verdict against Respondents, Respondents appealed to the Fifth Circuit, arguing that the FHWA letter should have entitled them to judgment as a matter of law. App.13a.

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[4] Petitioner Harman, an FCA whistleblower, is also referred to as "Relator".

While Respondents' appeal was pending in the Fifth Circuit and a week after Petitioner submitted their opposition brief, this Court issued its decision in *Universal Health Servs., Inc. v. United States* ("*Escobar*")[5], which Respondents argued in their reply papers[6] was determinative on the issue of materiality.

The Fifth Circuit ultimately issued an opinion reversing the jury verdict and entering judgment in favor of Respondents based upon the materiality standard articulated in *Escobar* and the FHWA's decision to "continue payment." App.39a-40a; 50a-51a. The Fifth Circuit wrote: "As revered as is the jury in its resolution of historical fact, its determination of materiality cannot defy the contrary decision of the government, here said to be the victim[7], absent some reason to doubt the government's decision as genuine." App.51a.

But in its 42-page opinion that re-weighed the evidence submitted at trial and drew all inferences and credibility determinations in favor of Respondents, the Fifth Circuit failed to consider certain salient facts that go directly to the materiality issue.

First, the Fifth Circuit missed the fact that the FHWA <u>never made a payment decision</u>.[8] In fact, the

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[5] 136 S.Ct. 1989, 2003-04, 195 L.Ed.2d 348 (2016).

[6] Petitioner made a motion to brief the issues raised by *Escobar*, but the Fifth Circuit denied Petitioner's request.

[7] The court adopted the terminology of Respondents in calling the FHWA "the victim"; Petitioner has steadfastly maintained that the taxpayers are the actual victims.

[8] The Fifth Circuit repeatedly identified the FHWA as the entity making the payment decision: "Here, FHWA insists that the 2005

FHWA has repeatedly emphasized that the state DOTs, not the FHWA, make the payment decisions.

> States own and operate the Federal aid highway system, make the day-to-day decisions on the use of federal funding within the statutory requirements prescribed by Congress and oversee the design, construction, maintenance, and operation of the system in compliance with federal and state regulations. States decide which safety hardware to install on their roads and are responsible for maintaining such hardware. They also set the safety criteria for roadside safety hardware as members of [American Association of State Highway and Transportation Officials].

ROA 13440 (FHWA Q&A on Guardrail Safety).

The FHWA's role in the Federal Highway-Aid Program is not to "regulate any product." ROA 13439. Instead, the FHWA performs a service for state DOTs by issuing letters "stating a device is eligible for Federal aid reimbursement if it meets [certain safety] criteria." *Id.* These letters—which have been dubbed "approval letters"—are only to be issued after the full disclosure by the manufacturer of all changes to the device since the last approval. ROA 9502. There is no dispute—and even the FHWA has acknowledged—that Respondents failed to follow this mandatory procedure and never disclosed the changes made in 2005 to the ET-Plus until after 2012. ROA 9038-9121;

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changes did not affect the decision to purchase the end terminals either in the past or the future." *E.g.*, App.32a; 40a.

ROA 17635; ROA 17428; App.133a-135a. There was also no dispute that there was no approval letter in place for the modified ET-Plus between 2005 and 2014. ROA 17344-17351; ROA 17650-51; App.133a-135a. This is the reason Respondents sought such an approval letter from the FHWA after the FCA lawsuit was filed. The FHWA accommodated by providing such a letter a week before trial in 2014.[9] ROA.16618-16619.

The evidence at trial showed that, by 2014, there had been dozens of grievous injuries and deaths around the country caused by the modified ET-Plus and, after trial, sales of the ET-Plus ceased. ROA 9314; 9323; ROA 17329; ROA 16970; ROA 16920-16926; ROA 17612. Relator's expert testified in detail how the undisclosed dimensional changes made by Respondents caused the ET-Plus to lock up when impacted, causing the guardrail to bend and break, turning it into a spear. ROA 17140-17151; ROA 16498-16506; ROA 4082-4168. Evidence at trial also showed that Respondents knew that their dimensional changes compromised the ET-Plus's performance. ROA 17147-52; ROA 16959; ROA 16792-93; ROA 17643-45; ROA 17746. And crucially, by 2014, Respondents had already committed the fraud: they had falsely certified thousands of times from 2005 onward, to all 50 states, that the modified ET-Plus had an FHWA approval letter and that the device they were palming off on the state DOTs was identical to the device approved in 1999. App.138a. Respondents admitted at trial that it was not. App.133a-135a.

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[9] There were two trials in this matter. The first ended in a mistrial due to Respondents' misconduct. ROA 15791-15793. The second resulted in a verdict in favor of Petitioner. ROA 17985-86.

Second, the Fifth Circuit's materiality analysis missed other important factors going to materiality. For instance, the express certificate of compliance was mandatory: no payment would have been made by the states without it. App.133a-137a. In addition, there was overwhelming evidence presented at trial that Respondents' failure to seek approval for their 2005 modifications was intentional and that they took steps to conceal the changes which confirms Respondents' awareness that their actions were material. ROA 16691-16695; ROA 17808-09; ROA 17354; ROA 16672; ROA 16941; ROA 9214-9216.

Moreover, although Relator had obtained some evidence of internal FHWA deliberations from an earlier litigation, the FHWA refused to provide any discovery in the *qui tam* action that would explain its regulatory position. The record is undisputed, however, that the FHWA made a 180-degree turn, killing a highly critical draft letter directed to, but never sent to, Respondents, after a secret meeting between a senior FHWA official and Respondents' executives at an industry convention, and after Respondents dramatically increased their companies' contributions to members of Congress with oversight of the FHWA. ROA 9363; ROA 9365-9367; ROA.17329.

REASONS FOR GRANTING THE WRIT

I. THE FIFTH CIRCUIT'S APPROACH TO MATERIALITY DOES NOT COMPORT WITH THE PURPOSE OF THE FCA, THE STANDARD SET OUT IN *ESCOBAR*, OR WITH THE PUBLISHED DECISIONS OF THREE OTHER CIRCUITS.

A. If Congress Had Intended That Federal Agencies Be Given the Power to Derail False Claims Act Cases, Congress Would Have Written That Power into the FCA.

The *Escobar* standard for materiality, as urged by Respondents below and as applied by the Fifth Circuit, offers unfettered power to federal agencies to ignore or forgive frauds at the expense of taxpayers by the simple act of continuing to pay claims. Under this standard, federal agencies that have already ignored, missed, or even helped to perpetrate a fraud, now have an opportunity to ensure that their malfeasance or misfeasance is never punished and that the contractors with whom they work hand-in-hand, never face the consequences.

The legislative history of the FCA is replete with evidence that this "continued to pay" standard is not what was intended by the writers of the False Claims Act. In the 1986 FCA amendments, in fact, legislators were as concerned about the failures of the government bureaucracy to act against frauds as they were about contractors perpetrating frauds against the taxpayers:

> We need only review the disturbing array of examples from the past several years of fraudulent use of taxpayer dollars to realize our Government is not able—and in too many cases not willing—to adequately protect the money entrusted it by its citizens.

131 Cong. Rec. S10800-01, 1985 WL 720612, at *160-62 (Grassley).

> [Recounting calls from] potential whistle-blowers . . . who were aware of illegal practices, but were not sure what they should do with the information. They were fearful that if they went to the Government or their employers with the information, at best nothing would be done, and at worst, they would be fired.

132 Cong. Rec. H6474-02, 1986 WL 785922 (Berman).

> At a more fundamental level, some people may question whether it is right for the Government to encourage informers and to give them standing to bring suit in court on behalf of the Government. But during my years in Congress, people have told me that they have reported fraud to the proper authorities but that no one seemed interested and nothing was done. Even if the authorities are interested, they are overwhelmed by work already. Also, in many cases, the authorities will not prosecute for political reasons.

132 Cong. Rec. H6474-02, 1986 WL 785922 (Bedell).

The Congressional expansion of the whistleblower standards of the FCA in 1986 came on the heels of

reports of widespread fraud perpetuated on the government. Senate leaders noted "most fraud goes undetected due to the failure of Governmental agencies to effectively ensure accountability on the part of program recipients and Government contractors." Senate Report 99-345, 1986 WL 31937 (1986), at 5268-70.

Indeed, Congress also relied upon a U.S. Merit System Protection Board study and a GAO Report in 1986 when deciding the FCA needed strengthening. The Board's study found that 69 percent of government officials surveyed believed they had direct knowledge of illegalities but failed to report the information to their superiors, fearing that nothing would be done and that they would be the subject of reprisals. *Id.* The GAO report estimated that in the early 1980s the Defense Department alone was losing "from $1 to $10 billion" a year, with losses of "more than $1 billion just from fraudulent billing practices." S. REP. 99-345, 3, 1986 U.S.C.C.A.N. 5266, 5268. The reason cited for the continuing, pervasive fraud was "a lack of deterrence" by government employees. *Id.* The GAO concluded in its 1981 study that most fraud goes undetected and unpunished due to the failure of Governmental agencies to effectively ensure accountability on the part of program recipients and Government contractors. The study states: "For those who are caught committing fraud, the chances of being prosecuted and eventually going to jail are slim . . . The sad truth is that crime against the Government often <u>does</u> pay." S. REP. 99-345, 3, 1986 U.S.C.C.A.N. 5266, 5268 (emphasis in original).

The distrust of government bureaucracy voiced by Congress in the 1986 amendments is consistent with

the legislative history of the FCA, which was first enacted in 1863 when Abraham Lincoln "recognized both the danger of government contractor profiteering and the need for private persons to become involved in its prevention . . . [after learning of] contractors selling boxes of sawdust in place . . . of muskets, and reselling horses to the cavalry two and three times." 131 Cong. Rec. S10800-01, 1985 WL 720612, at *160; *See, e.g.*, *United States ex rel. Marcus v. Hess*, 127 F.2d 233, 236 (3d Cir. 1942) (citing historical reference noting that "a large amount of the blame" for Civil War fraud "must go to the horde of government-paid officials who, either through criminal negligence or criminal collusion, permitted or encouraged this robbing of the government treasury."), *rev'd on other grounds*, 317 U.S. 537 (1943).

Under the rule applied by the Fifth Circuit, contractors caught substituting sawdust for gunpowder today would be exempt from all FCA liability as long as the Government continued to pay, no matter the reason for the continued payment. Congress never intended to hand this type of power to federal agencies and this cannot be the outcome contemplated by this Court in *Escobar*.

B. *Escobar* Identifies a Government Payment Decision as "Evidence" of Materiality, but the Fifth Circuit Treats the Payment Decision as Determinative.

The False Claims Act defines the term "material" as meaning an act "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). The Court in *Escobar* considered the FCA definition,

along with contract and tort law, finding that 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*, 136 S.Ct. 1989, 2002-03, quoting 26 R. Lord, *Williston on Contracts § 69:12*, p. 549 (4th ed. 2003) (Williston).

The standard for materiality set by *Escobar* requires consideration of a government agency's actual or expected payment decision as a factor in determining whether an implied certification of compliance might be material. Specifically, the standard enunciated by the Court is 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." *Escobar*, 136 S.Ct. at 2003-04.

Nowhere did this Court in *Escobar*, or elsewhere, enunciate a standard transforming a government's payment decision into an act determinative of materiality <u>as a matter of law</u>, especially where, as here, the federal agency refuses to provide an explanation for its decision. Nonetheless the Fifth Circuit has interpreted the *Escobar* standard in exactly this way, while three other circuits view a government's payment decision as simply some evidence of materiality.

a. Three Circuits Treat a Government's Payment Decision as "Evidence" of Materiality

On one side of the circuit split on this issue are circuits, including the Fifth Circuit, that apply an outcome materiality standard that gives a veto over

qui tam actions to government bureaucrats and to contractors. This materiality standard is used to dismiss cases or, as in this case, overturn jury verdicts, because if the government continues to pay, this decision is interpreted to mean that the false claims cannot be material as a matter of law.

On the other side are three circuits that impose a higher standard, viewing the totality of circumstances, including continuing payment by the government as "evidence" of materiality.

1. The First Circuit in two separate decisions, including the *Escobar* case on remand, has abided by this Court's materiality dictates as set out in *Escobar*, considering the government's payment decision to be one of several factors in determining materiality, with no single factor—including continuing payment—deemed to be determinative.

On remand, in *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103 (1st Cir. 2016) (*"Escobar 3"*), the First Circuit noted that the commonwealth's Medicaid compliance agency, MassHealth, had put in place a series of regulations "to ensure that clinical mental health counselors, psychiatrists and psychologists are of sufficient professional caliber to treat patients." *Id.* at 111. The defendant, a clinic that had failed to comply with these regulations, argued that MassHealth had continued to pay its claims. *Id.* Applying a "holistic approach" to materiality, the First Circuit stated that not only was there no evidence that MassHealth would have continued to pay if it knew of defendants' failure to comply with the regulations, but that it was important to consider the other factors laid out by this

Court. *Id.* at 110-111. Specifically, the First Circuit examined whether defendants' non-compliance with certain regulations was "central to the state's Medicaid program and thus material to the government's payment decision." *Id.*

This "holistic approach" is consistent with the First Circuit's opinions in two other cases issued since this Court's *Escobar* decision. In *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29 (1st Cir. 2017), the First Circuit upheld an FCA claim, similar to the FCA claim in this case, where defendants allegedly palmed off defective medical implants that defendants falsely claimed were the same as devices already approved by the Food and Drug Administration ("FDA"). *Id.* at 40. The Court found the pleadings to adequately allege materiality because there was "no suggestion in the pleadings—and no reason to infer based on the allegations—that the minute but material manufacturing defects were known to the doctors, the patients, or the government" at the time they were sold and implanted. *Id.* The First Circuit also adhered to its "holistic" approach to materiality in *United States ex rel. Winkelman et al. v. CVS Caremark Corp.*, 827 F.3d 201, 211 (1st Cir. 2016) (citing *Escobar*), when assessing the materiality of information provided by a relator and whether the information was central to the fraud alleged to have been perpetrated in the case.

2. The Fourth Circuit has similarly considered multiple factors in assessing materiality, including the government's payment decision, along with other, critical "common sense" factors. *United States v. Triple Canopy, Inc.*, 857 F.3d 174, 178 (4th Cir.), *cert.*

dismissed, 138 S.Ct. 370, 199 L.Ed.2d 275 (2017). *Triple Canopy* involved allegations that a military contractor for base stations in Iraq knowingly employed private guards who were unable to properly use their weapons, spurring the contractor to falsify marksmanship records and to present claims to the government for payment for the unqualified personnel. *Id.* Analyzing materiality in light of *Escobar*, the Fourth Circuit concluded that defendants' omissions were material for two reasons: "common sense and Triple Canopy's own actions in covering up the noncompliance." *Id.* The Fourth Circuit also noted that the government had continued to pay Triple Canopy throughout its contract, but had declined to renew the contract and had intervened in the *qui tam* action. *Id.* at 179.

3. The Ninth Circuit has taken a comparable tact in considering materiality, weighing factors other than the government's continuing payment in determining materiality. In *United States ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890, 906 (9th Cir. 2017), petition for certiorari pending, the government continued to pay for defendants' HIV drugs, but the Ninth Circuit did not consider that to be determinative. Instead, the court also considered that defendants made false statements about their compliance with FDA regulations and that the "fraudulently obtained FDA approval [shouldn't be used] as a shield against liability for fraud." *Id.* The Ninth Circuit also reasoned that "there are many reasons the FDA may choose not to withdraw a drug approval, unrelated to the concern that the government paid out billions of dollars for nonconforming and adulterated drugs." *Id.*

b. The Fifth Circuit's Approach to Materiality Is Irreconcilable with *Escobar*, Legislative Intent and Decisions from the First, Third and Ninth Circuits

This Court in *Escobar*, and the FCA statute itself, set forth the criteria for a meritorious claim under the FCA. "What matters is not the label that 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." *Escobar*, 136 S.Ct. 1989, 1994. The rule adopted by the Fifth Circuit turns this well-established paradigm upside down. Under the Fifth Circuit materiality standard, a defendant may knowingly violate a requirement that the defendant knows is material to the Government's payment decision, but nonetheless escape liability as long as the defendant can convince the Government—at any time after the fraud is discovered—to continue payments.

First, the Fifth Circuit has adopted an outcome materiality standard that considers evidence of a Government's actual payment decision many years after the fraud is discovered, but unlike the First, Third and Ninth Circuits, the Fifth Circuit does not consider other factors, including (a) whether the defendants' misrepresentations were "central" to the government program and therefore material to the government's payment decision, or (b) evidence of defendants' attempts to cover up their fraud, or (c) that there are many reasons government agencies may choose not to withdraw approvals, unrelated to the concern that the government paid out millions of dollars for non-conforming or dangerous goods.

Second, the Fifth Circuit relied on evidence of a federal agency's approval decision that occurred nine years after the fraud began and just a week before trial commenced. The FHWA would not agree to discovery in this case, so the actual reasons for its approval decision are unknown, including whether it relied on continuing misrepresentations and intentional omissions by Respondents. What is clear, however, is that a standard that allows a company to escape liability by securing a favorable decision from a federal agency at any time—even years—after an FCA claim is filed, ensures that companies will actively seek to lobby their way to an FCA dismissal.

A company, for instance, could know based upon past practice and the law at the time that it makes claims for taxpayer funds that the government would not pay its claims if it knew the company was selling non-conforming goods. The company could nonetheless decide to take the risk that the government will not find out about the fraud. Under the Fifth Circuit rule, this would not be much of a risk because, if the fraud is discovered, the company would then have another chance to escape liability by, for instance, lobbying the government for a favorable payment decision.

Third, unlike the standard set by the Fifth Circuit, the standard defined in the FCA and by this Court in *Escobar*, focuses on the potential effect of the false statement when it is made, rather than on the false statement's actual effect after it is discovered. This focus on materiality at the time of the actual fraud is also consistent with the legislative intent in 2009

when a definition for the term "material" was added to the FCA statute.

At that time, legislators chose a definition for "material" that they described as "consistent with the Supreme Court definition, as well as other courts interpreting the term as applied to the FCA." S. REP. 111-10, 12, 2009 U.S.C.C.A.N. 430, 439, citing *Neder v. United States*, 527 U.S. 1, 16 (1999); *United States v. Bourseau*, 531 F.3d 1159, 1171 (9th Cir. 2008); *United States v. Rogan*, 517 F.3d 449, 452 (7th Cir. 2008) ("a statement or omission is capable of influencing a decision even if those who make the decision are negligent and fail to appreciate the statement's significance") (J. Easterbrook); *United States ex rel. Bahrani v. Conagra, Inc.*, 465 F.3d 1189, 1204 (10th Cir. 2006); *United States ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Group, Inc.*, 400 F.3d 428, 446 (6th Cir. 2005); *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 913, 916-917 (4th Cir. 2003); *United States ex rel. Cantekin v. University of Pittsburgh*, 192 F.3d 402, 415-416 (3d Cir. 1999).

Each and every case cited in the 2009 Senate Report rejects an outcome materiality standard and applies the "natural tendency test" that looks to the potential effect of the false statement at the time the statement was made. *E.g. United States v. Bourseau*, 531 F.3d 1159, 1171 (9th Cir. 2008) (adopting the "natural tendency test" for materiality that had been adopted by the Fourth and Sixth Circuits); *U.S. ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Grp., Inc.*, 400 F.3d 428, 445 (6th Cir. 2005) (concluding that the "natural tendency test" is the correct test, focusing on

the potential effect of the false statement when it is made).

Other circuits have rejected an outcome materiality standard because they have recognized that there are good reasons why the actions of agency officials after the fraud is disclosed should not be determinative in an FCA case.

> Another way to see this is to recognize that laws against fraud protect the gullible and the careless—perhaps <u>especially</u> the gullible and the careless—and could not serve that function if proof of materiality depended on establishing that the recipient of the statement would have protected his own interests. The United States is entitled to guard the public fisc against schemes designed to take advantage of overworked, harried, or inattentive disbursing officers; the False Claims Act does this by insisting that persons who send bills to the Treasury tell the truth.

U.S. ex rel. Feldman v. Van Gorp, 697 F.3d 78, 95 (2d Cir. 2012) (emphasis in original), quoting *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008).

II. THE FIFTH CIRCUIT'S DECISION CONFLICTS WITH *ESCOBAR*'S FOCUS ON THE 'RECIPIENT' OF THE MISREPRESENTATION AND THE ACTUAL 'GOVERNMENT'S PAYMENT DECISION' THAT SHOULD BE CONSIDERED IN A MATERIALITY ANALYSIS.

The Fifth Circuit's opinion expands the reach of federal agency power such that the internal decisions of a federal agency may now overrule and allow courts to disregard state regulations and state actors when

states act as agents of both federal and state money in the context of a claim submitted under the FCA. This contravenes Congressional intent, is contrary to the analysis in *Escobar*, and is in conflict with the published decisions of at least two other circuits.

This issue arises in the context of "claims" made to the "recipients of federal funds under federal benefits programs" which Congress has identified as a type of claim subject to liability under the False Claims Act. *See* § 3729(b)(2)(A); *Escobar*, 136 S.Ct. at 1996. When the "recipients" of these funds are state governments that administer benefit programs like Medicaid or the Federal Highway-Aid Program, state governments not only contribute some of their own funds to the benefit program, but they have their own sets of rules and regulations for contractors seeking payment of program funds.

The states' program rules and regulations for these benefit programs often require express certifications of compliance with criteria considered important to the states as pre-conditions for contractors to receive payments. In this case, for instance, every state DOT in the country requires manufacturers and contractors selling roadside safety devices to expressly certify that (a) they had obtained FHWA approval for the device, and (b) that the device is identical to the device approved by the FHWA. Neither of these representations was true and Respondents admitted at trial that if state DOTs had known of their misrepresentations at the time the misrepresentations were made, Respondents would not have been paid. That is material.

Escobar's materiality analysis, should be applied to consider the materiality of state regulations in determining if the state's rules—not the federal rules —are material to payment. The Fifth Circuit considered the states' rules and regulations to be irrelevant— but this is contrary to the analysis set forth in *Escobar*.

Escobar underscored that a materiality analysis must focus on the "recipient" of the false claims and on the "Government" making the payment decisions. *Escobar*, 136 S.Ct. at 1994, 2002-03 (internal citations omitted). What this Court did not resolve is whether a court may instead consider after-the-fact internal decisions of a federal agency (even where the federal government makes no payment decisions) and ignore that it is the state government that is the "decision maker" on the actual claims, thereby negating the role of state actors and state regulations.

At least two other circuits have recognized that when the state government is the recipient of the contractor's misrepresentation and where the state government agency makes the payment decision regarding the false claim, and especially where the state government has expressly put in place its own specific rules that must be followed to receive payment, it is the state agency's "likely or actual behavior" that should be considered in an FCA materiality analysis.

The Fifth Circuit's opinion on materiality, which was based upon a federal agency's retroactive approval, never considered the materiality of Respondents' false statements to the states, even though it was undisputed (and admitted by Respondents) at trial that "in the mine run of cases" no state would have paid the claims

under all 50 states' rules if the states had known the express certifications were false.

A. Other Courts Have Recognized the Materiality of State Rules and Regulations, and State Payment Decisions.

This Court and the First Circuit in *Escobar* have recognized that a materiality analysis involving state actors running a federal benefits program, must look to the rules and regulations—and to the actual or likely behavior—of state government officials, not federal officials. *See Escobar*, 136 S.Ct. 1989, 2000-01 (considering MassHealth regulations); *Escobar 3*, 842 F.3d 103, 110-111 (determining materiality in the context of MassHealth regulations).

And the First Circuit in *New York v. Amgen Inc.*, 652 F.3d 103, 111 (1st Cir. 2011) explicitly rejected consideration of federal regulations in the context of an FCA action in which claims were submitted to state agencies as part of a federal benefits program. In that case, a whistleblower brought a *qui tam* case on behalf of seven states and the federal government against a pharmaceutical company and groups of dialysis clinics claiming that defendants violated federal and state anti-kickback statutes and submitted claims falsely certifying compliance with those statutes. *Id.*

Because the states had discretion over the Medicaid programs, the First Circuit considered only whether defendants "misrepresented compliance with a precondition of payment recognized by those particular programs . . . [s]o long as states have discretion over the operation of their Medicaid programs, generalities about national views as to what constitutes a

precondition of Medicaid payment cannot control." *Id.*, citing *Pharma Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 665 (2003).

The Third Circuit has also applied its analysis to state rules and regulations in the context of a federal benefits program run by the state DOT. The *U.S. Dep't of Transportation, ex rel. Arnold v. CMC Eng'g*, 564 F.3d 673, 679 (3rd Cir. 2009). In that case, once it was established that the program in question was disbursing funds received through the FHWA, the court turned to the Pennsylvania DOT and regulatory and funding schemes set up by the Pennsylvania DOT—not to the federal rules or regulations—to determine the viability of an FCA claim. *Id.*

This view is also supported by the legislative history of the FCA, and in particular, by the 2009 Fraud Enforcement and Recovery Act ("FERA") amendments to the FCA that expanded the definition of a "claim" to include money received and disbursed by states through federal benefit programs. Specifically, the definition of a "claim" was changed to include "any request or demand, whether under a contract or otherwise for money or property and whether or not the United States has title to the money or property" that is (1) presented directly to the United States, or (2) "to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest." 31 U.S.C. § 3729(b)(2)(A).

The 2009 changes were spurred, in part, by this Court's decision in *Allison Engine Co. v. U.S. ex rel. Sanders*, 553 U.S. 662, 668 (2008) where it was held that FCA liability attaches only to fraud perpetrated

directly against the federal government and not to frauds committed by contractors working on projects paid for with federal dollars through grant programs like Medicaid or the Federal Highway Aid program. *Id*; S. REP. 111-10, 12, 2009 U.S.C.C.A.N. 430, 439. With the FERA amendments Congress sought to shore up the FCA to ensure that the holding of *Allison Engine* did not survive and that the FCA would cover all types of fraud directed at federal taxpayer dollars.

> . . . FERA improves one of the most potent civil tools we have for rooting out waste and fraud in government-the False Claims Act. The effectiveness of the False Claims Act has recently been undermined by court decisions which limit the scope of the law and allow sub-contractors paid with government money to escape responsibility for proven frauds.

155 Cong. Rec. S1679-01, 155 Cong. Rec. S1679-01, S1682 (Grassley)

A materiality standard that looks to a payment decision should focus on the actual entity making the decision.[10] The standard applied by the Fifth Circuit does not but instead allows contractors to make false statements to state agencies in order to get paid federal funds administered by the state.

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[10] In *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7 (1st Cir. 2016) the First Circuit rejected a relator's claims premised on misrepresentations made to the Food and Drug Administration ("FDA") because payment decisions in that case were made by the Centers for Medicare & Medicaid Services ("CMS"), not the FDA, so the misrepresentations could not have been material. *Id.*

The Court should clarify the application of the materiality standard under *Escobar* and provide definitive guidance on whether a federal agency can negate a contractor's liability when a contractor perpetuates a clear cut fraud under state-mandated rules or regulations in the context of administering funds under federal benefits programs.

III. *ESCOBAR*'S MATERIALITY STANDARD WAS NOT INTENDED TO APPLY TO EXPRESS CERTIFICATION CASES.

Federal courts have expressed continuing uncertainty about whether the materiality standard outlined by *Escobar* applies to all causes of action brought under § 3729(a)(1)(A) or only to causes of action brought specifically on an implied false certification theory. *See* John H. Krause, *Reflections on Certification, Interpretation, and the Quest for Fraud that "Counts" Under the False Claims Act*, 2017 U. Ill. L. Rev. 1811, 1835-36 (2017).

While some courts have applied the *Escobar* materiality standard to only a subset of claims (*i.e.*, to legal falsity but not factual falsity), other courts have assumed Escobar applies to all types of FCA claims. Compare *United States ex rel. Wood v. Allergan, Inc.*, 246 F.Supp.3d 772, 811 (S.D.N.Y. 2017), *motion to certify appeal granted*, No. 10-CV-5645 (JMF), 2017 WL 1843288 (S.D.N.Y. May 4, 2017) (" . . . the Supreme Court did not address the theory of express certification . . . [t]hus, there is no reason to believe *Escobar* modified or eliminated existing law . . . pertaining to that theory of falsity") to *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 902-07 (9th Cir. 2017) (applying *Escobar*'s materiality standard to

the theories of factual falsity, implied false certification, and "promissory fraud" or fraudulent inducement); *See also D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7-8 (1st Cir. 2016) (applying *Escobar*'s materiality standard to a fraudulent inducement claim); *United States ex rel. Miller v. Weston Educ., Inc.*, 840 F.3d 494, 500 (8th Cir. 2016) (applying *Escobar*'s materiality standard to an FCA fraudulent inducement claim); *Lacey*, 14-cv-5739 (AJN), 2017 WL 5515860, at *6-*11 (S.D.N.Y. Sept. 26, 2017) (stating that *Escobar*'s materiality standard applies to all legally false claims, but not applying the materiality standard to a factually false claim that was "based on fraudulent inducement."); *United States v. Catholic Health Sys.*, 12-CV-4425 (MKB), 2017 WL 1239589, at *21 (E.D.N.Y. March 31, 2017) (stating that *Escobar* "adopted the materiality test for implied-false-certification claims"); *United States ex rel. Scharff v. Camelot Counseling*, 13-cv-3791 (PKC), 2016 WL 5416494, at *3 (S.D.N.Y. Sept. 28, 2016) (stating that *Escobar*'s materiality standard applies to legally false claims "that falsely certify compliance with a regulation or a statute").

Escobar's heightened materiality analysis is logically applied only to implied certification claims because these claims are based upon fraudulent omissions that by their very nature may not provide defendants with notice of their potential liability. Respondents enter into contracts referencing sometimes dozens or even hundreds of regulations and rules, and often impliedly certify compliance with each contractual clause and each rule and regulation when making a claim for payment. This Court was naturally concerned about the possibility that a contractor, merely by submitting an invoice for payment, would

be held liable in treble damages because it failed to comply with one of a myriad number of regulations that would not be material to the government's decision to make payment.

The defendants in *Escobar* urged the Court to adopt an implied certification rule mandating that only rules or statutes that expressly condition payment upon compliance can be the basis for liability. *Escobar*, 136 S.Ct. at 2002. But the Court rejected such a rule and instead reasoned that "concerns about fair notice and open-ended liability can be effectively addressed through strict enforcement of the Act's materiality and scienter requirements" to ensure the FCA is not turned into "'an all-purpose antifraud statute,' or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Id.*, citing *Allison Engine*, 553 U.S., at 672. Such concerns about open-ended liability, fair notice and garden-variety breaches are not an issue in express certification cases. Unlike implied certifications, which focus on the underlying contracts, statutes, rules or regulations to ascertain liability, express certification claims rely upon actual misrepresentations of compliance. Defendants can hardly claim they don't have notice or that they fear being punished for garden-variety regulatory violations, when their liability is based upon express and knowing fraudulent representations.

Here, Respondents' false certifications could not have been more central to the decisions by the states to buy the ET-Plus and to pay Respondents for those purchases. It was undisputed at trial that not a single state would buy the ET-Plus if Respondents had revealed that it made changes to the dimensions of

the ET-Plus without receiving advanced approval by the FHWA. App.137a. This review and approval was not some mere "technicality." As the authors of the testing standard adopted by the FHWA emphasized, even minor variations in dimensions can drastically affect the performance of highway safety devices. And despite the Fifth Circuit's best efforts to construe all the facts in Respondents' favor, the evidence was overwhelming that Respondents' changes to the ET-Plus significantly degraded its ability to perform, resulting in numerous fatalities on the nation's highways.

The fact that *Escobar* was decided in the limited context of implied certification, is further buttressed by the fact that none of the parties presented to this Court in *Escobar* the long-standing case law, developed in the context of express certification or factual falsity, that the reaction of the particular federal agency after the fraud has been discovered, should never be determinative of materiality. In a long line of cases, including prior decisions by the Fifth Circuit, the federal circuit courts explained that there may be many reasons why a particular federal agency may choose not to take action against the fraudster and, because of that, the agency's action cannot be determinative of whether the statute was violated. This is especially true when the court and jury do not have evidence before them of the reasons for the agency's decision, as occurred here. *See, e.g.*, *Triple Canopy, Inc.*, 775 F.3d at 639 ("[M]ateriality focuses on the potential effect of the false statement when it is made not the actual effect of the false statement when it is discovered.") (emphasis in original); *United States ex rel. Longhi*, 575 F.3d 458, 468-70 (5th Cir. 2009) ([T]he FCA requires proof only that the defendants'

false statements "could have" influenced the government's payment decision or had the "potential" to influence the government's decision, not that the false statements actually did so.); *United States v. Rogan*, 517 F.3d 449, 452-53 (7th Cir. 2008) (same); *United States ex rel. Feldman v. Van Gorp*, 697 F.3d 78, 95 (2d Cir. 2012) ("[M]ateriality is determined not by what a program officer at NIH declares material, but rather [is] based on the agency's own rules and regulations.") (internal quotations omitted); *Varljen v. Cleveland Gear Co., Inc.*, 250 F.3d 426, 430 (6th Cir. 2001) ("The government's inspection and acceptance of a product do not absolve a contractor from liability for fraud under the FCA"); *United States v. National Wholesalers*, 236 F.2d 944, 950 (9th Cir. 1956) ("In such palming off as we have here we do not believe that Congress ever intended that contracting officers should have the power to officiate the False Claims statute," thus, the Army's decision to pay under the contract did not affect the validity of the fraud claim); *United States v. Rippetoe*, 178 F.2d 735, 736-37 (4th Cir. 1949) (it would be contrary to Congressional intent to allow possibly corrupted federal officials' acquiescence in the fraud to bar an FCA claim); *United States ex rel. Anti-Discrimination Center of Metro New York, Inc. v. Westchester County, N.Y.*, 668 F.Supp.2d 548, 570 (SDNY 2009) ("[A]n individual government employee's decision to approve or continue such funding, even with full access to all relevant information or knowledge of the falsity of the applicants['] certification does not demonstrate that the falsity was not material. . . . Thus, the assertion that certain HUD bureaucrats reviewed the County's submissions and continued to grant the County funding cannot some-

how make the false AFFH certifications immaterial, when the funding was explicitly conditioned on the certifications.").

The DOJ has emphatically rejected the notion that any agency other than the Attorney General could, through its actions or decisions, either estop or compromise an FCA claim in any way. DOJ Amicus Br. in *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 2003 WL 25936477 (Jan. 31 2003), at *14-16. The Fourth Circuit readily agreed, expressly rejecting the idea that "a court would be bound to find no materiality whenever a government entity investigates an alleged [organizational conflict of interest] but decides to continue funding the contract." *U.S. ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 916 (4th Cir. 2003). Yet, the Fifth Circuit in direct conflict held here that continuing funding established materiality as a matter of law.

IV. THE QUESTIONS PRESENTED ARE IMPORTANT, RECURRING, AND WARRANT THIS COURT'S IMMEDIATE RESOLUTION.

The disagreement among the circuits over how to apply the FCA materiality standard, added to the Fifth Circuit decision's dangerous transfer of unprecedented power to federal agencies to absolve FCA defendants of liability, highlights the need for this Court to clarify the materiality standard. With millions of dollars in taxpayer funds at stake, now is the time for the Court to provide additional guidance about the scope and outlines of the FCA materiality standard before the FCA becomes a "no purpose", toothless statute that is routinely thwarted by every deep-pocketed defendant who is able to convince federal

agency bureaucrats to continue paying claims despite defendants' fraud on the public fisc. This is an issue not only implicating fraud within the Federal Highway Program, but involves every agency and every industry as the issues that may make an agency miss fraudulent conduct are not limited by type of industry or government program. Agencies may fail to do their jobs for a variety of reasons, including "the gullible and the careless . . . the overworked, harried or inattentive", as well as those who seek to cover up their own mistakes or transgressions. *See e.g.*, *U.S. ex rel. Feldman v. Van Gorp*, 697 F.3d 78, 95 (2d Cir. 2012) (emphasis in original), quoting *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008). As Justice Holmes put it, "[m]en must turn square corners when they deal with the Government." *Rock Island, Arkansas & Louisiana R.R. v. United States*, 254 U.S. 141, 143 (1920).

And at times more insidious forces may be at work. Federal bureaucrats may themselves be committing fraud or malfeasance, or—as has been well documented—government agencies may fall victim to regulatory capture, becoming institutions that exist to serve the regulated rather than to serve the public.

"With every agency, the fear of regulatory capture is ever-present." *PHH Corp. v. Consumer Fin. Prot. Bureau*, No. 15-1177, 2018 WL 627055, at *88 (D.C. Cir. Jan. 31, 2018) (internal citations omitted). "Capture . . . prevent a neutral, impartial agency assessment of what rules to issue or what enforcement actions to undertake or how to resolve adjudications." *Id.*, citing Lisa Schultz Bressman & Robert B. Thompson, *The Future of Agency Independence*, 63 Vand. L. Rev. 599,

611 (2010); *see also* Robert E. Cushman, *The Independent Regulatory Commissions* 153 (1941) (noting, in reference to Federal Reserve Act of 1913, that it "seemed easier to protect a board from political control than to protect a single appointed official").

Whistleblower lawsuits are intended to be an antidote to regulatory capture and a mechanism for the public to second-guess the adequacy of the government's oversight of taxpayer funds. A materiality standard that further empowers agencies, necessarily deflates citizen whistleblowers and incentivizes corporate lobbying by FCA fraudsters who would rather deal with one agency official than with seven jurors. Such a standard undermines both the purpose and the efficacy of the False Claims Act.

Finally, this case presents an ideal vehicle for the Court's review. As outlined above, the *Escobar* case left open more than one question about the standard for materiality, all of which are presented by this case.

CONCLUSION

The Petition for a Writ of Certiorari should be granted.

Respectfully submitted,

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