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Materiality in the Post-Escobar Era: An Argument for Supreme Court Clarification of Materiality

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INTRODUCTION:

In June of 2016, the Supreme Court passed down a unanimous decision endorsing the implied false certification theory as a basis for False Claims Act ("FCA") liability, answering a divisive split in the Circuits below.[1] More importantly, however, the Supreme Court established a set of factors to guide the analysis of the materiality requirement of the FCA.[2] In describing these factors, the Court stated:

> [A] condition of payment is relevant but not automatically dispositive. […] Proof of materiality can [also] include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims. […] If the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.[3]

While the Court did use the wording "very strong" to denote the importance of Government payment, ambiguity remains among the courts below with regard to how to weigh the factor of continued government payment. *Gilead Sciences, Inc. v. United States, ex rel. Campie*, coming out of the Ninth Circuit, would give the Supreme Court the opportunity to address the discrepancies in the courts below and describe more clearly how continued Government payment

[1] Universal Health Svcs., Inc. v. United States *ex rel.* Escobar, 136 S.Ct. 1989, 1996, _ U.S. _ (2016).
[2] *Id*.
[3] *Id*. at 2003-04.

is to be interpreted. [4][5]

Justice Thomas correctly articulated that the standard for the materiality determination of a false claim is a balancing test of a number of factors. Continued government payment is noted as being very strong evidence; however, the circuits below are misusing this factor. In several instances, the circuits are ignoring the circumstances surrounding the payment and therefore, failing to account for additional reasons why the Government might continue to pay in the face of a potential false claim. The Supreme Court should articulate more clearly the weight attributed to Government payment, while accounting for a full inquiry into the circumstances as to why the Government has still paid in the face of a potential fraudulent claim.

HISTORY OF THE FALSE CLAIMS ACT:

In relevant part, the current text of the False Claims Act imposes liability on any person who knowingly presents a false statement or record to the Government that is material to a claim for payment[5]

The Act defines "knowing" or "knowingly" as when a person has actual knowledge of the information, acts in "deliberate ignorance" of the truth, or acts recklessly with regard to the truth or falsity of the knowledge. [6] A "claim" comprises any request or demand, whether under a contract or otherwise, for money or property that is presented to the United States or a contractor.[7] The statute states that a claim is "material" when it has a natural tendency to influence, or is capable of influencing, the payment or receipt of money or property.[8]

[4] Gilead Sciences, Inc. v. United States, *ex rel.* Jeffrey Campie, *et al.*, Petition for Writ of Certiorari 17-936 (January 3, 2018).
[5] U.S.C.A. § 3729.
[6] *Id*. at (iii)(1).
[7] *Id*. at (iii)(2).
[8] *Id*. at (iii)(4).

The False Claims Act was enacted in 1863 during the Civil War to address concerns that some organizations sold supplies to the Union Army that were not as they were represented, thereby defrauding the Government.[9] Congress amended the modern FCA in 1986 to enhance the Government's ability to recover losses due to alleged fraud.[10] However, the FCA was not created to serve as an all-purpose vehicle to prosecute "garden-variety" frauds, but instead, severe frauds perpetrated against the Government.[11]

Congress amended the FCA again in 2009 as part of the Fraud Enforcement and Recovery Act (FERA) to resolve ambiguities surrounding the materiality element.[12] Specifically, in FERA, Congress imposed liability on one who "knowingly makes, uses, or causes to be made or used, a false record or statement *material* to a false or fraudulent claim."[13] Previously absent from the statute, the addition of the word "material" did not create a new materiality standard, but instead, "merely made explicit and consistent that which had previously been a judicially-imposed, and oftentimes conflicting, standard."[14] As the First Circuit noted in *U.S. ex rel. Loughren v. Unum Group*, "under both versions, [Relator] was required to prove falsity, materiality, and scienter." Therefore, the requirements were unchanged, however after 2009; it was explicit from the statute that this was the method of inquiry under the FCA.[15] The real issue with the FCA prior to 2009 was not that the materiality requirement was absent, but rather, that without an express definition, the circuits had to guess at its meaning.[16]

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[9] *Escobar*, 136 S.Ct at 1998.
[10] Todd B. Castleton, *Compounding Fraud: The Costs of Acquiring Relator Information Under the False Claims Act and the 1993 Amendments to Federal Rules of Civil Procedure*, 4 GEO. MASON L. Rev., 327, 340 (1996).
[11] *Escobar*, 136 S.Ct at 1998.
[12] Pub. L. No. 111-21, 123 Stat. 1617 (2009) (codified as amended in scattered sections of 18 and 31 U.S.C.).
[13] United States *ex rel.* Spay v. CVS Caremark Corp., 875 F.3d 746, 761 (3d Cir. 2017) (emphasis added).
[14] *Id*.
[15] *Loughren*, 613 F.3d at 316 n.7.
[16] *Spay*, 875 F.3d at 762.

Prior to FERA, the two controlling fraud cases passed down by the Supreme Court were *United States v. Wells* and *Neder v. United States*. In 1997 the Court in *Wells* held that, when it came to knowingly making false statements to federally insured banks, after a "natural reading of the full text," materiality was not explicitly written, and thus not an element of a claim.[17] Two years later, the Court in *Neder* held that it was not incorrect when it concluded in *Wells* that materiality was not a written element of many fraud statutes, however, when the statute included the wording "fraud" as opposed to "false statement," it was correct to impose a common law materiality requirement to that fraud.[18] The synthesis of these two cases led to the general finding that statutes using the word "false", if lacking an express materiality requirement, presumptively did not have such a standard. While statutes using the word "fraud" were interpreted to include a materiality requirement, unless the clear language of the statute said otherwise.[19] Prior to FERA, no iteration of the False Claims Act ever included the word materiality.[20] Therefore, using the *Wells/Neder* framework, the "natural reading of the text" did not include materiality as an element. Further, the FCA used neither the words "false statement" nor "fraud," but instead, "false claim." This led many courts below to struggle with the *Wells/Neder* framework when determining whether the FCA included an "inherent common-law materiality" or instead no "presumption of materiality." This illustrates the importance of Congress' enacting FERA in 2009, in order to offer clarity on the materiality divide.[21]

PRE-ESCOBAR:

[17] United States v. Wells, 519 U.S. 482, 483 (1997)(citation omitted).
[18] Neder v. United States, 527 U.S. 1, 22-23(1999).
[19] *See Wells*, 519 U.S. at 483; *see also*, *Neder*, 527 at 23-25.
[20] *See* Act of Mar. 2, 1863, ch. 67, 12 Stat. 696 (1863); U.S. Rev. Stat. tit. 36 §§ 3490-3494 (1865); *Id*. §§ 34903494 (1875); 31 U.S.C. §§ 231-235 (1926); *Id*. §§ 231-235 (1935); *Id*. §§ 231-235 (1943); *Id*. §§ 3729-3731 (1982); *Id*. §§ 3729-3733(1986); *Id*. §§ 3729-3733 (1988).
[21] *See Wells*, 519 U.S. at 483; *see also*, *Neder*, 527 at 23-25.

Much like the pre-FERA materiality ambiguities caused a rift among the circuits in their FCA enforcement, so did the theory of "implied false certification." This theory holds that, "when a defendant submits a claim, it impliedly certifies compliance with all conditions of payment. But if that claim fails to disclose the defendant's violation of a material statutory, regulatory, or contractual requirement, so the theory goes, the defendant has made a misrepresentation that renders the claim false or fraudulent under § 3729(a)(1)(A)."[22] Specifically, *Universal Health Svcs. Inc., v. United States ex rel. Escobar* rejected the holding from the Seventh Circuit in *Sanford-Brown* that expressly rejected the implied certification theory.[23]

Historically, liability under the FCA arose from allegations that claims were factually false, or one of two theories of false certification: express false certification, or implied false certification. The implied certification theory is a judicially created theory first addressed in *Ab–Tech Construction, Inc. v. United States,* in 1994.[24][25] An important decision by The Second Circuit in *Mikes v Straus* rejected the implied certification theory.[26] More importantly however, it articulated the growing confusion over the materiality standard in the FCA.[27] The Second Circuit joined the Fourth, Fifth, Ninth, and D.C. Circuits in finding that a claim is legally false

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[22] *Escobar*, 136 S.Ct. at 1994.
[23] *Id*. at 1989, *see also* United States v. Sanford-Brown, 788 F.3d 696, 711-12 (7th Cir. 2015)
[24] Ab–Tech Construction, Inc. v. United States, 31 Fed.Cl. 429 (Fed. Cl. 1994), *aff'd*, 57 F.3d 1084 (Fed. Cir.1995) (unpublished table decision); *See* 31 U.S.C.A. § 3729.
[25] In *Ab-Tech,* The Court of Federal Claims held that the defendants' submission of payment vouchers, although containing no express representation as to what, implicitly certified their adherence to the requirements of a federal small business program. The defendants' failure to adhere to rules did not directly preclude payment, but submitting a claim while knowingly not being in compliance with said rules nonetheless constituted a false statement in connection to a claim for payment, resulting in False Claims Act liability.
[26] Mikes v. Straus, 274 F.3d 687 (2d Cir. 2001).
[27] *Id.*

only where a party certifies compliance with a statutory condition to payment.[28] In reference to materiality under the FCA, the court stated in dicta that:

> "[…] although materiality is a related concept, our holding is distinct from a requirement imposed by some courts that a false statement or claim must be material to the government's funding decision. A materiality requirement holds that only a subset of admittedly false claims is subject to False Claims Act liability. We rule simply that not all instances of regulatory noncompliance will cause a claim to become false. We need not and do not address whether the Act contains a separate materiality requirement.[29]

Although not a holding of the case, this statement echoed nationwide confusion on when, and if, the materiality requirement applied in all FCA claims. A statement that the Supreme Court took the opportunity to answer in *Escobar.*

UNIVERSAL HEALTH SERVICES, INC. V. U.S. (*ESCOBAR*):

While addressing the viability of the implied certification theory for an FCA claim, the Supreme Court in January of 2016, articulated a decisive standard with regard to the function of the materiality requirement in a false claims inquiry, answering a divisive split in the Circuits below.[30] Justice Thomas articulated a set of factors to use for a balancing test when determining the materiality of a false claim.

In *Escobar,* a young girl's parents brought a *qui tam* suit under the False Claims Act after their daughter died of a seizure following treatment at a Universal Health Services mental health clinic by several unlicensed and unsupervised doctors and aides in violation of Medicaid regulations.[31] She received counseling services for approximately five years, and after being

[28] *Id*. at 697 (citing United States *ex rel.* Siewick v. Jamieson Sci. & Eng'g, Inc., 214 F.3d 1372, 1376 (D.C. Cir. 2000); United States *ex rel.* Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 902 (5th Cir. 1997); United States *ex rel*. Hopper v. Anton, 91 F.3d 1261, 1266–67 (9th Cir. 1996); Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 786 (4th Cir. 1999)).
[29] *Id*. at 697 (citing *Harrison*, 176 F.3d at 785; United States *ex rel.* Cantekin v. Univ. of Pittsburgh, 192 F.3d 402, 415 (3d Cir. 1999), *cert. denied*, 531 U.S. 880 (2000))(internal citations omitted).
[30] *Escobar*, 136 S.Ct. 1996.
[31] *Id*. at 1989.

diagnosed with bipolar disorder, a "doctor" at the facility prescribed her medication for her disease.[32] Rivera's condition declined until she died of a seizure caused by an adverse reaction to the medication.[33] It was later revealed that few of the Arbour employees were actually licensed to administer mental health counseling or authorized to prescribe medication.[34] The "doctor" who diagnosed Yarushka as bipolar represented herself as a psychologist with a Ph.D. to the Escobars, but did not mention that her degree came from an unaccredited Internet college and that Massachusetts had denied her application to be a licensed psychologist.[35] The practitioner who prescribed medicine to Yarushka was actually a nurse who lacked authority to prescribe medications without doctor supervision.[35]

The Escobars brought the claim in the District Court of Massachusetts alleging that Universal Health defrauded the Medicaid program by seeking reimbursement for services rendered by professionals without disclosing that these professionals were unlicensed.[36] The District Court granted Defendants' motion to dismiss on the basis that there is no liability when the licensing requirements were not a "condition of payment."[38] The Escobars then appealed to the First Circuit, which reversed in relevant part and remanded, holding that every claim impliedly represents that the facility had complied with the required regulations, so an undisclosed violation makes the claim false.[37] The First Circuit held that those regulations were a material condition of payment.[38]

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[32] *Id*.
[33] *Id*.
[34] *Escobar*, 136 S.Ct. at 1989.
[35] *Id*. at 1997.
[35] *Escobar*, 136 S.Ct. at 1997.
[36] United States *ex rel.* Escobar v. Universal Health Serv., 2014 WL 1271757 (D. Mass. Mar. 26, 2014). [38] *Id*.
[37] United States *ex rel.* Escobar v. Universal Health Serv., 780 F.3d 504, 517 (1st Cir. 2015).
[38] *Id*.

The Supreme Court attempted to clarify the confusion among the Circuits about the test for determining materiality under the False Claims Act by stating:

> False Claims Act liability for failing to disclose violations of legal requirements does not turn on whether those requirements were expressly designated as conditions of payment [....] [w]hat matters is not the label the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision.[39]

The Court noted, "liability does not depend on whether the regulatory or contractual requirements were expressly designated as a condition for payment."[40] The deciding factor is whether the misrepresentation was material to the payment decision.[41] In evaluating materiality for purposes of the FCA, express identification of a condition of payment is not "automatically dispositive" although it is relevant.[42] It is, "whether the defendant knowingly violated a requirement known to be material to the payment decision."[43] The Court described the materiality standard as "rigorous" and "demanding" noting that it is insufficient that the Government merely would have had the option to decline payment with knowledge of noncompliance.[44] Ultimately, "what matters is not the label the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knew [was] material to the payment decision."[45]

Justice Thomas quoted the *Neder* Court in explicating the concept of materiality, "[T]he term 'material' means having a natural tendency to influence, or be capable of influencing, the

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[39] *Id*. at 1996.
[40] *Escobar*, 136 S.Ct. at 1994.
[41] *Id*.
[42] *Id*.
[43] *Id*.
[44] *Id*. at 2003.
[45] *Escobar*, 136 S.Ct at 1994.

payment or receipt of money or property."[46] Moreover, the Court held, "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."'[47] However, the Court was clear that the FCA materiality standard was not as easy to satisfy as its common-law equivalent.[48] Holding specifically, "[t]he materiality standard is demanding. The False Claims Act is not an all-purpose antifraud statute, or a vehicle for punishing garden-variety breaches of contract or regulatory violations."[49] The Court emphasized that the FCA is a vehicle for only for claims of serious fraud, unlike its common-law ancestors.[50] Once the Court was clear on the nature of the standard, the Court then articulated "factors" that are relevant when reviewing a claim for materiality.[51]

The Court rejected reliance on an express statement that a requirement is a condition of payment by stating, "[a] misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment."[52] A Government decision to put a provision in a statute or Government contract is relevant to the inquiry, but not the end of the inquiry.[53]

Justice Thomas then articulated his materiality standard as:

> [P]roof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is

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[46] *Id*. at 2002.
[47] *Id*. (citing 26 R. Lord, Williston on Contracts § 69:12, p. 549 (4th ed. 2003) (Williston)).
[48] *Id*. at 2003.
[49] *Escobar, 136 S.Ct. at 2003)*(citing Allison Engine Co., Inc., v. U.S. *ex rel.* Sanders, 553 U.S. 662, 672 (2008))(internal quotation omitted).
[50] *Id*.
[51] *Escobar,* 136 S.Ct. at 2003.
[52] *Id*.
[53] *Id*.

> very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.[54]

Although the Court did designate certain factors as "strong evidence" or "very strong evidence," the ultimate holding was that these were simply factors, none of which was strong enough to be dispositive by itself.[55] Justice Thomas never claimed that this list was exhaustive, highlighting the point that the *Escobar* materiality standard is a nuanced one that requires the courts below to engage in an evaluation of the full breadth of the circumstances to determine if the alleged false claim was material to the Government's decision. The Court held that the materiality standard under the FCA still looked to the natural tendency and likely or actual effect a false claim would have on the Government's decision to pay the claim, which is a highly fact-sensitive determination.[56]

In addition to concluding what materiality was, Justice was also clear that materiality should not rest solely on the fact that the Government deems something a condition of payment, or that the Government would have the *option* to decline payment should it find out about a violated condition. Contrary to what the First Circuit held, the Supreme Court said although these factors are *relevant* to the materiality inquiry, those factors are not the end of the inquiry.[59] The Supreme Court's primary objective in articulating the new materiality standard was to directly overturn the First Circuit and moderate what is an "extraordinarily expansive view of materiality."[57] The Court sought to disallow situations where noncompliance is minor or

[54] *Id*. at 2003-4.
[55] *See Id*.
[56] *Escobar*, 136 S.Ct. at 2003
[59] *Id*.
[57] *Id*.

insubstantial, otherwise noncompliance would always be material, and a violation of a condition of payment would always trigger FCA liability.[58]

Despite the Supreme Court's clear admonition to the contrary, the Circuits below have misused the factors elicited by Justice Thomas by over-emphasizing continued government payment without considering the breadth of the circumstances. *Campie* presents the perfect opportunity for the Supreme Court to clarify that, although continued government payment is a factor, the courts below cannot ignore the circumstances surrounding that continued payment. This test was intended to be a nuanced balancing test, using the whole picture of the facts, therefore, it is improper to rely on one factor without reference to the others.

POST-ESCOBAR SPLIT:

The circuit courts are divided in their analysis of materiality on what sort of weight should be applied to continued Government payment when it knows that the claimant violated some law or regulation, about which the vendor may or may not have made a representation in connection with the claim for payment, and which may or may not be relevant to the services or product provided to the Government. [59] The majority of the circuits hold that when the Government continues to pay, despite the fact that it has knowledge a vendor violated some law while certifying compliance with all laws, in regard to its claim for payment, that usually ends the inquiry. However, recently, circuits have begun to hold in the alternative, finding that not every instance of continued Government payment is decisive evidence of materiality, which

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[58] *Id.*

[59] *See, e.g.*, 41 U.S.C. § 7103(c)(1) (This section does not authorize an agency head to settle, compromise, pay, or otherwise adjust any claim involving fraud.); 48 C.F.R. § 33.210(b) (The authority to decide or resolve claims does not extend to… The settlement, compromise, payment or adjustment of any claim involving fraud.); Medicare Program Integrity Manual § 3.7.3.3 (2017), available at http://go.cms.gov/2iUyMKx (If it is believed that the overpayment resulted from potential fraud, a refund may not be requested from the provider until the potential fraud issue is resolved.).

supports the correct balancing standard articulated by Justice Thomas that accounts for the entire circumstance of the alleged false claim.[60]

This issue is very common in the context of fraudulent inducement, where the provider either misleads or omits relevant information in order to secure Government payment. Omissions are relevant when the vendor certifies or implies compliance with standards, despite the fact the vendor is no longer in compliance with said standards. Therefore, although the vendor is not affirmatively making misrepresentations, the failure to include that the vender is no longer in compliance with requirements could lead to false claim liability. In sum, if a misrepresentation or an omission has the natural tendency to influence the Government's decision to pay then that that false claim is material.

Frequently these cases involve products approved by the Food & Drug Administration (the "FDA"). The FDA does not make payments, however the Agency approves drugs or devices, for which the Government will then reimburse through various programs for which FDA approval is a condition precedent. Therefore, if there is an initial fraudulent inducement against the FDA to get the drug or device approved, then there are practical obstacles that restrict the ability of the Government to stop payment.

One of leading the cases regarding misrepresentations in the context of FDA approval is *D'Agostino v. ev3, Inc*.[61] The relator alleged that ev3 made three different fraudulent representations to the FDA in order to secure FDA approval of ev3's Onyx device.[65] The Defendants allegedly disclaimed certain uses for the device, overstated training it provided for

[60] United States *ex rel.* Harman v. Trinity Indus. Inc., 872 F.3d 645 (5th Cir. 2017); United States ex rel. Campie v. Gilead Scis., Inc., 862 F.3d 890 (9th Cir. 2017).
[61] D'Agostino v. ev3, Inc., 845 F.3d 1, 7 (1st Cir. 2016). [65]
Id. at 7.

the device, and omitted safety information that was vital to the function of the device.[62] The First Circuit struggled with the fact that CMS reimbursed the surgeons that used the device and not the FDA themselves; therefore, the court was searching for a causal link between the claims to the FDA and the CMS payments.[63] The court was unreceptive to the argument that FDA approval was a pre-condition for CMS payment stating that, "alleging that fraudulent representations could have influenced the FDA to approve Onyx falls short of pleading a causal link between the representations made to the FDA and the payments made by CMS. If the representations did not actually cause the FDA to grant approval it otherwise would not have granted, CMS would still have paid the claims."[64] In response, Plaintiff argued that, "as long as [Defendant's] representations at issue could have influenced the FDA to grant approval, then that would be material."[65] Once again, the court dismissed the argument stating that the fraudulent representation must be material to the Government's payment decision itself.[66] The court bolstered this conclusion by observing that CMS continued to pay for the device, even after learning of relator's claims, thereby undermining the suggestion that the misrepresentations were material to CMS' reimbursement decision.[67] Explaining its holding, the court stated, "[t]o rule otherwise would be to turn the FCA into a tool with which a jury of six people could retroactively eliminate the FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA sees no reason to do so."[72] In the wake of

[62] *Id.*
[63] *Id.*
[64] *Id.*
[65] *D'Agostino,* 845 F.3d at 7.
[66] *Id.*
[67] *Id.*
Id.

D'Agostino, many courts have used this quote to dismiss claims pleading materiality in the face of continued Government payment.

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One such case is *United States ex rel. Harman v. Trinity Industries, Inc.*, from the Fifth Circuit.[68] Plaintiff brought an action against a rival manufacturer of highway guardrails claiming that the defendant misrepresented conformance with federal regulations.[74] The federal government subsidizes the cost of highway construction and improvements through grants given to the states.[69] During the periods relevant to the facts of the Harman case, acceptance by the Federal Highway Administration (FHWA) of the products used in the state highway improvements was a prerequisite to eligibility for reimbursement.[70] The plaintiff claimed that the defendant failed to disclose revisions in the guardrail design in a report to the FHWA.[71] Plaintiff alleged that this design revision was a defect that led to several highway deaths.[72] After significant back-and-forth between defendant and the FHWA, including extensive testing, it was found that, despite the failure to disclose the change, the guardrail complied with regulations and thus the Government continued making guardrail cost reimbursements to states.[73]

[68] United States *ex rel.* Harman v. Trinity Indus. Inc., 872 F.3d 645, 661 n. 61 (5th Cir. 2017).
[74] *Id*. at 648.
[69] *Id*. at 648.
[70] *Id*.
[71] *Id.*
[72] *Harman*, 872 F.3d at 648.
[73] *Id*. at 648-49.

Even though the court had relatively stark facts to show the defect was not material, the court remained true to the nuanced materiality-balancing test.[74] The court stated, "the FCA requires proof only that the defendant's false statements 'could have' influenced the Government's pay decision or had the 'potential' to influence the Government's decision, not that the false statements actually did so [...]."[75] The court turned to its sister circuits, identifying the decisions from the First, Seventh, Ninth, D.C, and Third Circuits[76] all holding that continued government payment is enough to dismiss the FCA allegation.[83] Eventually opining that, "[t]he lesson we draw from these well-considered opinions is that, *though not dispositive*, continued payment by the federal government after it learns of the alleged fraud substantially increases the burden on the relator in establishing materiality."[84] Of note however, is the fact that the *Harman* court, unlike many of its sister courts, recognized the "gravity" and "clarity" of governmental decisions, in certain payment decisions.[85] In reference to their own facts though, the court was bound by the fact that this particular decision "risked the lives on our nation's highways, not just undue expense."[86]

Even in the face of such an important Government decision, risking life and limb, the *Harman* court still iterated that, "there are and must be boundaries to government tolerance of a supplier's failure to abide by its rules."[87] The Defendant still argued that when the Government learns of alleged false claims, investigates said claims, and still formally approves the product, there is no materiality argument.[88] Plaintiff countered with the argument that "post-revelation

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[74] *Id.*

[75] *Id*. at 661.

[76] United States *ex rel.* Petratos v. Genentech Inc., 855 F.3d 481, 490 (3d Cir. 2017) is one of the main cases interpreting the post-Escobar materiality standards. In *Petratos,* the court relied heavily on the fact that plaintiff

Id.

actions" by the Government are not determinative in an FCA action, and that the materiality test is "holistic" and no single element is dispositive.[89] Handcuffed by the deliberate inaction of the Government, in light of years of FHWA approval, the court had to decide on behalf of

failed to show any set of facts to establish, and effectively conceded that, the drug makers deficiency was not material because the Government had full knowledge of the violation, yet still paid in full and the FDA certified 3 subsequent drugs from Defendant Genetech. Therefore, if the Government had full knowledge of the violation, the court refused to substitute its decision for that of the Government and could not find materiality.

[83] *Harman*, 872 F.3d at 661 (citing *D'Agostino*, 845 F.3d 1 (1st Cir. 2017); *Sanford-Brown*, 840 F.3d 445 (7th Cir. 2016*);* United States *ex rel.* Kelly v. Serco, Inc., 846 F.3d 325 (9th Cir. 2017); United States *ex rel.* McBride v. Halliburton Co., 848 F.3d 1027 (D.C. Cir. 2017); United States *ex rel.* Petratos v. Genentech Inc., 855 F.3d 481, 490 (3d Cir. 2017).

[84] *Id*. at 663.

[85] *Harman*, 872 F.3d at 663.

[86] *Id*.

[87] *Harman*, 872 F.3d at 664.

[88] *Id*.

[89]

Defendant, finding a lack of materiality.[77] However, the court was receptive to the fact that under different facts, wherein the FHWA acted unaware of the facts of the fraud, the decision to continue payment could be undermined.[78]

The case that gave the Fifth Circuit pause in *Harman* was *United States ex rel. Campie v. Gilead Scis., Inc.*, from the Ninth Circuit.[79] Relators, two former Gilead employees, filed a *qui tam* suit against their former employer alleging it violated the False Claims Act by making false statements about its compliance with Food and Drug Administration regulations regarding the manufacture of certain HIV drugs, resulting in the receipt of billions of dollars from the Government.[80] In order to get a drug approved for manufacture and sale in the United States, a

[77] *Id*. at 665.

[78] *Id*.

[79] *Id*. at 664, 668.

[80] *Campie*, 862 F.3d at 895.

manufacturer must submit a "new drug application" to the FDA, in which it states the chemical composition of a drug and specifies the facilities where it will be made, as well as "methods and controls" used in the manufacturing process.[81] Acceptable facilities must meet federal standards, known as "good manufacturing practices."[82] The FDA may refuse an application or withdraw a previously approved application if the methods or facilities "are inadequate to preserve [the drug's] identity, strength, quality, and purity."[83] For consideration under the Act, the facility must be "acceptable", meaning it must meet certain federal standards, known as "good manufacturing practices."[84] The FDA may refuse an application or withdraw an approved application if the methods or facilities "are inadequate to preserve [the drug's] identity, strength, quality, and purity."[85] Finally, once approved, the drug maker must seek FDA approval to make any "major changes" to the process for the making of the drug before distributing it.[86] All of these requirements entail certification in order to receive and maintain FDA approval.[87]

In the mid-2000,'s Gilead submitted new drug applications and received FDA approval for three HIV drugs.[88] In these drug applications, Gilead certified that the active ingredient in the drugs came from "specific registered factories" located in Canada, Germany, United States, and South Korea.[89] Relators alleged that as early as 2006, Gilead contracted with Synthetics

[81] *Id*. (citing 21 U.S.C. § 355(a), (b)(1); 21 C.F.R. § 314.50(d)(1)).
[82] *Id*.
[83] *Id*.
[84] *Id*.
[85] *Id*. (citing 21 U.S.C. § 355(d), (e)).
[86] *Campie,* 862 F.3d at 895.
[87] *Id*.
[88] *Id*.
[89] *Id*. at 896.
Id.

China to make unapproved FTC at unregistered facilities, and masked this fact by bringing the FTC into the United States through its Canadian and South Korean factories.[90] Gilead ultimately successfully sought approval from the FDA to use Synthetics China's FTC in October 2008, but according to relators, Gilead had been including products from Synthetics China in its finished drug products for at least two years before obtaining approval in 2010.[91] More importantly, relators also alleged that Gilead falsified or concealed data in support of its application to get Synthetics China approved by the FDA.[92] Relators contend that one specific representation regarding drug testing was false, as two of three batches had failed internal testing.[106] Further, Gilead never acknowledged or notified the FDA about the bad test results or the contamination issues.[107] Ultimately, the three claims asserted by relators were that; (1) Gilead actively concealed its use of illicit FTC products by bringing it in through its registered Canada factory

[107]

and changing the labels; (2) augmenting paperwork in order to conceal the source of the FTC; and (3) crediting its approved factories with the product from Synthetics China.[93]

[90] *Id.*
[91] *Campie*, 862 F.3d at 896.
[92] *Campie*, 862 F.3d at 896. [106]
Id. at 896.
[93] *Id*. at 897.

In this instance, the Ninth Circuit determined that FDA approval was the "sine qua non" of federal funding; if the FDA approved the drug then Medicaid would reimburse it.[94] Further, contrary to *D'Agostino*, the *Campie* court emphasized that the FDA and CMS were part of a single agency, Health and Human Services ("HHS").[110] The court noted the fact that the Government was still paying for the drugs created an uphill battle for proving materiality, however, the court was receptive to practical arguments.[111] Specifically, the court stated when fraudulent FDA approval deceives HHS:

> [T]o read too much into the FDA's continued approval—and its effect on the government's payment decision—would be a mistake. First, to do so would allow Gilead to use the allegedly fraudulently-obtained FDA approval as a shield against liability for fraud. Second, as argued by Gilead itself, 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. Third, unlike *Kelly*, where the government continued to accept noncompliant vouchers, *Gilead ultimately stopped using FTC from Synthetics China. Once the unapproved and contaminated drugs were no longer being used, the government's decision to keep paying for compliant drugs does not have the same significance as if the government continued to pay despite continued noncompliance*.[95]

The court stated that these very issues are "matters of proof," and therefore it would be inappropriate to dismiss the claim using 12(b)(6), addressing a stated concern in *D'Agostino* regarding the nature of "proofs" needed to clarify an FDA approval decision.[96] This case is

[94] *Id*. at 905 (citing U.S. *ex rel.* Hendow v. Univ. of Phoenix, 461 F.3d 1166, 1176 (9th Cir. 2006).
[110] *Campie*, 862 F.3d at 905 [111] *Id*. at 906.
[95] *Id*. at 906 (internal citation omitted).
[96] *Campie*, 862 F.3d at 906.
Id.

currently pending a Writ of Certiorari, asking the Supreme Court to address what significance continued Government payment should have.[97][98]

ARGUMENT FOR SUPREME COURT ACCEPTANCE OF THE WRIT FOR CAMPIE:

Campie presents the exact circumstances where, although the Government did continue to pay in light of potential false claims, there are other reasons for the decision, sufficient to survive a 12(b)(6) motion. Unlike many of its sister circuits, the Ninth Circuit correctly viewed continued government payment as but a factor of a larger balancing test. The majority of circuits have been less receptive to the other factors and have put an over-emphasis on continued government payment. There is an ambiguity below as to when, and if, continued Government payment is rebuttable. The majority of circuits seem to say that this rebuttal is near impossible, however practically this is not true, as articulated by *Campie, Miller,* and *Harman.*

When describing the factors in *Escobar* Justice Thomas stated that, "Continued payment or acceptance by the Government of the fraudulent claim is very strong evidence against materiality."[99] Many of the circuits below that dismiss almost all claims where the Government continues to pay are misusing this quote.[100] Many of these Circuits, like the Third Circuit in

[97] Gilead Sciences, Inc. v. United States, *ex rel*. Jeffrey Campie, *et al*., Petition for Writ of Certiorari 17-936 (January 3, 2018).

[98] The final main case in the series of post-Escobar materiality cases is *United States ex rel. Miller v. Weston Educ., Inc.*, 840 F.3d 494 (8th Cir. 2016). Like *Sanford-Brown*, cited above, *Miller* involved false certification of school records in violation of the Higher Education Act. In *Miller*, the court placed significant weight on a pre-condition of payment because this specific condition certified in three separate ways, therefore overcoming the fact that the Government continued to pay the school. If the Government were to rely on these falsely certified records then there would be no reason for them not to pay claims by the school. The court found it important that this condition was so heavily bargained for, stressing the importance of the school's honest record keeping, with regard to the Government's payments.

[99] *Escobar*, 136 S.Ct. at 1995.

[100] *D'Agostino*, 845 F.3d 1 (1st Cir. 2017); *Sanford-Brown*, 840 F.3d 445 (7th Cir. 2016*);* United States *ex rel*. Kelly v. Serco, Inc., 846 F.3d 325 (9th Cir. 2017); United States *ex rel*. McBride v. Halliburton Co., 848 F.3d 1027 (D.C. Cir. 2017); United States *ex rel*. Petratos v. Genentech Inc., 855 F.3d 481, 490 (3d Cir. 2017).

Petratos, have had facts that make the continued payment a relatively clear statement of immateriality. However, there are circumstances where courts should be more receptive to practical and public policy limitations for the Government to stop payment.

For example, in *United States ex rel. Kelly v. Serco, Inc.*, the Ninth Circuit grappled with materiality again.[101] However, in that case the court relied heavily on Justice Thomas's "option to not pay" wording about possible violations, while at the same time dismissing the fact that the Government relied on Defendant's reports to make its payment decisions.[102] Therefore, if the reports omitted certain details or misrepresented facts, the Government would be rely on those reports and make payments above and beyond what was actually required.[103] This is not the type of fact that Justice Thomas envisioned discarding so easily when he established his materiality requirement. The Ninth Circuit essentially considered the Government's reliance on said reports as irrelevant, in direct contrast with how Thomas instructed courts to view payment options.[104] Perhaps the court still might have decided in the same manner, but still the Government's reliance on the reports is relevant, as per Justice Thomas's instructions.

The Supreme Court could cite *Miller* as a way of showing how government reliance on contractual provisions functions in a manner that respects the relevancy of all of Justice Thomas's factors. In *Miller*, while it was true that the Government did continue to pay defendant's claims, it was relevant that the Government relied heavily on the academic reports the school was required to submit as a pre-condition of payment.[105] Keenly aware of the importance of these reports, the court was vigilant to include them in the analysis, keeping in

[101] *Kelly*, 846 F.3d at 334.
[102] *Id.*
[103] *Id.*
[104] *Id.*
[105] *Miller*, 840 F.3d at 504.

mind that Justice Thomas said these types of pre-conditions, while not dispositive, were still relevant.[106] The court in Miller exercised the proper type of balancing Justice Thomas envisioned.[107] If the court were to have over-emphasized continued government payment, the court would have missed a key factor of materiality in this case, highlighting the importance of Justice Thomas's holistic test.

D'Agostino presents another case in which a lower court misused the *Escobar* materiality test. This is problematic because *D'Agostino* is one of the most highly cited cases when it comes to interpreting the *Escobar* standard. The First Circuit failed to recognize that the FDA and CMS are actually one agency of the Government.[108] Therefore, a fraud on the FDA is not independent from the Government's decision as the FDA and CMS function as one, HHS, in making payment decisions. From the outset, the First Circuit's interpretation is flawed. However, what is more egregious is the fact that the court was highly dismissive of the fact that by defrauding the FDA into granting approval, the defendant effectively guaranteed payment by the Government.[126] If the FDA approves the drug then CMS will pay for it. It is not within CMS's purview to investigate drugs if the FDA has approved them. Therefore, until the FDA pulls approval the Government will continue to pay. This set of facts highlights the importance of Justice Thomas's factors, as a whole, deciding materiality, not just continued government payment alone. One factor cannot tell the whole story of materiality; therefore, it is vital that the Supreme Court accept the writ in *Campie,* and reinforce the premise that no one factor is

[106] *Id*.
[107] *Id*.
[108] *D'Agostino*, 845 F.3d at 7 [126]
Id.

dispositive, or else the courts below will continue to over-emphasize continued government payment.

In *Campie*, the court acknowledged the fact that the FDA may have many different reasons for pulling, or not pulling a drug's approval, and until that time comes, the Government will have a hard time denying payment for a drug that is FDA approved.[109] The drugs made by Gilead were vital drugs for the treatment of HIV.[110] There is a significant community of individuals afflicted with HIV, on Medicaid or Medicare, reliant on these drugs. Gilead provided the only three makes of this particular HIV drug, so with its drug off the CMS list, the patients had no alternatives. If the FDA approves a drug, and it is medically necessary with no adequate alternative, then CMS will automatically pay for that drug, until the FDA either pulls the approval or approves a new, cheaper alternative. As stated in *Campie*, the FDA approval is the *sine qua non* of receipt of state funding.[129] Therefore, if while the FDA investigated these potential fraudulent misrepresentations, the Government pulled reimbursement of these drugs, then a large population of very sick individuals might be without vital medication until the potential false claim is resolved.

If the Supreme Court were to allow the lower courts to misuse Justice Thomas's test and over-emphasize government payment then it would force agencies, like CMS, to change their reimbursement procedures. In order to maintain an FCA claim, CMS would need to start pulling funding when the FDA gains knowledge of a potential false claim. Otherwise, if the Government continues to pay, as it currently does, while the FDA is investigating, defendant's will always have a claim that the Government's continued payment while it had knowledge of a

[109] *Campie*, 862 F.3d at 905.
[110] *Id*. at 896. [129]
Id. at 905.

potential violation shows the violation was not material. This would be a problematic procedure for any government agency to abide by, especially CMS where it involves the health of our nation. In the event that the FDA finds the fraud to be negligible, all that irreparable harm upon those patients was for naught. Perhaps Justice Thomas contemplated this scenario when creating his balancing test, but in any event, the Justice's balancing test is still that; a balancing test. The courts below, in decisions like *D'Agostino* and *Kelly*, are acting in direct contravention of the Supreme Court's directive and are thus, promulgating poor case law.

Second, In *Campie*, Gilead was able to use the FDA approval as a shield against the materiality argument, in that the FDA approval was the starting point for Government payment. The strict materiality standard, in that instance, allowed Gilead to promulgate a fraud on the FDA to secure approval, and then in turn receive funding from HHS based on that initial fraud on the FDA, while avoiding a materiality argument.[111] This is inapposite to the purpose of the materiality standard of the FCA as iterated in *Escobar*. Especially in light of the fact that, once the FDA began investigating Gilead, it ceased using Synthetics China, and thus came into conformance with the FDA's initial approval. To allow Gilead to escape in this instance, essentially allows companies to commit a fraud until caught, then simply come into compliance, and use the continued payment after their re-conformance as a sword against materiality. Gilead was content to continue its fraudulent activity, until the FDA finally realized that something with the drugs manufacturing process was amiss. While it is true that Gilead ultimately came into conformance with regulations, the fraud promulgated upon the FDA initially should not be ignored simply because Gilead changed their misdoings.

[111] *Id*. at 899.

The Supreme Court can also use the holding from the First Circuit in *Escobar*, to reinforce how their balancing test works when it comes to misrepresentations in general, outside of the FDA context.[112] While it is true that the Government continued to reimburse Universal Health Services, the Government only did so because of the misrepresentations made by the workers at the facility.[113] Had it not been for those misrepresentations the Government would not have paid.[114] Further, the Government relied on the billing report as being accurate and in compliance with the standards proscribed by the program and thus continued to pay the claims.[115] The First Circuit faithfully used the factors as just that, factors, all weighed in reference in to the whole of the circumstance, not simply just looking at continued government payment.

The above argument shows why this is a standard, in some circumstances, best left for decision at a later stage than at a 12(b)(6) motion to dismiss. To answer this question, it is vital to prove what "actual knowledge" the Government had.[116] This position receives support from the premise that many times the communication between the Government and its Agencies responsible for regulation in various industries is not always efficient. It might take some time for the Government to become aware of an FDA, or another agency's investigation, and then even more time for them to decide, and actually have the ability to pull funding. There are several steps of proofs in order to say definitively the Government had "actual knowledge" necessary to decide if a violation is material or not.

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[112] United States *ex rel.* Escobar v. Universal Health Servs., Inc., 842 F.3d 103, 109 (1st Cir. 2016).
[113] *Id*. at 110.
[114] *Id*.
[115] *Id*.
[116] *Campie*, 862 F.3d at 905-6.

The Court can use a combination of *Campie, Harman,* and *Miller* to provide clarity for the courts below when it interprets cases involving continued government payment. The Supreme Court can use *Campie* to explain how the circumstances behind continued government payment might say more as to why the Government continued to pay. *Campie, D'Agostino,* and *Petratos* all showed that if there were a misrepresentation made to the FDA to secure approval fraudulently then CMS would pay for that drug automatically. The Supreme Court will need to address the issue in Circuits' interpretations that allows defendants to plead a lack of materiality because CMS continued to pay while the FDA was investigating whether it should pull a drug's approval. Practically, it would be very problematic for CMS to pull funding at the beginning of every investigation by the FDA. The Supreme Court could relate a spectrum of facts ranging from *Petratos* to *Campie,* the former leading to a finding of no materiality and the latter a finding of materiality. In *Petratos,* the FDA investigated the drug and found the misrepresentation to be negligible, so obviously the false claim was not material to the Government's decision. The Supreme Court could use those facts as one end of the spectrum. Contrast those facts with *Campie*, where Gilead directly violated the FDA agreements, changed ingredients and failed to disclose failed drug tests. It is clear there that if the FDA had known of such serious violations; the Agency would have pulled the approval, therefore pulling the Government payment as well. With that spectrum of facts established it would give the lower courts a clear articulation on how to view misrepresentations made to secure payments and clear up the over-emphasis on continued payment.

Moreover, the Court could use *Miller* to emphasize how in certain instances bargained for contractual provisions could be highly relevant to materiality despite the fact that the Government continued to pay. In *Miller*, it was clear how important the bargained-for

requirements for academic reporting's were. The Government made it exceedingly clear that it would rely on those reports in making its payment decisions. While it is true that Justice Thomas stated these pre-conditions are merely "relevant and not dispositive" in some instances, the Court should remain true to the "natural tendency" test also articulated by Thomas. If parties take such painstaking efforts to create contractual provisions, like in common-law, those provisions should hold some weight. Further, when it is clear the Government is relying on them, so if the defendant has falsified those provisions then the Government would obviously pay. Therefore, the Court can use *Miller* to illustrate how in some cases, the contractual provisions can hold weight beyond continued government payment.

When there are ambiguities among the circuits, it is vital for the Supreme Court to answer that ambiguity, and provide clarity. *Campie* provides the platform for the Court to address the discrepancy head on. The Supreme Court here can remain true to its standard created by Justice

Thomas, and use Circuit cases to show the courts how to faithfully apply that balancing standard.