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Editorial Office
230 Park Ave., 7th Floor, New York, NY 10169 (800) 543-6862
www.lexisnexis.com

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The Evolution of *Escobar* in 2017 and the False Claims Act Today

By Dismas N. Locaria, Michael T. Francel, and Spencer P. Williams*

In 2017, a number of courts wrangled with the interpretation and fallout from Escobar, *which in turn is making for an interesting 2018. In addition, several memoranda have been issued by the Department of Justice that will significantly alter the False Claims Act landscape for years to come. The authors of this article review the legal issues and note that recipients of federal funds should take stock of such developments in order to be prepared for the road ahead.*

As we continue to see civil enforcement under the False Claims Act resulting in eye-popping recoveries, and in the wake of the U.S. Supreme Court's 2016 False Claims Act ("FCA") decision in *United Health Services, Inc. v. United States ex rel. Escobar* ("*Escobar*"),[1] the FCA has never been of greater interest. 2017 was particularly interesting as we saw a number of courts wrangle with the interpretation and fallout from *Escobar*, which in turn is making for an interesting 2018. Furthermore, several memoranda have been issued by the Department of Justice ("DOJ") that will significantly alter the FCA landscape for years to come. As a consequence, it is important for recipients of federal funds (whether contracts or grants) to take stock of such developments in order to be prepared for the road ahead.

RECALLING *ESCOBAR*

In June of 2016, the Supreme Court, in its *Escobar* decision, affirmed but constrained the implied certification theory based on the materiality of the subject of the implied certification. In particular, the Supreme Court held that the implied certification theory can create FCA liability when:

- "the claim does not merely request payment, but also makes specific representations about the goods or services provided"; and
- "the defendant's failure to disclose noncompliance with *material* statutory, regulatory, or contractual requirements makes those repre-

* Dismas Locaria, a partner at Venable LLP, a member of the firm's Government Contracts Group, and a member of the Board of Editors of *Pratt's Government Contracting Law Report*, assists government contractors in all aspects of working with the federal government. Michael T. Francel and Spencer P. Williams are associates in the firm's Government Contracts Group. The authors may be reached at dlocaria@venable.com, mtfrancel@venable.com, and spwilliams@venable.com, respectively.

[1] 136 S. Ct. 1989 (2016).

sentations misleading half-truths."[2]

But the Court curtailed the scope of this theory by limiting material requirements to those that are not "minor and insubstantial" and explained that the parties' course of conduct may indicate whether a requirement was in fact material. For example, if certain noncompliances were known, but the government continued to pay, that would be strong indicia that the requirement was not material.[3] Consequently, 2017 has seen a number of appellate level decisions flushing out the difference between material and non-material requirements.

COURTS' HANDLING OF MATERIALITY IN 2017

As noted above, the decision to pay, despite actual knowledge of a noncompliance was considered by the *Escobar* Court as strong indicia that a requirement is not material. In the year following *Escobar*, several U.S. Courts of Appeal examined this issue.

In *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*,[4] the U.S. Court of Appeals for the First Circuit found, in the context of its approval of medical devices, that the Food and Drug Administration ("FDA") "possesses a full array of tools for 'detecting, deterring, and punishing false statements made during . . . approval processes' " and that the FDA's decision "not to employ these tools in the wake of Relators' allegations so as to withdraw or even suspend its approval of the . . . device leaves Relators with a break in the causal chain between the alleged misstatements and the payment of any false claim."[5] The First Circuit stated that the FDA's decision not to act "renders a claim of materiality implausible."[6] Quoting the "very strong evidence" language from *Escobar* regarding the government's continued payment, the First Circuit found compelling that "the FDA allowed the device to remain on the market" despite the Relators' allegations.[7] The First Circuit relied heavily on its decision in *D'Agostino v. ev3, Inc.*, from late 2016 that also focused on government payment despite full knowledge of violations of requirements.[8]

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[2] *Id.* at 2001 (emphasis added).

[3] *Id.* at 2003 (holding "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.") (emphasis added).

[4] 865 F.3d 29 (1st Cir. 2017), *cert. denied,* (U.S. Apr. 6, 2018) (No. 17-1108).

[5] *Id.* at 34.

[6] *Id.*

[7] *Id.* at 35.

[8] *See D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7 (1st Cir. 2016) ("The fact that CMS has not

The U.S. Court of Appeals for the Third Circuit applied *Escobar*'s materiality standard with respect to government payment twice in 2017, each time finding that the relator's allegations were insufficient to meet the high standard. In *United States ex rel. Petratos v. Genentech Inc.*,[9] the relator alleged that Genentech concealed information about a cancer drug's health risks. The Third Circuit, affirming the district court's dismissal, found that an alleged misrepresentation is not material "when the relator concedes that the Government would have paid the claims with full knowledge of the alleged noncompliance."[10] In *United States ex rel. Spay v. CVS Caremark Corporation*,[11] in affirming the district court's summary judgment in favor of the defendant, the Third Circuit concluded that the claims were not material because the Centers for Medicare & Medicaid ("CMS") specifically knew of the violations at issue (use of dummy identification numbers by Pharmacy Benefit Managers ("PBMs")) and routinely paid the PBMs despite the use of the dummy numbers.[12]

The U.S. Court of Appeals for the Fifth Circuit also twice addressed materiality in the context of the government's continued acquiescence through payments. In *Abbott v. BP Exploration & Production*,[13] the plaintiffs asserted that BP falsely certified compliance with various regulatory requirements with respect to the Atlantis Platform, an oil production facility located in the Gulf of Mexico. In response, the Department of the Interior ("DOI") conducted a full investigation, finding that the allegations were without merit and that no grounds existed to suspend operations of the Atlantis Platform. In affirming the district court's grant of summary judgment in favor of BP, the Fifth Circuit concluded: "As recognized in *Escobar*, when the DOI decided to allow the Atlantis to continue drilling after a substantial investigation into Plaintiffs' allegations, that decision represents 'strong evidence' that the requirements in those regulations are not material."[14] In *United States ex rel. Harman v. Trinity Industries Inc.*,[15] the Federal Highway Administration ("FHWA") approved defendant's guardrail end terminals and found them eligible for reimbursement

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denied reimbursement for Onyx in the wake of D'Agostino's allegations casts serious doubt on the materiality of the fraudulent representations that D'Agostino alleges.").

[9] 855 F.3d 481 (3d Cir. 2017).

[10] *Id.* at 490.

[11] 875 F.3d 746 (3d Cir. 2017).

[12] *Id.* at 764–65.

[13] 851 F.3d 384 (5th Cir. 2017).

[14] *Id.* at 388.

[15] 872 F.3d 645 (5th Cir. 2017), *petition for cert. filed* (U.S. Feb. 12, 2018) (No. 17-1149), *docketed* (U.S. Feb. 16, 2018).

despite a flawed crash test report sent to FHWA by the defendant that had inadvertent omissions about design changes. After analyzing other recent Circuit Court decisions interpreting the *Escobar* materiality standard, the Fifth Circuit reasoned 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."[16] Finding a lack of materiality and rendering judgment as a matter of law in favor of the defendant (and in turn overturning a $633 million jury verdict), the Fifth Circuit emphasized FHWA's explicit approval of the end terminals and insistence that the changes made did not affect its decision to purchase the end terminals.

In *United States ex rel. Kelly v. Serco, Inc.*,[17] the U.S. Court of Appeals for the Ninth Circuit, in affirming the district court's grant of summary judgment in favor of the defendant, in part relied on the fact that the Department of Homeland Security ("DHS") knew of the defendant's cost tracking system, had approved it, and had paid for the work provided:

> Given the demanding standard required for materiality under the FCA, the government's acceptance of Serco's reports despite their non-compliance with ANSI-748, and the government's payment of Serco's public vouchers for its work under Delivery Orders 49 and 54, we conclude that no reasonable jury could return a verdict for Kelly on his implied false certification claim.[18]

Finally, in *United States ex rel. McBride v. Halliburton Co.*,[19] the U.S. Court of Appeals for the D.C. Circuit, in affirming the district court's grant of summary judgment in favor of the defendant and finding no materiality with respect to violations of requirements through the maintenance of inflated headcounts at U.S. Army recreation centers, relied on the fact that "the DCAA investigated McBride's allegations and did not disallow any charged costs" and "KBR continued to receive an award fee for exceptional performance under Task Order 59 even after the Government learned of the allegations."[20] The D.C. Circuit found that this was " 'very strong evidence' that the requirements allegedly violated by the maintenance of inflated headcounts are not material."[21]

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16 *Id.* at 663.

17 846 F.3d 325 (9th Cir. 2017).

18 *Id.* at 334.

19 848 F.3d 1027 (D.C. Cir. 2017).

20 *Id.* at 1034.

21 *Id.*

Notwithstanding these circuit court decisions, as eluded to by the Fifth Circuit in *United States ex rel. Harman v. Trinity Industries Inc.*, the government's decision to pay is not dispositive.[22] In fact, in *United States ex rel. Campie v. Gilead Sciences, Inc.*,[23] the Ninth Circuit held differently. Here, Gilead Sciences, a drug manufacturer, had represented in its new drug applications ("NDAs") to the FDA that it would source an ingredient for its drugs from registered facilities in Canada, Germany, the United States, and South Korea.[24] Gilead began sourcing the ingredient from a Chinese facility but claimed that the ingredient had come from South Korea. The relators asserted that Gilead had been inserting products from the Chinese facility into its finished drugs for at least two years before it sought approval from the FDA to do so.[25] Gilead eventually stopped using the Chinese facility as a supplier following continued contamination issues.[26] Relators alleged that "because the drugs paid for by the government contained [an ingredient] sourced at unregistered facilities, they were not FDA approved and therefore not eligible for payment under the government programs."[27] Gilead argued that the continued FDA approval of and payment for the drugs after the FDA knew of the noncompliance make the violations not material to its payment decision. The Ninth Circuit disagreed, finding that "[i]t is undisputed that at all times relevant, the drugs at issue were FDA-approved, and that the government continues to make direct payments and provide reimbursements for the sale of the three drugs" and thus the relators "face an uphill battle in alleging materiality sufficient to maintain their claims."[28] Despite these statements, the Ninth Circuit instead found persuasive plaintiffs' argument that one should not "read too much into the FDA's continued approval—and its effect on the government's payment decision," for several reasons:

> 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

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[22] 872 F.3d at 663.

[23] 862 F.3d 890 (9th Cir. 2017), *petition for cert. filed* (U.S. Dec. 26, 2017) (No. 17-936), *docketed* (U.S. Jan. 3, 2018).

[24] *Id.* at 895–96.

[25] *Id.* at 896.

[26] *Id.*

[27] *Id.*

[28] *Id.* at 905.

> adulterated drugs. Third, unlike *Kelly*, where the government continued to accept noncompliant vouchers, Gilead ultimately stopped using [the ingredient] from [the Chinese facility]. 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.[29]

Relevant to the Ninth Circuit's conclusion was the fact that it was disputed, and there was no evidence before the court, whether and when the FDA had actual knowledge of the violations.[30] Therefore, the Ninth Circuit found that the relators had sufficiently pled materiality and reversed the district court's dismissal of the claims. As discussed further below, Gilead filed its petition for certiorari to the Supreme Court in December 2017, which was docketed in January 2018.

CASES TO WATCH

Whether the government's continued payments despite knowledge of a violation constitutes materiality as a matter of law may reach the Supreme Court as Gilead Sciences petitioned the Court to grant certiorari.[31] Gilead contends that the Ninth Circuit misapplied the *Escobar* materiality standard by requiring defendants "to show immateriality, even where the government continued to make purchases."[32] The Ninth Circuit had revived this whistleblower action, citing a dispute between the relators and the defendant about "exactly what the government knew and when," making it unclear whether the government's acquiescence through continued payments was made knowing Gilead was in noncompliance.[33] In *Gilead*, relators claimed Gilead's requests for payment for FDA-approved drugs impliedly certified that Gilead's drugs were manufactured at approved facilities and not adulterated, when in fact the drugs were not.[34] Though Gilead countered that under *Escobar* the government's continued payment despite knowledge of the violation demonstrated the violations were not material, the Ninth Circuit decided the issue raised by the

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[29] *Id.* at 906 (citation removed).

[30] *Id.* at 906–07.

[31] Petition for Certiorari, *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890 (9th Cir. 2017), *petition for cert. filed* (U.S. Dec. 26, 2017) (No. 15-16380), *docketed* (U.S. Jan. 3, 2018).

[32] *Id.* at 19.

[33] 862 F.3d at 906–07.

[34] *Id.* at 894.

parties was a matter of proof, not law.[35] Gilead's petition has been joined by multiple third parties, including the U.S. Chamber of Commerce,[36] the Coalition for Government Procurement,[37] and others.

Another case to follow is *Rose v. Stephens Institute*, in which the relator claimed defendant defrauded the U.S. Department of Education ("DOE") by falsely alleging compliance with Title IV of the Higher Education Act.[38] While defendant argued that DOE knew of the violation but continued to make payments, indicating the violation was not material, the district court found that "the DOE's decision to not take action against AAU despite its awareness of the allegations in this case is not terribly relevant to materiality."[39] The district court relied in part on a pre-*Escobar* decision that found compliance with the Title IV requirement at issue was determined to be material.[40] Following the district court's decision, the defendant moved to certify the court's order for interlocutory appeal and oral arguments were held on December 6, 2017.[41] During oral arguments, Judge Graber of the Ninth Circuit commented that there could be many reasons that the government pays a claim despite knowledge of a violation, and thus government acquiescence should not be dispositive.[42] Whether or not this comment—or some iteration of it—works its way into a final decision will be of interest as it is a departure from other circuits who have viewed continued acquiescence as proof of immateriality.[43] The comment, however, harkens back to the Ninth Circuit's

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[35] *Id.* at 906–07.

[36] Brief for Amicus Curiae, *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890 (9th Cir. 2017), *brief for amicus curiae in support of petitioner filed* (U.S. Feb. 1, 2018) (No. 17-936) (also joined by the National Defense Industrial Association, the American Tort Reform Association, the American Health Care Association, and the National Center for Assisted Living).

[37] Brief for Amicus Curiae, *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890 (9th Cir. 2017), *brief for amicus curiae in support of petitioner filed* (U.S. Feb. 2, 2018) (No. 17-936).

[38] No. 09-CV-05966-PJH (N.D. Cal. Sept. 20, 2016), *motion to certify appeal granted sub nom. Rose v. Stephens Institute*, No. 09-CV-05966-PJH (N.D. Cal. Oct. 28, 2016).

[39] *Id.*

[40] *Id.* ("However, *Hendow* further found that 'if the University had not agreed to comply with [the ICB], it would not have gotten paid.' As a result, this court finds that *Hendow* and *Escobar* are not 'clearly irreconcilable,' and thus *Hendow* remains binding precedent." (internal citation omitted)).

[41] Recording of Oral Argument, *United States ex rel. Rose et al. v. Stephens Institute*, 17-15111 (9th Cir. Dec. 6, 2017).

[42] *Id.*

[43] *See, e.g.*, *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 35 (1st Cir.

decision in *Campie* discussed above, in which the court stated 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."[44] It will be interesting to see whether the Ninth Circuit follows the same path in *Rose* as it did in *Campie*.

In a recent decision, a district court granted judgment as a matter of law for the defendants for relator's failure to offer proof of materiality and vacated a $350 million jury verdict for the relator.[45] In *Ruckh v. Salus Rehabiliation*, *LLC*, the relator claimed that the defendants filed false claims against the government by failing to maintain a "comprehensive care plan" as required by Medicaid regulations and by submitting unsigned and undated documents for reimbursement by Medicare. According to the court, however, the relator failed to demonstrate that the government would have considered either violation material, especially in light of the government's knowledge of the violations.[46] More importantly, the decision describes *Escobar*'s materiality standard as one that "rejects a system of government traps, zaps, and zingers that permits the government to retain the benefit of a substantially conforming good or service but to recover the price entirely—multiplied by three—because of some immaterial contractual or regulatory non-compliance."[47] On February 8, 2018, the relator filed a Notice of Appeal to the U.S. Court of Appeals for the Eleventh Circuit.[48]

Though the Eleventh Circuit has not yet wrestled with the materiality standard under *Escobar*, it did recently revive a pre-*Escobar* whistleblower suit relating to the sale of helicopters under the U.S. foreign military sale ("FMS") program in *United States ex rel. Marsteller et al. v. Tilton et al.*[49] There, the relators alleged that improprieties in the relationship between a U.S. Army procurement official and several military contractors required that the defen-

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2017) (affirming district court's dismissal on materiality grounds when "the complaint allege[d] that Relators told the FDA about every aspect of the design . . . that they felt was substandard, yet the FDA allowed the device to remain on the market"), *petition for cert. filed* (U.S. Feb. 5, 2018), *docketed* (Feb. 7, 2018) (No. 17-1109).

[44] 862 F.3d at 906.

[45] *United States ex rel. Ruckh v. Salus Rehab., LLC*, No. 8:11-CV-1303-T-23TBM (M.D. Fla. Jan. 11, 2018).

[46] *Id.*

[47] *Id.*

[48] Relator's Notice of Appeal, *United States ex rel. Ruckh v. Salus Rehab., LLC*, No. 8:11-CV-1303-SDM-CPT (M.D. Fla. Feb. 8, 2018), ECF No. 476.

[49] 880 F.3d 1302 (11th Cir. 2018).

dants disclose the relationship under FAR 52.203-13, Contractor Code of Business Ethics and Conduct, and the Truth in Negotiations Act ("TINA").[50] The district court had dismissed relators' claims because none of the contracts in question required compliance with either requirement as an express condition of payment.[51] In reviving the suit, the Eleventh Circuit noted an express condition of payment is no longer dispositive and directed the district court to analyze the allegations under the *Escobar* materiality standard—specifically whether the alleged violations were "garden-variety breaches" or not.[52]

THE DEPARTMENT OF JUSTICE'S CHANGING DIRECTION

Also impacting the FCA this year and into the foreseeable future are several memoranda issued by the Department of Justice. Two related memoranda were issued on November 16, 2017, by Attorney General Sessions ("Sessions Memorandum"), and a second on January 25, 2018, by Associate Attorney General Rachel Brand ("Brand Memorandum"). The Sessions Memorandum prohibits DOJ components from issuing guidance documents that purport to create rights or obligations without such guidance first undergoing the notice-and-comment rulemaking process.[53] As it relates to FCA compliance, this memorandum prohibits DOJ from using these guidance documents to force regulated parties into taking action or refraining from taking action based on applicable statutes or lawful regulation.[54] The Brand Memorandum plays off of the Sessions Memorandum by stating that the "principles from the [Sessions Memorandum] are relevant to more than just [DOJ's] own publication of guidance documents [and] also should guide [DOJ] litigators in determining the legal relevance of other agencies' guidance documents in affirmative civil enforcement" (*i.e.,* the FCA).[55] In practice this means that DOJ attorneys should not be imposing guidance documents as establishing binding rules, from which to predicate civil enforcement actions.

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[50] *Id.* at 1307. 10 U.S.C. § 2306a.

[51] *Id.* at 1311.

[52] *Id.* at 1313 ("The Supreme Court explicitly rejected a standard for implied certification claims that focuses exclusively on whether the Government expressly designates a contractual, statutory, or regulatory obligation as a condition of payment. Whether a condition is so designated is 'relevant to but not dispositive of the materiality inquiry,' but not a precondition to the theory of liability itself." (quoting *Escobar*, 136 S. Ct. at 2001)).

[53] Memorandum from Jeff Sessions, Attorney General of the U.S. to all components of the U.S. Dep't of Justice (November 16, 2017).

[54] *Id.*

[55] Memorandum from Rachel Brand, Assistant Attorney General of the U.S. Dep't of Justice to U.S. Attorneys (January 25, 2018) at 1.

In addition to these memoranda, on January 10, 2018, Michael Granston, Director of the Commercial Litigation Branch of DOJ's Fraud Section, issued a memorandum explaining that due, in part, to the record number of *qui tam* cases filed in recent years, Department attorneys, when evaluating whether to intervene in a *qui tam* action, should also consider whether the government should seek to dismiss the case altogether.[56] Granston explained that this approach is needed because of the resources required to monitor these cases, even those where the government does not intervene, and the potential for adverse decisions stemming from such cases that could impact the government's ability to enforce the FCA.[57] As a result, Granston lays out a non-exhaustive list of seven factors that DOJ attorneys can use as a basis for dismissal:

- Curbing meritless *qui tam* cases;
- Preventing parasitic or opportunistic *qui tam* actions;
- Preventing the interference with agency policies and programs;
- Controlling litigation brought on behalf of the United States;
- Safeguarding classified information and national security interests;
- Preserving government resources; and
- Addressing egregious procedural errors.[58]

THE FUTURE

There is no question that while the FCA has led to record breaking numbers in recent years, changes are on the horizon. The *Escobar* decision appears to have placed a marker that makes clear that should the government become aware and not take exception to a noncompliance, and in particular, make payment, subsequent allegations of fraud may fail on the basis of materiality. This may ultimately result in greater delays in payment and/or earlier and more frequent claims of breach, yet, with respect to fraud and the treble damages associated with it, the *Escobar* decision and the early circuit court decisions are largely providing some respite to contractors. Couple this with DOJ's position to limit the types of materials from which it can rely upon to impose civil enforcement and potentially a new found desire to curb certain *qui tam* complaints, we may see FCA recoveries begin to ease, which would certainly be

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[56] Memorandum from Michael Granston, Director of the Fraud Section of the Commercial Litigation Branch, U.S. Dep't of Justice to Fraud Section Attorneys and U.S. Attorneys handling False Claims Act Cases (January 10, 2018) at 1.

[57] *Id.*

[58] *Id.* at 3–7.

a welcome relief from recipients of federal funds, most of which take pride in the work they do for and on behalf of the federal government.