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From Guns that Do Not Shoot to Foreign Staplers

HAS THE SUPREME COURT'S MATERIALITY STANDARD UNDER *ESCOBAR* PROVIDED CLARITY FOR THE HEALTH CARE INDUSTRY ABOUT FRAUD UNDER THE FALSE CLAIMS ACT?

Deborah R. Farringer[†]

INTRODUCTION

It all started out simply enough. Members of Congress became aware of stories involving rampant fraud against the federal government: Brooks Brothers, a government contractor that during the Civil War contracted to manufacture 12,000 uniforms for the Union Army, glued together “shredded, often decaying rags, pressed them into a semblance of cloth, and sewed the pieces into uniforms,” which promptly disintegrated upon being exposed to rain for the first time, all in an effort to maximize profit on the contract;¹ Army Quartermasters purchased the same mules again and again from suppliers; the government procured infantry boots for Union soldiers that were made of cardboard and would wear out after only a mile’s long march.² Thus, in an effort to curb the “grossest frauds upon the Government,”³ the U.S. Congress enacted the False Claims Act

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¹ Ron Soodalter, *The Union’s ‘Shoddy’ Aristocracy*, N.Y. TIMES: OPINIONATOR (May 9, 2011, 9:30 PM), <https://opinionator.blogs.nytimes.com/2011/05/09/the-unions-shoddy-aristocracy> [<http://perma.cc/J9H8-4WME>].

² James B. Helmer, Jr., *False Claims Act: Incentivizing Integrity for 150 Years for Rogues, Privateers, Parasites and Patriots*, 81 U. CIN. L. REV. 1261, 1264 (2013) (citing 132 CONG. REC. H6482 (daily ed. Sept. 9, 1986) (statement of Rep. Berman); CONG. GLOBE, 37th Cong., 3d Sess. 955 (1863)).

³ CONG. GLOBE, 37th Cong., 3d Sess. 956.

(FCA).⁴ Utilizing a legal mechanism originating in England known as a *qui tam* suit,⁵ the FCA, enacted March 2, 1863, permits both private individuals and the federal government (through the U.S. district attorneys' offices) to file an action in court on behalf of the United States against a government contractor believed to have knowingly submitted false claims to the federal government for payment.⁶

During the 150-plus years since enactment of the FCA, it has become one of the federal government's most successful enforcement mechanisms against government contractors and in no industry has it been more impactful than in health care.⁷ While it was clear in 1863 that selling the same mule to the federal government over and over was fraud, in the complicated and highly regulated structure of the U.S. health care system, with multiple federal health care programs that provide payment and services to individuals in various forms, identifying fraud has become increasingly challenging.⁸ If knowingly billing the federal government for a physician visit that never actually took place is the submission of a "false claim" to the federal government,⁹ what about billing for a service that,

⁴ False Claims Act, ch. 67, 12 Stat. 696 (1863) (codified as amended at 31 U.S.C. § 3729 *et seq.* (2012)).

⁵ Helmer, *supra* note 2, at 1262 (noting that "the concept of enlisting members of the public to protect the King's property is actually hundreds of years old" and that the suits are "called *qui tam* actions because they are brought by a person *qui tam pro domino rege quam pro si ipso in hac parte sequitur*, that is, '[w]ho sues on behalf of the king as well as for himself.'" (quoting *Qui Tam Action*, BLACK'S LAW DICTIONARY (6th ed. 1990))).

⁶ False Claims Act, 12 Stat. at 696–99.

⁷ Press Release, U.S. Dep't of Justice, Justice Department Recovers Over \$4.7 Billion from False Claims Act Cases in Fiscal Year 2016 (Dec. 14, 2016), <https://www.justice.gov/opa/pr/justice-department-recovers-over-47-billion-false-claims-act-cases-fiscal-year-2016> [<http://perma.cc/U3Z5-8SC3>] [hereinafter Justice Dep't Recovers Over \$4.7 Billion] (reporting that, in fiscal year 2016, the health care industry accounted for over 53 percent of the total recovery under the FCA); *see also* Press Release, U.S. Dep't of Justice, Justice Department Recovers From False Claims Act Cases in Fiscal Year 2017 (Dec. 21, 2017), <https://www.justice.gov/opa/pr/justice-department-recovers-over-37-billion-false-claims-act-cases-fiscal-year-2017> [<https://perma.cc/PP7Q-BVQ3>] [hereinafter Justice Dep't Recovers Over \$3.7 Billion] (reporting that, in fiscal year 2017, the health care industry accounted for \$2.4 billion of the \$3.7 billion total that was collected, which equals just over 64 percent).

⁸ Federal health care program is defined as "(1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government . . . ; or (2) any State health care program, as defined in Section 1320a-7(h)." 42 U.S.C. § 1320a-7b(f) (2012). The Office of Inspector General has not created an official list of federal health care programs that qualify under the definition, so the exact number of federal health care programs is not entirely know. *See* Judith A. Waltz & Adam Hepworth, *Medicare and Medicaid Administrative Enforcement*, 4 HEALTH L. HANDBOOK § 1:4 (2017).

⁹ The Office of Inspector General issued a Special Fraud Alert in 1996 stating definitively that billing for services that were never rendered is fraud. Publication of OIG Special Fraud Alert: Fraud and Abuse in the Provision of Services in Nursing Facilities, 61 Fed. Reg. 30,623 (June 17, 1996).

under applicable state licensure law, was required to be provided by a licensed psychiatrist but was instead provided by a registered nurse?¹⁰ If knowingly billing the federal government for a service to a complex patient with multiple co-morbidities when the service was actually provided to a non-complex patient with no co-morbidities is the submission of a “false claim,”¹¹ what about billing for a home health service on a date that is prior to when a physician actually certifies the need for such home health services in a face-to-face visit as required under applicable Medicare regulations?¹²

For health care entities subject to the FCA, these questions are not just an academic exercise, but present real issues and problems for purposes of compliance. Not only might noncompliance with regulations present potential FCA liability as a result of a *qui tam* relator claim, but retention of known overpayments is also actionable as a false claim.¹³ Thus, entities subject to the FCA need to know and understand when and in what circumstances noncompliance with regulations constitutes a false or fraudulent claim in order to not only correct the problem, but also remit known overpayments.¹⁴ Clear guidance and direction regarding what does or does not constitute fraud under the FCA is paramount.

While the U.S. Department of Justice (DOJ) and *qui tam* relators’¹⁵ counsel have been arguing for over twenty years that

¹⁰ See *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1997 (2016) (involving a claim that certain false representations, such as a nurse prescribing medication as a psychiatrist without appropriate licensing, violate the False Claims Act).

¹¹ See, e.g., *United States v. Larm*, 824 F.2d 780, 782 (9th Cir. 1987) (involving a case in which the physician and his wife billed for an examination or evaluation related to a new treatment or illness for routine allergy shots that were administered only by the physician’s nurse). This sort of scheme is often referred to as upcoding, or “DRG creep,” in the hospital context, in which the hospital bills for a service at a higher reimbursement rate than is necessary for the patient. See DAVID E. MATYAS ET AL., *LEGAL ISSUES IN HEALTHCARE FRAUD AND ABUSE: NAVIGATING THE UNCERTAINTIES* 267–68 (4th ed. 2012).

¹² See *United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 838 F.3d 750, 758–59 (6th Cir. 2016) (involving a case in which home health service was provided before the required physician certification of the service).

¹³ 31 U.S.C. § 3729(a)(1)(G) (2012).

¹⁴ *Id.*

¹⁵ A *qui tam* relator is the name given to those individuals who file a lawsuit under the FCA on behalf of the federal government. 31 U.S.C. § 3730(b)(1). These individuals are also often referred to as whistleblowers. *Mikes v. Straus*, 274 F.3d 687, 692 (2d. Cir. 2001), *abrogated by Escobar*, 136 S. Ct. 1989; see also Thomas R. Lee, *The Standing of Qui Tam Relators Under the False Claims Act*, 57 U. CHI. L. REV. 543, 543 (1990) (“The qui tam provision of the Act authorizes private individuals to adopt the government’s cause of action and sue on behalf of the United States. These qui tam plaintiffs, or ‘relators,’ receive a ‘bounty’ of up to thirty percent of the damage award or settlement, plus expenses, attorney fees, and costs of suit.” (footnotes omitted)).

all of the above-referenced instances are false claims,¹⁶ the various federal circuit courts have not shared widespread agreement on whether all such examples necessarily constitute “fraud” under the FCA in all instances.¹⁷ The distinction between these examples lies in whether the alleged fraud is based on misleading or fraudulent *facts* submitted on the claim form regarding the services provided or based on misleading or fraudulent *certification* on the claim form implying that the claimant provided such services in compliance with all applicable underlying laws, rules, and regulations.¹⁸ Courts have referred to the latter example as an “implied false certification.”¹⁹ While most courts were in agreement that FCA liability did extend to cover at least some forms of implied false certification claims, there was a lack of consensus about how far to extend such liability in these sorts of claims.²⁰ Then, in the case of *Universal Health Services, Inc. v. U.S. ex rel. Escobar*,²¹ the Supreme Court sought to clarify (a) whether the FCA could be used by both *qui tam* relators and the government to sustain a claim that a contractor’s failure to comply with certain underlying regulatory

¹⁶ Although not so named, the so-called “implied false certification” theory of liability, which will be explained in more detail in Part II of this article, seemed to first be recognized in the cases of *Ab-Tech Const., Inc. v. United States*. *Ab-Tech Const., Inc. v. United States*, 31 Fed. Cl. 429, 434 (1994), *aff’d*, 57 F.3d 1084 (Fed. Cir. 1995) (stating that the use of payment vouchers as implied certifications resulted in fraudulent claims); *see also Mikes*, 274 F.3d at 699 (“The implied certification theory was applied in *Ab-Tech Construction, Inc. . . .*”).

¹⁷ *See, e.g.*, *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377, 385–88 (1st Cir. 2011); *United States v. Sci. Applications Int’l Corp.*, 626 F.3d 1257, 1268–69 (D.C. Cir. 2010); *Mikes*, 274 F.3d at 697 (joining the position of only four circuit courts regarding what is required for a claim to be false under the FCA).

¹⁸ Some circuit courts have described this distinction as a claim being either “factually false” or “legally false”; that is, is the falsity based on facts regarding the service itself or is the falsity because the claimant fails to comply with a legal requirement (even if the service itself was provided and information on the claim form regarding the actual service is true and correct.). *See, e.g.*, *Mikes*, 274 F.3d at 697.

¹⁹ *Id.* at 699. The name “implied false certification” was first utilized by a district court in the case of *United States ex rel. Mikes v. Straus*, although the general concept had been recognized by other courts prior to this case. *See United States ex rel. Mikes v. Straus*, 84 F. Supp. 2d 427, 434–37 (S.D.N.Y. 1999) (noting that while the Second Circuit had not yet considered this theory of fraud, it had been considered and utilized by the Federal Court of Claims in *Ab-Tech Constr., Inc.*, and while rejected for certain cases based on the facts of such case, recognized as being utilized “only in those exceptional circumstances where the claimant’s adherence to the relevant statutory or regulatory mandates lies at the core of its agreement with the Government, or, in more practical terms, where the Government would have refused to pay had it been aware of the claimant’s non-compliance.”). Note that courts have also recognized a theory known as “express false certification,” which is the name utilized when compliance with a particular law, rule, or regulation is expressly a condition to submission of the claim form itself. *See Mikes*, 274 F.3d at 697–98.

²⁰ *See supra* note 17 and accompanying text.

²¹ *See generally* *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016).

requirements constitutes a false claim by virtue of the implied certification that the contractor makes in order to receive payment; and, if yes, (b) whether such underlying regulation is required to be a precondition to payment (i.e., the government will not pay the claim unless the claimant complies with such regulation).²²

The Court quieted at least part of the existing debate, finding that the implied false certification theory can be utilized as a basis for liability under the FCA in certain instances.²³ It perhaps fueled a greater debate, however, in rejecting the strict limitation regarding such underlying law, rule, or regulation being a precondition to payment and holding instead that any liability requires a showing that the claimant's "misrepresentation about compliance with a statutory, regulatory, or contractual requirement . . . be *material* to the Government's payment decision."²⁴

Abandoning the need for a detailed analysis into the basis and intention behind myriad regulations,²⁵ the unanimous Court indicated a need to return to legal fundamentals, providing guidance based on common law principles for establishment of materiality.²⁶ Seemingly, the Court's guidance

²² *Id.* at 1995–96.

²³ *Id.* at 1999.

²⁴ *Id.* at 1996 (emphasis added). With this holding, the Court abrogated *Mikes*, which held that the "implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid." *Mikes*, 274 F.3d at 700 (emphasis in original). Recognition of the idea that liability could exist under the FCA was adopted by nearly all circuits. See *United States ex rel. Quinn v. Omnicare, Inc.*, 382 F.3d 432, 441 (3d Cir. 2004). Only some courts, however, have also recognized that such claims would be limited to those regulations that are a condition to payment. See *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 467–68 (6th Cir. 2011) (acknowledging that the theory of implied false certification was adopted by *United States ex rel. Augustine v. Century Health Servs., Inc.*, 289 F.3d 409, 415 (6th Cir. 2002), but failing to find liability under the implied false certification theory because the plaintiffs failed to allege that the Medicare regulation in question did not "require compliance with an industry standard as a prerequisite to payment."); *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1170 (9th Cir. 2006) (recognizing that the theory of implied false certification was recognized by *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996)); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 (4th Cir. 1999); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997); *Ab-Tech Constr., Inc.*, 31 Fed. Cl. at 434. *But see* *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377, 385–88 (1st Cir. 2011) (finding that a regulation be a precondition of payment is not found in the text of the FCA); *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1268–69 (D.C. Cir. 2010); *United States ex rel. Conner v. Salina Regional Health Center, Inc.*, 543 F.3d 1211, 1218 (10th Cir. 2008).

²⁵ The usual analysis for determining whether a regulation was a condition of participation or a condition of payment often involved detailed analysis about where in the statute such regulation was located. See *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 309 (3d Cir. 2015).

²⁶ See Joan H. Krause, *Reflection on Certification, Interpretation, and the Quest for Fraud that "Counts" Under the False Claims Act*, 5 UNIV. OF ILL. L. REV. 1811, 1813 (2017).

was intended to assist contractors in understanding what might matter for purposes of compliance with a vast number of federal and state laws and regulations to which government contractors are subject, especially federal health care program participants.²⁷ So, as federal district courts and courts of appeals attempt to apply the Court's dictates in *Escobar*, it is necessary to ask whether the Court succeeded in easing the complexity of this aspect of the FCA. Have lower courts been able to consistently apply the new standards to assess materiality? Or, has the opinion, which arguably both broadened and narrowed application of the implied false certificate theory and when liability might attach,²⁸ further muddied the waters for courts and parties attempting to determine whether behavior is of the sort that qualifies as "fraud"? Most importantly, what impact has the *Escobar* opinion had on providers and other government contractors for purposes of trying to determine whether noncompliance with a regulation of any sort constitutes fraud for purposes of the FCA?

In reviewing lower court opinions analyzing FCA claims in accordance with the dictates of *Escobar*, this article argues that while *Escobar* does seem to be motivating lower courts to apply a rigorous and demanding materiality standard, the Court's "back-to-basics" approach in determining materiality seems to be providing little consistency regarding what type of evidence would need to be proffered to satisfy the new materiality standard. To the extent such lack of consistency endures, providers, suppliers, manufacturers, and other parties potentially subject to application of the FCA in the health care setting will continue to struggle to determine how to consider *Escobar* for purposes of assessing and prioritizing compliance risk.

Part I of this article briefly examines the history of the FCA and explores how the FCA has evolved as the primary enforcement tool for health care fraud and abuse. This Part

²⁷ *Escobar*, 136 S. Ct. at 2001. The Court adopted a two-part test for what sorts of claims might qualify as viable implied false certification claims under the FCA. *Id.* The details of the two-part test and how lower courts are interpreting such test is addressed in Part II, *infra*.

²⁸ As will be explored more fully in Part II, *infra*, the opinion seems to broaden application of the implied false certification theory on the basis that it potentially opened up the possibility of types of implied false certification claims that would have been rejected under a stricter application requiring that only such regulations that are conditions of payment, and not conditions of participation, would qualify for purposes of implied false certification liability. *See Mikes*, 274 F.3d at 700. The Court then narrowed application of this theory, however, when it stated definitively that such claims must be limited by materiality and such materiality standards should be demanding, so as to avoid application of the FCA as "an all-purpose antifraud statute." *See Escobar*, 136 S. Ct. at 2003 (quoting *Allison Engine v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)).

further examines the origins of the implied false certification theory and the various splits and issues among the circuit courts that prompted the Supreme Court to review this issue in *Escobar*. In Part II, this article examines the details of the *Escobar* case and outlines the specific findings of the Supreme Court as well as how the DOJ, federal district courts, and federal courts of appeals have interpreted the *Escobar* opinion. Then, Part II analyzes the approaches of various courts in applying the new materiality standard to examine the impact the standard will have on future FCA cases relying on the implied false certification theory. It further highlights consistent themes, open questions, or distinctions that have emerged since the issuance of the *Escobar* opinion. Next, Part III argues that while *Escobar* may succeed in ensuring a more exacting and demanding standard for claims relying on an implied false certification theory, and thus a broader number of defenses available to defendants involved in FCA cases, the lack of consistency for specific types of proof that constitute materiality will have a detrimental effect on ongoing compliance efforts by those entities subject to the FCA. These challenges will be particularly acute for health care entities, including providers and suppliers, in trying to prioritize and assess risk and in operation of effective compliance programs under the countless regulations to which such entities are subject. Finally, this article concludes by offering some suggestions for potentially mitigating or lessening some of the confusion that might arise through the Centers for Medicare and Medicaid Services (CMS) and other state regulatory agencies by issuing clear and precise communication about what types of fraud those agencies believe should be actionable under the FCA.

I. BACKGROUND

A. *History of the False Claims Act*

Although use and application of the FCA has gone through various changes since its 1863 enactment, the goals of the FCA today are not too dissimilar to this description of the purpose of the law declared in 1943:

[The False Claims Act] is intended to protect the treasury against the hungry and unscrupulous host that encompasses it on every side, and should be construed accordingly. It was passed upon the theory . . . that one of the least expensive and most effective means of preventing frauds on the treasury is to make the perpetrators of them

liable to actions by private persons acting . . . under the strong stimulus of personal ill will or the hope of gain.²⁹

The concept of incentivizing private individuals to report suspected fraud may be somewhat novel under the bulk of today's laws, but this legal mechanism was actually quite common in the early history of the United States.³⁰ Adopted from English tradition, laws that not only relied on, but also encouraged and incentivized private individuals to seek recovery and reward on behalf of the federal government were rather typical and found to be a relatively effective means of prosecuting crimes.³¹ When enacting what was sometimes referred to as the "Informer's Act" or "Lincoln's Law,"³² Congress recognized that a monetary reward (then 50 percent of the recovery amount) would be strong incentive for an individual to "betray[] his co-conspirator."³³ By the mid-1940s, the federal government had established the Department of Justice (DOJ) and the need for private citizens to alert the government to bad actors as a means for prosecution began to lessen due to the new role of a federal prosecutor.³⁴

As a result of the new agency and the thought that the DOJ should be able to appropriately prosecute fraud against the government, many began to become concerned that the FCA was actually feeding "parasitic" lawsuits.³⁵ Thus, a 1943 amendment greatly cut back on the incentives, and consequently the use of the FCA by *qui tam* relators.³⁶ For the next forty-plus years, use

²⁹ *United States v. Griswold*, 24 F. 361, 366 (D. Or. 1885); *see also* *Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939, 949 (1997) (citing *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 541 n.5 (1943)).

³⁰ *See* Helmer, *supra* note 2, at 1263 (noting that ten to twelve of the first fourteen laws to be enacted under the first Continental Congress of the United States authorized *qui tam* suits).

³¹ *Id.* at 1263–64.

³² *See* *United States ex rel. Graber v. City of New York*, 8 F. Supp. 2d 343, 352 (S.D.N.Y. 1998).

³³ Helmer, *supra* note 2, at 1265–66 (quoting CONG. GLOBE, 37TH CONG., 3D SESS. 955 (1863) (statement of Sen. Howard)).

³⁴ *Id.* at 1267 ("As a result of WWII, a whole new class of war profiteers surfaced. But unlike 1863, by 1943 the federal government had a Department of Justice, including the Federal Bureau of Investigation, which pursued criminal prosecutions against some government contractors.").

³⁵ *In re* *United States ex rel. S. Praver and Co. v. Fleet Bank of Maine*, 24 F.3d 320, 324 (1st Cir. 1994) ("During the New Deal and World War II, there was a notable increase in the number of contracts awarded by the government to private individuals and entities. Along with this increase came a concomitant surge in the number of *qui tam* actions brought by relators under the FCA. This litigational surge, in turn, brought to the fore the fact that the *qui tam* provisions then in effect were too susceptible to abuse by 'parasitic' relators." (internal citations omitted)).

³⁶ *Id.* at 325 (noting that the amendment essentially prohibited any claim by a relator that was "based on evidence or information the Government had when the action was brought" (quoting 31 U.S.C. § 3730(b)(4) (1982))).

of the FCA as a mechanism for identifying and prosecuting fraud was extremely limited.³⁷ In fact, it was so limited that, due to Congress's concern that widespread fraud was draining the public fisc, it amended the FCA in 1986 to strike a better balance between incentivizing relators to report fraud and also preventing parasitic lawsuits.³⁸

Although the FCA has been amended on a few occasions since 1986, it was this more extensive amendment in 1986 that gave rise to the modern day application of the FCA.³⁹ Indeed, with an average annual recovery of almost \$4 billion in federal money since 2009,⁴⁰ there is little question that in recent years the FCA has become an extremely powerful tool for the federal

³⁷ *Id.*

³⁸ False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153 (codified as amended at 31 U.S.C. § 3729 *et seq.* (2012)). These changes were accomplished primarily by adding an original source provision as an exception to the prohibition against government knowledge and enacting other provisions that attempted to achieve the “twin goals of rejecting suits which the government is capable of pursuing itself, while promoting those which the government is not equipped to bring on its own.” United States *ex rel.* Springfield Terminal Railway Co., v. Quinn, 14 F.3d 645, 651 (D.C. Cir. 1994); *see also* James B. Helmer, Jr. & Robert Clark Neff, Jr., *War Stories: A History of the Qui Tam Provisions of the False Claims Act, The 1986 Amendments to the False Claims Act, and their Application in the United States ex rel. Gravitt v. General Electric Co. Litigation*, 18 OHIO N.U. L. REV. 35, 44 (1991). Helmer and Neff note that the changes to the FCA included loosening the knowledge requirement, increasing penalties for violations of the FCA, permitting the *qui tam* relator to pursue the claim even if the federal government chose not to intervene, increasing the relator's share of the proceeds from no greater than 10 percent to 25 percent and an even greater recovery for relators proceeding on his/her own, and altering the bar against claims in which the government had prior knowledge (often referred to as the public disclosure bar) to permit these claims to the extent that the relator could claim to be an “original source,” as defined in the statute. *Id.* at 45–50.

³⁹ *See* Press Release, U.S. Dep't of Justice, Justice Department Celebrates 25th Anniversary of False Claims Act Amendments of 1986 (Jan. 31, 2012), <https://www.justice.gov/opa/pr/justice-department-celebrates-25th-anniversary-false-claims-act-amendments-1986> [<http://perma.cc/BM8A-CX7N>] (“The False Claims Act has been called the single most important tool that American taxpayers have to recover funds when false claims are made to the federal government, including health care fraud, mortgage fraud, and procurement fraud. ‘In the last quarter century, the False Claim Act’s success has been unparalleled with more than \$30 billion dollars recovered since it was amended in 1986 and \$8.8 billion since January 2009,’ said Attorney General Eric Holder.”).

⁴⁰ Justice Dep't Recovers Over \$4.7 Billion, *supra* note 7. 31 U.S.C. § 3729 *et seq.* can be used to recover money improperly paid to or retained by entities or person who contract with the federal government. There are certain programs, such as state Medicaid programs, that involve a mix of federal and state funding and therefore many False Claims Act cases include allegations regarding not just fraud against the federal government, but also against state programs that include both state and federal funding. Thus, utilizing similar state false claims statutes, there are often portions of a recovery that inure back to states. Robin Rudowitz, *Medicaid Financing: The Basics*, KAISER FAMILY FOUND. (Dec. 22, 2016), <https://www.kff.org/report-section/medicaid-financing-the-basics-issue-brief/> [<https://perma.cc/DTE2-8EBC>] (describing the Medicaid program as a program in which the “federal government matches state spending for eligible beneficiaries and qualifying services”); *see also Medicaid Fraud Control Units—MFCUs*, U.S. DEP'T OF HEALTH & HUM SERVS., <https://oig.hhs.gov/fraud/medicaid-fraud-control-units-mfcu/index.asp> [<https://perma.cc/WDS4-W59F>].

government to identify fraud and recover money that has been improperly paid to, or retained by, government contractors.⁴¹ The DOJ has reported that 60 percent of its FCA recoveries since 1986 have come in the last eight years⁴² and the total recovery since 1986 is over \$36 billion.⁴³

B. *Health Care and the False Claims Act*

Much of the \$36 billion recovery has arisen out of claims from the health care industry, which includes providers (e.g., hospitals, physicians, nursing homes, etc.), pharmaceutical companies, medical device manufacturers, and suppliers (e.g., laboratories, durable medical equipment companies, ambulance services, etc.).⁴⁴ Any entity or individual participating in a federal health care program, including Medicare and Medicaid, or any entity or individual supplying items, goods, or services that are reimbursable by a federal health care program—even if such entity or individual does not, by itself, contract with the federal government—is potentially liable under the FCA.⁴⁵ Given the breadth of the FCA's language and the structure of the U.S. health care system, it is not surprising that the FCA has become the primary enforcement mechanism for confronting health care fraud for the federal government⁴⁶ and has become equally big business for relators.⁴⁷ With over fifty-eight million

⁴¹ Justice Dep't Recovers Over \$4.7 Billion, *supra* note 7.

⁴² *Id.*; Justice Dep't Recovers Over \$3.7 Billion, *supra* note 7.

⁴³ DEPT OF JUSTICE, CIVIL DIV., FRAUD STATISTICS—HEALTH AND HUMAN SERVICES 2017 [hereinafter FRAUD STATISTICS], <https://www.justice.gov/opa/press-release/file/1020116/download> [<https://perma.cc/G5K4-CBJH>] (citing statistics between October 1, 1986 through September 30, 2017).

⁴⁴ *See, e.g.*, Justice Dep't Recovers Over \$4.7 Billion, *supra* note 7 (stating that in 2016, of the \$4.7 billion recovered of federal dollars, almost \$2.5 billion was monies recovered from the health care industry); Justice Dep't Recovers Over \$3.7 Billion, *supra* note 7 (stating that in 2017, of the \$3.7 billion recovered of federal dollars, almost \$2.4 billion was monies recovered from the health care industry).

⁴⁵ 31 U.S.C. § 3729(a)(1) (applies to “any person who (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; . . . (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government”).

⁴⁶ Justice Dep't Recovers Over \$4.7 Billion, *supra* note 7.

⁴⁷ *Id.* (noting that of the 702 *qui tam* cases that were filed, 501 of them (71 percent) were health care related and recovery from health care *qui tam* relators accounted for 93 percent of the total health care recovery of almost \$2.5 billion total recovery amount). It should be noted that although the percentage of FCA cases that are filed by a *qui tam* relator are high, the recovery amount for cases in which the federal government declines to intervene remain low. In 2016, the percentage of recovery that was attributed to non-intervened cases was 2 percent. This percentage is consistent with the average percentage of recovery in years' past, with the exception of 2015 in which

Medicare beneficiaries and over seventy-two million Medicaid beneficiaries in the United States,⁴⁸ there are few hospitals, physicians, or other providers or suppliers that do not participate in federal health care programs.⁴⁹ Thus, application of the FCA extends nearly universal reach over all players in the health care industry.

In addition to the ability to apply FCA provisions to nearly all sectors of the health care industry, the potential damages and liability that could be imposed under the FCA is a further factor that has made the FCA such a powerful and effective enforcement tool. Violations of the FCA include (1) an obligation to remit to the federal government any payments made by the government pursuant to a claim that is considered to be false, (2) the ability for the federal government to seek treble damages on the total amount of the payments to be remitted to the government, and (3) the ability for the federal government to impose fines ranging from \$10,781.40 to \$21,562.80 per claim submitted.⁵⁰ Additionally, to the extent

relators in cases in which the federal government declined to intervene accounted for 32 percent of the total recovery. FRAUD STATISTICS, *supra* note 43. While it is difficult to tell for sure, it seems likely that 2015 was an outlier as opposed to a new trend.

⁴⁸ CTRS. FOR MEDICARE & MEDICAID SERVS., CMS FAST FACTS (2018), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Fast-Facts/index.html> [<https://perma.cc/BSU5-ZUTX>].

⁴⁹ *Id.* at 8–9. According to Centers for Medicare and Medicaid Services (CMS), in calendar year 2016, there were 6,146 total hospitals participating in Medicare, along with 11,956 home health agencies, 15,274 skilled nursing facilities, 254,133 labs, 2,080 outpatient physical therapy/speech pathology facilities, 4,153 rural health clinics, 7,723 federally qualified health centers, 5,529 ambulatory surgical centers, 193 comprehensive outpatient rehabilitation facilities, and 4,473 hospices. Also, there are 1,249,691 total non-institutional providers (e.g., physicians and nurse practitioners) participating in the Medicare program. It is difficult to glean what such participation is as a percentage relative to total hospitals, as available data does not necessarily track the same data points. For example, the American Hospital Association (AHA) in 2018 states that there is a total of 5,534 “registered” hospitals in the U.S. AM. HOSP. ASS’N, FAST FACTS ON U.S. HOSPITALS (2018), <https://www.aha.org/system/files/2018-02/2018-aha-hospital-fast-facts.pdf> [<https://perma.cc/8N78-HVZ2>]. “Registered hospitals are those hospitals that meet the AHA’s criteria for registration” that may or may not also be members of the AHA. *Id.* Individual provider statistics are also challenging, but based on census data there were approximately 916,264 actively licensed physicians in the U.S. See Aaron Young et al., *A Census of Actively Licensed Physicians in the United States, 2014*, 101 J. MED. REG. 8, 11 (2015).

⁵⁰ 31 U.S.C. § 3729(a)(1); *False Claims Act Penalties*, FINDLAW (2018), <http://employment.findlaw.com/whistleblowers/false-claims-act-penalties.html> [<https://perma.cc/EC2L-AUBT>] (“Under the text of the FCA, those who submit fraudulent claims to the government are subject to a civil penalty of between \$5,000 and \$10,000 for each claim. However, because the Act allows for inflationary adjustments, as of 2016, violators now face penalties of between \$10,781.40 and \$21,562.80 per claim.”). The civil penalty assessed per claim was increased as of February 3, 2017 to the limits referenced above. Civil Monetary Penalties Inflation Adjustment for 2017, 82 Fed. Reg. 9131, 9133 (Feb. 3, 2017) (to be codified at 28 C.F.R. § 85.3(a)(9)). Note that with respect to what amounts are necessary to be remitted, courts have taken different approaches regarding what might constitute the amount of the overpayment. Some prosecutors have sought, and

that an FCA claim is based on an underlying violation of the Antikickback Statute⁵¹ or knowing violation of the Physician Self-Referral Statute (otherwise known as the Stark Law),⁵² not only would the penalties under the FCA apply, but penalties for violations of the Antikickback Statute and Stark Law would also apply, adding additional penalties of \$21,916 per claim for each violation of the Antikickback Statute⁵³ and penalties ranging from a maximum of \$24,253 per claim or \$161,692 for a fraudulent scheme under the Stark Law.⁵⁴

Given the potential penalties and damages associated with the FCA, not to mention reimbursement of funds (often for services that were in fact rendered), liability under the FCA is an incredibly high-stakes game for those in the health care industry. It also means the possibility of a very lucrative monetary “reward,” or windfall, to a potential whistleblower who might be willing to bring the claim.⁵⁵ It is this combination of factors that has made the FCA such an effective tool for the federal government and such a source of stress and consternation for providers, suppliers, manufacturers, and

courts have awarded, any and all monies paid to a provider pursuant to any claim that is considered fraudulent. Other courts have sought only the difference between the amount that was paid in excess of the amount that would have been paid if the service had been billed properly (e.g., the difference between the reimbursement paid for the appropriate DRG level vs. the amount paid for the highest DRG level). *See United States v. Mackby*, 339 F.3d 1013, 1017 (9th Cir. 2003) (noting that the judgment against the plaintiff did not exceed the Excessive Fines Clause because the government could have sought damages for 8,499 claims “[s]ince the use of [fraudulent use of Mackby’s father’s UPIN] led to liability, all 8,499 claims constitute violations of the FCA” but the government chose to only seek damages for the claims that were submitted that exceeded a billing cap).

⁵¹ The federal Antikickback Statute imposes penalties for “knowingly and willfully [offering or paying] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind” in return for referring “an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program” 42 U.S.C. § 1320a-7b(b)(2) (2012).

⁵² The Stark Law prohibits a physician (or the physician’s immediate family member, as defined in the statute) from making referrals for certain services known as “designated health services” to any entity with which the physician has a “financial relationship.” 42 U.S.C. § 1395nn(a)(1).

⁵³ 28 C.F.R. § 85.3(a)(13) (2017). The penalties were increased on February 3, 2017. Civil Monetary Penalties Inflation Adjustment for 2017, 82 Fed. Reg. at 9133 (Feb. 3, 2017) (to be codified at 28 C.F.R. § 85.3(a)(13)).

⁵⁴ Annual Civil Monetary Penalties Inflation Adjustment, 82 Fed. Reg. 9174, 9179–80 (Feb. 3, 2017) (to be codified at 42 C.F.R. § 1003.310).

⁵⁵ While the percentage of the *qui tam* relator’s “award” has varied since 1863, current recovery amounts under Section 3730(d)(1) are “at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim” for suits in which the federal government intervenes and under Section 3730(d)(2) are “not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement.” 31 U.S.C. § 3730(d)(1)–(2).

others potentially liable under this statute.⁵⁶ Facing penalties and damages sometimes upward of hundreds of millions of dollars, these devastating outcomes have pushed a majority of defendants to settle their claims.⁵⁷ Even if the claims may be explainable or defensible or when the relators might have only part of the facts, when faced with the possibility of an FCA suit many entities will settle such claims with the federal government in lieu of taking their chances with the court system.⁵⁸ In fact, of the “Significant False Claims Act Settlements & Judgment” reported by the federal government for years 2009–2016, only one of the forty reported cases were judgments as opposed to settlements.⁵⁹

This is not to say that the mere filing of an FCA claim equals success on the merits or that a defendant is unable to ever successfully defeat an FCA claim. On the contrary, the vast majority of amounts recovered in FCA cases result from cases in which the U.S. government has intervened, amounting to only about 25 percent of all *qui tam* cases.⁶⁰ While there has been an upward trend in success of *qui tam* relators who proceed on their own (i.e., achieve settlement or a favorable judgment after the DOJ has declined to intervene), defendants are ultimately successful in defeating most *qui tam* claims that *qui tam* relators

⁵⁶ Ryan Winkler, Note, *The Civil False Claims Act and its Unreasonably Broad Scope of Liability: The Need for Real “Clarifications” Following the Fraud Enforcement and Recovery Act of 2009*, 60 CLEV. ST. L. REV. 533, 551–52 (2012).

⁵⁷ It is difficult to glean from existing public data sources the sheer number of settlements versus judgments under the FCA, as the data that is reported is reported as amounts recovered from both settlements and judgments. Reading between the lines a little on some of the information reported, it seems the vast majority of major cases are settled and thus a majority of the monetary recovery amounts are settlements as opposed to successful judgments in court. See generally U.S. DEPT OF JUSTICE, FACT SHEET: SIGNIFICANT FALSE CLAIMS ACT SETTLEMENTS & JUDGEMENTS FISCAL YEARS 2009–2016 (2016) [hereinafter FACT SHEET], <https://www.justice.gov/opa/press-release/file/918366/download> [<http://perma.cc/HKY8-D2RX>] (citing to a total of forty major recoveries in seven years and \$19.3 billion in recovery amounts and noting that only one of the forty cases involved a judgment versus a settlement agreement).

⁵⁸ See *id.*

⁵⁹ *Id.* It should be noted that of those cases that were considered “Health Care Fraud” all reported cases involved settlements. The one case that resulted from a judgment was part of the “Other Fraud Recoveries” category and involved a global financial institution that was found to have violated the Department of Agriculture’s Supplier Credit Guarantee Program. *Id.* at 10–11.

⁶⁰ Eric Topor, *Intervention in False Claims Act Lawsuits: Is It Make or Break?*, BLOOMBERG LAW (Apr. 24, 2017), <https://www.bna.com/intervention-false-claims-n73014460786/> [<https://perma.cc/4W4B-F6DA>]. Note that there are also a portion of FCA claims that are filed directly by the DOJ in its capacity. For example, in the year 2016, approximately 4 percent of the total amount recovered under the FCA resulted from non-*qui tam* cases. *Id.*; see also Justice Dep’t Recovers Over \$3.7 Billion, *supra* note 7 (noting that \$3.4 billion of the \$3.7 billion in total recovery was due to *qui tam* lawsuits and a total of 669 *qui tam* lawsuits filed).

pursue in their own capacity.⁶¹ Thus, while the threat of the government intervening in the claim often encourages settlement, the ability to avoid a government intervention may actually result in greater ability of the defendant to succeed in defeating the claim. The threat of the potential penalties and likelihood of success *after* the government has intervened, however, is so great that despite some success in non-intervened cases,⁶² entities are nevertheless motivated to settle any alleged claims.

1. The Rise of Implied False Certification Cases

As use of the FCA increased following the 1986 amendments, so too did the sophistication and expansion of the types of claims that might be actionable under the FCA. In reviewing FCA jurisprudence between 1986 and 1994, most claims alleged fraud through factual misrepresentations regarding the services themselves, such as physicians billing for services that were never rendered,⁶³ clinics billing for services that were not medically necessary,⁶⁴ or providers billing for higher levels of care than were actually provided.⁶⁵ In addition to allegations of these “factually false” claims,⁶⁶ prosecutors and relators began alleging fraud arising out of misrepresentations

⁶¹ Topor, *supra* note 60 (noting that 23 percent of the total recovery of \$1.9 billion in 2015 was attributable to non-intervened cases, but clarifying that of that \$512 million in recovery that was attributable to non-intervened cases, \$472 million was due to a settlement with DaVita). While many have characterized what happened in 2015 as an anomaly, 2017 saw another spike in success of *qui tam* relators when the DOJ has not intervened with a total recovery of \$425 million of the \$3.7 billion total recovery. See FRAUD STATISTICS, *supra* note 43.

⁶² See Topor, *supra* note 60.

⁶³ See *United States v. Krizek*, 859 F. Supp. 5, 8–12 (1994) (finding liability under the FCA for a psychiatrist who submitted bills for services that far exceeded the amount of time that the psychiatrist spent providing the services); The OIG also issued two Special Fraud Alerts in 1995 and 1996 in response to behavior noted over the past decade of providers billing for services never rendered or for greater services than were actually rendered. See, e.g., Publication of OIG Special Fraud Alert: Home Health Fraud, Fraud and Abuse in the Provision of Medical Supplies to Nursing Facilities, 60 Fed. Reg. 40847, 40848 (Aug. 10, 1995) (providing examples of home health visits that were never made, visits to beneficiaries who are not in fact homebound, visits to beneficiaries not requiring a qualifying service, and visits not authorized by a physician); Publication of OIG Special Fraud Alert: Fraud and Abuse in the Provision of Services in Nursing Homes, 61 Fed. Reg. 30, 623–24 (June 17, 1996) (providing an example in a Special Fraud Alert about a physician who billed \$350,000 for examinations of nursing home residents, even though he never physically saw a single resident).

⁶⁴ See, e.g., Press Release, U.S. Dep’t of Justice, Gambro Healthcare Agrees to Pay Over \$350 Million to Resolve Civil & Criminal Allegations in Medicare Fraud Case (Dec. 2, 2004), https://www.justice.gov/archive/opa/pr/2004/December/04_civ_774.htm [<https://perma.cc/UFZ6-UWYB>].

⁶⁵ See *supra* note 63 and accompanying text.

⁶⁶ See *Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001), *abrogated by* *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016).

related to compliance with an underlying statute, law, or regulation.⁶⁷ This was first recognized as a viable claim in the case of *Ab-Tech Construction, Inc. v. United States*. In *Ab-Tech*, the alleged false claim was that an executive certified compliance with the eligibility requirements under the then-current version of the Small Business Act,⁶⁸ but the company was not in compliance with certain aspects of such law.⁶⁹

As the viability of this type of claim began to take hold in various courts, it also made its way into the health care context, with the United States Court of Appeals for the Second Circuit providing the most comprehensive analysis of this issue—in the case of *Mikes v. Straus*.⁷⁰ The *Mikes* court ultimately concluded that the allegations—the relator alleged that her former physician partners were violating the FCA because of their failure to properly calibrate a piece of medical equipment in accordance with industry guidelines—did not constitute a violation of the FCA.⁷¹ The court nevertheless recognized that violations of the FCA could encompass not only claims that make misrepresentations about the facts of a particular claim, but misrepresentations about legal compliance related to the rendering of services in connection with a claim, otherwise known as an implied false certification.⁷²

In recognizing this as a viable claim, however, the *Mikes* court was quick to identify its hesitancy about permitting this rule to be too expansive in the health care context:

The *Ab-Tech* rationale, for example, does not fit comfortably into the health care context because the False Claims Act was not designed as a blunt instrument to enforce compliance with all medical regulations—but rather only those regulations that are a precondition

⁶⁷ *Id.* at 699.

⁶⁸ 15 U.S.C. §§ 631–697c (1988 & Supp. IV 1993).

⁶⁹ See *Ab-Tech Constr., Inc. v. United States*, 31 Fed. Cl. 429, 434 (Fed. Cl. 1994), *aff'd*, 57 F.3d 1084 (Fed. Cir. 1995) (“The payment vouchers represented an implied certification by Ab-Tech of its continuing adherence to the requirements for participation in the 8(a) program. Therefore, by deliberately withholding from SBA knowledge of the prohibited contract arrangement with Pyramid, Ab-Tech not only dishonored the terms of its agreement with that agency but, more importantly, caused the Government to pay out funds in the mistaken belief that it was furthering the aims of the 8(a) program. In short, the Government was duped by Ab-Tech’s active concealment of a fact vital to the integrity of that program. The withholding of such information—information critical to the decision to pay—is the essence of a false claim.”).

⁷⁰ *Mikes*, 274 F.3d at 696–702.

⁷¹ *Id.* at 699.

⁷² *Id.* (“An implied false certification claim is based on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment.”).

to payment—and to construe impliedly false certification theory in an expansive fashion would improperly broaden the Act’s reach.⁷³

Thus, in an attempt to limit the application of this theory of liability, the court noted that for a plaintiff to sustain an implied false certification claim, the plaintiff must show that the underlying statute, rule, or regulation is a condition of payment.⁷⁴ Moreover, the court specified that its requirement that the underlying regulation be a condition of payment was distinct from a requirement of materiality, which was a requirement that many courts already imposed on claims arising under the FCA.⁷⁵ The court did not determine how to apply the materiality requirement or if it should be implied, rather, it stated: “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.”⁷⁶

⁷³ *Id.* The court went on to also state that health care and regulation of the provision of health services has typically been a matter of local law and thus should not necessarily be enforced on a wide-spread basis by the federal government. *Id.* at 700.

⁷⁴ *Id.* at 697. The court noted that it was following the Fourth, Fifth, Ninth, and District of Columbia Circuits in its position regarding condition of payment; however, it is not clear that those circuits have necessarily maintained that position. *Id.* The District of Columbia Circuit later reversed its position regarding implied false certifications. See *United States v. TDC Mgmt. Corp.*, 288 F.3d 421, 426 (D.C. Cir. 2002). Further, the Supreme Court in its opinion in *Escobar* cited to the District of Columbia as holding in the case of *United States v. Science Applications Int’l Corp.* that “conditions of payment need not be expressly designated as such to be a basis for False Claims Act liability.” *Escobar*, 136 S. Ct. at 1999 (citing *United States v. Sci. Applications Int’l Corp.*, 626 F.3d 1257, 1269 (D.C. Cir. 2010)). Likewise, while the *Mikes* court mentions the Fifth Circuit for supporting the theory of implied certification based on violations of conditions of payment and the Seventh Circuit case in *United States v. Sanford-Brown, Ltd.* for seemingly rejecting the theory of implied false certification, the Fifth Circuit has not really asserted a specific position that aligns with either circuit. See *United States v. Sanford-Brown, Ltd.*, 788 F.3d 696, 711–12 (7th Cir. 2015); *Mikes*, 274 F.3d at 697; see also *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 268 (5th Cir. 2010) (“The implied-certification theory of liability under the FCA is based on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment.’ This Court has not yet recognized the implied-certification theory. . . . We need not resolve the issue today, because in any event the factual allegations in Steury’s amended complaint provide no basis for implying a false certification.” (quoting *Mikes*, 274 F.3d at 699)).

⁷⁵ See, e.g., *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999) (“Liability under each of the provisions of the False Claims Act is subject to the further, judicially-imposed, requirement that the false statement or claim be material. Materiality depends on ‘whether the false statement has a natural tendency to influence agency action or is capable of influencing agency action.’” (footnote omitted) (quoting *United States ex rel. Berge v. Bd. of Trustees of Univ. of Ala.*, 104 F.3d 1453, 1459 (4th Cir. 1997))).

⁷⁶ *Mikes*, 274 F.3d at 697.

2. Circuit Splits Abound

As more and more cases alleging FCA violations related to underlying laws, rules, or regulations made their way through various courts, the courts have developed differing approaches to the theory of implied false certification. Several circuit courts agreed with the *Mikes* court, finding that an implied false certification claim must be based on noncompliance with a condition of payment.⁷⁷ Contrary to the position of the *Mikes* court, however, the First Circuit in *United States ex rel. Hutcheson v. Blackstone Medical, Inc.* abandoned the *Mikes* court's categories and labels on the basis that such terms were not supported by the actual text of the FCA and might narrow the FCA in unintended ways.⁷⁸ The *Blackstone Medical* court further held that FCA already imposes limitations in the form of the materiality requirement and the scienter requirement.⁷⁹ In addition to the First Circuit, the District of Columbia Circuit reversed one of its earlier opinions, adopting the more liberal standard first articulated in *Ab-Tech* and later adopted by the First Circuit, that implied false certification claims are subject to existing scienter and materiality requirements.⁸⁰ Finally, it should be noted that at least one circuit formerly rejected the theory of implied false certification entirely. The Seventh Circuit took the position that it was declining to join other circuits recognizing an implied false certification theory on the basis that it seemed unreasonable that an institution—in this case, an educational institution under Department of Education regulations—would be required on an ongoing basis to comply with thousands of pages of federal statutes and regulations for the purpose of assessing liability under the FCA.⁸¹

In the midst of this circuit split, the question of the viability of an implied false certification claim and how one would analyze it under the FCA was further complicated when Congress enacted amendments to the FCA in 2009 under the Fraud Enforcement and Recovery Act of 2009 (FERA).⁸² Section 3729(b)(4) resolved a separate circuit split regarding the proper

⁷⁷ See, e.g., *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 309-10 (3d Cir. 2011); *United States ex rel. Chesbrough v. VPA, P.C.*, 655 F.3d 461, 468 (6th Cir. 2011).

⁷⁸ *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377, 387-88 (1st Cir. 2011).

⁷⁹ *Id.* at 388.

⁸⁰ *United States v. TDC Mgmt. Corp.*, 288 F.3d 421, 426 (D.C. Cir. 2002).

⁸¹ *United States v. Sanford-Brown, Ltd.*, 788 F.3d 696, 711-12 (7th Cir. 2015).

⁸² Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, 123 Stat. 1617 (codified as amended in various sections in Titles 18 and 31 of the United States Code).

definition of materiality under the FCA by adopting a formal statutory definition that reads: “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.”⁸³ The DOJ and courts have treated such definition as a relatively low bar for materiality.⁸⁴ Although two circuits had adopted the position that the plaintiff must prove materiality in order to sustain an implied false certification claim, the changes to FERA did not necessarily affect or impact the ongoing circuit split regarding the viability or application of implied false certification claims.⁸⁵ This was due to the fact that it was not obvious after the change to “materiality” under FERA whether the new definition actually applied to implied false certification claims.⁸⁶ Specifically, the word “material” does not actually appear in Section 3729(a)(1)(A), which is the statute under which implied false certification claims are typically brought.⁸⁷ Rather, the word “material” appears in Section 3729(a)(1)(B), addressing fraud by a party causing another party to submit a claim⁸⁸ and Section 3729(a)(1)(G), addressing so-called reverse false claims in which a party knowingly retains money to which it was not entitled.⁸⁹ Thus, for those courts that

⁸³ 31 U.S.C. § 3729(b)(4) (2012). FERA was enacted primarily for the purposes of addressing perceived accountability lapses that led to the economic collapse of 2008, but included in its provisions “important clarifications to current criminal and civil fraud statutes to ensure that law enforcement has the tools it needs to prevent and punish these frauds, as well as to recover taxpayer money lost to these frauds.” S. Rep. No. 111-10, at 1–2 (2009) <https://www.congress.gov/111/crpt/srpt10/CRPT-111srpt10.pdf> [<https://perma.cc/Z23Z-T9WW>]. Prior to enactment of FERA, there was no definition of “material” under the statute and thus there was a split among the circuits about what “material” meant for purposes of claims under the FCA. Under FERA, Congress ultimately adopted the definition utilized by the Seventh Circuit in *United States v. Rogan*. *United States v. Rogan*, 517 F.3d 449, 452 (7th Cir. 2008) (quoting *Kungys v. United States*, 485 U.S. 759, 770 (1988)) (citing *Neder v. United States*, 527 U.S. 1, 16 (1999)). This was contrary to some other circuits that proposed a stricter “outcome materiality” definition; that is, “a falsehood or misrepresentation must affect the government’s ultimate decision whether to remit funds to the claimant in order to be ‘material.’” *United States v. Southland Mgmt. Corp.*, 288 F.3d 665, 676 (5th Cir. 2002), *reh’g en banc granted* by *United States v. Southland Mgmt. Corp.*, 307 F.3d 352 (5th Cir. 2002).

⁸⁴ See Joan H. Krause, *Holes in the Triple Canopy: What the Fourth Circuit Got Wrong*, 68 S. C. L. REV. 845, 851 (2017) (“While FERA’s ‘natural tendency’ test did not specifically address the debate, many courts nonetheless interpreted the legislation as adopting the lower ‘claim materiality’ threshold.”).

⁸⁵ *Id.*

⁸⁶ *Id.* at 850–51.

⁸⁷ *Id.*

⁸⁸ 31 U.S.C. § 3729(a)(1)(B) (any person who “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim”).

⁸⁹ *Id.* § 3729(a)(1)(G) (any person who “knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government”). A good example of a “reverse false claim” that might be actionable under Section 3729(a)(1)(G) is when a hospital becomes aware that it has violated the

had adopted the position that implied false certification claims should simply be limited by the existing materiality standard, the new statutory definition provided some further confusion about whether such standard would thus apply to implied false certification claims.⁹⁰

II. THE *ESCOBAR* OPINION AND ITS AFTERMATH

A. *The Escobar Opinion*

It was with this backdrop that the case of *Universal Health Services v. United States ex rel. Escobar* made its way to the Supreme Court.⁹¹ Amid confusion about whether the theory of implied false certification was even valid, and, if so, how one assesses whether liability should attach to the underlying law, statute, or regulation on which the claim is premised, the Supreme Court opted to review and decide a case involving an analysis of state Medicaid regulations.⁹² *Escobar* involved allegations against a Massachusetts mental health clinic owned and operated by Universal Health Services that had treated a teen-aged girl, a Massachusetts Medicaid beneficiary, for mental health issues over the period of five years.⁹³ After seeing several different providers at the clinic, the girl, Yarushka Rivera, was diagnosed with bipolar disorder and was later prescribed treatment medication by an individual at the clinic claiming to be a doctor.⁹⁴ Unfortunately, Ms. Rivera had an adverse reaction to the medication, causing seizures and her eventual death.⁹⁵ After Rivera's death, the family was notified that only one of the

Antikickback Statute. Under applicable regulations, the provider has sixty days from the date of discovery to remit any monies paid to the hospital pursuant to an illegal referral. See 42 C.F.R. § 401.305 (2017). To the extent the hospital does not remit the payments, retaining such monies is thus considered a false claim under Section 3729(a)(1)(G).

⁹⁰ *Escobar*, 136 S. Ct. at 2002 (“We need not decide whether § 3729(a)(1)(A)’s materiality requirement is governed § 3729(b)(4) or derived directly from the common law.”).

⁹¹ *Id.* at 1989. Simultaneous to *Escobar*, there were three other cases that had also petitioned the Supreme Court for certiorari regarding the theory of implied false certification. See *United States ex rel. Miller v. Weston Educ., Inc.*, 784 F.3d 1198 (8th Cir. 2015) (holding that defendant could be liable under the FCA because noncompliance with Title IV is material); *United States ex rel. Nelson v. Sanford-Brown, Ltd.*, 788 F.3d 696 (7th Cir. 2015) (holding that the implied false certification theory is not valid under the FCA); *United States ex rel. Badr v. Triple Canopy, Inc.*, 775 F.3d 628 (4th Cir. 2015) (holding that the government pleads an implied false certification claim when it alleges facts that a request for payment is made and the requestor has knowingly withheld information about its noncompliance with material contractual requirements in submission of such claim).

⁹² *Escobar*, 136 S. Ct. at 1996–97.

⁹³ *Id.* at 1997.

⁹⁴ *Id.*

⁹⁵ *Id.*

five providers who saw Rivera was actually properly licensed in accordance with Massachusetts law and that the nurse who had prescribed the medication did so without authority.⁹⁶ In all, twenty-three of the employees of the mental health clinic did not have appropriate licenses and lacked appropriate qualifications, all of which was in violation of applicable regulations under the state's Medicaid program.⁹⁷

Following a complaint by Rivera's family, the state Medicaid agency issued a report identifying over twelve violations of state Medicaid regulations, and Universal Health Services subsequently agreed to a remedial plan.⁹⁸ The family then filed a lawsuit alleging that Universal Health Services' violation of Massachusetts Medicaid regulations was an implied false certification and thus a violation of the FCA.⁹⁹ The district court in the case dismissed the claim on the basis that while the implied false certification theory was valid, the underlying regulations were not conditions of payment.¹⁰⁰ The First Circuit reversed, however, finding that submission of a bill is an implicit communication that it is conforming to all relevant rules and the regulations were clearly material "because they identified adequate supervision as an 'express and absolute' condition of payment and 'repeated[ly] reference[d]' supervision."¹⁰¹ In granting the petition for certiorari, the Supreme Court thus defined the purpose of its review to determine the scope and validity of the implied false certification theory of liability.¹⁰²

In *Escobar*, the Court established two major holdings. First, in response to the validity of the implied false certification theory, the Court acknowledged the viability of the theory, but noted that such viability was not absolute.¹⁰³ Relying on a back-to-basics approach, the Court stated that absent a specific

⁹⁶ *Id.* The Court noted that "the practitioner who prescribed medication to Yarushka, and who was held out as a psychiatrist, was in fact a nurse who lacked authority to prescribe medications absent supervision" and further observed that the person who diagnosed Rivera with bipolar disorder represented herself as a psychologist with a PhD, but she had obtained her degree from an online unaccredited institution and had been rejected for licensure in the state. *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.* at 1997–98. State Medicaid regulations require clinics such as the one at which Rivera was treated to have certain types of providers on staff based on their licensure classification and also require certain supervision of other staff members. Universal Health Services was not following these rules, but was nevertheless billing for services rendered to patients as if such rules were being followed. *Id.* at 1998.

¹⁰⁰ *Id.*

¹⁰¹ *Id.* (alteration in original) (quoting *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 780 F.3d 504, 514 (1st Cir. 2015)).

¹⁰² *Id.* at 1998–99.

¹⁰³ *Id.* at 1999.

definition in the statute of what might constitute “fraud,” courts should look to those meanings established under common law fraud claims, which have always included “misrepresentations by omission” if such claims are materially misleading.¹⁰⁴ Thus, in order to distinguish between the types of claims that might be actionable as fraud and the types of claims that would not, the Court established the following two-part test: “first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant’s failure . . . makes those misrepresentations misleading half-truths.”¹⁰⁵

In the second major holding, in response to the scope of the implied false certification theory, the Court rejected the position of the majority of circuits in holding that such claims could only be maintained to the extent that the underlying law or regulation was expressly designated as a condition of payment.¹⁰⁶ Rather, the Court stated, there is no statutory basis for limiting claims only to violations of express conditions of payment and that appropriate limitations already exist to ensure that not every violation of any underlying statute, regulation, or contractual provision would somehow trigger FCA liability.¹⁰⁷ The Court gave the following example in connection with the limitation of scienter: “If the Government failed to specify that guns it orders must actually shoot, but the defendant knows that the Government routinely rescinds contracts if the guns do not shoot, the defendant has ‘actual knowledge.’”¹⁰⁸ Therefore, the federal government should not necessarily be required to label a particular rule or regulation as an express condition of payment in order to signal to contractors what rules or regulations may be material. Such information can be gleaned based on a showing of the government’s past actions or communications and the defendant’s knowledge of such communications.

Indeed, the Court reiterated this position when it provided guidance regarding what might constitute materiality.¹⁰⁹ Although the FCA contains a definition of “material” in the statute,¹¹⁰ the

¹⁰⁴ *Id.*

¹⁰⁵ *Id.* at 2001.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Id.* The Court went on to specify that scienter was an additional limitation when it stated, “Likewise, because a reasonable person would realize the imperative of a functioning firearm, a defendant’s failure to appreciate the materiality of that condition would amount to ‘deliberate ignorance’ or ‘reckless disregard’ of the ‘truth or falsity of the information’ even if the Government did not spell this out.” *Id.* at 2001–02.

¹⁰⁹ *Id.* at 2002–04.

¹¹⁰ 31 U.S.C. § 3729(b)(4) (2012) (defining material as “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.”).

Court did not specifically answer the question as to whether such definition was applicable under the implied false certification theory.¹¹¹ Rather, it stated, “We need not decide whether the § 3729(a)(1)(A) materiality requirement is governed by § 3729(b)(4) or derived directly from the common law.”¹¹² Instead, the Court looked to the common law understanding of materiality to conclude that to determine if something is material, one “look[s] to the effect on the likely or actual behavior of the recipient of the actual misrepresentation.”¹¹³

Using such definition, the Court provided three examples of what might prove whether a claim is or is not material under an FCA claim.¹¹⁴ The examples are all based on what the government has communicated is material and what the defendant knows about the government’s past payment actions. First, the Court stated that to prove materiality one might show 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.”¹¹⁵ Second and alternatively, for a defendant to show that a claim is *not* material, one might show that “the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated.”¹¹⁶ Third, a defendant could also show a claim is *not* material if it shows that “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.”¹¹⁷ Thus, while an underlying statute or regulation being an express condition of payment may be evidence of materiality, it is not dispositive.¹¹⁸

The Court also refused to adopt the government’s more expansive view of materiality. That is, a violation of a statute, regulation, or contractual provision is material if the defendant knows that the government could withhold payment if it became aware of such violation.¹¹⁹ In rejecting this more expansive view of materiality, the Court specifically mentioned an example that

¹¹¹ Implied false certification claims are typically brought under Section 3729(a)(1)(A), which provision under the FCA does not contain the word “material” within its language. *Id.* § 3729(a)(1)(A).

¹¹² *Escobar*, 136 S. Ct. at 2002.

¹¹³ *Id.* (alteration in original) (quoting 26 WILLISTON ON CONTRACTS § 69:12 (4th ed. 2003)).

¹¹⁴ *Id.* at 2003.

¹¹⁵ *Id.*

¹¹⁶ *Id.* at 2003.

¹¹⁷ *Id.* at 2003–04.

¹¹⁸ *Id.* at 2003.

¹¹⁹ *Id.* at 2004.

had come up in oral argument—the American-made stapler.¹²⁰ The Court noted that it did *not* think that the FCA was intended to extend liability to a situation in which a regulation requires contractors to purchase American-made staplers, but a contractor subsequently fails to disclose use of foreign stapler.¹²¹ These examples and similar limitations are littered throughout the opinion: the FCA is “not an all-purpose antifraud statute;”¹²² the materiality standard set forth in the case is “demanding;”¹²³ and the FCA is intended to capture fraud and *not* medical malpractice.¹²⁴

Thus, a few things are clear from the opinion. First, based on principles of common law fraud, FCA liability can include fraud that is related to a material misrepresentation of a misleading half-truth, which further includes express misrepresentations and also omissions (i.e., implied false certifications).¹²⁵ Second, when contemplating what types of implied false certification claims should be actionable, claims should not be limited to those premised on an express condition of payment, but rather should extend to any misleading half-truth that is material to the government as part of the contract—like guns that do not shoot.¹²⁶ Third, materiality should be a demanding standard based on the effect on the government’s behavior (likely or actual) of the alleged misrepresentation.¹²⁷ Accordingly, the government’s knowledge that a contractor used a foreign-made stapler in violation of a regulation would not result in FCA liability.¹²⁸

Like many Supreme Court opinions, the *Escobar* opinion answered a few questions and raised a few more. Now, nearly two years removed from *Escobar*, the lower courts are grappling with how to apply the guidelines. While some aspects of the opinion appear to be easily applied across jurisdictions, there are a number of other areas that are causing a great deal of confusion and variability in terms of application of the new materiality standard.

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² *Id.* at 2003 (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)).

¹²³ *Id.* at 1994.

¹²⁴ *Id.* at 2004.

¹²⁵ *Id.* at 2001.

¹²⁶ *Id.*

¹²⁷ *Id.* at 2002.

¹²⁸ *Id.* at 2004.

B. *Reaction of the Department of Justice*

Following a Supreme Court opinion, one of the biggest drivers of how the case is interpreted is the DOJ's position in subsequent cases and briefs regarding how such opinion should be viewed by lower courts.¹²⁹ It could be said that the DOJ was both a winner and a loser in the *Escobar* opinion. Perhaps the most successful aspect of *Escobar* from the DOJ's perspective is the fact that the case does extend liability under the FCA to implied false certification cases and goes so far as to include underlying rules or regulations that could be conditions of payment or conditions of participation.¹³⁰ In contrast, however, the Court rejected a broad materiality standard and instead stressed that the materiality standard should be demanding and should protect against reading *Escobar* as significantly expanding liability under the FCA.¹³¹ Consequently, *Escobar* seems to be the new favorite defense for entities accused of violations of the FCA.¹³² The DOJ, on the other hand, seems to be focused on trying to convince courts that *Escobar* actually changes very little in terms of FCA precedent and that the opinion simply reiterated how lower courts were always interpreting implied false certification claims.¹³³ Indeed, one case noted in its opinion, “[t]he United States argues that ‘nothing in *Escobar* purports to overrule preexisting cases like *Wilkins* that affirmed a broader view of implied certification than the Supreme Court needed to address in *Escobar*.’”¹³⁴

1. “Specific Misrepresentations”

There are two primary aspects of the *Escobar* opinion that the DOJ has focused on in its briefs and in arguments to the court. First, in an effort to keep the ability to bring implied false certification claims as expansive as possible, the DOJ has taken the position that the two-part test articulated by the Supreme Court for what may be necessary to show when alleging an implied false certification is simply one way to plead

¹²⁹ Douglas W. Baruch & Jennifer M. Wollenberg, *FCA Implied Certification Cases—Justice Department’s Aggressive Post-Escobar Briefing Signals Its Concern Over the Decision’s Potential Impact*, 58 GOV’T CONTRACTOR ¶ 375 (2016).

¹³⁰ See *Escobar*, 136 S. Ct. at 2001–04.

¹³¹ See *id.*; see also Krause, *supra* note 84, at 851.

¹³² Baruch & Wollenberg, *supra* note 129.

¹³³ *Id.*

¹³⁴ United States *ex rel.* Schimpelpfenig v. Dr. Reddy’s Laboratories, Ltd., Civil Action No. 11-4607, 2017 WL 1133956, at *5 (E.D. Pa. Mar. 27, 2017).

an implied false certification claim.¹³⁵ Specifically, the DOJ has seized onto the introductory phrase in the two-part test: “[W]e hold that the implied certification theory can be a basis for liability, *at least where two conditions are satisfied*.”¹³⁶ In an effort to retain the ability to bring an implied false certification claim that does not necessarily involve a claim making a “specific representation,” the DOJ has been arguing in some cases that the requirements set forth in *Escobar* are not exclusive.¹³⁷ By way of example, the DOJ has argued in certain pleadings: “Although *Escobar* affirmed the implied false certification theory in situations where the defendant provides some description of the goods or services that render the claim misleading, the Court did not suggest that this is the *only* circumstance when the implied false certification theory applies.”¹³⁸ At this point, most courts seem to be applying both conditions set forth in *Escobar*, either without discussion of the phrase “at least” or, instead, rejecting altogether the argument that *Escobar* provides merely one circumstance for proving an implied false certification claim.¹³⁹ The DOJ position has been

¹³⁵ The government has been most successful making this argument in California because of an existing case, *United States ex rel. Ebeid v. Lungwitz*, in which the Ninth Circuit held that it is not necessary for the plaintiff to provide an express representation in order to sustain an implied false certification claim. *United States ex rel. Ebeid v. Lungwitz*, 616 F.3d 993 (9th Cir. 2010). Therefore, after *Escobar*, the DOJ and relators’ counsel have all been arguing that the two-part test articulated in *Escobar* does not overrule *Ebeid*, but rather specifies another means by which an implied false certification case can be proven. See United States’ Statement of Interest Regarding *Universal Health Services, Inc. v. United States ex rel. Escobar* at 5, *United States ex rel. Mateski v. Raytheon Co.*, No. 2:CV06-3614ODW(FMOx) (C.D. Cal. Aug. 16, 2016), ECF No. 163 [hereinafter United States’ Statement of Interest] (“[T]he United States urges the Court to find that the Ninth Circuit’s decision in *Ebeid* remains good law, and that claims for payment by a contractor impliedly certify that the contractor has complied with all material terms of its contract.”).

¹³⁶ *Escobar*, 136 S. Ct. at 2001 (emphasis added).

¹³⁷ Baruch & Wollenberg, *supra* note 129 (citing United States’ Statement of Interest, *supra* note 135, at 1–2).

¹³⁸ *Id.*

¹³⁹ See, e.g., *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 332 (9th Cir. 2017) (affirming the grant of summary judgment for the defendant on the basis that there was no “specific representation” about Serco’s performance made by its submission of public vouchers to the Department of Defense); *United States ex rel. Sheet Metal Workers Int’l Ass’n v. Horning Investments, LLC*, 828 F.3d 587, 592–93 (7th Cir. 2016) (applying the test while omitting the “at least in certain circumstance” caveat); *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445, 447 (7th Cir. 2016) (applying the test as if the conditions must be met); *United States ex rel. Schimelpfenig*, Civil Action No. 11-4607, 2017 WL 1133956, at *5–6 (E.D. Pa. Mar. 27, 2017) (holding that despite the arguments from the government on this issue, the Third Circuit already adopted *Escobar*’s requirements regarding specific representations in the case of *United States ex rel. Whatley v. Eastwick College*, 657 Fed. App’x 89, 94 (3d Cir. 2016)); but see *United States ex rel. Badr v. Triple Canopy, Inc.*, 857 F.3d 174, 178 (4th Cir. 2017) (holding that “specific representation” requirement related to falsity of the claim and that an invoice that simply lists the number of guards and hours worked could be considered false because of its omissions).

successfully adopted by a few district courts,¹⁴⁰ however, and the specific question as to whether presentation of the two conditions are required in each implied false certification theory has been certified as a question to the Ninth Circuit.¹⁴¹

While this appears to be a significant issue for the DOJ relative to the FCA generally, it is not entirely clear that it will actually be a significant issue in cases involving health care companies. Many of the courts that have addressed this issue have compared the “specific representations” in *Escobar*—which contains specific codes regarding the types of services that were provided and corresponding regulations about the types of licensed providers who were supposed to provide the service—to rather vague representations such as invoices or reports.¹⁴² Unlike some situations involving the Department of Defense or the Department of Education, which often involve submission of reports or submission of simple invoices, health care claims seem to automatically involve a “specific representation” based on the

¹⁴⁰ As noted above, the DOJ has been most successful in making this argument in California because of existing case law that held that it was not necessary for a claim to make specific representations to be actionable under the FCA. *See Ebeid*, 616 F.3d at 995; *see also supra* note 135 and accompanying text. For examples of cases in which this has been an issue, see *United States v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1044–45 (C.D. Cal. Dec. 28, 2016) (“Celgene argues that Brown cannot proceed on an implied certification theory because she cannot satisfy the two conditions mentioned in *Escobar*. Celgene misreads that decision. The Court explicitly declined to ‘resolve whether all claims for payment implicitly represent that the billing system is legally entitled to payment.’ Nor were the two conditions intended to describe the outer reaches of FCA liability: the Court stated that liability could be found ‘at least’ where these conditions were satisfied.” (citation omitted) (quoting *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 2001 (2016))); *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1034 (D.C. Cir. 2017); *United States v. DynCorp Int’l, LLC*, 253 F. Supp. 3d 89, 99–100 (D.D.C. 2017); *United States ex rel. Landis v. Tailwind Sports Co.*, 234 F. Supp. 3d 180 (D.D.C. 2017); *but see United States ex rel. Mateski v. Raytheon Co.*, Case No. 2:06-cv-03614-ODW(KSx), 2017 WL 1954942, at *3 (C.D. Cal. Feb. 10, 2017) (“Raytheon argues that *Escobar* limits the implied false certification theory to instances where the claim for payment contains specific representations regarding the goods or service rendered, as opposed to merely requesting payment. Mateski and the Government respond that *Escobar*’s holding is not so broad, and that the Supreme Court expressly withheld judgment on whether an implied false certification theory of liability could encompass claims that simply request payment—thus leaving intact the Ninth Circuit’s prior case law on that specific issue. After briefing on this Motion was complete, the Ninth Circuit issued its opinion in *United States ex rel. Kelly v. Serco, Inc.* which applied *Escobar* to an FCA claim under an implied false certification theory. The Court concludes that *Escobar*, as interpreted by *Kelly*, requires that the claim contain specific representations to be actionable.” (internal citation omitted)).

¹⁴¹ *Rose v. Stephens Inst.*, No. 09-CV-05966-PJH, 2016 WL 6393513, at *3 (N.D. Cal. Oct. 28, 2016). The district court certified the following question to the Ninth Circuit, “whether *Escobar*’s ‘two conditions’ are necessary conditions for liability.” The court also certified three other questions to the Ninth Circuit with this question. As of April 13, 2018, the Ninth Circuit has not issued an opinion in this case.

¹⁴² *Badr*, 857 F.3d at 178 (noting that representations were invoices); *Kelly*, 846 F.3d at 332 (noting that the reports contained no “specific representations” as was the case in claims submitted in *Escobar*).

fact that each claim will include information regarding the service that was claimed to be rendered and applicable regulations typically tied to how the service is rendered.¹⁴³ Even FCA allegations that might stem from the filing of cost reports would likely be interpreted to contain a distinct representation regarding specific costs that were reported to the Centers for Medicare and Medicaid Services (CMS) based on the understanding of the regulations regarding what costs are and are not reimbursed.¹⁴⁴ Thus, while this may be an issue in connection with FCA claims involving Department of Defense or Department of Education, it seems most health care claims will already meet the test set forth in *Escobar*. Given that, even if a majority of courts adopt the position that the two-part test set forth in *Escobar* is not exclusive, it is unlikely to affect the ability to bring health care claims because they appear to meet both the *Escobar* test and any other less exacting test that could be applied in the courts.

2. Existing “Materiality” Definition

The second issue that the DOJ has focused on in subsequent briefs and oral arguments relates to how the materiality inquiry that the Court articulated in *Escobar* relates to the definition of “material” in the statute and whether the directive that the standard be “demanding” changes how a court should assess materiality.¹⁴⁵ Consistent with its position generally on the impact of *Escobar* on existing FCA enforcement, the DOJ is largely taking the position that the opinion does not indicate a change to the manner in which courts have been assessing materiality; that is, “materiality” under the FCA should be assessed based on whether the fraud (or in the case of implied false certification, the noncompliance) has a “natural tendency to influence” the government in its payment decision.¹⁴⁶

¹⁴³ DEPT OF HEALTH & HUMAN SERVS., CTRS. FOR MEDICARE & MEDICAID SERVS., FACT SHEET MEDICARE BILLING: 837P AND FORM CMS-1500, MEDICARE LEARNING NETWORK 2 (n.d.), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/form_cms-1500_fact_sheet.pdf [<http://perma.cc/K7NS-XBFH>] (describing how claims should be coded and the level of detail required when submitting a claim for a particular service).

¹⁴⁴ See generally *Cost Reports*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/research-statistics-data-and-systems/downloadable-public-use-files/cost-reports/> [<http://perma.cc/JJ99-TQYT>].

¹⁴⁵ Baruch & Wollenberg, *supra* note 129.

¹⁴⁶ See *United States ex rel. Johnson v. Golden Gate Nat'l Senior Care, L.L.C.*, 223 F. Supp. 3d 882, 891 (D. Minn. 2016) (holding that the requirement of materiality as defined by Section 3729(b)(4) of the FCA must be met to maintain a claim under Section 3729(a)(1)(A) or 3729(a)(1)(B) and the materiality factors set forth in *Escobar* are to be used as a guide). As noted above, the “natural tendency to influence” standard

Although the Court in *Escobar* specifically declined to opine as to whether that specific statutory definition of material applied to implied false certification cases, the DOJ is taking the position that the standard applied in *Escobar* is not a heightened standard beyond the usual standard of a “natural tendency.”¹⁴⁷ Thus, the DOJ argues the *Escobar* materiality inquiry is simply for the purpose of determining whether the omission or misrepresentation has the natural tendency to influence.

While lower courts do universally seem to be embracing the assertion set forth in *Escobar* that the materiality standard should be demanding,¹⁴⁸ courts have expressed some confusion and have taken varied approaches regarding whether *Escobar*’s clarification on how to assess materiality in implied false certification cases is a new standard or should be assessed somehow in conjunction with an historical standard.¹⁴⁹ For example, some courts have taken the position that the standard set forth in *Escobar* has little distinction from the “natural tendency” standard:

In analyzing materiality, we noted that a material falsehood was one that was capable of influencing the Government’s decision to pay. We explained that the standard was a high one intended to keep FCA liability from attaching to “noncompliance with any of potentially hundreds of legal requirements” in a contract. Applying the standard, we found Triple Canopy’s omissions material for two reasons: common

arises out of the definition of “material” under Section 3729(b)(4) of the FCA that was enacted as part of FERA, which itself was adopted based on long-standing application of that definition under applicable case law. *See supra* notes 69–71 and accompanying text. The definition that was adopted under FERA arose out of case law, as courts for years had viewed the materiality standard as one simply being capable or having a natural tendency to influence and not requiring a showing that such influence was successful. *See United States v. Rogan*, 517 F.3d 449, 452 (7th Cir. 2008) (“Instead [Rogan] argues that the omissions were not material. By this he does not mean the usual definition, under which a ‘statement is material if it has “a natural tendency to influence, or [is] capable of influencing, the decision of the decisionmaking body to which it was addressed.’” (quoting *Neder v. United States*, 527 U.S. 1, 16 (1999))).

¹⁴⁷ *See* Supplemental Brief for the United States at 12, *United States ex rel. Badr v. Triple Canopy, Inc.*, 857 F.3d 174 (4th Cir. 2017) (Nos. 13-2190(L), 13-2191), 2016 WL 4425869 (“[T]he Supreme Court did not impose a heightened test for materiality beyond the ‘natural tendency’ test codified in the False Claims Act.”).

¹⁴⁸ *See, e.g.*, *United States ex rel. Petratos v. Genentech, Inc.*, 855 F.3d 481, 489–91 (3d Cir. 2017) (“The Court described [the *Escobar* standard] as ‘demanding’ and ‘rigorous’ and explained that a material misrepresentation is one that goes ‘to the very essence of the bargain.’” (quoting *United States ex rel. Escobar*, 139 S. Ct. 1989, 2002–2003, 2003 n.5 (2016))); *see also United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 331 (9th Cir. 2017); *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445, 447 (7th Cir. 2016).

¹⁴⁹ *See Petratos*, 855 F.3d at 489; *Johnson*, 223 F. Supp. 3d at 891–92; *United States v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1044–45 (C.D. Cal. 2016); *see also United States ex rel. Worthy v. Eastern Maine Healthcare Systems*, 2:14-cv-00184-JAW, 2017 WL 211609, at *26 (D. Me. Jan. 18, 2017); *United States ex rel. Thayer v. Planned Parenthood of the Heartland, Inc.*, No. 4:11-cv-00129-JAJ-CFB, 2016 WL 7474797, *5–6 (S.D. Iowa June 21, 2016).

sense and Triple Canopy's own actions in covering up the noncompliance. That conclusion perfectly aligns with [*Escobar*].¹⁵⁰

Some other courts have analyzed materiality under both the definitional standard and independently under the *Escobar* standard. In the case of *United States ex rel. Petratos v. Genentech, Inc.*, the United States Court of Appeals for the Third Circuit identified that the FCA defines materiality as “having a natural tendency to influence” and described the Supreme Court’s ruling in *Escobar* as providing “guidance as to how the materiality requirement should be enforced.”¹⁵¹ The court goes on to seemingly analyze the “guidance” potentially as its own test—separate and apart from the statutory definition—to state that the “Supreme Court’s guidance . . . also militates against a finding of materiality.”¹⁵² Many courts seem to be taking an approach similar to that of the Third Circuit, viewing the standard set forth in *Escobar* as the factors necessary for the purpose of meeting the statutory definition under the FCA.¹⁵³

Two observations arise in connection with this particular issue. First, the *Escobar* Court’s decision not to address the relationship between the statutory definition of “material” found in Section 3729(b)(4) and the guidance it set forth regarding how to assess materiality has caused confusion among the lower courts about how to square these two standards. Despite the Court’s clear choice not to utilize the statutory definition in *Escobar*, many courts seem compelled by either precedent or statutory interpretation to utilize the definition as part of any analysis.¹⁵⁴ It would seem then, that the DOJ is realizing some success as it relates to its argument that *Escobar* has not really altered the broadly-applied natural tendency standard. It does appear, however, that while courts may be applying the statutory definition, they are simultaneously endorsing the idea that *Escobar* firmly establishes that the materiality standard for FCA cases is intended to be demanding and rigorous.¹⁵⁵ Consequently, when courts continue to utilize the statutory definition, the manner in which such courts are considering whether an omission or misrepresentation has a natural tendency to influence or is capable of influencing the decision maker is analyzed through a more rigorous and exacting lens.

¹⁵⁰ *Badr*, 857 F.3d at 178 (quoting *United States ex rel. Badr v. Triple Canopy*, 775 F.3d 628, 637 (4th Cir. 2015), *vacated and remanded by* 136 S. Ct. 2504 (2016)).

¹⁵¹ *Petratos*, 855 F.3d at 489.

¹⁵² *Id.* at 490 (emphasis added).

¹⁵³ See *supra* note 149 and accompanying text.

¹⁵⁴ See *supra* notes 149–152.

¹⁵⁵ See *supra* note 140.

III. FINDING PROOF OF MATERIALITY

Predictably, one of the most closely watched aspects of the *Escobar* opinion is how lower court cases interpret the guidelines for materiality and the type of proof that may be necessary (or is not sufficient) to meet this demanding standard. While the Court has instructed that selling the government guns that do not shoot despite no express regulation indicating such *would* be material and using foreign-made staplers notwithstanding a law requiring use of American-made staplers would *not* be material, the opinion itself does not provide examples for what might fall in between these two extremes.¹⁵⁶

In this middle area lies the Court's direction regarding regulations that are expressly conditions of payment. The Court made clear that a regulation that is expressly a condition of payment is relevant to materiality, although not dispositive.¹⁵⁷ In order to reconcile the previously common analysis regarding whether a regulation was a condition of payment with the new position under *Escobar*,¹⁵⁸ some lower courts have dedicated a great deal of analysis to whether a regulation is an express condition of payment and how that conclusion might affect the materiality analysis.¹⁵⁹ While lower courts have continued to analyze whether a regulation is an express condition of payment, how courts have utilized their conclusion on this issue for purposes of assessing materiality has varied, with some using it as evidence of materiality and others utilizing it to hold that *Escobar* made clear this finding alone does not establish materiality.¹⁶⁰ Although this seems to have made it more difficult to determine prior to the filing of any FCA claim whether a particular regulation is or is not material, the outcome certainly seems to be in furtherance of the Supreme Court's intention that lower courts look more at whether the fraud is the type that would rise to the level of common law fraud.

¹⁵⁶ *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2001–04 (2016).

¹⁵⁷ *Id.* at 2001.

¹⁵⁸ Many of the cases analyzing the *Escobar* opinion have done so on a remand from a higher court because the lower court holding was based on a finding that the implied certification theory did or did not apply based on the fact that the regulation was or was not an express condition of payment. *See, e.g., Badr*, 857 F.3d at 177–78; *United States ex rel. Miller v. Weston Educ., Inc.*, 840 F.3d 494, 503–04 (8th Cir. 2016).

¹⁵⁹ *Miller*, 840 F.3d at 504.

¹⁶⁰ *See Badr*, 857 F.3d at 177–78; *cf. United States ex rel. Petratos v. Genentech, Inc.*, 855 F.3d 481, 489–90 (3d Cir. 2017).

A. Treatment of Conditions of Payment

In *United States v. Triple Canopy, Inc.*—a case that the United States Court of Appeals for the Fourth Circuit remanded back to the lower court on the same day that the Supreme Court released its *Escobar* opinion—the specific regulation upon which the claim was premised was not an express condition of payment.¹⁶¹ Based on *Escobar*, the Fourth Circuit reaffirmed its previous conclusion that, absent an express condition of payment, materiality could be proven based on “common sense” and Triple Canopy’s own actions to conceal any noncompliance.¹⁶² In support of its assertion that its previous holding was consistent with the materiality standard in *Escobar*, the court stated that “Guns that do not shoot are as material to the Government’s decision to pay as guards that cannot shoot straight.”¹⁶³ Similarly, the Eighth Circuit held in *United States ex rel. Miller v. Weston Educational, Inc.* that although falsifying grade records and attendance records was not expressly a condition of payment, the misrepresentation was clearly material because recordkeeping itself was a precondition—in three different ways—for participation in the government program and thus payment under the program.¹⁶⁴

In contrast, the Third Circuit analyzed a regulation that was expressly a condition of payment, but relied on *Escobar*’s holding that such finding was not dispositive to find that the plaintiff failed to plead that CMS consistently refused to pay the type of claims set forth in the complaint.¹⁶⁵ Rather, the plaintiff conceded that such claims were consistently reimbursed.¹⁶⁶ The plaintiff had argued that whether a claim is material should not focus on the *government’s* decision to pay, but instead should look to whether the false statements were material to those submitting the claims—the providers in this instance.¹⁶⁷ In support of this position, the plaintiff cited to the following line in *Escobar*: “materiality ‘look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.’”¹⁶⁸

¹⁶¹ *Badr*, 857 F.3d at 179.

¹⁶² *Id.* at 178.

¹⁶³ *Id.* at 179.

¹⁶⁴ *Miller*, 840 F.3d at 504.

¹⁶⁵ *Petratos*, 855 F.3d at 485.

¹⁶⁶ *Id.* at 485–86 (involving claims against a pharmaceutical company that it was causing providers to make claims for the drug Avastin that were not “reasonable and necessary”).

¹⁶⁷ *Id.* at 490–91.

¹⁶⁸ *Id.* at 491 (alteration in original) (quoting *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2002 (2016)).

The court specifically rejected this idea, however, stating that such reference in the context of the *Escobar* opinion was referring to fraud against the federal government (not fraud against a third party who then bills the federal government), which the Third Circuit claimed was most consistent with other holdings.¹⁶⁹ Similar to the Third Circuit, the Ninth Circuit also analyzed a regulation that was determined to be a condition of payment.¹⁷⁰ Despite this finding, the court nevertheless dismissed the claim on the basis that, among other things, the government's behavior in the past reflected the fact that it did not view the allegedly falsified reports as helpful or necessary for purposes of payment.¹⁷¹ In both instances, the court found that the fact that the regulation was an express condition of payment was irrelevant due to the evidence presented that the federal government had consistently paid similar types of claims in the past despite awareness of fraudulent activity.¹⁷²

As the cases above demonstrate, while conditions of payment and how such finding affects materiality remains a common issue, it seems that the thrust of the *Escobar* opinion—and thus the primary emphasis with lower courts—is the newly established focus on the government's behavior and the defendant's knowledge of such behavior.¹⁷³ Moreover, these cases seem to also indicate a shift away from the statutory “natural tendency” standard, which would only require proof that the misrepresentation *would have a tendency to* affect the government's decision to pay, toward a materiality standard that requires evidence that the government was in fact influenced—it knew of the noncompliance and chose to pay the claim regardless.¹⁷⁴

Because the Supreme Court provided guidance regarding both what might be necessary to substantiate materiality and what might negate materiality, some courts have used evidence to prove a claim is material and some have used evidence to prove a claim is not material. For example, in *Abbott v. BP Exploration & Production, Inc.*, the Fifth Circuit dismissed the FCA claim on the basis that the government was aware of BP Exploration & Production, Inc.'s actions and chose not to

¹⁶⁹ *Id.* at 491–92 (citing *United States ex rel. Garzione v. PAE Gov't Servs., Inc.*, 670 Fed. App'x 126, 127 (4th Cir. 2016)); see *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445, 447 (7th Cir. 2016).

¹⁷⁰ See *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 332 (9th Cir. 2017).

¹⁷¹ See *id.* at 334.

¹⁷² See generally *Kelly*, 846 F.3d 325; *Petratos*, 855 F.3d 481.

¹⁷³ *Escobar*, 136 S. Ct. at 2002–03.

¹⁷⁴ See, e.g., *Kelly*, 846 F.3d at 334.

suspend operations or to revoke the contract. This government inaction thus showed that the government did not find BP Exploration & Production, Inc.'s noncompliance material.¹⁷⁵ Quoting *Escobar's* directive that “courts need not opine in the abstract when the record offers insight into the Government’s actual payment decisions,” the District of Columbia Circuit has found similarly that a claim did not establish materiality because it was not clear that the government actually used the alleged fraudulent data for purposes of payment.¹⁷⁶ Likewise, an allegation of a regulation as a condition precedent to payment was insufficient for proving materiality absent additional evidence that the government found this material through its payment actions.¹⁷⁷ In contrast, evidence used to show materiality—as opposed to a showing that a regulation was not material—has included language in the regulations and testimony from regulators themselves about whether or not such regulations are material to the government’s payment decision¹⁷⁸ or a lack of knowledge on the part of the government during the time that claims were paid.¹⁷⁹

B. *The Impact of “Timing”*

While the Supreme Court in *Escobar* provided guidelines about types of evidence that would prove materiality, it provided little information regarding when such behavior might occur,

¹⁷⁵ *Abbot v. BP Expl. & Prod., Inc.*, 851 F.3d 384, 388 (5th Cir. 2017). The case involved allegations that BP had inadequate documentation and further documentation that was not appropriately approved by engineers in connection with the building of an oil production platform. U.S. Congress conducted an investigation into the matter, as did the Department of Interior. The Department of Interior concluded in a report in 2011 that the allegations were without merit. *Id.* at 386.

¹⁷⁶ *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1032 (D.C. Cir. 2017) (citing *Escobar*, 136 S. Ct. at 2002).

¹⁷⁷ *See United States ex rel. Scharff v. Camelot Counseling*, No. 13-cv-3791 (PKC), 2016 WL 5416494, at *8 (S.D.N.Y. Sept. 28, 2016) (finding that the plaintiff had failed to plead materiality in connection with alleged violations of mental health regulations due to failure to keep adequate notes, incorrectly billing time spent with patients, and maintenance of records that contained patient signatures).

¹⁷⁸ *See United States v. Dynamic Visions, Inc.*, 216 F. Supp. 3d 1, 16 (D.D.C. 2016) (“Finally, Plaintiff provides the declaration of the Medicaid Director of the District of Columbia Medicaid Program that states that DHCf does not, in fact, reimburse providers for services provided where there is no plan of care, where the plan of care has not been signed by a physician or advanced practice nurse, where the plan of care has been signed but only after services had been rendered, or where a signed plan of care exists but the services billed exceed the scope of that plan.”).

¹⁷⁹ *See United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 111–12 (1st Cir. 2016) (holding on remand that the claims were material even though there was evidence that the government continued to pay the claims because it was during a time of a lack of government knowledge).

either before or after the fraud has been alleged.¹⁸⁰ For example, in *Triple Canopy, Inc.*, in addition to the Fourth Circuit's finding that materiality was simply "common sense," the court found that the defendant's own behavior substantiated materiality.¹⁸¹ Specifically, the court found that the defendant's attempt to conceal that many of its guards did not possess the necessary certification as marksman pursuant to the contract was clearly representative of the fact that the defendants *knew* that the government would not pay the claims if it knew the guards did not have such qualifications.¹⁸² In other words, the defendant would never have felt compelled to make the fraudulent representations unless the defendant suspected that the government would not pay the claims if it knew.¹⁸³ The court also cited to the government's behavior as evidence, noting that when the government became aware that it was possible that Triple Canopy's guards did not meet necessary qualifications, the federal government did not renew the contract with the company and also immediately intervened in the FCA case after the whistleblower filed the claim.¹⁸⁴ In this case, the court used prospective knowledge of the defendant and retrospective behavior of the government to show materiality.

A similar example of when a court looked to the retrospective behavior of the government for purposes of proving materiality is the First Circuit's analysis on remand of the *Escobar* case.¹⁸⁵ Universal Health Services argued that the state Medicaid program was aware of the company's violations because the plaintiffs, prior to filing the FCA case, had actually filed a complaint with the state Medicaid program and the Medicaid program continued to pay claims despite being made aware of the allegations by the family.¹⁸⁶ The First Circuit rejected this reasoning, however, on the basis that "mere awareness of allegations concerning noncompliance with

¹⁸⁰ See, e.g., *United States ex rel. Badr v. Triple Canopy, Inc.*, 857 F.3d 174, 179 (4th Cir. 2017) (utilizing the fact that the DOJ intervened on the FCA case *after* it was filed as proof of materiality); *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 337 (9th Cir. 2017) (holding that although the federal government had noted a particular recordkeeping requirement as a condition of payment prior to the filing, this was nevertheless not dispositive of a finding of materiality because the government did not rely on the reports for purpose of payment); *Escobar*, 842 F.3d at 112 (holding that although the state of New York was arguably aware of the fraud after investigation of the provider following a complaint, the fact that the state continued to pay the claim despite this knowledge was not determinative of a finding that the claims were not material).

¹⁸¹ *Badr*, 857 F.3d at 176–78.

¹⁸² *Id.* at 176.

¹⁸³ *Id.*

¹⁸⁴ *Id.* at 179.

¹⁸⁵ See *Escobar*, 842 F.3d at 105.

¹⁸⁶ *Id.* at 111–12.

regulations is different from knowledge of actual noncompliance” and there was no evidence of actual knowledge by the government such that it would negate a finding of materiality.¹⁸⁷ The court does not opine as to whether its finding of materiality would be negated if the government continued to pay the claims despite actual knowledge, but the opinion does seem to suggest that to the extent that one intends to prove a claim is not material, actual knowledge of noncompliance would be a necessary prerequisite.¹⁸⁸

Most of the cases analyzing materiality based on the government’s knowledge of the noncompliance have relied on evidence regarding the government’s knowledge *and action or inaction* prior to the filing of the FCA claim, and few at this point have identified the scheme itself as indicative of materiality.¹⁸⁹ Thus, while it appears that most courts are examining past behavior, the possibility that evidence of behavior retrospective to the filing of an FCA claim or, indeed the alleged fraud itself, does have the potential for confusion and challenges. Distinct from an express condition of payment, which would have put a government contractor on notice as to whether violation of such regulation would be subject to liability under the FCA, the new materiality standard requires a case-by-case analysis as to the government’s knowledge of each action and the defendant’s awareness of the government’s knowledge. While the materiality standard might more closely resemble claims asserting common law fraud, it provides potentially less clarity to contractors regarding the types of behavior that may or may not be actionable under the FCA and what interactions with government regulators might mean for future FCA liability.

¹⁸⁷ *Id.* at 112 (“[T]here is no evidence in the complaint that MassHealth, the entity paying Medicaid claims, had actual knowledge of any of these allegations (much less their veracity) as it paid UCH’s claims.”).

¹⁸⁸ *Id.* (“Because we find no evidence that MassHealth had actual knowledge of the violations at the time it paid the claims at issue, we need not decide whether actual knowledge of the violations would in fact be sufficiently strong evidence that the violations were not material to the government’s payment decision so as to support a motion to dismiss in this case.”).

¹⁸⁹ *See, e.g.,* United States *ex rel.* Petratos v. Genentech Inc., 855 F.3d 481, 492 (3d Cir. 2017); United States *ex rel.* Campie v. Gilead Scis., Inc., 862 F.3d 890, 905–06 (9th Cir. 2017) (holding that, while the FDA was at least aware of the noncompliance because of a warning letter and an inspection and noncompliance letter and the government continued to pay claims, FDA’s failure to withdraw approval of the drug does not suffice to provide the claims were material for purposes of FCA); A1 Procurement, LLC v. Thermcor, Inc., No. 2:15cv15, 2017 WL 2881350, at *6 (E.D. Va. July 5, 2017). *But see Badr*, 857 F.3d at 178.

IV. ARGUMENT: THE IMPACT OF *ESCOBAR* ON HEALTH CARE COMPANIES

As courts of appeals and district courts wade through allegations against contractors with the Department of Defense, Department of Education, and Department of Health and Human Services under the FCA,¹⁹⁰ the *Escobar* opinion has provided helpful guidance by affirming the validity of implied false certification claims and by emphasizing that the materiality standard under the FCA is demanding and rigorous and thus should be applied strictly.¹⁹¹ Like many Supreme Court opinions, however, it has also raised a number of questions and issues, resulting in inconsistent application of different aspects of implied false certification claims. The DOJ seems to be doing its best to argue that *Escobar* has changed little to nothing about the legal analysis for implied false certification claims.¹⁹² While this has had at least some success,¹⁹³ it does seem that most courts view *Escobar* not simply as affirmation to permit implied false certification claims, but a directive to apply a stricter and more precise application of implied false certification claims.¹⁹⁴ As such, most courts appear to be at least considering *Escobar* to require analyzing regulations and materiality with a different lens.

It should be noted, however, that while many courts appear to be giving credence to this more demanding standard, it is not entirely clear whether these same cases would have come out differently had *Escobar* instead adopted the position of the majority of circuits permitting implied false certification claims to proceed only in connection with regulations expressly designated as conditions of payment. While a few courts have in fact permitted claims to proceed that are seemingly based on

¹⁹⁰ See Justice Dep't Recovers Over \$3.7 Billion, *supra* note 7 (noting that FCA recoveries arise out of the health care industry, but also from "defense and national security, food safety and inspection, federally insured loans and mortgages, highway funds, small business contracts, agricultural subsidies, disaster assistance, and import tariffs").

¹⁹¹ See, e.g., *Petratos*, 855 F.3d at 489; *A1 Procurement, LLC*, 2017 WL 2881350 at *3; *United States ex rel. Lee v. N. Adult Daily Health Care Ctr.*, 205 F. Supp. 3d 276, 295 (E.D.N.Y. 2016); *United States ex rel. Brown v. Celgene Co.*, 226 F. Supp. 3d 1032, 1049 (C.D. Cal. 2016).

¹⁹² *Baruch & Wollenberg*, *supra* note 129.

¹⁹³ See discussion *supra* note 140.

¹⁹⁴ In perhaps one of the most notable examples of this application to date, a district judge in Florida negated a \$350 million judgment against a nursing home operator for alleged violations of the FCA on the basis that "[t]he defendants argue persuasively that the relator failed to offer evidence of materiality, defined unambiguously and required emphatically by *Universal Health Services, Inc. v. Escobar*." See Jeff Overley, *Escobar Erases Nursing Co.'s \$350M FCA Verdict*, LAW360 (Jan. 11, 2018, 6:27 PM), <https://www.law360.com/articles/1001439> [<https://perma.cc/38RG-NYPN>].

violations of conditions of participation,¹⁹⁵ the large bulk of FCA claims that actually proceed to court—in lieu of settlement—are typically dismissed on a motion for summary judgment.¹⁹⁶ Further, in the bulk of these cases, the government has reviewed the case and chosen not to intervene, and thus the relator is proceeding on his/her own.¹⁹⁷ While intervention in a case should not be used in all instances as a marker for the viability of the case itself, there are many cases in which the government declines to intervene or proceed to settlement because the claim does not have sufficient merit to be successfully argued in court.¹⁹⁸ Thus, given that the vast majority of the examples of the application of *Escobar* are in cases making their way through the court system—and thus have been unsealed due to the government’s declination to intervene—it is challenging to understand and fully comprehend the impact that *Escobar* and the new materiality standard actually has on FCA claims. The bulk of legal analysis and interpretation of *Escobar* has thus far and will continue to arise out of claims that may have been flawed or legally unsustainable for entirely other reasons. Given that, it is somewhat dubious or dangerous to claim that *Escobar* has entirely changed the legal landscape such that the new exacting standard is dismissing vastly more claims than would be dismissed prior to *Escobar*. Courts seem to be aware that *Escobar* stands for the notion that implied false certification claims must

¹⁹⁵ See, e.g., *United States ex rel. Johnson v. Golden Gate Nat’l Senior Care, L.L.C.*, 223 F. Supp. 3d 882, 894 (D. Minn. 2016).

¹⁹⁶ In a review of cases from the federal courts of appeals in the twelve months following the *Escobar* opinion that cited to *Escobar* in some manner in their opinion, there were only six cases of the thirty-two that did not affirm the district court opinion and, of those twenty-nine cases, nearly all affirmed the dismissal of the FCA claim in the district court. Note that while the vast majority of these cases were FCA cases, at least a few were related to another law, but utilized *Escobar* for purposes of analyzing materiality. See, e.g., *In re Vivendi, S.A. Securities Litigation*, 838 F.3d 223 (2d Cir. 2016) (citing to *Escobar* to support the legal premise that “half-truths . . . can be actionable misrepresentations” (quoting *Universal Health Servs. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2000 & n.3 (2016))). Many of the cases involved dismissal of the claim for failure to plead with particularity or failure to state a claim and were not actually dismissed based on either failure to please a specific representation in an implied false certification claim or meet the new materiality standard. See, e.g., *United States ex rel. McGrath v. Microsemi Corp.*, 690 Fed. App’x 551, 552 (9th Cir. 2017) (affirmed dismissal under Rules 8(a) and 9(b) of the Federal Rules of Civil Procedure); *Olson v. Fairview Health Servs. of Minnesota*, 831 F.3d 1063, 1066 (8th Cir. 2016) (affirmed dismissal under Rule 12(b)(6) of the Federal Rules of Civil Procedure); *United States & Wisconsin ex rel. Presser v. Acacia Mental Health Clinic, LLC*, 836 F.3d 770, 772–73 (7th Cir. 2016) (affirmed dismissal of the bulk of claims for failure to state a claim under Rule 9(b) of the Federal Rules of Civil Procedure).

¹⁹⁷ See FRAUD STATISTICS, *supra* note 43, at 1.

¹⁹⁸ David Freeman Engstrom, *Public Regulation of Private Enforcement: Empirical Analysis of DOJ Oversight of Qui Tam Litigation under the False Claims Act*, 107 NW. U. L. REV. 1689, 1693–94 (2013).

be viewed rigorously, but this does not appear to be the sole or singular reason that courts are dismissing FCA claims.¹⁹⁹

It is possible that there could be some clarity on this front, given the DOJ's current position regarding how department prosecutors should address FCA claims in which the DOJ has chosen not to intervene.²⁰⁰ In an internal memorandum dated January 10, 2018, Director Michael D. Granston noted to attorneys in the Commercial Litigation Branch, Fraud Section that while the number of *qui tam* cases has increased greatly over the last few years, the DOJ's intervention rate has "remained relatively static."²⁰¹ Because the government still expends a substantial amount of money to monitor and participate in non-intervened cases, Director Granston instructed prosecutors to consider whether to seek a dismissal of claims that the prosecutors believe lack substantial merit.²⁰² While Granston stated that dismissal should be used "only where truly warranted," the memorandum is a directive to prosecutors to be more proactive regarding not just declining to intervene in meritless cases, but actively working towards curbing meritless claims.²⁰³ Thus, while this directive will not eliminate all non-intervened cases, there should be perhaps fewer meritless claims applying the *Escobar* analysis. This may in turn provide a more accurate assessment of how stringently *Escobar* will be applied to meritorious claims.

A. *Assessing Common Law Fraud*

Regardless of whether the reason certain cases are dismissed is standards set forth in *Escobar* or because of other pleading or evidentiary challenges, there is nevertheless a great body of precedent that is building regarding the impact of *Escobar* on implied false certification claims. Beyond the umbrella themes related to a rigorous and demanding standard, the Supreme Court seems to be attempting to steer FCA application, which

¹⁹⁹ See, e.g., *D'Agostino v. EV3, Inc.*, 845 F.3d 1, 6 (1st Cir. 2016) (affirming dismissal based on plaintiff being barred by the public disclosure bar); *Hagerty ex rel. United States v. Cyberonics, Inc.*, 844 F.3d 26 (1st Cir. 2016) (affirming dismissal based on failure to plead with particularity); *United States ex rel. Whatley v. Eastwick College*, 657 Fed. App'x 89 (3d Cir. 2016).

²⁰⁰ Internal Memorandum from Michael Granston, Director of United State Dep't of Justice, Commercial Litigation Branch, Fraud Section, Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A), Internal Memorandum, (Jan. 10, 2018), <https://www.fcadefenselawblog.com/wp-content/uploads/sites/561/2018/01/Memo-for-Evaluating-Dismissal-Pursuant-to-31-U-S.pdf> [<https://perma.cc/5SYG-SB4V>].

²⁰¹ *Id.* at 1.

²⁰² *Id.*

²⁰³ *Id.* at 2–3.

has ballooned into what can be described as “big business” for the federal government,²⁰⁴ towards a back-to-basics application akin to common law fraud. As is the case of common law fraud, the Court’s new analysis advises lower courts that there is no strict definition of “fraud,” rather the court must look at whether a particular admission or omission of certain details was a misrepresentation made for the purpose of misleading or defrauding.²⁰⁵ The Court’s examples bear this out: contractors that are selling the government guns, but such guns do not actually shoot, are perpetuating a fraud and contractors that are selling the government guns, but are using foreign-made staplers to staple their invoices as opposed to American-made staplers, even if in violation of a federal regulation, are not perpetuating a fraud.²⁰⁶ Thus, the Court is telling relators, prosecutors, and courts alike that they should stop focusing on the regulation and the characteristics of the regulation and instead focus on the act itself and whether such act is intended to defraud.

There is no doubt that *Escobar* has changed the manner in which implied false certification claims are pleaded and the type of evidence that parties are putting forth in order for the claims to be successful—or at least to survive the summary judgment stage. Certainly, the prosecutors’ bar and relators’ bar are closely monitoring lower court cases analyzing *Escobar* for purposes of litigation strategy and careful pleading.

In addition to their watchful eyes, however, there are a whole host of health care transactional attorneys, compliance officers, medical coding professionals, and health care regulatory experts trying to also determine how *Escobar* is changing the legal landscape. Specifically, those entities most commonly subject to the FCA, particularly health care providers and suppliers, are paying considerably close attention for purposes of assessing compliance risk and managing legal liability.²⁰⁷ With thousands of statutes and regulations—both federal and state—governing the services and operations of

²⁰⁴ See *supra* notes 7, 39–40 and accompanying text.

²⁰⁵ See RESTATEMENT (SECOND) OF TORTS § 525 (AM. LAW INST. 1977) (defining common law fraud as “[o]ne who fraudulently makes a misrepresentation of fact, opinion, intention or law for the purpose of inducing another to act or to refrain from action in reliance upon it, is subject to liability to the other in deceit for pecuniary loss caused to him by his justifiable reliance upon the misrepresentation”).

²⁰⁶ See *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2001–04 (2016).

²⁰⁷ See generally Paul F. Khoury et al., *Government Contractors Deal with the Uncertain Shadow of Universal Health Services, Inc. v. United States ex rel. Escobar*, 52 PROCUREMENT LAW. 12 (2017).

health care providers and suppliers, such entities might submit hundreds of claims per day all impliedly certifying compliance with any number of statutes, rules, and regulations to which such provider or supplier is subject.²⁰⁸

Based on the *Escobar* opinion, at least some of these underlying statutes, rules, and regulations (collectively, the “regulations”) are clearly material enough that noncompliance with such regulations could result in FCA liability.²⁰⁹ It is equally clear, however, that some of these regulations are more for purposes of dictating how care should be delivered or certain operations should take place, but are not entirely material to the government’s payment decision. Trying to now decipher the distinction between those regulations based on the guidance from *Escobar* and the opinions analyzing *Escobar*, all with unique facts and unique regulations, may be the biggest challenge yet to be faced.

One argument consistently averred by defendants prior to the opinion in *Escobar* was that to the extent that implied false certification claims are viable, liability must be limited to express false certification claims in order to provide defendants with “fair notice” regarding what might be fraudulent under the FCA.²¹⁰ In response to Universal Health Service’s use of this argument in *Escobar*, the Court stated:

Universal Health’s approach [of limiting implied false certification claims to regulations that are expressly designated conditions of payment] risks undercutting [the FCA’s] policy goals. The Government might respond by designating every legal requirement

²⁰⁸ Entities that participate in the Medicare program (both providers and suppliers) are subject to federal Medicare statutes, rules, and regulations as participants. See DEPT OF HEALTH & HUMAN SERVS., MEDICARE ENROLLMENT APPLICATION (CMS-855A) 48 (Expires Aug. 2019), <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855a.pdf> [<http://perma.cc/46CE-ATNE>] (“I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. The Medicare laws, regulations and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions . . . , and on the provider’s compliance with all application conditions of participation in Medicare.”). Entities may also choose—separately—to participate in state Medicaid programs. Because the Medicaid program is a program that is jointly operated and funded by the states and the federal government, there are both federal statutes, rules, and regulations that govern Medicaid providers and also state statutes, rules, and regulations that govern Medicaid providers operating in a particular state. See generally *Federal Policy Guidance*, MEDICAID.GOV, <https://www.medicaid.gov/federal-policy-guidance/federal-policy-guidance.html> [<http://perma.cc/CVN8-MY5Z>]; see also, e.g., TENN. CODE ANN. § 71-5-102 (2017) *et seq.*; TENN. COMP. R. & REGS. 1200-13-01 (2016) *et seq.*; see also *Financing & Reimbursement*, MEDICAID.GOV, <https://www.medicaid.gov/medicaid/financing-and-reimbursement/> [<https://perma.cc/235B-JZ8H>] (“The Medicaid program is jointly funded by the federal government and states.”).

²⁰⁹ *Escobar*, 136 S. Ct. at 1996, 2002–04.

²¹⁰ *Id.* at 2002.

an express condition of payment. But billing parties are often subject to thousands of complex statutory and regulatory provisions. Facing False Claims Act liability for violating any of them would hardly help would-be defendants anticipate and prioritize compliance obligations. And forcing the Government to expressly designate a provision as a condition of *payment* would create further arbitrariness. Under Universal Health's view, misrepresenting compliance with a requirement that the Government expressly identified as a condition of payment could expose a defendant to liability. Yet, under this theory, misrepresenting compliance with a condition of eligibility to even participate in a federal program when submitting a claim would not.²¹¹

It is certainly a valid point that to the extent that implied false certification claims were limited to express conditions of payment that one reaction from the government could be simply to identify all claims as conditions of payment.²¹² It seems unlikely, however, that CMS would revise the myriad regulations to designate all regulations as conditions of payment merely to create liability under the FCA. This is especially true if the government is truly only interested in litigating FCA claims that are material to the government's decision to pay the claim *and* there is a genuine interest in preventing parasitic lawsuits under the FCA. Further, to the extent that all regulations were reclassified or amended to be expressly designated as conditions of payment, there would be no need for a materiality standard or a scienter requirement at all under an FCA claim.

To the extent that all regulations were expressly designated as conditions of payment, then essentially all such regulations would be considered automatically material and all defendants would have the necessary scienter because they would be on notice that all regulations are expressly designated as condition of payment. Thus, two of the most basic, necessary FCA pleading requirements—excluding other general pleading requirements such as particularity or failure to state a claim or other procedural challenges such as the public disclosure bar²¹³—would be met without any requirement that the plaintiffs have to actually prove such requirements.²¹⁴ Given the efforts

²¹¹ *Id.*

²¹² *Id.*

²¹³ See generally Joel D. Hesch, *Restating the "Original Source Exception" to the False Claims Act's "Public Disclosure Bar" in Light of the 2010 Amendments*, 51 U. RICH. L. REV. 991 (2017); Aaron Rubin, *To Present Bills or Not to Present? An In-Depth Analysis of the Burden of Pleading in Qui Tam Suits*, 8 SETON HALL CIR. REV. 467 (2012).

²¹⁴ The Court in *Escobar* discussed the relationship between the requirements of materiality and scienter in connection with a FCA claim. The Court stated, "A defendant can have 'actual knowledge' that a condition is material without the Government expressly calling it a condition of payment." *Escobar*, 136 S. Ct. at 2001. "What matters is not the label the Government attaches to a requirement, but whether

over the years to ensure the proper balance between capturing fraud against the federal government and protecting against parasitic lawsuits, it seems an unlikely result that Congress or administrative agencies would adopt a position that would make *all* regulations preconditions to payment or effectively eliminate the need to affirmatively prove materiality and scienter.

B. Escobar's Effect on Compliance and Risk Management

The question remains, then, even if it may be unlikely that the federal government would actually have adopted the tact of expressly designating each regulation as a condition of payment, how will the Court's rejection of a bright-line rule under *Escobar* affect compliance and risk management? Will contractors be able to adequately assess risk and prioritize compliance based on the guidance and dictates of *Escobar*? Because the health care industry represents the entity with the largest FCA remittance to the federal government,²¹⁵ this industry seems an appropriate example for purposes of exploring the potential compliance impact of the *Escobar* opinion. With the thousands of regulations that apply to health care providers and suppliers, compliance programs and prospective efforts to reduce legal liability—primarily related to billing and collection—have become a fairly substantial part of the operation of health care entities.²¹⁶ Indeed, each year, the Office of Inspector General of the Department of Health and Human Services releases work plans that provide information

the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." *Id.* at 1996. To the extent that the Court had adopted a position that implied false certification claims were required to be conditions of payment, this would meet both materiality and scienter requirements.

²¹⁵ See *supra* note 7 and accompanying text.

²¹⁶ The Office of Inspector General has a webpage dedicated to compliance titled, "Compliance 101" in which it advises providers and suppliers about "health care fraud and abuse laws and the consequences of violating them." *Compliance Education Materials: Compliance 101*, OFFICE OF INSPECTOR GEN., <https://oig.hhs.gov/compliance/101/> [<http://perma.cc/VX7B-HZP7>]. Compliance and the need for compliance programs has its roots in the 1990s and stems largely from language in the U.S. Sentencing Commission's promulgation of Federal Sentencing Guidelines for Organizations, which would reduce sanctions against a corporation if such corporation adopted "an effective program to prevent and detect violations of law." Thomas E. Bartrum & L. Edward Bryant, Jr., *The Brave New World of Health Care Compliance Programs*, 6 ANNALS HEALTH L. 51, 55 (1997) (quoting UNITED STATES SENTENCING GUIDELINES MANUAL § 8C2.5(f) (1995)). The requirement for an effective compliance program was tested in the settlement proposal to the Delaware Supreme Court in which the court approved a settlement proposal because the court found that that Board of Directors for Caremark International, Inc. was not aware that the company had been violating certain provisions of a federal antibribery law and once the board discovered such issue, it exercised reasonable oversight in accordance with its existing and effective compliance program. See *In re Caremark Intern., Inc. Derivative Litigation*, 698 A.2d 959 (Del. Ch. 1996).

and guidance to various types of providers and suppliers for the sole purpose of informing such industries about the government's concerns regarding legal compliance priorities for that particular industry.²¹⁷

With the myriad regulations governing operations and the exceedingly varied operations of health care entities,²¹⁸ the simple reality is that it is exceptionally difficult for providers and suppliers to be in constant and complete compliance with all health care regulations at all times. This can be seen from the Office of Inspector General (OIG) Work Plan and compliance guidance itself; at any given time, for any given sector of health care, there are a number of different concerns that the OIG cites to regarding what its area of compliance focus is for that particular time period.²¹⁹ Thus, compliance offices must assess all of the various risk factors identified and then not only correct the noncompliance and address the processes going forward, but also prioritize the order in which such action steps will occur. For example, to the extent that a compliance officer uncovers four to five risk areas during a routine internal audit—or worse yet during an audit by a Medicare contractor or the OIG—the compliance officer must determine which of the risk areas should be addressed first and the manner in which the issues will be addressed.²²⁰

²¹⁷ See *Work Plan*, U.S. DEPT OF HEALTH & HUM. SERVS., <https://oig.hhs.gov/reports-and-publications/workplan/> [<http://perma.cc/2QLP-5MAK>]. “The Office of Inspector General’s (OIG) work planning process is dynamic and adjustments are made throughout the year to meet priorities and anticipate and respond to emerging issues with the resources available. . . . The OIG Work Plan sets forth various projects including OIG audits and evaluations that are underway or planned to be addressed during the fiscal year and beyond by OIG’s Office of Audit Services and Office of Evaluation and Inspectors.” *Id.*

²¹⁸ A large hospital or health system might operate an inpatient hospital, outpatient clinics, post-acute services, ancillary services (such as imaging services), or other physician services and would be responsible for billing and compliance for each of these types of services that are all governed by unique and distinct rules and regulations. Even if owned by (and all services billed by) a single legal entity, each type of entity is subject to separate Medicare regulations and applicable state regulations. For example, a hospital operating in the state of Tennessee alone would be required to comply with applicable state law. See, e.g., TENN. CODE ANN. § 68-11-1601 *et seq.* (2017) (establishing a health care facility); *id.* § 68-11-201 *et seq.*; TENN. COMP. R. & REGS. 1200-08-01. The hospital would also have to comply with applicable federal law. See, e.g., 42 C.F.R. § 485.50 *et seq.* (2017) (governing conditions of participation for hospitals). As such health system may increase services, additional laws and regulations become applicable.

²¹⁹ The most recent Work Plan, updated in July 17, 2017, lists six different topics in its “What’s New” area. See *Work Plan*, *supra* note 217; see also *Compliance Guidance*, U.S. DEPT OF HEALTH & HUM. SERVS., <https://oig.hhs.gov/compliance/compliance-guidance/index.asp> [<http://perma.cc/2FBS-23BG>] (providing links to compliance program guidance for nursing homes, researchers, hospitals, ambulance suppliers, etc.).

²²⁰ See Bartrum & Bryant, *supra* note 216, at 60–61 (“Few facilities, however, have the resources necessary to adopt an all-inclusive compliance program in one fell

Typically, compliance offices can prioritize risk based on the level of legal exposure for the risk areas. For instance, discovery of errors in billing processes that have resulted in higher reimbursement than is warranted or discovery that a number of leases with referring physicians have expired would result not only in immediate action both to correct the errors on a go-forward basis, but also likely assessment of whether any amounts need to be remitted to the government for overpayments.²²¹ Thus, what may or may not be actionable under the FCA is of vital importance to a compliance office or officer when assessing risk and trying to prioritize how to and in what manner to assess such risk.

While the result in *Escobar* may be a better assessment of the kind of fraud that the government is actually concerned about preventing under the FCA, which may ultimately lead to less arbitrary application of the FCA, it is nevertheless a larger challenge for the purpose of utilizing the opinion as guidance on whether a particular instance of noncompliance is or is not actionable under the FCA. Based on the *Escobar* guidance, it seems that a contracting entity must, at all times, assess the entity's own knowledge about the government's position on regulations whether or not the government has communicated in some manner (thus putting the entity "on notice") about if a particular regulation is material to the government's decision to pay. Likewise, the entity must monitor the government for communication, both personal to the company as demonstrated by analysis in *Triple Canopy, Inc.*²²² and on a more general level as demonstrated by analysis in *Dynamic Visions, Inc.*²²³

swoop. There are just too many laws that impact health care facilities. Accordingly, it is necessary to prioritize. For most hospitals, Medicare billing, especially in the area of clinical laboratories, is a concern. Accordingly, a compliance program should be implemented for this area first.”).

²²¹ Once a billing error has been discovered by an entity, retaining any amounts that have been paid to the entity in excess of amounts the entity is actually owed are considered an overpayment. Under the FCA, it is a violation of the FCA to retain such amounts any longer than sixty days from the date such overpayments were discovered. 31 U.S.C. § 3729(a)(1)(G) (2012). Similarly, permitting a referring physician to lease space without a lease in place—subject to certain exceptions such as certain holdover allowances—may be a violation of either or both the Antikickback Statute and the Stark Law. See 42 U.S.C. § 1320a-7b(b)(2) (2012); 42 U.S.C. § 1395nn(a)(1).

²²² Communication that is “personal” to the company is specific information that may be communicated regarding its particular behavior. In *Badr*, part of what the Fourth Circuit relied on in arriving at its conclusion was that the government had not renewed its contract with the defendant company and that the DOJ had intervened in the case. These are communications that are specific to Triple Canopy, Inc. itself, not general communication about a statute or rule as it might apply across the industry. See United States *ex rel.* *Badr v. Triple Canopy, Inc.*, 857 F.3d 174, 179 (4th Cir. 2017).

²²³ More general communication is communication that the federal government, specifically the Department of Health and Human Services through CMS

Additionally, the entity must monitor for communication both prior to the alleged fraud and potentially also after the alleged fraud—such as the cancelling of a contract or decision to intervene in the case²²⁴—to determine whether the government has communicated in some manner regarding its position on whether it will reimburse despite certain noncompliance. While the federal government (and state governments to some extent) publishes guidance and compliance resources, such as the OIG Work Plan and Compliance Program Guidance for various industries,²²⁵ there is no doubt that the government cannot and does not address or communicate about each regulation on a regular basis. Moreover, it is not entirely clear what sort of communication from the government would be sufficient to constitute materiality to the extent that such communication was not specific as to materiality for purposes of FCA. As can be seen from some of the cases mentioned above, there have been cases in which the plaintiff did provide evidence of at least some government communication, but such communication was not sufficient to constitute materiality.²²⁶

The DOJ has subsequently issued an internal memorandum, since made public, which perhaps will provide some clarity for courts regarding the types of communication on which courts can rely for purposes of application of *Escobar*'s materiality test.²²⁷ While not specifically tied to FCA cases, the memorandum was issued for the purpose of instructing DOJ attorneys about the impact of what the memorandum refers to as “guidance documents” and their use by the DOJ in connection with litigation.²²⁸ By way of background, the Attorney General had issued an earlier memorandum on November 16, 2017, which prohibited departments “from issuing guidance documents that effectively bind the public without undergoing the notice-and-comment rulemaking process.”²²⁹ Former Associate Attorney

and OIG, communicates about a particular rule, regulation, or compliance within a certain industry. See *United States v. Dynamic Visions, Inc.*, 216 F. Supp. 3d 1, 16 (D.D.C. 2016) (presenting evidence from the Medicaid director about statements she had made regarding the Medicaid department's position regarding whether a regulation is material to payment).

²²⁴ See *Badr*, 857 F.3d at 179.

²²⁵ See *Compliance Guidance*, *supra* note 219; *Work Plan*, *supra* note 217.

²²⁶ See, e.g., cases set forth in *supra* note 180.

²²⁷ Internal Memorandum from Assoc. Att'y Gen, U.S. Dep't of Justice, to Head of Civil Litigating Components, U.S. Att'ys, Limited Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases (Jan. 25, 2018), <https://www.justice.gov/file/1028756/download> [https://perma.cc/TLY7-A6QV].

²²⁸ *Id.* at 1.

²²⁹ *Id.* The memorandum defines “guidance documents” as “any agency statement of general applicability and future effect, whether styled as ‘guidance’ or otherwise, that is designed to advise parties outside the federal Executive Branch about

General, Rachel Brand, states in the memorandum that the directives set forth in a November 16, 2017, memorandum issued by Attorney General Jeff Sessions applies to the DOJ litigators for purposes of determining the use of guidance documents in affirmative civil enforcement (ACE) actions.²³⁰ Specifically, the 2018 memorandum states, “effective immediately for ACE cases, the [DOJ] may not use its enforcement authority to effectively convert agency guidance documents into binding rules. Likewise, [DOJ] litigators may not use noncompliance with guidance documents as a basis for violations of applicable law in ACE cases.”²³¹ The 2018 memorandum notes that while such guidance documents cannot be used as if they were binding law, they can be used as evidence to show that a party “had the requisite knowledge” of whatever legal mandate as may be referenced in the guidance documents.²³² The 2018 memorandum will have the effect of likely reducing the number of cases that meet *Escobar* standards, on the basis that the guidance documents will not be able to be applied in the same ways as if they were a rule or law. But, the intended use of the documents is to aid in being able to prove knowledge of compliance requirements, and thus, knowledge of one’s actions for failure to comply.²³³ While these documents might assist in proof of scienter, they might not help in addressing the issues noted above regarding whether such communication is sufficiently clear to indicate materiality.

C. *Need for Clarification on Timing*

Similarly, it is not entirely clear as to whether the government’s actions can be either general prospective communication or retrospective communication based on the misrepresentation itself. In *United States ex rel. Petratos v. Genentech, Inc.*, the Third Circuit found that although the regulation in question was expressly designated as a condition

legal rights and obligations. This memorandum does not apply to adjudicatory actions that do not have aim or effect of bind anyone beyond the parties involved, documents informing the public of agency enforcement priorities or factors considered in exercising prosecutorial discretion, or internal directives, memoranda, training materials for agency personnel.” *Id.* at n.1.

²³⁰ *Id.* (“Affirmative civil enforcement’ refers to the Department’s filing of civil lawsuits on behalf of the United States to recover government money lost to fraud or other misconduct or to impose penalties for violations of Federal health, safety, civil rights or environmental laws. For example, this memorandum applies when the Department is enforcing the False Claims Act, alleging that a party knowingly submitted a false claim for payment by falsely certifying compliance with material statutory or regulatory requirements.”).

²³¹ *Id.* at 2.

²³² *Id.*

²³³ *Id.*

of payment (potentially an example of a prospective communication regarding materiality), the plaintiff had failed to provide evidence that the misrepresentations were material to the government's payment decision because the plaintiff conceded that the government did continue to pay the claims.²³⁴ In contrast, *Abbott v. BP Exploration & Production, Inc.* relied on an investigation and report conducted by the Department of Interior regarding some specific reporting practices in order to prove that the government's lack of punishment or change in practices following the issuing of the report was insufficient in showing that compliance with the regulations in question was material.²³⁵

Thus, trying to decipher the type of communication that will suffice for purposes of proving materiality and at what point such communications are rendered to health care contractors for purposes of the filing of an FCA action appears easier in a courtroom setting—with ample time for the court to consider the various issues and consequences before making a determination—than in the fast-paced and multifaceted setting of the compliance office. This is not to say, however, that the Court's *Escobar* decision should have either completely rejected the possibility of implied false certification claims or, alternatively, adopted the position that all implied false certification claims must be based on regulations that are expressly designated as conditions of payment. Certainly, there are cases like that of *Yaruska Rivera* in which the misrepresentations or fraudulent behavior are so egregious that it would seem to fly in the face of the entire intention behind the FCA to claim that simply because the fraud was against the law instead of related to a specific fact that it should not be actionable.²³⁶ Likewise, consistent with the Court's stated concerns (and what would have also resulted in a dismissal in the *Escobar* case), adopting a bright-line rule that limits the applicability of implied false certification claims may arbitrarily create liability for certain regulations over the other, with no basis in the origins or underpinnings of the FCA.

²³⁴ *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 489–90 (3d Cir. 2017).

²³⁵ *Abbot v. BP Expl. & Prod., Inc.*, 851 F.3d 384, 387–88 (5th Cir. 2017).

²³⁶ It should be noted that *Escobar* misrepresentations could be classified as both factual falsities and legal falsities because not only was the clinic in violation of application Medicaid regulations because they did not have the appropriate and properly licensed staff as required by law, but it also lied about the factual nature of the credentials of the individuals working at the clinic. This is characterized as a legal falsity, however, because of how the claim was brought under the FCA and the specific regulation that the clinic was alleged to have violated. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1997–98 (2016).

Thus, this article does not argue that *Escobar* was wrongly decided or that adopting a different position entirely would have been a better result. Rather, it argues that understanding when a regulation may or may not be material under the FCA is extremely important not just for litigants, but for health care entities and their compliance offices and that the *Escobar* Court's guidance does not go far enough in providing sufficient details about what liability may lie between guns that do not shoot and foreign-made staplers. While lower court cases are starting to provide a bit more detail regarding what types of noncompliance might look like closer to errant guns and what types of noncompliance look more like foreign staplers, it may take quite some time for courts to arrive at a consensus position on certain regulations or types of regulations. Moreover, to the extent that most cases involve situations in which the federal government has declined to intervene, the majority of cases are dismissed prior to trial and thus it might be easier to determine what is not material as opposed to what is material.²³⁷ Through this process, health care entities are thrust into the position of assuming, as least absent very clear evidence to the contrary, that noncompliance with most regulations *could be* material under the FCA. Entities can feel some comfort in the fact that *Escobar* seems to impose a stricter standard on claims, but that is not helpful for purposes of trying to assess and prioritize risk and compliance concerns in real time.

Given the nature of FCA claims and the time that it takes to bring an FCA claim to resolution, this lack of clarity may also affect settlements—the primary means by which most FCA cases are resolved.²³⁸ While *Escobar* enables potential defendants the possibility of arguing against liability, even to the extent that the underlying rule or regulation is an express condition of payment, the opinion also enables the DOJ to argue that nearly any regulation could be sufficiently material for purpose of establishing an FCA claim.²³⁹ Without sufficient clarity regarding materiality and an ability to manage risk, entities under investigation might feel greater pressure to settle—despite the possibility of imposition of a stricter standard in court—because the scope of regulations that are potentially material is broader. To the extent that parties feel compelled to settle because of a lack of either knowledge or confidence

²³⁷ See FRAUD STATISTICS, *supra* note 43, at 1.

²³⁸ See FACT SHEET, *supra* note 57.

²³⁹ *Escobar*, 136 S. Ct. at 1995 (holding that implied false certification can be a basis for liability, but it is not limited to claims based only on conditions of payment, but can also include claims based on conditions of participation).

regarding what may be actionable under the FCA, the possibility of parasitic lawsuits will greatly increase.

Moreover, to the extent that materiality can be proven based on evidence of the government's communication subsequent to the misrepresentations, such as whether or not the government intervened in the case as in *Triple Canopy, Inc.*, the communication between the parties prior to the unsealing of the case and whether a defendant can convince the government to intervene may become even more critical.²⁴⁰ To the extent government intervention is proof of materiality, then it would seem that all the government has to do during settlement negotiations is make clear to the defendant its intention to intervene and the defendant will likely feel pressure to settle or face the possibility of a long and protracted litigation—at least unless there are other grounds for dismissal at the pleading stage.

While parties can simply wait and monitor cases in the hopes that enough clarity eventually evolves from the district courts and courts of appeals as they analyze *Escobar*, the more expedient solution might be to encourage greater and more specific clarity from CMS and other state agencies regarding what they really believe to be material. To the extent that this communication is precise and directed, this could be helpful for providers and suppliers to appropriately manage risk and compliance initiatives. If CMS and other state agencies share the same opinions about *Escobar* and how it should impact FCA liability as the DOJ, however, it seems unlikely that this clarity is coming. The DOJ is trying to convince courts to reject those aspects of *Escobar* that would result in greater scrutiny of claims, while at the same time embracing the broader view that implied false certification claims encompass both conditions of payment and conditions of participation.²⁴¹ Nevertheless, greater communication and clarity regarding materiality remains potentially the most expedient and efficient way of providing some much needed detail and transparency for compliance offices about how to assess what may or may not be actionable under the FCA and thus prioritize compliance initiatives and legal risk. Absent this communication, materiality under the FCA may be clear in the more extreme and egregious instances of noncompliance (or alternatively in the most obviously insignificant instances of noncompliance) only, but will remain opaque in the vast amount of the cases in the middle.

²⁴⁰ United States *ex rel.* Badr v. Triple Canopy, Inc., 857 F.3d 174, 179 (4th Cir. 2017).

²⁴¹ See *supra* notes 196–99 and accompanying text.

CONCLUSION

WILLISTON ON CONTRACTS states: “a misrepresentation must be material in order that the law may take notice of it as a fraud.”²⁴² It is with this backdrop that the Supreme Court tried to ensure that application of the FCA was consistent with its roots: the statute was established to capture fraud against the federal government and that “fraud” is and should be based on the common law principles of what courts know and recognize fraud to be.²⁴³ Further, under such common law principles, the legal system is only concerned about fraud that may cause another to take action to their detriment that they otherwise would not have taken but for the fraud.²⁴⁴ And thus, the Court through *Escobar* is steering lower courts into a back-to-basics approach in which they examine not the type of regulation or the section of a particular code, rule book, or statute in which the regulation happens to be located, but the regulation itself and the government’s communication regarding whether that regulation is or is not material to its payment decision. Such approach does seem most consistent with the origins of the FCA and a good way of assuring that courts and prosecutors stay focused on fraud or misrepresentations that seem to go to the “essence of the bargain.”²⁴⁵ Despite all of this, there are significant challenges in the type of approach that the Court has adopted in *Escobar*.

While it is clear that violation of a law, rule, or regulation that is part and parcel of the necessary performance of the contract (e.g., if you are selling the government guns, the guns should shoot, even if there is not a statute or regulation that expressly provides that failure to comply would result in the government’s refusal to pay the claim) is material and that a violation of a law, rule, or regulation that is largely unrelated to the necessary performance of the contract (like whether or not the contractor is using American-made office products) is not material, it is not entirely clear what precisely stands in the middle of these two extremes. While being able to argue this point in the context of litigation strategy might be less problematic, trying to use the words of *Escobar* and some of the interpretations of the lower courts to determine what the compliance risk might be related to a discovery of noncompliance

²⁴² WILLISTON, *supra* note 113, at § 69:12.

²⁴³ *Escobar*, 136 S. Ct. at 2002–03.

²⁴⁴ See WILLISTON, *supra* note 113, at § 69:12.

²⁴⁵ *Escobar*, 136 S. Ct. at 2003, n.5 (quoting *Junius Constr. Co. v. Cohen*, 178 N.E. 672, 674 (N.Y. 1931)).

is significantly more difficult. Although adoption of a bright line may have led to arbitrary results, there does need to be an increased emphasis on assisting government contractors, especially providers and suppliers who participate in federal health care programs, with a more clearly articulated position on the types of noncompliance that lie in the mysterious middle of “material.”

Given the types of cases and claims under the FCA that are typically reviewed and analyzed by courts, and also the slow and rather confusing and meandering method and process of developing guidance through case law, it seems necessary to be able to assist compliance offices and companies in prioritizing and assessing risk. This can be done by providing more detail and comment regarding those regulations that CMS and state agencies are truly most concerned. Not only will this communication be key for ongoing compliance and general operations, but it will further guard against dangers that contractors will be compelled in almost all instances to settle for fear of government intervention and how that might impact materiality. Providing this increased communication and direction will assist in assuring that the FCA continues for years to come and strikes the right balance between capturing fraud against the government while protecting innocent actors against parasitic lawsuits.