NOTES

AN IMPLIED DEFENSE: SELF-DISCLOSURE OFFERS A DEFENSE TO THE EXPANDED FALSE CLAIMS LIABILITY AFTER *UNIVERSAL HEALTH SERVICES V. ESCOBAR*

INTRODUCTION

Congress enacted the False Claims Act (FCA) in 1863 to combat fraud during the Civil War.[1] Since its enactment, the FCA has served as the federal government's primary tool for imposing liability on persons and organizations who defraud government programs.[2] Recently, the government ramped up FCA enforcement, prioritizing FCA claims in specific industries, including health care, where the ability to defraud is prevalent and cost recovery is significant.[3]

Since 1986, the Department of Justice (DOJ) has recovered more than $56 billion from civil FCA enforcement actions.[4] In 2017 alone, the DOJ recovered more than $3.7 billion; $2.4 billion of this recovery stemmed directly from the health care industry, marking the eighth consecutive year that health care recoveries have totaled over $2 billion.[5] One health care company paid a settlement of $145 million after allegations surfaced that its skilled nursing facilities had submitted claims for services that were unreasonable and unnecessary.[6] A health records software company paid $155 million after allegations that it falsely obtained certification for its software.[7] While the FCA aids the federal government in recovering

1. *See* United States v. Bornstein, 423 U.S. 303, 309 (1976) ("The Act was originally aimed principally at stopping the massive frauds perpetrated by large contractors during the Civil War."); ENCYCLOPEDIA OF WHITE-COLLAR & CORPORATE CRIME 321 (Lawrence M. Salinger ed., 2d ed. 2013); *see also* United States v. McNinch, 356 U.S. 595, 599 (1958) ("The [FCA] was originally adopted following a series of sensational congressional investigations into the sale of provisions and munitions.... Testimony ... painted a sordid picture of how the United States had been billed for nonexistent or worthless goods, charged exorbitant prices for goods delivered, and generally robbed in purchasing the necessities of war.").

2. *See* False Claims Act, 31 U.S.C. §§ 3729-3733 (2012); Press Release, U.S. Dep't of Justice, Justice Department Recovers over $3.7 Billion 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/4NTY-YHFL].

3. *See* Press Release, U.S. Dep't of Justice, *supra* note 2.

4. *Id.*

5. *Id.* Between 2009 and 2016, the DOJ recovered $19.3 billion in FCA settlements and judgments related to health care fraud. U.S. DEP'T OF JUSTICE, FACT SHEET: SIGNIFICANT FALSE CLAIMS ACT SETTLEMENTS & JUDGMENTS FISCAL YEARS 2009-2016 (2016), https://www.justice.gov/opa/press-release/file/918366/download [https://perma.cc/D6T2-45ZU].

6. *See* Press Release, U.S. Dep't of Justice, *supra* note 2.

7. *See id.*

money for fraudulent claims, it also imposes enormous risk and liability on health care providers[8] struggling to understand and weave through the minefield of government regulations.[9]

In 2016, the FCA landscape was altered. After debate among the lower courts, the United States Supreme Court held in *Universal Health Services, Inc. v. United States ex rel. Escobar* that implied false certification was a viable FCA liability theory.[10] Under this theory, FCA liability can attach to a health care provider who fails to disclose noncompliance of any regulatory, contractual, or statutory requirement—as such failure may constitute presentation of a "false or fraudulent claim."[11] By validating this theory, the Supreme Court expanded the scope of the FCA, an Act that was already formidable in magnitude and risk for health care providers faced with constantly evolving and complex regulations.[12] Additionally, the post-*Escobar* uncertainty of the implied false certification theory's implications heightened the concern for liability under the FCA.[13]

While *Escobar* increased the scope of liability for health care providers, it also developed a potential defense for defendants facing FCA liability.[14] The Court focused on materiality as a basis for liability, stating that the government's payment practices after

8. The FCA does not define health care providers, but other federal provisions offer a definition. This Note will rely on the definition found in the Health Insurance Portability and Accountability Act of 1996 (HIPAA). *See* Pub. L. No. 104-191, § 262, 110 Stat. 1936, 2022 (codified as amended at 42 U.S.C. § 1320d(3) (2012)). Under the Department of Health and Human Service's interpretation of HIPAA, a "health care provider" is "a provider of services ..., a provider of medical or health services..., and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business." 45 C.F.R. § 160.103 (2017).

9. Initially in 1986, FCA violations were subject to civil fines of $5,000 to $10,000 per claim plus treble damages. 31 U.S.C. § 3729(a)(1) (2012). Recently, pursuant to the Bipartisan Budget Act of 2015, the DOJ adjusted for inflation those FCA civil penalties assessed after January 15, 2018, to between $11,181 and $22,363 per claim. *See* Civil Monetary Penalties Inflation Adjustments, 83 Fed. Reg. 3944, 3945 (Jan. 29, 2018) (to be codified at 28 C.F.R. § 85).

10. *See* 136 S. Ct. 1989, 1999 (2016).

11. *Id.* (quoting 31 U.S.C. § 3729(a)(1)(A) (2012)); *see also* Mikes v. Straus, 274 F.3d 687, 697 (2d Cir. 2001) (recognizing and describing the implied false certification theory).

12. *See* Deborah R. Farringer, *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?*, 83 BROOK. L. REV. 1227, 1228-29 (2018).

13. *See id.* at 1230-32.

14. *See Escobar*, 136 S. Ct. at 2003-04.

obtaining actual knowledge of any noncompliance can be used to determine whether such noncompliance qualifies as a material violation.[15] Thus, the Supreme Court effectively created a defense for FCA violators in situations in which the government has knowledge of a violation but continues to make reimbursements or payments.[16]

This Note provides health care providers and others facing potential FCA liability under the implied false certification theory with a strategy for reducing or negating liability. The *Escobar* decision examined the interplay between potential FCA violations and the government's conduct—specifically, its payment practices.[17] Voluntary self-disclosure is the process by which individuals or companies disclose potential violations to the government[18] in order to qualify for reduced penalties under the FCA.[19] This Note argues that such disclosure can be used in certain circumstances to formulate a defense against FCA liability by providing the government with actual knowledge of noncompliance and using the government's subsequent payment practices to determine whether the noncompliance was material.[20]

Part I of this Note introduces the FCA, including the breadth of the Act and the various theories of liability that fall under it, focusing considerably on the implied false certification theory. Part II reviews the debate over the implied false certification theory among the courts, which wrestled with the viability and the scope of the theory but ultimately held the implied false certification theory is valid. Part II then elaborates on the materiality standard developed by the Supreme Court and discusses how courts have interpreted this standard in subsequent cases.[21] Part III of this Note presents a strategy for defending against FCA liability. Specifically, Part III demonstrates that voluntary self-disclosure provides the

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15. *See id.*
16. *See id.*
17. *See id.*
18. *See* OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., UPDATED OIG'S PROVIDER SELF-DISCLOSURE PROTOCOL 3-4 (2013), https://oig.hhs.gov/compliance/self-disclosure-info/files/provider-self-disclosure-protocol.pdf [https://perma.cc/Q8D9-3UC2] [hereinafter OIG SELF-DISCLOSURE PROTOCOL]; *see also* Publication of the OIG's Provider Self-Disclosure Protocol, 63 Fed. Reg. 58,399, 58,399-400 (Oct. 30, 1998).
19. *See* 31 U.S.C. § 3729(a)(2) (2012).
20. *See infra* Part III.A.
21. *See infra* Part II.C.

government with actual knowledge of noncompliance and argues that observations of the government's subsequent payment practices can be used as evidence to potentially negate liability for FCA violations at the pleading stage. Lastly, Part IV details the risks and benefits of voluntary self-disclosure and offers guidance on determining when disclosure is in fact the best option.

I. OVERVIEW OF THE FALSE CLAIMS ACT

The FCA—a Civil War "relic"—is now one of the government's most powerful tools against modern fraud and abuse.[22] To better understand its scope and complexity, this Part provides a basic introduction to the FCA, specifically discussing the implied false certification theory of liability.

A. General Liability Under the False Claims Act

The FCA, coined "Lincoln's Law,"[23] was enacted during the Civil War.[24] At that time, fraud was rampant throughout the United States—government contractors supplied defective materials to the Union, including substandard clothing, fraudulent supplies, and old or disabled animals.[25] While the FCA proved an effective measure against fraud during the Civil War,[26] amendments to the FCA in 1943 significantly limited its utility.[27] However, Congress drastically amended the FCA in 1986 after a series of significant and highly-publicized accounts of fraud in the defense industry surfaced.[28] These amendments increased financial incentives for whistleblowers and expanded whistleblowers' role by reducing a number of

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22. Patricia Meador & Elizabeth S. Warren, *The False Claims Act: A Civil War Relic Evolves into a Modern Weapon*, 65 TENN. L. REV. 455, 456 (1998).

23. *See, e.g.*, Am. Bankers Mgmt. Co. v. Heryford, 885 F.3d 629, 634 n.4 (9th Cir. 2018).

24. 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, 35-36 (1991).

25. *See* James B. Helmer, Jr., *False Claims Act: Incentivizing Integrity for 150 Years for Rogues, Privateers, Parasites and Patriots*, 81 U. CIN. L. REV. 1261, 1264-65 (2013).

26. *See* Helmer, Jr. & Neff, Jr., *supra* note 24, at 37.

27. *See id.* at 39-40.

28. *See id.* at 40-41, 44.

barriers that had inhibited prior actions.[29] Since the passage of the 1986 amendments, the FCA has grown exponentially,[30] becoming the federal government's most effective tool in combatting fraud and abuse in government spending.[31]

There are multiple provisions of the FCA, but the two most pertinent to this Note include: (1) the basic provision for liability, which applies when someone "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval";[32] and (2) the provision prohibiting false records and statements, which applies when someone "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."[33] Additionally, the statute provides a definition for "knowingly," specifying that the standard is not just limited to actual knowledge of fraud, but also includes deliberate ignorance and "reckless disregard of the truth."[34] The statute further acknowledges that liability does not require intent to defraud.[35] Thus, when a government contractor overcharges the government for providing goods or services, the contractor may violate the FCA;[36] similarly, if a health care provider submits a claim to Medicare for a service that was not provided, regardless of his or her intent to do so, the provider may be subject to FCA liability.[37]

The broad scope of the FCA is largely due to its *qui tam* provision, which permits private citizens to bring actions on the government's behalf.[38] Through this mechanism, a wide range of individuals, rather than exclusively federal prosecutors, can file FCA suits; these

29. *See id.* at 44-50.

30. *See* CIVIL DIV., U.S. DEP'T OF JUSTICE, FRAUD STATISTICS—OVERVIEW (2016), https://www.justice.gov/opa/press-release/file/918361/download [https://perma.cc/EP3A-CHJ5] (presenting data that the total value of settlements and judgments related to fraudulent government spending grew from $86,479,949 in 1987 to $4,761,357,835 in 2016).

31. *See* Helmer, Jr., *supra* note 25, at 1261-62.

32. 31 U.S.C. § 3729(a)(1)(A) (2012).

33. *Id.* § 3729(a)(1)(B).

34. *Id.* § 3729(b)(1).

35. *See id.* § 3729(b)(1)(B).

36. *See id.* § 3729(a)-(b).

37. *See id.*

38. *See id.* § 3730(b); *see also* Vt. Agency of Nat. Res. v. United States *ex rel.* Stevens, 529 U.S. 765, 787 (2000) (holding that relators have standing to pursue FCA claims).

individuals are known as relators or whistleblowers.[39] The government benefits from this scheme because *qui tam* relators can discover fraud related to government spending at a greater level than the government could on its own;[40] relators benefit by receiving a large portion of the proceeds.[41]

The 1986 FCA amendments significantly increased the benefits for *qui tam* relators, which effectuated enormous growth in FCA actions and FCA liability.[42] In 1987, relators brought only 8 percent of FCA claims through *qui tam* suits; more recently, in 2016, *qui tam* plaintiffs brought 83 percent of FCA claims.[43] Whistleblowers are commonly employees or former employees of defendants who "often file *qui tam* lawsuits to get even for the wrongs they believe they have suffered or are experiencing at work."[44] Though opinions of whistleblowers are mixed, U.S. Senator Chuck Grassley, author of the 1986 amendments, emphasized his views on the importance of whistleblowers in identifying fraud: "No matter what we do to deter waste and fraud, whistleblowers are the key to the government finding out when that act happens."[45]

B. The Implied False Certification Theory of Liability

The main provision of the FCA imposes liability when an individual submits a "false or fraudulent claim for payment or approval" to

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39. *See* 31 U.S.C. § 3730(b)(1). Consequently, a provider's "competitors, employees, and patients or their representatives" can initiate an FCA action. Joan M. Krause, *Reflections on Certification, Interpretation, and the Quest for Fraud that "Counts" Under the False Claims Act*, 2017 U. ILL. L. REV. 1811, 1816 (2017).

40. *See* 161 CONG. REC. S6103 (daily ed. July 29, 2015) (statement of Sen. Grassley) ("Whistleblowers have always been crucial in helping Congress and the Federal Government root out fraud and misconduct.").

41. *See* 31 U.S.C. § 3730(d)(1)-(2). If the government intervenes and proceeds with the action, then the relator may receive between 15 and 25 percent of the proceeds. *Id.* § 3730(d)(1). If not, then the relator may receive between 25 and 30 percent of the proceeds. *Id.* § 3730(d)(2).

42. *See* U.S. DEP'T OF JUSTICE, *supra* note 30; Helmer, Jr., *supra* note 25, at 1273-75.

43. U.S. DEP'T OF JUSTICE, *supra* note 30.

44. Jesse A. Witten & Patrick H. Thompson, *Avoiding* Qui Tam *Lawsuits by Properly Handling Disgruntled Employees: There Are a Number of Ways that Providers Can Mitigate Risk*, J. HEALTH CARE COMPLIANCE, Sept.-Oct. 2015, at 31, 31.

45. *False Claims Act: Hearing Before the Subcomm. on the Constitution & Civil Justice of the H. Comm. on the Judiciary*, 113th Cong. 9 (2014) (statement of Sen. Grassley).

the government or government program.[46] The requisite "false or fraudulent claim" is not defined in the FCA, but has been interpreted to mean both "*factually* false" and "*legally* false" claims.[47] Historically, most health care FCA cases were based on straightforward "factually false" misrepresentations,[48] "which involve[ ] an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided."[49] "Factually false" claims arise when there is a misrepresentation about the items or services themselves.[50] For example, reimbursement claims for medical services never provided would qualify as "factually false" claims.[51]

Federal prosecutors and *qui tam* relators can also invoke the FCA against "legally false" claims.[52] These "legally false" claims arise when there is a false certification of compliance with a federal statute, regulation, or contract provision.[53] Thus, in the health care context, "legally false" claims may arise when an item or service has been provided to patients, but an underlying federal rule was violated, such as nonadherence to a Medicare requirement for participation.[54]

Complicating the FCA further, courts often divide the theory of legal falsity into two parts by distinguishing between express certification and implied certification.[55] Under the theory of express certification, a defendant can be subject to FCA liability by falsely certifying "compliance with a particular statute, regulation, or

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46. 31 U.S.C. § 3729(a)(1)(A); *see also* Mason v. Medline Indus., Inc. 731 F. Supp. 2d 730, 736 (N.D. Ill. 2010).

47. *E.g.*, Mikes v. Straus, 274 F.3d 687, 697 (2d Cir. 2001) (emphasis added).

48. *E.g.*, United States *ex rel.* Conner v. Salina Reg'l Health Ctr., Inc., 543 F.3d 1211, 1217 (10th Cir. 2008) ("In a run-of-the-mill 'factually false' case, proving falsehood is relatively straightforward." (quoting *Mikes*, 274 F.3d at 697)).

49. *Mikes*, 274 F.3d at 697 (citing Robert Fabrikant & Glenn E. Solomon, *Application of the Federal False Claims Act to Regulatory Compliance Issues in the Health Care Industry*, 51 ALA. L. REV. 105, 111-12 (1999)).

50. *See id.*

51. *See id.*

52. *See id.* at 696-97.

53. *See id.* at 697; *see also* S. REP. NO. 99-345, at 9 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5274 ("[A] false claim may take many forms, the most common being a claim for goods or services not provided, or *provided in violation of contract terms, specification, statute, or regulation.*" (emphasis added)).

54. *See Mikes*, 274 F.3d at 696-97.

55. *See, e.g.*, *id.* at 697-702 (examining the allegations under both theories).

contractual term" when such "compliance is a prerequisite to payment."[56] This false certification relating to a claim may be made through any express means, including "a certification, assertion, statement, or secret handshake."[57]

In contrast to the express certification theory, the implied false certification theory treats a claimant's request for payment as an implied certification of compliance with all relevant statutes, regulations, or contract requirements that are material conditions of payment.[58] Under the implied certification theory, failure to disclose a violation of any material requirements is treated as a misrepresentation that renders the claim "false or fraudulent."[59] In her article on white collar crime and the FCA, Professor Joan Krause emphasized the implied certification theory's impact on the scope of the FCA: "Implied certification extends FCA liability from straightforward false statements of compliance to potentially any failure to comply with the larger universe of federal program rules, even if they are not explicitly reflected in any compliance statement."[60] Because the implied false certification theory had such a large impact on the scope of the FCA, the courts heavily debated its viability.

II. THE IMPLIED FALSE CERTIFICATION THEORY IN THE COURTS

The implied false certification theory first appeared in a 1994 case, *Ab-Tech Construction, Inc. v. United States.*[61] In *Ab-Tech*, the government received statutory damages against a small business that failed to obtain the Small Business Administration's (SBA) requisite approval.[62] The court found that the payment vouchers Ab-Tech had presented impliedly certified adherence to the SBA program's participation requirements, and thus violated the FCA

56. United States *ex rel.* Conner v. Salina Reg'l Health Ctr., Inc., 543 F.3d 1211, 1217 (10th Cir. 2008) (quoting *Mikes*, 274 F.3d at 698).

57. United States *ex rel.* Hendow v. Univ. of Phx., 461 F.3d 1166, 1172 (9th Cir. 2006).

58. *See Conner*, 543 F.3d at 1218.

59. *See* Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 1995 (2016).

60. Joan H. Krause, *Holes in the* Triple Canopy*: What the Fourth Circuit Got Wrong*, 68 S.C. L. REV. 845, 849 (2017).

61. 31 Fed. Cl. 429, 433-34 (1994).

62. *Id.*

when such requirements were in fact unmet.[63] Consequently, *Ab-Tech*'s introduction of the "implied certification" theory sparked a debate over the theory's viability that would not be resolved for over twenty years.[64] This Part discusses that debate, focusing first on the various interpretations among the lower courts and later discussing the Supreme Court's *Escobar* holding, which ultimately validated the theory but narrowed its use through its definition of "materiality."[65]

A. The Lower Court Debate

Prior to the Supreme Court's decision in *Escobar*, lower courts had mixed views on the viability of the implied false certification theory of FCA liability. One side of the spectrum held the FCA should never apply to express or implied certifications.[66] Holders of this view believed government agencies, not the courts, were in control of and responsible for regulating and sanctioning individuals and entities that made false certifications.[67] Other courts thought that the FCA should impose liability only on false certifications involving an express condition of payment.[68] Finally, applying the FCA most broadly, many courts held FCA liability should extend beyond express conditions of payment and include implied certifications as well.[69] The Supreme Court took on *Escobar* to answer this

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63. *Id.* at 434.

64. The *Ab-Tech* decision, decided in 1994, introduced the implied certification theory to the courts. *See id.* This theory was then debated in lower courts, until it finally arrived at the Supreme Court in 2016. *Escobar*, 136 S. Ct. at 1998-99.

65. *See Escobar*, 136 S. Ct. at 1995-96.

66. *See, e.g.*, United States v. Sanford-Brown, Ltd., 788 F.3d 696, 712 (7th Cir. 2015).

67. *See id.* ("[U]nder the FCA, evidence that an entity has violated conditions of participation after good-faith entry into its agreement with the agency is for the agency—not a court—to evaluate and adjudicate.").

68. *See, e.g.*, Ebeid v. Lungwitz, 616 F.3d 993, 998 (9th Cir. 2010); Mikes v. Straus, 274 F.3d 687, 700 (2d Cir. 2001) ("[I]mplied false certification is appropriately applied only when the underlying statute or regulation ... *expressly* states the provider must comply in order to be paid.").

69. *See* United States *ex rel.* Escobar v. Universal Health Servs., Inc., 780 F.3d 504, 513 (1st Cir. 2015) ("[W]hile the district court concluded that *only* claims premised on misrepresentation of compliance with a condition of payment are cognizable under the FCA, we find that any payment/participation distinction is not relevant here."); United States v. Sci. Applications Int'l Corp., 626 F.3d 1257, 1266 (D.C. Cir. 2010) ("This circuit has endorsed the implied certification theory."); United States *ex rel.* Lemmon v. Envirocare of Utah, Inc. 614 F.3d

heavily debated question over the viability of the implied false certification theory.[70]

Yarushka Rivera was a teenage Medicaid beneficiary receiving mental health counseling and treatment from Arbor Counseling Services, a Universal Health Services subsidiary.[71] Throughout a five-year period of intermittent counseling, Rivera was diagnosed with bipolar disorder and prescribed medication.[72] The prescribed medication caused Rivera to suffer multiple seizures and ultimately led to her death at the age of seventeen.[73] Shortly after Rivera's death, her parents, Julio Escobar and Carmen Correa, discovered that a number of the employees who diagnosed Rivera and prescribed her medication were in fact unlicensed, unauthorized to counsel patients, unauthorized to write prescriptions, and mostly unsupervised despite compulsory state regulations requiring supervision for unlicensed employees.[74] With this information, Rivera's parents brought a *qui tam* action against Universal Health Services based on a theory of implied false certification.[75] Her parents alleged that Universal Health Services violated the FCA by submitting false claims to Medicaid—asserting that their claims were false because they included provider and payment codes that implicitly certified qualifications of the staff that they in fact lacked.[76]

The district court dismissed the complaint based on its interpretation of multiple First Circuit decisions.[77] It construed First Circuit

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1163, 1169 (10th Cir. 2010).

70. *See Escobar*, 136 S. Ct. at 1995 ("This case requires us to consider [the implied false certification] theory of liability and to clarify some of the circumstances in which the False Claims Act imposes liability.").

71. *Id.* at 1997.

72. *Id.* for a full discussion of *Escobar*, see generally Mark E. Haddad & Naomi A. Igra, Universal Health Services, Inc. v. Escobar, *in* TOP FOOD & DRUG CASES, 2016 & CASES TO WATCH, 2017, at 67, 67-68, https://www.fdli.org/wp-content/uploads/ 2017/05/Top-Cases-2016-17.pdf [https://perma.cc/N6U2-QRZG].

73. *Escobar*, 136 S. Ct. at 1997.

74. *Id.*

75. *Id.*

76. *Id.* at 1997-98.

77. *See* United States *ex rel.* Escobar v. Universal Health Servs., Inc., No. 11-11170-DPW, 2014 U.S. Dist. LEXIS 40098, at *13 (D. Mass. Mar. 26, 2014) ("[T]he First Circuit repeatedly confirmed that it does not recognize ... the 'artificial categories' of false claims used by other circuits, such as 'legally false' as compared with 'factually false' or 'express certification' as compared with 'implied certification.'"); *see also* United States *ex rel.* Jones v. Brigham & Women's Hosp., 678 F.3d 72, 85 (1st Cir. 2012) ("[W]e rejected rigid divisions between factual

precedent as extending liability only to defendants who misrepresented compliance with a government program's express condition of payment.[78] In *Escobar*, the regulations that Universal Health Services's employees purportedly violated were express conditions of participation for the state's Medicaid program—not express conditions of payment.[79] Thus, the district court granted the defendant's motion to dismiss.[80]

On appeal, the First Circuit reversed, determining that the district court had misinterpreted the precedents on which it relied.[81] The First Circuit held the submission of any claim by a billing party constitutes implicit certification of compliance with *all* program requirements—including both conditions of payment and conditions of participation.[82] The court determined that a billing party may be liable under the FCA by falsely certifying compliance with a requirement even when the requirement is not explicitly deemed a condition of payment.[83] The First Circuit held that compliance with Medicaid participation requirements was an implied condition of payment, and therefore the Riveras' FCA claims could proceed.[84]

While the First Circuit was clear in establishing the implied false certification theory's viability, not all circuits followed suit. Shortly after the First Circuit's decision, the Seventh Circuit rejected the First Circuit's broad interpretation of the theory.[85] In *United States*

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and legal falsity, and express and implied certification, noting that the text of the FCA does not make such distinctions."); New York v. Amgen Inc., 652 F.3d 103, 110-11 (1st Cir. 2011) ("The only question presented ... is whether the claims at issue misrepresented compliance with a material precondition of payment."); United States *ex rel.* Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 385-86 (1st Cir. 2011) ("The text of the FCA does not refer to ... 'express certification' or 'implied certification.'... In light of this, and our view that these categories may do more to obscure than clarify the issues before us, we do not employ them here.").

78. *See Escobar*, 2014 U.S. Dist. LEXIS 40098, at *15-16.

79. *See id.* at *17-19 (citing United States *ex rel.* Dyer v. Raytheon Co., No. 08-10341-DPW, 2011 U.S. Dist. LEXIS 83335, at *9 (D. Mass. July 29, 2011)).

80. *Id.* at *40 ("The [FCA] ... [is] directed at materially false statements presented to obtain government reimbursement. The Plaintiffs have not ... made adequate allegations regarding such statements.").

81. United States *ex rel.* Escobar v. Universal Health Servs., Inc., 780 F.3d 504, 513-14 (1st Cir. 2015).

82. *Id.* at 516.

83. *See id.*

84. *See id.*

85. *See* United States v. Sanford-Brown, Ltd., 788 F.3d 696, 712 (7th Cir. 2015).

v. Sanford Brown, Ltd., the Seventh Circuit held that "[t]he FCA is simply not the proper mechanism for government to enforce violations of conditions of participation contained in—or incorporated by reference into—a [Program Participation Agreement]."[86] Furthermore, even among the circuits that recognized the implied false certification theory, the scope of liability under the doctrine was disputed. On one hand, the Second Circuit imposed liability only if a defendant's false certification was an express condition of payment.[87] But like the First Circuit, the Ninth,[88] Tenth,[89] and D.C.[90] Circuits extended liability beyond express conditions of payment.

B. The Supreme Court's Decision in Universal Health Services v. United States *ex rel.* Escobar

The Supreme Court granted certiorari in *Escobar* to resolve the implied false certification theory's conflict in the lower courts.[91] In a unanimous decision written by Justice Thomas, the Court endorsed the implied false certification theory's viability. At the outset of the opinion, the Court held that "at least in certain circumstances, the implied false certification theory can be a basis for [FCA] liability."[92] In reaching this conclusion, the Court clarified that the FCA is not limited only to fraudulent or false statements and misrepresentations, but also applies to misleading omissions.[93] The Court established that the implied false certification theory can create liability when two conditions are met: "[F]irst, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's

86. *Id.* at 712 (citing Mikes v. Straus, 274 F.3d 687, 699 (2d Cir. 2001)).

87. *See Mikes*, 274 F.3d at 700.

88. *See* Ebeid v. Lungwitz, 616 F.3d 993, 996 (9th Cir. 2010).

89. *See* United States *ex rel.* Lemmon v. Envirocare of Utah, Inc., 614 F.3d 1163, 1169 (10th Cir. 2010).

90. *See* United States v. Sci. Applications Int'l Corp., 626 F.3d 1257, 1266 (D.C. Cir. 2010).

91. Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 1998 (2016).

92. *Id.* at 1995.

93. *Id.* at 1999 ("When ... a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services provided.").

failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths."[94]

By validating the implied false certification theory, the Court effectively broadened the FCA's already expansive reach; however, in an effort to limit FCA liability exposure, the Court also established a narrower and more demanding materiality standard.[95] The Supreme Court rejected the express condition of payment theory set forth by many lower courts, cautioning that "[a] misrepresentation cannot be deemed material merely because the Government designates compliance ... as a condition of payment."[96] Therefore, rather than determining whether a requirement is an express condition of payment, the opinion focused on whether the requirement is *material* to the government's decision to pay the claim.[97] The Supreme Court declared that the requirement for materiality is a "rigorous one" and that plaintiffs must plead materiality with particularity and plausibility to avoid summary judgment or dismissal at the pleading stage.[98] Consequently, the Supreme Court established materiality as the central method of proving falsity or fraud.[99]

The FCA statute defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property," and most courts had addressed this standard as a general element of FCA liability.[100] The *Escobar* Court expanded on the materiality definition by reviewing the statutory, common law, tort law, and contract law definitions independently, but concluded that "[u]nder any understanding of the concept, materiality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'"[101] To further clarify, the Court

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94. *Id.* at 2001.

95. *Id.* at 1996.

96. *Id.* at 2003.

97. *Id.* at 2001 ("Whether a provision is labeled a condition of payment is relevant to but not dispositive of the materiality inquiry.").

98. *Id.* at 2004 n.6.

99. *See id.* at 1996.

100. 31 U.S.C. § 3729(b)(4) (2012).

101. *Escobar*, 136 S. Ct. at 2002 (quoting 26 R. LORD, WILLISTON ON CONTRACTS § 69:12, at 549 (4th ed. 2003)). The Court began with the statutory definition and stated the statutory definition descends directly from common law, and "the common law could not have conceived of 'fraud' without proof of materiality." *Id.* (quoting Neder v. United States, 527 U.S. 1, 22

established the following standard for determining whether a condition is material:

> [P]roof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.[102]

Thus, the Court illustrated that materiality is a subjective standard, and the analysis is based on the unique facts of each case.[103] With this guidance, the Court vacated and remanded the First Circuit's opinion.[104]

(1999)). The Court also looked to the tort law definition, which provides two circumstances when something is material:

> (1) "[if] a reasonable man would attach importance to [it] in determining his choice of action in the transaction"; or (2) if the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter "in determining his choice of action," even though a reasonable person would not.

Id. at 2002-03 (quoting RESTATEMENT (SECOND) OF TORTS § 538 (AM. LAW INST. 1997)). Lastly, the Court referred to the contract definition: "'[A] misrepresentation is material' only if it would 'likely ... induce a reasonable person to manifest his assent,' or the defendant 'knows that for some special reason [the representation] is likely to induce the particular recipient to manifest his assent' to the transaction." *Id.* at 2003 (quoting RESTATEMENT (SECOND) OF CONTRACTS § 162(2) & cmt. c (AM. LAW INST. 1979)). In her article, Professor Krause stated that "the problem is that these various conceptions of materiality, at least as applied under the FCA, historically have not been treated as equivalent." Krause, *supra* note 39, at 1833. Krause argues that "the Justices rejected the payment-prerequisite standard as the defining characteristic of implied certification, only to seemingly resurrect that standard as the core of the materiality test." *Id.* at 1833-34 (footnote omitted).

102. *Escobar*, 136 S. Ct. at 2003-04.

103. *See id.*

104. *Id.* at 2004.

*C. Materiality in the Post-*Escobar *Courts*

The *Escobar* decision ended the debate over the implied false certification theory's viability, but it also sparked new debates over the seemingly heightened materiality standard—specifically, when considering the government's payment practices. Since the *Escobar* holding, evidence that the government paid claims despite having actual knowledge of the defendant's noncompliance has been a significant consideration in several district court and appellate cases.

In a First Circuit decision post-*Escobar*, the court ultimately affirmed a district court's decision to dismiss a motion to amend the complaint, holding that the claims presented were not adequately pleaded.[105] The main claim alleged that Onyx, the defendant medical device company, made fraudulent representations to the Food and Drug Administration (FDA) in seeking approval for its device.[106] The court, however, held that the representations were immaterial and, in keeping with *Escobar*, stated the "fact that [the Center for Medicare and Medicaid Services (CMS)] has not denied reimbursement for Onyx in the wake of [the relator's] allegations casts serious doubt on the materiality of the fraudulent representations that [the relator] alleges."[107]

Similarly, the D.C. Circuit affirmed summary judgment for the defendants in *United States ex rel. McBride v. Halliburton Co.* based on the materiality standard.[108] In *McBride*, the plaintiff alleged FCA violations by a government contractor for inflating headcount data used to track the number of troops utilizing recreation centers at various camps in Iraq.[109] The court observed, "we have the benefit of hindsight and should not ignore what actually occurred" and determined "what actually occurred" was that the Defense Contract Audit Agency investigated the allegations but continued to pay and did not discontinue or disallow any charged costs.[110] Thus, the court followed *Escobar* and held that the government's continued payment

105. *See* D'Agostino v. ev3, Inc., 845 F.3d 1, 12 (1st Cir. 2016).
106. *Id.* at 7.
107. *Id.*
108. 848 F.3d 1027, 1028 (D.C. Cir. 2017).
109. *Id.*
110. *Id.* at 1034.

practices were "'very strong evidence' that the requirements allegedly violated ... [we]re not material."[111]

In *Abbott v. BP Exploration & Production, Inc.*, the Fifth Circuit affirmed summary judgment for the defendant after a former employee alleged that BP falsely certified compliance with various regulations.[112] The court focused on the Department of the Interior's (DOI) actions after becoming aware of the allegations and found that the DOI permitted BP to maintain operations.[113] This permission was very influential in the court's decision, which stated that "[a]s recognized in *Escobar*, when the DOI decided to allow [BP] to continue drilling after a substantial investigation into Plaintiffs' allegations, that decision represents 'strong evidence' that the requirements in those regulations are not material."[114]

In *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.,* the First Circuit also discussed the materiality standard and found that some of the pleaded claims lacked materiality because the FDA failed to withdraw, or even suspend, its approval of a medical device after receiving knowledge of noncompliance.[115] The relators alleged that the defendant medical device company misrepresented the safety and efficacy of one of its devices in order to secure FDA approval.[116] However, the court, referencing *Escobar*, stated that continued payment or approval "becomes compelling when an agency armed with robust investigatory powers to protect public health and safety is told what Relators have to say, yet sees no reason to change its position."[117]

The materiality standard set forth in *Escobar* has also been followed closely in the district courts. In *City of Chicago v. Purdue Pharma L.P.*, Chicago alleged that Purdue provided physicians with misleading information regarding the risks associated with opioids, thereby causing the submission of false claims.[118] However,

111. *Id.* (citing Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 2003 (2016)).

112. 851 F.3d 384, 385-86 (5th Cir. 2017).

113. *Id.* at 388.

114. *Id.* (citing *Escobar*, 136 S. Ct. at 2003-04).

115. 865 F.3d 29, 36-37 (1st Cir. 2017).

116. *Id.* at 32-33.

117. *Id.* at 35.

118. 211 F. Supp. 3d 1058, 1063 (N.D. Ill. 2016).

the court followed the materiality standard: "The City argues that it was unaware that claims were false when it paid them, but the Court has difficulty understanding how the City remained unaware that the claims were false after the lawsuit."[119] Similarly, in *United States ex rel. Kolchinsky v. Moody's Corp.*, the district court dismissed an FCA claim alleging that the defendant participated in a practice of issuing false or inflated credit ratings that negatively impacted nationwide financial markets prior to the 2008 financial crisis.[120] The court dismissed the complaint, largely based on *Escobar's* materiality standard, because the government continued to pay the defendant despite awareness of the alleged credit reporting fraud during the time period.[121]

While the trend in the lower courts favors viewing materiality via the standard set forth in *Escobar*—placing great weight on government conduct after awareness of noncompliance—a minority of courts have ignored the Supreme Court's standard. In both the First and the Ninth Circuits, the appellate courts chose to consider the government's payment practices as observations to be considered, but not factors dispositive to materiality.[122] In considering *Escobar* on remand (*Escobar II*), the First Circuit gave little weight to the payment practices of the government and instead focused on the centrality of the licensing and supervision requirements to Massachusetts's health program.[123] The Ninth Circuit also decided against the *Escobar* standard of materiality in *United States ex rel. Campie v. Gilead Sciences, Inc.*[124] In that case, it was undisputed that the government continued payments after becoming aware of the defendant's noncompliance with FDA regulations, but the court was persuaded by the plaintiff's arguments that "to read too much into the FDA's continued approval—and its effect on the government's

119. *Id.* at 1079.

120. 238 F. Supp. 3d 550, 553 (S.D.N.Y. 2017).

121. *Id.* at 558-59.

122. *See infra* notes 123-25.

123. *See* United States *ex rel.* Escobar v. Universal Health Servs., Inc. (*Escobar II*), 842 F.3d 103, 112 (1st Cir. 2016) ("While it may be the case that MassHealth continued to pay claims to UHS despite becoming aware that they were not in compliance with the pertinent regulations at the Arbour facility ... at this time Relators have stated a claim under the FCA sufficient to survive a Motion to Dismiss.").

124. 862 F.3d 890, 895 (9th Cir. 2017).

payment decision—would be a mistake."[125] Nevertheless, these decisions remain in the minority, and most courts have followed the Supreme Court in viewing the government's conduct as strong evidence of materiality.

III. GOVERNMENT PAYMENT PRACTICES AS A DEFENSE TO LIABILITY

In *Escobar*, the Court explained that when the government has actual knowledge of noncompliance, its subsequent payment practices qualify as strong evidence in determining whether the noncompliance at issue is material.[126] This Part discusses voluntary self-disclosure, a procedure that essentially provides the government with actual knowledge of noncompliance, and how such procedure can be used to potentially form a defense against FCA liability.

A. The Demand for Increased Compliance Procedures and Self-Disclosure

The *Escobar* decision irrefutably guaranteed one thing: the implied false certification theory is a valid basis for FCA liability.[127] Because of this decision and the expansion of the FCA, legal scholars and corporate counsel have urged companies within government-regulated industries to ramp up compliance efforts in anticipation of the implied false certification theory's undoubted effect on these businesses.[128] Although focusing on compliance and auditing procedures is critical for avoiding violations, it is also an essential tool for identifying significant noncompliance and

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125. *Id.* at 905-06.

126. *See* 136 S. Ct. 1989, 2003-04 (2016).

127. *Id.* at 2001.

128. *See* Cynthia A. Howell, *Rough Road Ahead for Businesses?—The Impact of the Supreme Court's Ruling in* Universal Health Services, Inc. v. United States *ex rel.* Escobar, 19 DUQ. BUS. L.J. 97, 112-13 (2017) ("In order to mitigate any potential exposure to a potential allegation of noncompliance, healthcare providers will need to adjust and/or adopt an effective internal compliance program and implement external audit program."); *Attorneys Dish on* Escobar*'s FCA Impact One Year Later*, LAW360 (June 16, 2017), https://www.law360.com/articles/932786/attys-dish-on-escobar-s-fca-impact-one-year-later [https://perma.cc/TX85-BZ8E].

aggressively defending against any potential liability.[129] In light of the *Escobar* decision and the materiality standard established therein, voluntary self-disclosure of identified noncompliance can be used to formulate a strong defense against false claims liability.[130] At a minimum, voluntary self-disclosure can offer numerous benefits by reducing the consequences that stem from FCA liability.[131] However, more thoroughly discussed here is how voluntary self-disclosure may assist in forming a defense to avoid FCA liability entirely.

Voluntary self-disclosure is the process by which health care providers, or other individuals and entities subject to civil monetary penalties, voluntarily disclose evidence of potential fraud.[132] Voluntary self-disclosure may bring forth benefits in the FCA context, regardless of whether liability is imposed.[133] Although the FCA levies colossal damages liability, enforcement agencies may discount penalties for individuals who self-disclose.[134] Both the Office of the Inspector General (OIG) for the Department of Health and Human Services (HHS)[135] and CMS[136] encourage providers' voluntary disclosure of potential FCA violations. Additionally, the FCA itself contains a provision discussing the reduced penalties for individuals who voluntarily disclose.[137] Thus, voluntary self-disclosure has two overarching benefits: (1) upon a finding of noncompliance, self-disclosure can lead to reduced consequences;[138] and (2) self-disclosure

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129. *See* Howell, *supra* note 128, at 112-13.

130. *See, e.g.*, 31 U.S.C. § 3729(a)(2) (2012); *see also Escobar*, 136 S. Ct. at 2003-04.

131. *See infra* Part IV.B; *see also* 31 U.S.C. § 3729(a)(2).

132. *See* OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., SEMIANNUAL REPORT TO CONGRESS 46 (2017), https://oig.hhs.gov/reports-and-publications/archives/semiannual/2017/sar-fall-2017.pdf [https://perma.cc/RN9X-KSMC]; *see also* OIG SELF-DISCLOSURE PROTOCOL, *supra* note 18, at 3-4.

133. *See infra* Part IV.B; *see also* 31 U.S.C. § 3729(a)(2).

134. *See* 31 U.S.C. § 3729(a)(2).

135. The OIG utilizes the OIG's Self-Disclosure Protocol (SDP). OIG SELF-DISCLOSURE PROTOCOL, *supra* note 18, at 1-2.

136. CMS utilizes the Self-Referral Disclosure Protocol (SRDP). *See Self-Referral Disclosure Protocol,* CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html [https://perma.cc/5AUY-77QK] (last updated June 7, 2017, 10:57 AM). The SRDP should be used exclusively for the disclosure of conduct related to Stark Law violations and is less applicable to this Note. *See id.*

137. *See* 31 U.S.C. § 3729(a)(2).

138. *See infra* Part IV.B; *see also* 31 U.S.C. § 3729(a)(2).

may present circumstances that provide an individual with a strong defense to liability.[139] This latter benefit is more pertinent to this Note.

Voluntary disclosure provides the government with actual knowledge of noncompliance. As discussed, the *Escobar* Court emphasized the utility of observing government payment practices to determine whether noncompliance is material.[140] The Court stated that the government's decision to make payments or reimbursements despite having actual knowledge of noncompliance may be used as *strong evidence* that a violation is not material.[141] When a violation is immaterial, there is no FCA liability.[142] Thus, by self-disclosing, an individual can quickly determine whether noncompliance is material based on the subsequent actions of the government.

Ultimately, voluntary self-disclosure produces two outcomes. If the government continues to pay despite having actual knowledge obtained by the disclosure, then that subsequent payment can be used as a defense against liability.[143] This defense can be brought forth at the pleading stage and result in a successful motion to dismiss or summary judgment.[144] Conversely, the government may decide to stop payment based on the noncompliance.[145] While this generates a less desirable outcome—as the discontinued payments would establish evidence of materiality—the decision to voluntarily self-disclose would still be beneficial.[146] Voluntary self-disclosure likely would lead to reduced damages for material noncompliance that could have resulted in much heftier fines and also would allow providers to avoid additional consequences of liability.[147]

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139. *See, e.g.*, Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 2003-04 (2016).

140. *See id.*

141. *See id.*

142. *See id.* at 2002.

143. *See id.* at 2003-04.

144. *See id* at 2004 n.6.

145. *See id.* at 2003.

146. *See, e.g.*, 31 U.S.C. § 3729(a)(2) (2012).

147. *See id.*; *infra* Part IV.B.

B. Government Payment Practices Allow for Liability Avoidance at the Pleading Stage

Materiality can be viewed as a legal question—a question that a judge can answer at the pleading stage.[148] Therefore, the pleading stage seems to be the most appropriate place to bring forth the FCA defense of the government's continued payment practices. Despite its sweeping scope, FCA allegations require plaintiffs to plead with particularity,[149] which is an exacting standard.[150] This standard is required by Rule 9(b) of the Federal Rules of Civil Procedure, which states that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake."[151] In footnote six of the *Escobar* opinion, the Court gave clear guidance that the pleading stage was an appropriate place for dismissal of FCA claims based on materiality.[152] The Court stated:

> We reject Universal Health's assertion that materiality is too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss or at summary judgment. The standard for materiality that we have outlined is a familiar and rigorous one. And False Claims Act plaintiffs must also plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b) by, for instance, pleading facts to support allegations of materiality.[153]

With this guidance, many courts have affirmed dismissals at the motion to dismiss or motion for summary judgment stages.[154] In

148. *See Escobar*, 136 S. Ct. at 2004 n.6.

149. *See* FED. R. CIV. P. 9(b); *see also* United States *ex rel.* Schmidt v. Zimmer, Inc., 386 F.3d 235, 242 n.9 (3d Cir. 2004); United States *ex rel.* LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 234 (3d Cir. 1998); Cooper v. Blue Cross & Blue Shield of Fla., Inc., 19 F.3d 562, 567 (11th Cir. 1994).

150. Shapiro v. UJB Fin. Corp., 964 F.2d 272, 284 (3d Cir. 1992) (FCA claims require a plaintiff to "plead (1) a specific false representation of material fact; (2) knowledge by the person who made it of its falsity; (3) ignorance of its falsity by the person to whom it was made; (4) the intention that it should be acted upon; and (5) that the plaintiff acted upon it to his damage." (citing Christidis v. First Pa. Mortg. Tr., 717 F.2d 96, 99 (3d Cir. 1983))).

151. FED. R. CIV. P. 9(b).

152. *See Escobar*, 136 S. Ct. at 2004 n.6.

153. *Id.*

154. Grants of motions to dismiss were affirmed in the following cases: United States *ex rel.* Petratos v. Genentech Inc., 855 F.3d 481, 493-94 (3d Cir. 2017); United States *ex rel.* Kelly

United States ex rel. McBride v. Halliburton Co., the D.C. Circuit Court discussed this standard further, stating that to avoid dismissal at the pleading stage, the plaintiff "must show that a reasonable factfinder, drawing all justifiable inferences from the evidence in her favor, could find that [the defendant] violated a contractual or regulatory requirement that was material to the Government's decision to pay."[155] Additionally, the plaintiff cannot merely "rely on the allegations of her own complaint ..., but must substantiate them with evidence."[156] The Southern District of New York offered a succinct review of the requisite standard to plead materiality at the pleading stage in *United States ex rel. Kolchinsky v. Moody's Corp.*:

> To plead materiality with the requisite particularity, a relator may draw inferences from various sources, including the Government's history of declining to pay claims for failure to comply with the applicable regulation. By contrast, materiality is absent at the pleading stage when the relator's chronology suggests that the Government *knew* of the alleged fraud, yet paid the contractor anyway.[157]

Despite the clear guidance proffered by the Supreme Court in footnote six[158] and followed by many of the subsequent court decisions, the DOJ believes that "it would be premature, at least at the pleading stage, to impute agencies with 'actual knowledge' of fraud."[159] In a Statement of Interest, the DOJ relayed its concerns regarding the Court's opinion in *Escobar* and the materiality

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v. Serco, Inc., 846 F.3d 325, 337 (9th Cir. 2017); D'Agostino v. ev3, Inc., 845 F.3d 1, 12 (1st Cir. 2016); United States *ex rel.* Whatley v. Eastwick Coll., 657 F. App'x 89, 97 (3d Cir. 2016). Grants of motions for summary judgment were affirmed in the following cases: Abbott v. BP Expl. & Prod., Inc., 851 F.3d 384, 388-89 (5th Cir. 2017); United States *ex rel.* McBride v. Halliburton Co., 848 F.3d 1027, 1028 (D.C. Cir. 2017); United States v. Sanford-Brown, Ltd., 840 F.3d 445, 447 (7th Cir. 2016).

155. 848 F.3d at 1032 (citing United States *ex rel.* Folliard v. Gov't Acquisitions, Inc., 764 F.3d 19, 29 (D.C. Cir. 2014)).

156. *Id.* (quoting Grimes v. Dist. of Columbia, 794 F.3d 83, 94 (D.C. Cir. 2015)).

157. 238 F. Supp. 3d 550, 558 (S.D.N.Y. 2017) (citations omitted).

158. *See* Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 2004 n.6 (2016).

159. Statement of Interest of the United States in Connection with Relator's Rule 59(e) Motion to Alter Judgment at 5, United States *ex rel.* Kolchinksy v. Moody's Corp., 238 F. Supp. 3d 550 (S.D.N.Y. 2017) (No. 1:12-cv-1399-WHP) [hereinafter Statement of Interest].

standard articulated therein.[160] The DOJ argued that without "actual knowledge" of fraud, whether a government agency chooses to discontinue payment or change its course of conduct cannot be viewed as "strong evidence" or "dispositive proof" of immateriality.[161] While many of the post-*Escobar* court decisions have referred to allegations and investigations as providing the government with knowledge of fraud,[162] that is not an issue of concern in this present argument. By self-disclosing noncompliance to the government, providers or entities in violation of government requirements effectively provide the government with actual knowledge of such violation. Therefore, the government's subsequent payment practices and conduct would warrant strong evidence of materiality.[163]

Throughout its statement, the DOJ also consistently referred to the "holistic approach" established within the *Escobar* decision,[164] yet these words never appear in the body of the *Escobar* Court's opinion.[165] In discussing the factors to make a "holistic" assessment, the DOJ suggested consideration of,

> inter alia, (i) whether the defendant's misrepresentation or omission goes to the "very essence of the bargain," or is instead "minor or insubstantial;" (ii) the defendant's awareness that disclosure of its misrepresentation would cause "the Government [to] consistently refuse[ ] to pay claims;" and (iii) how the Government has reacted to the same or similar types of misconduct when it had "actual knowledge" of them.[166]

The DOJ provided numerous reasons why government practices are insufficient in determining materiality and, instead, relied almost exclusively on whether something went to the essence of the bargain.[167] Though the Supreme Court did not offer an exact

160. *See id.* at 3.
161. *Id.* at 5.
162. *See Escobar*, 136 S. Ct. at 2003-04.
163. *See id.*
164. *See, e.g.*, Statement of Interest, *supra* note 159, at 3.
165. *See generally Escobar*, 136 S. Ct. 1989 (omitting a "holistic approach" in the opinion).
166. Statement of Interest, *supra* note 159, at 4 (first alteration in original) (emphasis omitted).
167. *Id.* at 7-8.

definition of materiality,[168] the Court did concretely establish government payment practices as strong evidence of materiality.[169]

Conversely, and almost as an aside embedded in the middle of a lengthy footnote, the Supreme Court quoted a 1931 New York case in which "a misrepresentation [was considered] material if it 'went to the very essence of the bargain.'"[170] This reference was made solely when analyzing the various definitions of materiality and was not established as a chief component of materiality.[171] As a result, a majority of subsequent court cases have followed the Supreme Court's guidance on materiality, placing significant emphasis on the government's payment practices[172] rather than the unsubstantiated "holistic approach" referenced by the DOJ.[173]

Through self-disclosure, a defendant is able to provide the government with actual knowledge, a factor discussed by both the Supreme Court and the DOJ.[174] A defendant can then use the government's subsequent payment practices as strong evidence to determine materiality.[175] If the government continues to pay a claim or fails to alter its conduct, then the defendant should not be found liable under the FCA because the plaintiff's claim lacks materiality.[176] Conversely, if the government stops payment or alters its conduct after receiving the disclosure, then the defendant is still able to lessen his or her liability and avoid additional consequences established conjunctively with FCA actions.[177]

IV. THE RISKS AND BENEFITS OF VOLUNTARY DISCLOSURE

Self-disclosure is not without risk, and health care providers should weigh the benefits and risks before deciding whether to opt or decline to voluntarily disclose noncompliance. This Part provides a cost-benefit analysis of self-disclosure in order to assist providers

168. *See supra* text accompanying note 102.
169. *See Escobar*, 136 S. Ct. at 2003-04.
170. *See id.* at 2003 n.5. (citing Junius Constr. Co. v. Cohen, 257 N.Y. 393, 400 (1931)).
171. *See id.* at 2002-03, 2003 n.5.
172. *See supra* Part II.C.
173. *See* Statement of Interest, *supra* note 159, at 4.
174. *See Escobar*, 136 S. Ct. at 2003-04; Statement of Interest, *supra* note 159, at 4.
175. *See Escobar*, 136 S. Ct. at 2003-04.
176. *See id.*
177. *See infra* Part IV.

in determining whether voluntary self-disclosure is the best course of action.

A. Voluntary Self-Disclosure Is Not Without Risk

There are several costly and time-consuming risks associated with self-disclosure.[178] Because there is no amnesty from FCA civil and/or criminal liability or waiver of damages in exchange for disclosure, the consequences of voluntary self-disclosure remain uncertain.[179] The OIG expressly refuses to provide any assurances in advance regarding the manner in which it will resolve any voluntary self-disclosure:

> Because a provider's disclosure can involve anything from a simple error to outright fraud, the OIG cannot reasonably make firm commitments as to how a particular disclosure will be resolved or the specific benefit that will enure to the disclosing entity. In our experience, however, opening lines of communication with, and making full disclosure to, the investigative agency at an early stage generally benefits the individual or company.[180]

While providers can look to past actions and settlements, self-disclosure cases are decided on a case-by-case basis and are wide-ranging—between 30 and 100 SDP settlements are reached each year[181] and the range of settlements lies anywhere between less than $10,000 to less than $10 million.[182] Because the government is not bound to resolve the noncompliance issue in any particular

178. *See* Stacy L. Brainin et al., *Internal Investigations in Health Care: Unique Enforcement Environment and the Dilemma of Disclosure*, *in* INTERNAL CORPORATE INVESTIGATIONS 421, 440-42 (Brad D. Brian et al. eds., 4th ed. 2017).

179. *See id.*

180. Publication of the OIG's Provider Self-Disclosure Protocol, 63 Fed. Reg. 58,399, 58,400 (Oct. 30, 1998).

181. Brainin et al., *supra* note 178, at 439.

182. *Id.*; *see also* OFFICE OF INSPECTOR GEN., *supra* note 132, at 46 ("During this semiannual reporting period, [April 1, 2017 to September 30, 2017,] provider self-disclosure cases resulted in $12.6 million in HHS receivables.").

manner,[183] providers take the risk of uncertainty when deciding to disclose.[184]

Perhaps the largest risk is cost. In this Note, the main goal of discussing disclosure is to formulate a defense against liability,[185] thereby eliminating costly damages;[186] however, if the government decides that a disclosed violation is material, then FCA liability would still attach[187] and thus, costs should be a consideration from the outset. Many argue that the penalties for those who self-disclose are too great and that health care providers who voluntarily disclose noncompliance should be given greater protections against liability.[188] One would expect that self-disclosure would require repayment of any overpayments;[189] beyond that, providers may still be faced with high settlement amounts that include multipliers.[190] However, this is often limited to a multiplier of 1.5,[191] rather than the treble damages that frequently accompany undisclosed FCA violations.[192]

Another concern is that self-disclosure will trigger a government investigation that could uncover other noncompliance or violations that were not disclosed.[193] Through self-disclosure, a provider essentially invites the government to inquire into different and broader areas than the initial disclosure covered,[194] and to refuse such

183. *See* OIG SELF-DISCLOSURE PROTOCOL, *supra* note 18, at 12-15.

184. *See* Brainin et al., *supra* note 178, at 440-41; Jeremy M. Sternberg & William F. Pezzolo, *Voluntary Disclosure: Risks & Benefits*, AHLA CONNECTIONS, July 2017, at 24, 25-26, https://www.healthlawyers.org/News/Connections/Documents/2017/Feature/July17_Feature2.pdf#search=Self%2DDisclosure [https://perma.cc/25ET-A5W3].

185. *See supra* Part III.

186. *See, e.g.*, 31 U.S.C. § 3729(a)(2) (2012).

187. *See supra* Part II.

188. *See, e.g.*, *Oversight of the False Claims Act: Hearing Before the Subcomm. on the Constitution & Civil Justice of the H. Comm. on the Judiciary*, 114th Cong. 1-2 (2016) (statement of Rep. Trent Franks). U.S. Congressman Franks encouraged the government to increase incentives for self-disclosure, stating: "The FCA has been successful because it's provided whistleblowers with a tremendous financial incentive for uncovering and disclosing false claims. It should be possible to complement the current incentives for whistleblowers ... with financial incentives for self-disclosure to uncover even more waste, fraud, and abuse." *Id.* at 2.

189. *See* Brainin et al., *supra* note 178, at 440 n.102.

190. *See id.* at 440.

191. *See* OIG SELF-DISCLOSURE PROTOCOL, *supra* note 18, at 2.

192. *See* 31 U.S.C. § 3729(a)(1) (2012).

193. Brainin et al., *supra* note 178, at 441; Sternberg & Pezzolo, *supra* note 184, at 26.

194. Sternberg & Pezzolo, *supra* note 184, at 26.

inquiries would be to go against the essential cooperation standard.[195] In his article, lawyer Robert Salcido stated that "any disclosure is fraught with risk."[196] Salcido then continued to clarify the risk, stating that "[i]f a company submits a Voluntary Disclosure it will, necessarily, be handing over documentation to the federal government that indicates that it may have violated federal rules and regulations governing the healthcare program and then trust the government to settle the matter on fair, even-handed terms."[197] Specifically, the government protocols for disclosure state that matters that are uncovered during the verification process will be treated as new matters outside of the disclosure.[198] Accordingly, self-disclosure does not offer protection against spin-off litigation, and the benefits of disclosure could be eviscerated should the government learn of nondisclosed issues.[199] Thus, it is imperative that providers perform a comprehensive internal investigation prior to self-disclosure.[200] Additionally, cooperation may require providers to disclose privileged work product to the OIG or investigating agency;[201] protection of attorney client privilege adds another risk that providers must weigh prior to disclosure.[202]

The OIG or agency that received the disclosure also may elect to implicate the DOJ under its civil or criminal authorities.[203] The DOJ is not guaranteed to agree with the OIG's decision in response to the self-disclosure, adding even greater uncertainty to the risk analysis.[204]

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195. *Id.*

196. Robert Salcido, *The Use of Voluntary Disclosures to Pre-Empt Qui Tam Actions Under the False Claims Act: An Analysis of the* Bank of Farmington *Case and the OIG's Voluntary Disclosure Program*, HEALTH L. DIG., Apr. 1999, at 3, 8.

197. *Id.*

198. *See* Brainin et al., *supra* note 178, at 441.

199. *See id.*

200. *See id.*

201. *See id.*

202. *See id.*

203. *See id.* at 440.

204. *See id.*

B. The Benefits of Voluntary Self-Disclosure

A substantial benefit of self-disclosure, discussed extensively throughout this Note, is the possibility of creating a defense based on the government's payment practice after disclosure.[205] However, there are a number of benefits of disclosure that extend beyond creating evidence against FCA liability.

1. Reduction in Costs and a Streamlined Process

Voluntary self-disclosure can significantly lower the damages required to be repaid to the government.[206] As discussed previously, the FCA allows courts to grant reduced damages when providers engage in voluntary disclosure.[207] In its protocol, the OIG reiterated that individuals who make a good faith effort to cooperate with the government deserve to pay lower damages, and thus, the OIG typically requires a multiplier of 1.5, rather than the FCA's treble damages.[208]

Additionally, an individual who chooses to disclose often retains more control over the situation.[209] Through self-disclosure, a health care provider is able to shape and frame the content of the violation in a way that is beneficial to the provider.[210] By offering a thorough disclosure, the government is much less likely to conduct its own investigation.[211] Self-disclosure allows a provider to engage in a process that is cooperative with the government rather than adversarial.[212] The OIG has emphasized its commitment to working with disclosing providers and has implemented procedures to facilitate timeliness in resolving such matters.[213]

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205. *See supra* Part III.
206. *See* OIG SELF-DISCLOSURE PROTOCOL, *supra* note 18, at 2.
207. *See* 31 U.S.C. § 3729(a)(2) (2012).
208. *See* OIG SELF-DISCLOSURE PROTOCOL, *supra* note 18, at 2; *see also* 31 U.S.C. § 3729(a)(1).
209. *See* Sternberg & Pezzolo, *supra* note 184, at 25.
210. *See id.*
211. *See id.* at 27.
212. *Id.* at 25.
213. *See* OIG SELF-DISCLOSURE PROTOCOL, *supra* note 18, at 2-3.

2. Avoiding Permissive Exclusion and Corporate Integrity Agreements

Liability under the FCA typically gives rise to liability under section 1128 of the Social Security Act.[214] Under this section, the OIG can use its discretion to determine if a provider should be excluded from federal health care programs, such as Medicare and Medicaid.[215] This presents one of the most devastating consequences to providers who engage in fraudulent practices, as exclusion forbids federal health care programs from paying for any items or services provided, ordered, or prescribed by excluded individuals.[216] Though exclusion is meant only to serve as a remedial measure aimed at protecting against fraud, it can create severe and long-term consequences for a provider and his or her practice.[217]

The question of whether to exclude often arises from FCA violations, and the OIG has discretion as to whether to impose exclusion under section 1128(b)(7) of the Social Security Act.[218] In determining whether to exercise its discretion, the OIG presumes that some "period of exclusion should be imposed against a person who has defrauded ... [a] [f]ederal health care program."[219] However, this presumption is rebuttable in certain circumstances, including when a provider agrees to create and follow a corporate integrity agreement (CIA), or when a provider "discloses the fraudulent conduct, cooperatively and in good faith, to [the] OIG."[220]

A CIA is a comprehensive compliance regime that is often negotiated between a provider and the OIG upon learning of fraudulent conduct.[221] While CIAs are meant to improve and promote health

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214. OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERVS., CRITERIA FOR IMPLEMENTING SECTION 1128(B)(7) EXCLUSION AUTHORITY 1 (2016), https://oig.hhs.gov/exclusions/files/1128b7exclusion-criteria.pdf [https://perma.cc/MXH7-6HRH].

215. *See id.*

216. Stephen Robert Geisler, *Voluntary Disclosure of Corporate Violations of Federal Law*, 51 ALA. L. REV. 375, 383-84 (1999).

217. *See* OFFICE OF INSPECTOR GEN., *supra* note 214, at 1.

218. *Id.*

219. *Id.*

220. *Id.* at 1-3.

221. *Corporate Integrity Agreements*, OFF. OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERVS., https://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp [https://perma.cc/MJ96-YXMB].

care compliance rather than to instill punishment, they are often viewed as one of the most powerful weapons in the OIG's arsenal.[222] CIAs as an enforcement tool are typically used in combination with FCA civil settlements between the government and a health care provider.[223] A CIA often lasts five years and subjects a provider to a number of requirements that establish monitoring, auditing, and reporting standards.[224] While CIAs are beneficial in allowing a provider to avoid permissive exclusion and, consequently, continue participating in federal health care programs, CIAs' requirements are extensive and extremely costly.[225]

Self-disclosure provides a rebuttal against the OIG's presumption for permissive exclusion and requirement of a CIA.[226] The OIG has stated: "[W]e believe that good faith disclosure of potential fraud and cooperation with OIG's review and resolution process are typically indications of a robust and effective compliance program."[227] Thus, the OIG is likely to forego the CIA requirement and also waive permissive exclusion when a provider chooses to voluntarily disclose.[228] Between 2008 and 2013, the OIG resolved 235 SDP cases through settlements, and in all but one of those cases the providers were waived from permissive exclusion without requiring the execution of a CIA.[229] Thus, regardless of outcomes, self-disclosure benefits providers by allowing them to remain included in federal

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222. *See* Michael Rosen, *Corporate Integrity Agreements: A Brief History*, PROVIDERTRUST (Apr. 18, 2017), https://www.providertrust.com/blog/corporate-integrity-agreements-a-brief-history/ [https://perma.cc/572Y-TXF4].

223. *Id.*

224. CORPORATE INTEGRITY AGREEMENTS, *supra* note 221.

225. *See id.*; Rosen, *supra* note 222.

226. *See* OFFICE OF INSPECTOR GEN., *supra* note 214, at 1-3.

227. OIG SELF-DISCLOSURE PROTOCOL, *supra* note 18, at 2; *see also* Open Letter from June Gibbs Brown, Inspector Gen., Office of Inspector Gen., Dep't of Health & Human Servs., to Health Care Providers (March 9, 2000), https://oig.hhs.gov/fraud/docs/openletters/openletter.htm [https://perma.cc/2HJY-HB9F] ("Perhaps the best evidence that a provider's compliance program is operating effectively occurs when the provider, through its compliance program, identifies problematic conduct, takes appropriate steps to remedy the conduct and prevent it from recurring, and makes a full and timely disclosure of the misconduct to appropriate authorities."). Gibbs further stated that self-disclosure often makes it so providers are not required to have a CIA. *Id.*

228. OIG SELF-DISCLOSURE PROTOCOL, *supra* note 18, at 2.

229. *Id.*

programs and also avoid the costly and rigorous obligation of executing and adopting a CIA.[230]

3. Avoiding Liability Under the ACA's Sixty-Day Rule

The Affordable Care Act (ACA) requires companies to report and return government overpayments within sixty days.[231] A company or its officers may be excluded, suspended, or disbarred from government programs if these mandatory disclosures are not made in a timely fashion.[232] This was not necessarily an issue prior to the Supreme Court's decision in *Escobar*, and there remains uncertainty regarding the types of noncompliance that result in overpayments needing to be reported and returned.[233] However, by affirming the viability of the implied false certification theory,[234] the Supreme Court created likely implications for overpayment liability as well. If a company or individual receives payment but that payment is later found to have been induced by fraud, then individuals could be held liable under both the FCA and the ACA's sixty-day rule.[235] As stated in an article discussing *Escobar* and the sixty-day rule, "where non-compliance creates half-truths that are material to the government's decision to pay a claim, such non-compliance may not only predicate FCA liability, but also create overpayments that must be reported and returned."[236]

Self-disclosure, once again, allows individuals to avoid this liability. Under a recently pronounced regulation, the overpayment obligation is suspended when a provider engages in voluntary

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230. *See id.*

231. Patient Protection and Affordable Care Act § 6402(a), 42 U.S.C. § 1320a-7k(d)(1)-(2) (2012).

232. Medicare Program; Reporting and Returning of Overpayments, 81 Fed. Reg. 7654, 7655-56 (Feb. 12, 2016) (to be codified at 42 C.F.R. pts. 401, 405).

233. Steven Chananie et al., *The Overpayment Rule and the Implied False Claims Theory: "What You Don't Know Can Still Hurt You,"* HEALTHCARE L. BLOG (July 13, 2016), https://www.sheppardhealthlaw.com/2016/07/articles/centers-for-medicare-and-medicaid-services-cms/the-overpayment-rule-and-the-implied-false-claims-theory-what-you-dont-know-can-still-hurt-you/ [https://perma.cc/43K6-5GUV].

234. *See* Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 1995 (2016).

235. *See id.* at 2003-04; Chananie et al., *supra* note 233.

236. Chananie et al., *supra* note 233.

disclosure.[237] Once the OIG acknowledges receipt of the disclosure and such disclosure is timely, a provider is not required to report and return an overpayment.[238] The obligation to return such payments also is suspended until the matter has been resolved.[239]

Observing the government's payment practices would also be beneficial for determining whether noncompliance was material.[240] Through observations, one would know whether a payment qualified as an overpayment that should then be reported and returned, or as an appropriate payment based on the immaterial noncompliance.[241] If the government changes its payment practices upon knowledge of the violation, then the individual or company should anticipate having to report and return the payment to avoid additional liability, as any payment resulting from noncompliance was likely inappropriate due to a material violation.[242] However, if the government continues payment, then the violation was likely immaterial and one can assume that the payment was appropriate.[243]

C. To Disclose or Not Disclose

After all is said and done, whether to disclose or not disclose remains an important question. Health care providers should first weigh the risks and benefits before making a determination.[244] Providers should be thorough in the internal investigations prior to determining whether to disclose in order to identify any issues that the government might uncover and to fully weigh the risks and benefits of disclosure.[245]

In deciding whether to disclose, health care providers should avoid disclosing minor or insubstantial noncompliance—the scope of the FCA was not intended to extend to the enforcement of all

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237. 42 C.F.R. § 401.305(b)(2)(i) (2017).
238. *Id.*
239. *Id.*
240. *See supra* Part III.A.
241. *See supra* Part III.A.
242. *See* 42 U.S.C. § 1320a-7k(d)(1)-(2) (2012); Chananie et al., *supra* note 233.
243. *See* Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 2003 (2016).
244. *See* Brainin et al., *supra* note 178, at 443-44.
245. *See id.* at 444.

contracts, statutes, and regulations.[246] While the Supreme Court made it clear that "insignificant" violations should not provide a basis for FCA liability, the Court did not detail what specifically comprises such inconsequential noncompliance.[247] Rather, while the Court stated that "[m]ateriality ... cannot be found where noncompliance is minor or insubstantial," it did not further define what specific noncompliance qualifies as "minor" or "insubstantial."[248] Therefore, health care providers and companies should monitor which actions courts deem "minor" or "insubstantial" as implied false certification cases progress in the courts.

Moreover, additional compliance procedures may aid in distinguishing between obviously small and insubstantial violations—those which should be corrected but not necessarily disclosed—and larger compliance issues that should be disclosed.

Professors Arlen and Kraakman also discussed other factors to consider when deciding whether to self-disclose.[249] In their article, they specifically discussed the rate of detection and stated that businesses "must ensure that ex post, after wrongdoing is detected, the firm is better off reporting the misconduct—and accepting the [costs of reporting]—than it is remaining silent and risking the default sanction."[250] Thus, a provider must weigh the likelihood of the government learning of the violation on its own with the certainty of a government investigation and the risk of the noncompliance being determined a material violation.[251]

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246. *See* United States *ex rel.* Steury v. Cardinal Health, Inc., 625 F.3d 262, 268 (5th Cir. 2010) ("The FCA is not a general 'enforcement device' for federal statutes, regulations, and contracts."); Mikes v. Straus, 274 F.3d 687, 699 (2d Cir. 2001) ("[T]he False Claims Act was not designed for use as a blunt instrument to enforce compliance with all ... regulations.").

247. *See Escobar*, 136 S. Ct. at 2004. The Court noted that the FCA is not "'an all-purpose antifraud statute,' or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Id.* at 2003 (internal citation omitted).

248. *See id.*

249. *See* Jennifer Arlen & Reinier Kraakman, *Controlling Corporate Misconduct: An Analysis of Corporate Liability Regimes*, 72 N.Y.U. L. REV. 687, 728 (1997).

250. *Id.*

251. *See id.*

While the decision to disclose is one that providers must make carefully, after the Supreme Court's decision in *Escobar*, voluntary self-disclosure could allow a noncompliant provider or entity to avoid FCA liability altogether.[252]

CONCLUSION

On the surface, the Supreme Court's decision in *Escobar* appeared to be a loss for government-regulated industries, especially health care. The FCA liability derived from the implied false certification theory's validity transformed the endless regulations and requirements imposed on health care professionals into a compliance nightmare.[253] However, the Court presented a gift to providers by establishing the materiality standard—providing those who fail to comply with government regulations a potential defense against liability.[254]

By disclosing noncompliance, health care providers can greatly reduce the consequences that may stem from false claims liability, and perhaps negate it altogether.[255] The actual knowledge that the government obtains from self-disclosure, as well as the government's subsequent payment practices, provide clarity on whether a court will find a noncompliant act material.[256] Therefore, to make this clear prediction, health care providers should strongly consider being transparent with the government, disclosing noncompliance, and waiting to see the outcome. At a minimum, the defendant will have a better understanding of whether its noncompliance was material and will gain access to the benefits of self-disclosure; even better, however, the defendant may equip itself with a strong defense to negate liability completely.[257]

Megan E. Italiano[*]

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252. *See supra* Part III.A.

253. *See supra* Part I.

254. *See supra* Part III.A.

255. *See* Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 2003-04 (2016).

256. *See id.*; *see also supra* Part II.C.

257. *See supra* Part III.A

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