

SCOTUS to Weigh in on Definition of “False” Under FCA

In recent years, the breadth of the *False Claims Act* (FCA) has become an increasingly divisive issue among federal courts, with many implications for the healthcare industry. At the heart of this issue is a key definition within the FCA—the definition of “*falsity*.” Many federal courts of appeals have reached contradictory opinions on this definition by applying different theories of “*falsity*.”¹ These contrary decisions are a source of confusion as to what is, or is not, fraud or abuse under the FCA.²

In a potential effort to resolve this issue, the *Supreme Court of the United States* (SCOTUS) accepted the writ of certiorari in *Universal Health Servs., Inc. v. United States ex rel. Escobar (Escobar)*, which examines the definition of “*falsity*” under the FCA.³ This Health Capital Topics article will describe the varying definitions of “*falsity*” between different U.S. courts, as well as examine the potential consequences of the SCOTUS decision that may impact healthcare providers.

The FCA is a federal statute that creates civil liability for any person who “*knowingly presents, or causes to be presented, to an officer or employee of the United States government [...] a false or fraudulent claim for payment or approval.*”⁴ Since Congress substantially amended the FCA in 1986, the FCA has developed into one of the most important enforcement methods used by the federal government to combat healthcare fraud and abuse, particularly when used in conjunction with the federal physician self-referral law (*Stark Law*) and the federal *Anti-Kickback Statute* (AKS).⁵ In particular, physician acceptance of kickbacks (i.e., monetary bribes, free travel, and various other prerequisites) from pharmaceutical and medical device manufacturers, as well as health systems, have been increasingly enforced under the FCA.⁶ The 1986 amendments strengthened the statute’s *qui tam* provision, also known as the whistleblower provision,⁷ allowing any private citizen to enforce the FCA by filing a complaint against a party alleging fraud against the federal government.⁸ *Qui tam* actions are often brought by former employees, but they also have been brought by competitors.⁹ The U.S. Department of Justice (DOJ) assumes primary responsibility for prosecuting the claim if it decides to intervene in the case,¹⁰ and the whistleblower is entitled to a portion of any recovery the government obtains.¹¹ Potential liability for healthcare providers can be significant, as the FCA provides for treble damages plus

an additional penalty between \$5,000 and \$10,000 for each false claim.¹² Thus, the question of “*falsity*” and how it is applied under the FCA is of significant importance to healthcare providers participating in government payor programs, such as Medicare and Medicaid.¹³

Nine of the twelve federal courts of appeals share a view of “*legal falsity*” that differs from “*factual falsity*” as defined under the FCA:¹⁴ (1) *factually false* claims involve claims for federal reimbursement regarding items or services never provided;¹⁵ and, (2) *legally false* claims fail to satisfy an underlying legal requirement because of a violation of statute, regulation, or contract.¹⁶

An example of a *factually false* claim would be a provider billing Medicare for providing a patient with durable medical equipment (DME), yet never ordering, receiving, or delivering the equipment to the patient. In contrast, an example of a *legally false* claim would be when a provider: (1) delivers DME to a patient and bills Medicare for providing the equipment without *certifying* the medical necessity of the equipment; and, (2) the provider “*has previously undertaken to expressly comply with [such an obligation] and that obligation is implicated by submitting a claim for payment even though a certification of compliance is not required in the process of submitting the claim.*”¹⁷ This type of *legally false* claim demonstrates the “*implied certification*” theory of *legal falsity* under the FCA, which has caused significant concern for healthcare providers because of its “*incredibly broad reach.*”¹⁸ The First, Second, Third, Fourth, Sixth, Ninth, Tenth, Eleventh, and D.C. circuits observe some form of *implied certification* theory under the FCA.¹⁹ Under this *implied certification* theory, providers may face FCA liability for noncompliance with what providers often view as “*a myriad of often lengthy and dense regulations or contractual provisions.*”²⁰

The delineation between what is “*factually false*” and “*legally false*” has become increasingly fragmented among the federal courts.²¹ In *United States ex rel. Susan Hutcheson v. Blackstone Med. Inc. (Hutcheson)*, the U.S. Court of Appeals for the First Circuit rejected the distinction between “*factually false*” and “*legally false*” FCA claims.²² In particular, the First Circuit identified the distinction as creating “*artificial barriers that obscure and distort [FCA] requirements.*”²³

The *Hutcheson* appeal stemmed from a *qui tam* action brought by Susan Hutcheson alleging that Blackstone Medical “engaged in a nationwide kickback scheme to induce physicians to use its medical devices in spinal surgeries and that Blackstone knew this scheme would cause physicians and hospitals (unwittingly) to present federal healthcare programs with payment claims that contained material misrepresentations.”²⁴ The court reversed the dismissal of the FCA claim by the district court in connection with the alleged AKS and FCA violations.²⁵ Notably, despite the lack of any express certification of payment claims by Blackstone Medical, the First Circuit held that Hutcheson’s complaint properly stated a claim under the FCA and that Blackstone’s payment claims “were materially false or fraudulent.”²⁶

In contrast, in *United States v. Sanford-Brown*, (*Sanford-Brown*), the U.S. Court of Appeals for the Seventh Circuit rejected the government’s reliance on what it identified as “this so-called doctrine of implied false certification.”²⁷ In *Sanford-Brown*, the educational institution formerly known as Sanford Brown College, entered into a *Program Participation Agreement* (PPA) with the U.S. Department of Education to receive federal education subsidies.²⁸ The PPA included an “obligation to abide by a panoply of statutory, regulatory, and contractual requirements” including forward-looking promises and regulations under Title IV, Volume 20 Section 1094 of the United States Code.²⁹ In this case, the court read the “knowingly presents [...] a false or fraudulent claim”³⁰ language of the FCA as an express “mens rea requirement.”³¹ In determining whether the institution violated the FCA, the Seventh Circuit required the government to show that Sanford-Brown entered into the PPA with the express intent “to defraud the government (thereby creating a ‘false record’) and then planned to ‘use’ the PPA thereafter to submit poisoned (and therefore, false) claims for payment.”³² The court held that the government failed to satisfy this burden, noting 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 PPA.”³³ According to Seventh Circuit, “The False Claims Act was not designed for use as a blunt instrument to enforce compliance with all [] regulations.”³⁴ In an apparent effort to resolve this confusion among the courts regarding the definition of “falsity” under the FCA, SCOTUS accepted the *Escobar* case for argument on December 4, 2015.³⁵

In *Escobar*, the relators’ teenage daughter was treated by several unlicensed providers at a mental health center operated by *Universal Health Services* (UHS) in Lawrence, Massachusetts.³⁶ Following a series of apparent missteps by UHS, the relators’ daughter died.³⁷ The relators consequentially brought a *qui tam* action against UHS asserting a violation of several Massachusetts Department of Public Health requirements in violation of the FCA.³⁸ The U.S. Court

of Appeals for the First Circuit applied the *implied certification* theory, ruling for the relators.³⁹ The court’s decision provided that the provider’s payment was conditioned upon state regulations,⁴⁰ noting that: “[a]lthough the record is silent as to whether [the provider] explicitly represented that it was in compliance with conditions of payment when it sought reimbursement from [Massachusetts], we have not required such ‘express certification’ in order to state a claim under the FCA.”⁴¹ The First Circuit’s opinion expressly noted “a healthcare provider’s noncompliance with conditions of payment is sufficient to establish the falsity of a claim for reimbursement, we need not address here whether the False Claims Act embraces a distinction between conditions of payment and conditions of participation.”⁴²

In accepting the case, SCOTUS will seek to answer two questions: (1) whether the “implied certification” theory of *legal falsity* under the FCA is viable; and, (2) if the “implied certification” theory is viable, whether a government contractor’s reimbursement claim can be legally “false” under that theory if the provider failed to comply with a statute, regulation, or contractual provision that does not state that it is a condition of payment.⁴³

With *Escobar* before SCOTUS in the upcoming session, a resolution of the circuit split concerning the contradictory definitions of *falsity* under the FCA may be forthcoming. Oral arguments will likely be held in March or April 2016, and a decision is expected before July 2016.⁴⁴ Notably, SCOTUS has previously remarked that Congress “wrote [the FCA] expansively, meaning ‘to reach all types of fraud, without qualification, that might result in financial loss to the Government.’”⁴⁵ Numerous legal commentators have encouraged providers with potential FCA exposure to follow the developments in *Escobar* as it could have a significant impact on FCA jurisprudence.⁴⁶ Additionally, providers may seek to avoid risk and establish a defensible position by obtaining a certified opinion, prepared in compliance with professional standards by an independent credential valuation professional (under the advice of legal counsel—and supported by adequate documentation), as to whether each of the elements of a proposed transaction are both at *Fair Market Value* (FMV) and commercially reasonable, and therefore more likely to withstand regulatory scrutiny.

1 “United States ex rel. Susan Hutcheson v. Blackstone Med. Inc.” 647 F.3d 377, 385 (1st Cir., 2011) (noting differing opinions across the second, third, and tenth circuits concerning “[t]he distinction between factually and legally false or fraudulent claims....”).

2 *Ibid.*

3 “Universal Health Servs., Inc. v. United States ex rel. Escobar” No. 15-7, 2015 WL 4078340, (U.S. Dec. 4, 2015).

4 “Civil Actions for False Claims” 31 U.S.C. § 3729(a) (2014).

5 “Health Care Fraud and Abuse: Practical Perspectives” By Linda A. Baumann, Health Law Section of the American Bar Association, Washington, DC: BNA Books, 2002, p. 112-113.

6 “Anti-Kickback Enforcement and Legislation Developments: What Drug, Medical Device and Biologics Companies Must

- Know” By Karen Gibbs, BNA Pharmaceutical Law & Industry Report, Vol. 6, No. 10 (March 7, 2008), http://www.crowell.com/documents/Anti-Kickback-Enforcement-and-Legislation-Developments_Pharmaceutical-Law_Gibbs.pdf (Accessed 1/19/2016), p. 1-2.
- 7 “The 1986 False Claims Act Amendments: A Retrospective Look at Twenty Years of Effective Fraud Fighting In America” Taxpayers Against Fraud, 2006, <http://www.taf.org/retrospective.pdf> (Accessed 1/19/2016), p. 5.
- 8 31 U.S.C. § 3730(b) (2014).
- 9 “Qui Tam Actions Under the False Claims Act” By James G. Gumbert, Medical Journal-Houston, July 2003, p. 1.
- 10 31 U.S.C. § 3730(c)(1) (2014).
- 11 *Ibid*, § 3730(d)(1) (2014).
- 12 *Ibid*, § 3729(a) (2014).
- 13 “The End of the Implied Certification Theory?: The U.S. Supreme Court Grants Certiorari in Case That Could Substantially Limit the False Claims Act” Cadwalader, Wickersham, & Taft LLP, December 11, 2015, <http://www.cadwalader.com/resources/clients-friends-memos/the-end-of-the-implied-certification-theory-the-us-supreme-court-grants-certiorari-in-case-that-could-substantially-limit-the-false-claims-act> (Accessed 1/18/2016).
- 14 *Ibid*.
- 15 “Will the Supreme Court Weigh In? Implied Certification Theory Under The False Claims Act” Mintz Levin Cohn Ferris Glovsky and Popeo PC, October 17, 2011, <https://www.mintz.com/newsletter/2011/Advisories/1428-1011-NAT-HCED/web.htm> (Accessed 1/18/2016).
- 16 647 F.3d 377, 385 (1st Cir., 2011); Mintz Levin Cohn Ferris Glovsky and Popeo PC, October 17, 2011.
- 17 “Ebeid ex rel, United States v. Lungwitz” 616 F.3d 993, 998 (9th Cir. 2010).
- 18 Cadwalader, Wickersham, & Taft LLP, December 11, 2015.
- 19 *See, inter alia*, “United States v. Universal Health Servs., Inc.” 780 F.3d 504, 512 (1st Cir. 2015); “United States v. Triple Canopy, Inc.” 775 F.3d 628, 636 (4th Cir. 2015); 647 F.3d 377 (1st Cir., 2011); “United States v. Sci. Application Int’l Corp.” 626 F.3d 1257, 1269 (D.C. Cir. 2010); Cadwalader, Wickersham, & Taft LLP, December 11, 2015.
- 20 “The Supreme Court will review False Claims Act circuit split regarding what counts as a ‘false’ claim for payment” Nixon Peabody, 12/9/2015, <http://www.nixonpeabody.com/Supreme-Court-will-review-False-Claims-Act-circuit-split> (Accessed 1/18/2016).
- 21 647 F.3d 377, 385 (1st Cir., 2011).
- 22 *Ibid*, p. 386.
- 23 *Ibid*, p. 385.
- 24 *Ibid*, p. 378.
- 25 *Ibid*, p. 395.
- 26 *Ibid*, p. 379.
- 27 “United States v. Sanford-Brown, Ltd.” 788 F.3d 696, 711 (7th Cir. 2015).
- 28 *Ibid*, p. 701.
- 29 *Ibid*.
- 30 31 U.S.C. § 3729(a) (2016).
- 31 788 F.3d 696, 709 (7th Cir. 2015).
- 32 *Ibid*.
- 33 *Ibid*, p. 712.
- 34 *Ibid*, quoting “Mikes v. Straus” 274 F.3d 687, 699 (2d Cir. 2001).
- 35 No. 15-7, 2015 WL 4078340, p. ii (U.S. Dec. 4, 2015).
- 36 780 F.3d 504, 508-509 (1st Cir. 2015).
- 37 *Ibid*.
- 38 *Ibid*, p. 512.
- 39 *Ibid*, p. 514.
- 40 *Ibid*, p. 512.
- 41 *Ibid*, p. 514; 647 F.3d 377, 385-86 (1st Cir. 2011) (rejecting labels of express and implied certification).
- 42 780 F.3d 504, 517 (1st Cir. 2015).
- 43 No. 15-7, 2015 WL 4078340, p. ii (U.S. Dec. 4, 2015).
- 44 “Supreme Court Will Take Up Implied Certification Theory of FCA Liability” Morrison Foerster, December 4, 2015, <http://govcon.mofo.com/health-care/supreme-court-implied-certification-theory-fca-liability/> (Accessed 1/25/2016).
- 45 “Cook County v. United States ex rel. Chandler” 538 U.S. 119, 129 (2003).
- 46 Cadwalader, Wickersham, & Taft LLP, December 11, 2015; “Government Contracts Insights” Morrison Foerster, 2015, <http://govcon.mofo.com/health-care/supreme-court-implied-certification-theory-fca-liability/> (Accessed 1/25/2016); Nixon Peabody, December 9, 2015.



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