

# THE CIRCUITS ARE SPLIT: THE AMBIGUITY OF A REGULATION MAY NOT 'FORECLOSE A FINDING OF SCIENTER' IN FALSE CLAIMS ACT CASES

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Investigations, Enforcement and White Collar Alert

By: Mark A. Rush, Kelly M. Locher, David I. Kelch

## INTRODUCTION

A split now exists among the circuit courts as to whether a defendant's assertion of a "reasonable interpretation defense" precludes a finding of a "knowing" *mens rea* under the False Claims Act (the "FCA"). On May 26, 2017, a unanimous three-judge panel of the Eleventh Circuit Court of Appeals held that defendants in FCA suits cannot rely on a "reasonable interpretation defense" to evade liability in complying with ambiguous regulations. In *United States v. Lincare Holdings Inc.*,<sup>[1]</sup> the court held that defendants who offer reasonable interpretations of otherwise unclear regulations may still have possessed the requisite scienter to be found civilly liable under the FCA.

The *Lincare* decision represents a marked departure from precedents set by the Eighth Circuit in 2016<sup>[2]</sup> and the D.C. Circuit in 2015.<sup>[3]</sup> These circuits determined that a defendant who reasonably sought to comply with unclear regulations could not properly be found to possess the requisite *mens rea* required for civil FCA culpability. In *Anesthesia Assoc. of Kansas City* (AAKC), the Eighth Circuit found that the language of a Medicare regulation permitting anesthesiologists to bill for CRNA services at a higher rate (but only under certain conditions) was ambiguous. Because AAKC reasonably interpreted a requirement that CRNAs be present during the "emergence of anesthesia,"<sup>[4]</sup> it could not be held liable.

Similarly, the dispute before the D.C. Circuit in *MWI Corp.* turned on the meaning of "regular commissions" as the term is understood in the banking industry. Plaintiffs alleged that MWI submitted false claims on certifications made to the Export-Import Bank in order to secure loan financing for the purchase of irrigation pumps and other equipment.<sup>[5]</sup> MWI claimed that it only paid "regular commissions" to the sales agents, but Plaintiffs alleged the commissions were too high to be considered "regular commissions." Since no government entity challenged MWI's "otherwise facially reasonable interpretation of that undefined and ambiguous term, the FCA's objective knowledge standard ... did not permit a jury to find that MWI "knowingly" made a false claim."<sup>[6]</sup>

In contrast, the *Lincare* panel stated: "although ambiguity may be relevant to the scienter analysis, it does not foreclose a finding of scienter."<sup>[7]</sup> The Eleventh Circuit stated that the proper standard in determining scienter is whether the defendant "*actually knew or should have known* that its conduct violated a regulation in light of any ambiguity at the time of the alleged violation."<sup>[8]</sup> Given these disparate interpretations of the FCA's *mens rea* requirement, this issue is ripe for review by the United States Supreme Court.

## LINCARE CASE BACKGROUND

Lincare Inc. ("Lincare") supplies oxygen, respiratory, and other therapy services to Medicare patients suffering from pulmonary diseases.<sup>[9]</sup> In 2004, Lincare created Diabetic Experts of America ("Diabetic Experts") to sell diabetic testing supplies.<sup>[10]</sup>

Plaintiffs Gerry Phalp and Matt Peoples, former salesmen for Lincare, brought a *qui tam* action under the FCA alleging that Lincare—through its subsidiary, Diabetes Experts—submitted claims to Medicare "without adequate authorization from the relevant Medicare beneficiaries."<sup>[11]</sup>

Plaintiffs alleged that, after selling diabetes supplies to patients, Diabetic Experts was submitting generic assignment of benefits ("AOBs") to Medicare for reimbursement. These AOBs were not drafted for diabetic testing, but were generic in nature and made no reference to diabetes or any other specific medical condition, product, medication or service.<sup>[12]</sup> In fact, the AOBs were the same forms that Lincare submitted when it was seeking reimbursement for services provided to beneficiaries related to pulmonary diseases.

The FCA imposes liability on those who "knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval; [or] knowingly make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim."<sup>[13]</sup> The FCA defines "knowing" as acting with "actual knowledge," "deliberate ignorance," or "reckless disregard."<sup>[14]</sup>

Plaintiffs proceeded against Lincare on a "false certification theory," arguing that Lincare's reimbursement claims were based upon "improper generic authorizations" in violation of Medicare regulations.<sup>[15]</sup> Defendants responded by arguing that they complied with the pertinent regulations (42 C.F.R. § 424.36(a) and its 2008 amendments), which do not by their plain language "[constitute] notice...that any authorization should have included the specific service being provided...."<sup>[16]</sup>

Siding with Lincare, the district court granted summary judgment on the basis that the available evidence was insufficient for a jury to find that Lincare submitted false claims knowingly. The district court stated that "to [p]revail under the False Claims Act, 'relators must show that there is no reasonable interpretation of the law that would make the allegedly false statement true.'"<sup>[17]</sup>

The Eleventh Circuit agreed that neither the evidence presented by relators nor the language of the Medicare regulation itself confirmed that defendants "believed or had reason to believe they were violating Medicare regulations."<sup>[18]</sup> Therefore, the relators failed to prove that defendants acted with the requisite scienter to establish an FCA violation.<sup>[19]</sup> However, the Eleventh Circuit refused to extend the "erroneous" <sup>[20]</sup> logic of the district court to hold that *any* finding of scienter can be defeated via a reasonable interpretation defense. Rather, the critical inquiry is whether the defendant "knew or should have known" that "its conduct violated a regulation...."<sup>[21]</sup>

The Eleventh Circuit recognized the relevance of regulatory ambiguity in analyzing a defendant's scienter, but stated that it should not be dispositive.<sup>[22]</sup> The court worried that a defendant could avoid liability by relying on "a reasonable interpretation ...manufactured post hoc, despite having actual knowledge of a different authoritative interpretation."<sup>[23]</sup> <sup>[24]</sup> The Eleventh Circuit's "knew or should have known" standard seeks to address this concern.

## LINCARE'S IMPLICATIONS

The Eleventh Circuit's ruling is significant for at least two reasons. First, it may increase the risk of civil FCA exposure for companies dealing in uncharted or ambiguous regulatory territory. Second, it created a split among the circuit courts on this issue, raising its profile and making the question ripe for review by the Supreme Court.

What does this mean for healthcare entities and other businesses seeking reimbursement from the government? Reliance on a "reasonable interpretation" of an ambiguous regulation to prevent FCA liability may be perilous. And, such a decision should not be made lightly. The Eleventh Circuit seems to require more than merely "reasonable" or "good-faith" efforts at compliance with ambiguous regulations, but the court did not provide explicit instructions on what additional steps are necessary.

Businesses may anticipate a Supreme Court resolution of this issue in the future. But, in the meantime, when submitting a claim for reimbursement to the government, companies should be sure to read all regulations governing their industry carefully. A mere reasonable interpretation of a regulation may not be sufficient. Businesses and contractors may also consider contacting the regulatory agency directly for further direction on the regulation. When making business decisions, clients should be cognizant that this area of the law is in constant flux. In the face of an ambiguous regulation, before deciding how to proceed, competent counsel should be engaged.

### Notes:

[1] *United States v. Lincare Holdings, Inc.*, No. 16-10532 (May 26, 2017), available at <http://media.ca11.uscourts.gov/opinions/pub/files/201610532.pdf>.

[2] In *United States v. Anesthesia Assoc. of Kansas City*, No. 15-2420 (8th Cir. Aug. 12, 2016), the court held that a reasonable interpretation of an ambiguous regulation "belies the scienter necessary to establish a claim of fraud under the FCA." The Eighth Circuit also rejected the argument that defendant acted in "reckless disregard" since it did not ask the Center for Medicaid and Medicare Services if its interpretation was consistent with the intent of the statute. *Id.* at 8 ("as the agency had not clarified an obvious ambiguity in its regulation for decades, AAKC's 'failure to obtain a legal opinion or prior [CMS] approval cannot support a finding of recklessness.'") In order for a "reckless disregard" theory to stand, the government would have to "warn a regulated defendant away from an otherwise reasonable interpretation." *Id.* at 7.

[3] In *United States v. MWI Corp.*, No. 14-5210 (D.C. Cir. Nov. 24, 2015) at \*4, the court writes: "[s]trict enforcement of the FCA's knowledge requirement helps to ensure that innocent mistakes made in the absence of binding interpretive guidance are not converted into FCA liability." See also *U.S. v. Siemens AG*, 991 F. Supp. 2d 540 (E.D. Pa. 2014) ("Without more than a relator's subjective interpretation of an imprecise contractual provision, a defendant's reasonable interpretation of its legal obligation precludes a finding that the defendant has knowledge of its falsity").

[4] *Anesthesia Assoc. of America*, at 2.

[5] *MWI Corp.*, at 2.

[6] *Id.* at 3.

[7] *Lincare*, at 12.

[8] *Id.* (emphasis added).

[9] *Id.* at 2.

[10] *Id.* at 2-3.

[11] *Id.* at 2.

[12] *Id.* at 3-4.

[13] 31 U.S.C. § 3729(a)(1)(A-B).

[14] See 31 U.S.C. § 3729(b).

[15] *Lincare*, at 4.

[16] *Id.* at 14.

[17] *Id.* at 6.

[18] *Id.* at 14.

[19] *Id.* at 9.

[20] *Id.* at 12.

[21] *Id.*

[22] *Id.*

[23] *Id.* at 12-13. The Eleventh Circuit noted that the 'reckless disregard' provision was added to the FCA in 1986 "to ensure that [it] captured the 'ostrich' type situation whether an individual has 'buried his head in the sand and failed to make simple inquiries which would alert him that false claims are being submitted.'" *Id.* at 11 (quoting *Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1058 (11th Cir. 2015) (internal quotations partially omitted)).

[24] The U.S. Department of Justice filed an amicus brief in *Lincare*. The DOJ warned that following the logic of the district court would allow defendants like *Lincare* to "escape liability merely by offering a 'reasonable' interpretation of a regulatory requirement . . . no matter how strong the evidence that it knew or should have known the proper interpretation, or that it acted in bad faith." The Department of Justice proposed that defendants' conduct should be measured against the regulation as *properly* interpreted, but the Eleventh Circuit did not adopt this view.

## KEY CONTACTS



**MARK A. RUSH**  
PARTNER

PITTSBURGH, WASHINGTON DC  
+1.412.355.8333  
MARK.RUSH@KLGATES.COM

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