No. 16-10532

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

GERRY PHALP, et al.,

Plaintiffs-Appellants,

v.

LINCARE, INC., et al.,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

BRIEF FOR THE UNITED STATES OF AMERICA AS AMICUS CURIAE IN SUPPORT OF NEITHER PARTY

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INTEREST OF THE UNITED STATES

The False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.*, is the federal government's primary tool to combat fraud and recover losses due to fraud in federal programs. Accordingly, the United States has a substantial interest in the proper interpretation of the FCA.

The interpretation of the FCA's scienter requirement is of particular significance to the government. The district court in this case stated that, where an FCA claim is premised on the violation of a regulatory requirement that is material to payment, a defendant may preclude a finding of scienter by identifying a reasonable interpretation of the requirement that would have permitted its conduct. The United States submits this amicus brief pursuant to Fed. R. App. P. 29(a) to explain why the district court's statement is erroneous.

STATEMENT OF THE ISSUE

Whether a defendant can preclude False Claims Act liability for a violation of a material regulatory requirement by proposing a reasonable interpretation of the requirement that would have permitted its conduct,

regardless of the defendant's actual state of mind at the time of the violations.

STATEMENT OF THE CASE

A. The False Claims Act

The False Claims Act is "the Government's primary litigative tool" for combatting fraud, and was intended "to reach all fraudulent attempts to cause the Government to pay out sums of money." S. Rep. No. 99-345, at 2, 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5266, 5274. Congress drafted the statute "expansively . . . 'to reach all types of fraud, without qualification, that might result in financial loss to the Government.'" *Cook Cty. v. United States ex rel. Chandler*, 538 U.S. 119, 129, 123 S. Ct. 1239, 1246 (2003).

The FCA imposes liability if a person "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). The statute also imposes liability if a person

"knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *Id.* § 3729(a)(1)(B).[1]

In 1986, Congress amended the statute to define the term "knowingly" to "mean that a person, with respect to information . . . (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b). The amendments further clarified that "no proof of specific intent to defraud" is required. *Id.*

[1] The conduct at issue in the district court's first summary judgment order occurred both before and after the FCA amendments in the Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1621-25 (FERA). *See* Vol. 3, Doc. 283, at 11 n.13 (App. 358 n.13). Because those amendments do not bear on the application of the scienter standard in this case, this brief refers only to the current version of the statute, as the district court did below. *See id.* at 2 n.4 (App. 349 n.4). The government notes, however, that the district court erred in stating that the amendments as a whole are retroactive to June 7, 2008. *Id.* The retroactivity provision cited by the district court applies only to subparagraph 3729(a)(1)(B); the other amendments to section 3729 took effect "on the date of enactment of [the] Act," May 20, 2009, "and . . . apply to conduct on or after the date of enactment." FERA § 4(f), 123 Stat. at 1625.

These amendments were part of an effort "to make the False Claims Act a more effective weapon against Government fraud." S. Rep. No. 99-345, at 4, *reprinted in* 1986 U.S.C.C.A.N. at 5269. The Senate Report explained that the changes were intended to address defendants' "'ostrich-like' conduct," stating that while the FCA was not intended to "punish honest mistakes or incorrect claims submitted through mere negligence," "the civil False Claims Act should recognize that those doing business with the Government have an obligation to make a limited inquiry to ensure the claims they submit are accurate." *Id.* at 7, *reprinted in* 1986 U.S.C.C.A.N. at 5272.

The FCA authorizes suits to collect statutory damages and penalties either by the Attorney General or by a private person (known as a *qui tam* relator) in the name of the United States. 31 U.S.C. § 3730(a), (b)(1); *see also Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 769, 120 S. Ct. 1858, 1860 (2000). If a relator files a *qui tam* action, the government may intervene and take over the case. 31 U.S.C. § 3730(b)(2). If the government declines to intervene, the relator conducts the litigation.

Id. § 3730(c)(3). Monetary proceeds from a *qui tam* suit are divided between the government and the relator. *Id.* § 3730(d).

B. The Present Litigation

1. The relators in this qui tam action are former salespeople for a medical equipment supplier that sold items to Medicare patients. Vol. 1, Doc. 43, at 3-5 (App. 78-80). The defendants are the relators' employer and related entities. Defendant Lincare, Inc. supplies Medicare patients with "chronic obstructive pulmonary disease with oxygen, respiratory, and other therapy services." Vol. 3, Doc. 283, at 11-12 (App. 358-59). Diabetic Experts of America is a fictional name Lincare registered in 2004 to sell diabetic-testing supplies. *Id.* Lincare Holdings, Inc. is a holding company for Lincare, Inc., and other subsidiaries. *Id.*

As relevant here, the relators allege that the defendants violated the False Claims Act by submitting reimbursement claims to Medicare that were not reimbursable because the defendants lacked adequate authorization from the relevant Medicare beneficiaries. Vol. 1, Doc. 43, at 1-3 (App. 76-78). Medicare generally permits a durable medical equipment

(DME) supplier to submit a claim on a customer's behalf only if the beneficiary signs the claim itself or another document "that contains adequate notice to the beneficiary . . . that the purpose of the signature is to authorize a provider or supplier to submit a claim to Medicare for specified services furnished to the beneficiary." 42 C.F.R. § 424.36(a). With respect to assigned claims for rental or purchase of DME, a beneficiary's signed request for payment statement may be "retained in the supplier's file" and "may be effective indefinitely." *Id.* § 424.40(d). Future claims may incorporate the authorization "by reference." *Id.* § 424.40(a). However, "this policy does not apply to unassigned claims for rental of DME, and a new statement is required if another item of equipment is rented or purchased." *Id.* § 424.40(d)(2).

The assignment-of-benefit forms (AOBs) at issue in this case were originally obtained by defendant Lincare, Inc., from customers of its respiratory services business. Vol. 3, Doc. 283, at 14-15 (App. 361-362). The forms described the services provided using phrases like "HME [home medical equipment] and Supplies" or "DME [durable medical

equipment]." *Id.* at 4 n.6, 16 (App. 351 n.6, 363). Diabetic Experts later made telemarketing calls to the same customers to sell diabetic-testing supplies. *Id.* at 14 (App. 361). After Diabetic Experts completed the sales, it submitted reimbursement claims to Medicare, relying on the AOBs kept on file by Lincare. *Id.* at 16-17 (App. 363-64).

The relators allege that these AOBs did not satisfy Medicare requirements for two reasons.[2] First, the relators contend that a description like "HME and Supplies" or "DME" is insufficiently specific to provide notice that it authorizes the supplier "to submit a claim to Medicare for specified services furnished to the beneficiary." Appellants' Br. 35-40; 42 C.F.R. § 424.36(a). Second, the relators contend that the items Diabetic Experts sold were a new "item of equipment" for purposes of the Medicare regulation providing that "a new statement is required if another item of equipment is rented or purchased." *Id.* at 42-47; 42 C.F.R. § 424.40(d)(2).

[2] Before the district court, the relators also argued that Diabetic Experts could not rely on Lincare AOBs because Diabetic Experts and Lincare were different suppliers. The district court rejected this argument, Vol. 3, Doc. 283, at 48 (App. 395), and the relators do not challenge that ruling on appeal.

As a result, the relators argue, the regulations required Diabetic Experts to obtain a new AOB for any diabetic-testing supplies sold before submitting a claim for reimbursement.

2. The district court granted partial summary judgment for the defendants on six exemplar transactions, relying on several overlapping grounds. Vol. 3, Doc. 283, at 2-3 (App. 349-50).

As relevant here, the district court concluded that the diabetic-testing supplies at issue were not new "items of equipment" that required new AOBs. The court reasoned that, although the Medicare statute includes blood-testing strips within the category of "durable medical equipment," the statute did not specify whether the strips were "equipment" for purposes of the relevant regulation or rather "supplies." Vol. 3, Doc. 283, at 50 (App. 397) (citing 42 U.S.C. § 1395x(n)). The court further noted that Medicare regulations define "[d]urable medical equipment" as "equipment" that "[c]an withstand repeated use," and, in a separate subpart, refers to a separate category of "[s]upplies necessary for the

effective use of DME." *Id.* at 51 (App. 398); 42 C.F.R. §§ 414.202, 414.402.[3] The court held that, because the diabetic-testing supplies at issue "cannot withstand repeated use," they were not "equipment" but rather "supplies necessary for the effective use of" equipment, namely a blood glucose testing monitor. Vol. 3, Doc. 283, at 52 (App. 399). The court concluded that Medicare regulations did not require the defendants to obtain new AOBs. *Id.*

Because it found that the defendants' conduct did not violate Medicare regulations, the district court held that the relevant claims were not false. Vol. 3, Doc. 283, at 58 (App. 405). The court further stated that "disputes as to the interpretation of regulations do not implicate False Claims Act liability" and that "[a] claim that turns on a 'disputed legal

[3] The court also cited a proposed Medicaid regulation that defined "medical equipment and appliances" as items that "can withstand repeated use, and can be reusable or removable," and "supplies" as items "that are consumable or disposable, or cannot withstand repeated use by more than one individual." *Id.* at 52 (App. 399) (quoting 76 Fed. Reg. 41,032, 41,034 (July 12, 2011)). Although that regulation addressed Medicaid, and not Medicare, the court noted that the regulation was intended to "better align" Medicaid's definitions with Medicare's. *Id.* That regulation is now codified at 42 C.F.R. § 440.70(b)(3) and takes effect on July 1, 2016.

question' rather than an objective falsehood is not false." *Id.* at 57 (App. 404).

The district court also held that the relators' evidence was insufficient to create a genuine issue of material fact with regard to scienter—that is, whether the defendants "knew or should have known that its policies or practices violated the applicable statutes and implementing regulations." Vol. 3, Doc. 283, at 53 (App. 400). The court reasoned that, of the two principal documents relators cited to demonstrate scienter, one dealt with an entirely different compliance issue. *Id.* at 54 (App. 401). The other, an October 2009 email in which Lincare personnel wrote that "they '[m]ay need to reconsider [their] process for Patient Agreements,'" postdated the relevant transactions by several months. *Id.* The court concluded that the email did not "allow a reasonable jury to conclude that Diabetic Experts knowingly submitted false claims." *Id.*

The court also opined on the proof necessary to establish scienter when the defendant claims that the governing law is ambiguous. The court cited *United States ex rel. Hixson v. Health Management Systems, Inc.*, 613 F.3d

1186, 1191 (8th Cir. 2010), for the proposition that, "[t]o prevail 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.'" Vol. 3, Doc. 283, at 55 (App. 402). The court further stated that "a defendant's 'reasonable interpretation of any ambiguity inherent in the regulations belies the scienter necessary to establish a claim of fraud under the FCA.'" *Id.* at 56 (App. 403) (quoting *United States ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825, 831-32 (8th Cir. 2013)). The court accordingly concluded "as a matter of law that, with regard to the six exemplars, no reasonable jury could find for Relators on the question[] of whether Defendants" acted "with the requisite scienter." *Id.* at 56-57 (App. 403-04).

The court subsequently granted summary judgment for the defendants on the relators' remaining claims. Vol. 3, Doc. 308, at 1 (App. 484). That ruling did not address the scienter standard or whether the relators' evidence satisfied that standard.[4]

[4] The district court's first summary judgment order also granted summary judgment for the defendants on the relators' claim that Medicare

Continued on next page.

SUMMARY OF ARGUMENT

The district court erred in stating that, when a regulation is ambiguous, a defendant can preclude a finding of scienter by identifying a reasonable interpretation that would have permitted its conduct, regardless of the defendant's state of mind at the time of the violation. The FCA's scienter provision does not turn on whether the relevant regulation is ambiguous, and scienter can exist even if defendant's interpretation is reasonable. A defendant acts with the requisite scienter if, for example, it has actual knowledge that the government interprets the rule to prohibit its conduct but nonetheless proceeds in reliance on a contrary interpretation. Scienter likewise exists if a defendant is on notice of the possibility that its interpretation is incorrect but refuses to inquire further. This result is consistent with Congress's purpose of addressing "ostrich-like" behavior and with the decisions of other courts of appeals. The district court's rule,

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regulations barred Diabetic Experts from telemarketing to Lincare customers. Vol. 3, Doc. 283, at 46-48 (App. 393-95). The relators do not challenge that ruling on appeal. The United States takes no position on the issues presented in that portion of the first order or in the second summary judgment order.

by contrast, could hamper the government's efforts to combat fraud and immunize fraudulent conduct from FCA liability.

The district court also erred in stating that ambiguity in a regulation precludes a finding that a claim was false. Falsity in such a case depends on whether the defendant's conduct violated the regulation as properly interpreted, regardless of whether the regulation was ambiguous.

Notwithstanding the district court's error, this Court can affirm the first summary judgment order on the ground that, even under the proper scienter standard, the relators failed to adduce sufficient evidence to survive summary judgment.

ARGUMENT

A. Ambiguity in a Regulatory Requirement Does Not Preclude a Finding of Scienter

1. The FCA's scienter element requires the relators to "show that the defendant acted 'knowingly,' which the Act defines as either 'actual knowledge,' 'deliberate ignorance,' or 'reckless disregard.'" *Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1058 (11th Cir. 2015). At issue here is the application of the scienter element when an FCA claim stems from alleged

violations of a material regulatory requirement that is susceptible to more than one meaning. Such ambiguity does not bear on whether the claim is false, because falsity turns on whether the defendant violated the requirement as properly interpreted. *See United States ex rel. Oliver v. Parsons Co.*, 195 F.3d 457, 463 (9th Cir. 1999). However, any ambiguity may be relevant to the question of scienter. The scienter inquiry requires the court to determine whether, in light of the ambiguity, the defendant nevertheless knew or should have known that its conduct violated the relevant requirement.

Mere ambiguity in the law does not foreclose a finding of scienter. The forms of knowledge encompassed in the FCA's definition of "knowingly" can each exist even if a rule is ambiguous. *Cf. United States v. R&F Props. of Lake Cty., Inc.*, 433 F.3d 1349, 1358 (11th Cir. 2005) (relying on case law holding that "question of fact" existed "as to the defendants' understanding of the meaning of the regulatory language," despite regulatory ambiguity). Scienter will almost certainly exist when the defendant relies on an unreasonable interpretation of a statute or

regulation. *See United States ex rel. Hixson v. Health Mgmt. Sys., Inc.*, 613 F.3d 1186, 1190 (8th Cir. 2010) (defendant's interpretation must be reasonable). But even a reasonable interpretation may give rise to liability if the defendant actually knew of, deliberately ignored, or recklessly disregarded the proper interpretation of the law. *See United States ex rel. Oliver v. Parsons Co.*, 195 F.3d 457, 464 (9th Cir. 1999) (requiring good faith).

For example, a defendant who knows the government's authoritative interpretation of a regulation but nonetheless chooses to rely on a different reading has "actual knowledge," regardless of any ambiguity. *United States ex rel. Minnesota Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1053-54 (8th Cir. 2002) (scienter is established if defendant knowingly disregards the proper interpretation of an ambiguous regulation). And if a defendant has notice of the possibility that its interpretation is wrong and fails to make a limited inquiry regarding the proper interpretation, then the defendant may be found to have acted with

deliberate ignorance or reckless disregard. *See* S. Rep. No. 99-345, at 7, *reprinted in* 1986 U.S.C.C.A.N. at 5272.[5]

2. This reading of the statute is consistent with congressional intent. In amending the FCA, Congress recognized that a claim's falsity may not be clear at the time of the relevant conduct. Rather than foreclose liability in such cases, Congress defined the term "knowingly" to impose liability on defendants that acted in bad faith. The legislative history of the amendments explains that Congress sought not only to distinguish "honest mistakes" from "'ostrich-like' conduct" and other forms of bad faith, but also to require defendants to conduct "a limited inquiry" to resolve the uncertainty and "ensure the claims they submit are accurate." S. Rep. No. 99-345, at 7, *reprinted in* 1986 U.S.C.C.A.N. at 5272.

3. Decisions of other courts of appeals support this reading. The Eighth Circuit held in *Allina* that a defendant's actual knowledge,

[5] Because the "knowingly" standard is evaluated at the time of the alleged violation, a defendant cannot escape FCA liability by developing a *post hoc* interpretation of the relevant rule that would have permitted its conduct. *See* 31 U.S.C. 3729(a)(1)(A)-(B) ("knowingly presents, . . . causes to be presented, . . . makes, uses, or causes to be made or used").

deliberate ignorance, or reckless disregard of the proper interpretation of an ambiguous regulation satisfies the scienter requirement. 276 F.3d at 1053-56. In a passage later quoted by this Court, *Allina* explained:

> If the [relator] shows the defendants certified compliance with the regulation knowing that the [government] interpreted the regulations in a certain way and that their actions did not satisfy the requirements of the regulation as the [government] interpreted it, any possible ambiguity of the regulations is water under the bridge."

Id. at 1053; *R&F Props.*, 433 F.3d at 1357. Likewise, scienter may exist if "the defendants were on notice of the possibility" that the government interpreted ambiguous regulations differently. *Allina*, 276 F.3d at 1053.

The Ninth Circuit has also emphasized that the reasonableness of a defendant's interpretation of an ambiguous statute does not necessarily preclude scienter; the defendant also must have adopted the interpretation in good faith. *Parsons*, 195 F.3d at 464. The court explained, "[a] contractor relying on a good faith interpretation of a regulation is not subject to liability, not because his or her interpretation was correct or 'reasonable' but because the good faith nature of his or her action forecloses the possibility that the scienter requirement is met." *Id.*

The D.C. Circuit reached a similar conclusion in *United States v. Science Applications International Corp.*, 626 F.3d 1257, 1271-73 (D.C. Cir. 2010). The court noted that, although "record evidence . . . support[ed]" the defendant's "contention that any false certifications . . . resulted from" the defendant's reasonable but erroneous interpretation of a rule, it also "support[ed] a contrary view" that the defendant knew or should have known that its conduct violated the rule. The court held that the jury was entitled to weigh the evidence and could reasonably conclude that the defendant's conduct satisfied the scienter requirement. *Id.*; *see also United States ex rel. K & R Ltd. P'ship v. Massachusetts Hous. Fin. Agency*, 530 F.3d 980, 983 (D.C. Cir. 2008) (explaining that even the absence of "unreasonableness" in the defendant's asserted interpretation "does not preclude a finding of knowledge").

B. The District Court's Contrary Statements Misread the Statute, Lack Support in Case Law, and Could Immunize Fraudulent Conduct from Liability

For the reasons stated above, the district court erred in stating that a defendant may foreclose FCA liability merely by pointing to the existence of a reasonable interpretation that would have permitted its conduct.

1. The cases cited by the district court do not establish the contrary. The district court cited two decisions of the Eighth Circuit, *Hixson* and *United States ex rel. Ketroser v. Mayo Foundation*, 729 F.3d 825 (8th Cir. 2013), that contain language focusing on the reasonableness of the defendant's interpretation of the relevant requirement.

Those cases are best understood, however, as applications of the Eighth Circuit's earlier decision in *Allina*, which held that a relator can establish scienter when a defendant's interpretation of an ambiguous legal requirement is unreasonable or when a defendant actually knows of, deliberately ignores, or recklessly disregards the correct interpretation. 276 F.3d at 1053-56. In *Allina*, the Eighth Circuit reversed a grant of summary judgment for the defendants because there was evidence that the

defendants were on notice of the government's contrary interpretation and because the defendants' interpretation was unreasonable. *See, e.g.*, *id.* at 1053 ("[T]he defendants were on notice of the possibility that" the government would interpret the requirement to prohibit their conduct); *id.* at 1055 ("Nothing in the [regulatory guidance] could have led the defendants to think that" their interpretation was correct).

Neither element was present in *Hixson* or *Ketroser*. In both cases, the Eighth Circuit stated that the defendants' interpretation was "a reasonable interpretation, perhaps even the most reasonable one." *Hixson*, 613 F.3d at 1190; *Ketroser*, 729 F.3d at 832 (quoting *Hixson*, 613 F.3d at 1190). Moreover, in both cases, the relators failed to plausibly allege that the defendants actually knew of, deliberately ignored, or recklessly disregarded the "correct" interpretation at the time they sought payment. *See, e.g.*, *Hixson*, 613 F.3d at 1190 (noting that there was "no authoritative contrary interpretation of [the] statute"); *Ketroser*, 729 F.3d at 831 (concluding, after considering relevant regulations, industry practice, and "common sense," that "all Relators have plausibly alleged is their *desire*" to interpret the law

in a certain way). The Eighth Circuit therefore had no occasion to rule on whether regulatory ambiguity forecloses FCA liability even in the face of evidence that the defendants actually knew, deliberately ignored, or recklessly disregarded that their interpretation was incorrect.

For these reasons, *Hixson* and *Ketroser* are properly read as supporting *Allina*'s rule that, if a relator can establish actual knowledge, deliberate ignorance, or reckless disregard, any regulatory ambiguity is "water under the bridge." And to the extent they conflict with *Allina*, the controlling decision in the Eighth Circuit is the earlier decision in *Allina*. *See Mader v. United States*, 654 F.3d 794, 800 (8th Cir. 2011) (en banc). [6]

The D.C. Circuit's opinion in *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281 (D.C. Cir. 2015), also provides no support for the district court's broad statements in this case. *Purcell* rejected the argument that "a defendant cannot be held liable under the FCA so long as it has an

[6] The United States has filed an amicus brief in the Eighth Circuit addressing the proper interpretation of *Allina*, *Hixson*, and *Ketroser*. *See* U.S. Amicus Br., *United States ex rel. Donegan v. Anesthesia Associates*, No. 15-2420 (8th Cir. Sept. 16, 2015). The Eighth Circuit has not yet issued an opinion in that case.

objectively reasonable interpretation of an ambiguous provision" and held that "[p]roving knowledge is in part an evidentiary question," even in cases of regulatory ambiguity. *Id.* at 288.

Purcell erred, however, in other aspects of its analysis. The court stated that "informal guidance . . . is not enough to warn a regulated defendant away from an otherwise reasonable interpretation" of a regulatory requirement and "that subjective intent—including bad faith—is irrelevant" to scienter when a defendant relies on an erroneous but reasonable interpretation. 807 F.3d at 289-90. As the United States explained in petitioning for rehearing and rehearing en banc, that approach is inconsistent with the FCA and precedent of the D.C. Circuit and other courts of appeals. *See* Pet. for Reh'g En Banc, *United States ex rel. Purcell v. MWI Corp.*, Nos. 14-5210, 14-5218 (D.C. Cir. Feb. 8, 2016) (*Purcell* Reh'g Pet.).[7]

Purcell's analysis relied on an unwarranted extension of the Supreme Court's decision in *Safeco Insurance Co. v. Burr*, 551 U.S. 47, 127 S.

[7] The government's rehearing petition remains pending.

Ct. 2201 (2007). *Safeco* construed the statutory term "willfully" in the Fair Credit Reporting Act (FCRA) to encompass "reckless disregard" but held that the defendant had not acted recklessly under that standard. *Id.* at 56-57, 70, 127 S. Ct. at 2208, 2216. *Safeco*'s analysis does not control under the FCA because *Safeco* dealt with a different statute employing different language. Unlike the FCA, FCRA does not use the terms "actual knowledge" or "deliberate ignorance," and FCRA's recklessness standard is the result of judicial construction of a term the Court warned was context-dependent. *See* 15 U.S.C. § 1681n(a); *Safeco*, 551 U.S. at 57, 127 S. Ct. at 2208 (explaining that "'willfully' is a 'word of many meanings whose construction is often dependent on the context in which it appears'"); *see also id.* at 68, 127 S. Ct. at 2215 ("'[T]he term recklessness is not self-defining[.]'"). Nor did anything in the Court's examination of FCRA's legislative history reveal a purpose comparable to Congress's express objective in amending the FCA of imposing liability for "ostrich-like" behavior. *See id.* at 58-60, 127 S. Ct. at 2209-10.

Moreover, *Safeco*'s holding addressed only what might constitute "reckless" behavior under certain circumstances, and not the standard for "actual knowledge" or "deliberate ignorance." *Safeco* did not override the plain meanings of the latter terms, which require consideration of the defendant's state of mind and the facts the defendant knew or should have known at the time of the relevant conduct. And even as to recklessness, *Safeco* decided the question on the understanding that the defendant, at the time of its unlawful conduct, had actually relied on a reasonable (though erroneous) interpretation of the law. *See* 551 U.S. at 68, 127 S. Ct. at 2215. It did not hold that defendants can rely on an ambiguity manufactured *post hoc*, as *Purcell* suggested. *See Purcell* Reh'g Pet. at 11-14.

2. The district court's broad statements regarding the scienter standard, if adopted by this Court, could have significant adverse effects on the government's ability to combat fraud in federal programs. Under that approach, a defendant can escape liability merely by offering a "reasonable" interpretation of a regulatory requirement—perhaps even one developed for litigation *post hoc*—no matter how strong the evidence that it

knew or should have known the proper interpretation, or that it acted in bad faith. Such a rule could immunize a significant amount of fraudulent behavior from FCA liability as a matter of law. That result is inconsistent with Congress's intent to reach both intentional efforts to deceive and "ostrich-like" behavior.

3. The district court also erred in stating that "[a] claim that turns on a 'disputed legal question' rather than an objective falsehood is not false." Vol. 3, Doc. 283, at 57 (App. 404). "[I]t is [the defendant's] compliance with [the relevant] regulations, as interpreted by this [C]ourt, that determines whether its [conduct] resulted in the submission of a 'false claim' under the Act." *Parsons*, 195 F.3d at 463 ("[W]hile the reasonableness of Parsons' interpretation of the applicable accounting standards may be relevant to whether it knowingly submitted a false claim, the question of 'falsity' itself is determined by whether Parsons' representations were accurate in light of applicable law."). Regulatory ambiguity—which the district court also interpreted as a lack of "objective falsehood"—therefore does not preclude a finding of falsity.

This Court rejected the district court's position in *R&F Properties*, 433 F.3d at 1356. In that case, this Court found a regulation ambiguous but rejected the argument that the ambiguity "necessarily foreclose[d], as a matter of law, the falsity" of the claims in question. The Court further held that courts can consider "evidence outside the language" of a regulation to understand its meaning and therefore whether the defendant's claims were false. *Id.* at 1357.[8]

The district court's position is also inconsistent with Congressional purpose. As noted above, Congress understood in amending the FCA's standard for scienter that a claim's falsity may be ambiguous at the time of

[8] The district court's citations to *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1478 (9th Cir. 1996), and other decisions relying on *Hagood*, are inapposite. The Ninth Circuit has expressly held that "*Hagood* does not stand for the proposition that a 'reasonable interpretation' of a regulation precludes falsity." *Parsons*, 195 F.3d at 463. The court explained that *Hagood* turned on the unique circumstance of a statute that granted the government "discretion in deciding the cost allocation that the plaintiff claimed was false" and does not govern falsity when the relevant regulations are "ultimately the subject of judicial interpretation." *Id.* *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1019 (7th Cir. 1999), and *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 377 (4th Cir. 2008), are also inapposite because they involved no regulatory ambiguity like that alleged in this case.

the relevant conduct, and it sought in such cases to distinguish "honest mistakes" from various forms of bad faith. *See supra* p. 16. Holding that regulatory ambiguity precludes a finding of falsity—and therefore liability under the FCA—would subvert that objective.

C. This Court Can Affirm the First Summary Judgment Order Under the Proper Scienter Standard

Notwithstanding the district court's erroneous statements regarding the scienter standard, this Court can affirm the district court's first summary judgment order on the ground that the relators' evidence was insufficient to survive summary judgment under the correct standard.

As noted above, the district court did consider the relators' evidence on scienter. The court ultimately found a March 2009 email exchange irrelevant because it addressed an entirely different compliance issue. Vol. 3, Doc. 283, at 54 (App. 401). The court held that the other cited document—an October 2009 email exchange in which employees of the defendant stated that they "[m]ay need to reconsider [their] process for Patient Agreements"—was not probative of the defendants' state of mind at the time of the alleged violations because it was written months after the

conduct in question. *Id.* The relators identify no error in this analysis, and the government is aware of none. *See* Appellants' Br. 47-49.

On appeal, the relators also rely on an email exchange from November 2008. Appellants' Br. 22-23, 47. In that exchange, an employee asks whether Lincare can share its AOBs with Diabetic Experts. The response merely states the defendants' policy at the time, which permitted such sharing. Vol. 7, Doc. 231-35, at 1 (App. 1247). Nothing in the exchange suggests that any of the employees involved believed or had reason to believe that doing so would violate Medicare regulations.

This Court's decision in *R&F Properties* does not require a different result. In that case, the Court held that a variety of evidence, including "bulletins published by [an administrative contractor] (and received and maintained by [the defendant]) . . . , programs for seminars attended by [the defendant's] personnel . . . , and copies of notes handwritten by [the defendant's] personnel documenting conversations between [the defendant's] administrative personnel and a billing consultant" were "relevant to . . . [the defendant's] understanding of" the regulation's

meaning and precluded summary judgment. 433 F.3d at 1358. Such evidence may indeed be relevant to scienter. The relators offer no similar evidence here, however. The relators cite training presentations offered by Medicare Administrative Contractors (MACs), Appellants' Br. 13, 37, but they do not allege that the defendants saw those presentations or explain why they should be charged with knowledge of their contents.

Finally, the relators rely on the language of the amendment to 42 C.F.R. § 424.36(a) that introduced the requirement of "adequate notice to the beneficiary . . . that the purpose of the signature is to authorize a provider or supplier to submit a claim to Medicare for specified services furnished to the beneficiary." Appellants' Br. 23.[9] But the term "specified services" does not eliminate the ambiguity as to whether a description like

[9] The relators also cite "technical direction" given to Medicare MACs, but that direction merely paraphrases the regulation and does not expand on its meaning in any relevant way. *See* Appellants' Br. 23; Vol. 7, Doc. 238-4, at 12 (App. 1264).

"HME and Supplies" is sufficiently specific.[10] Such a description at least distinguishes the services provided from other covered services like "medical diagnosis and treatment, drugs and biologicals, . . . medical social services, and use of hospital, CAH, or SNF facilities." 42 C.F.R. § 400.202. The amendment therefore does not establish that the defendants' interpretation of the regulation was unreasonable or that the defendants acted with the requisite scienter.

[10] Although this regulation may have been ambiguous at the time of the relevant conduct in this case, the United States does not take the position that the defendants' interpretation of the regulation is correct.

CONCLUSION

For the foregoing reasons, the Court should hold that a defendant's reasonable interpretation of an ambiguous regulation does not preclude a finding of scienter.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains **5,632 words**, excluding the parts of the brief exempted under Rule 32(asp)(7)(B)(iii) and this Court's local rules, according to the count of Microsoft Word.

s/ Weili J. Shaw
WEILI J. SHAW

CERTIFICATE OF SERVICE

I hereby certify that on May 6, 2016, I electronically filed the foregoing with the Clerk of the Court using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the CM/ECF system.

s/ Weili J. Shaw
WEILI J. SHAW