IN THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

UNITED STATES OF AMERICA, ex. rel. LINDA DONEGAN, Administrator of the ESTATE OF RELATOR JOHN TIMOTHY DONEGAN,

Relator-Appellant,

v.

ANESTHESIA ASSOCIATES OF KANSAS CITY, P.C.,

Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING NEITHER PARTY

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Appellate Case: 15-2420 Page: 1 Date Filed: 09/16/2015 Entry ID: 4317194

TABLE OF CONTENTS

		1	Page(s)				
INTRODUCTION AND SUMMARY1							
STA	ГЕМЕ	NT OF THE CASE	3				
Α.	Statutory and Regulatory Background						
	1.	The False Claims Act	3				
	2.	"Medical Direction" Regulations	3				
В.	Factu	aal Background and Prior Proceedings	4				
ARGUMENT							
		efendant's Reasonable Interpretation of an Ambiguous lation Does Not Preclude Scienter	7				
CON	ICLUS	ION	17				
CER'	ΓIFIC	ATE OF COMPLIANCE					
CER'	TIFIC	ATE OF SERVICE					

Appellate Case: 15-2420 Page: 2 Date Filed: 09/16/2015 Entry ID: 4317194

TABLE OF AUTHORITIES

Cases:	Page(s)
Mader v. United States, 654 F.3d 794 (8th Cir. 2011) (en banc)	14
Minnesota Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp., 276 F.3d 1032 (8th Cir. 2002)	0, 11, 12, 13, 15
Robbins v. Becker, 794 F.3d 988 (8th Cir. 2015)	16
United States ex rel. Hixson v. Health Mgmt. Sys., Inc., 613 F.3d 1186 (8th Cir. 2010)	6, 8, 12, 13, 14
United States ex rel. K & R Ltd. P'ship v. Massachusetts Hous. Fin. Agency, 530 F.3d 980 (D.C. Cir. 2008)	10, 11
United States ex rel. Ketroser v. Mayo Found., 729 F.3d 825 (8th Cir. 2013)	6, 12, 14
United States ex rel. Oliver v. Parsons Co., 195 F.3d 457 (9th Cir. 1999)	8, 10, 11
Statutes:	
28 U.S.C. § 517	1
31 U.S.C. § 3729(a)(1)	3, 8
31 U.S.C. § 3729(b)(1)(A)	3, 8
31 U.S.C. § 3729(b)(1)(B)	3
Regulations:	
42 C.F.R. § 415.110(a)	3
42 C.F.R. § 415.110(a)(1)(iii)	4

I	Legis]	lative	Ma	ateria	l:
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S. Rep. No. 99-345 (1986), reprinted in 1986 U.S.C.C.A.N. 5266.....9

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BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING NEITHER PARTY

Pursuant to Rule 29 of the Federal Rules of Appellate Procedure and 28 U.S.C. § 517, the United States submits this brief as amicus curiae in support of neither party.

INTRODUCTION AND SUMMARY

This is a False Claims Act (FCA) suit premised on alleged violations of a federal regulation. The district court held that the FCA's scienter requirement is not satisfied in this case because the regulation is ambiguous and because defendant offered a reasonable interpretation of that regulation. The court did not consider defendant's state of mind at the time the claims were submitted. Instead, the court broadly held that a defendant's reasonable interpretation of an ambiguous regulation

Appellate Case: 15-2420 Page: 5 Date Filed: 09/16/2015 Entry ID: 4317194

precludes FCA liability, "even if the defendant's behavior is somewhat opportunistic." Add. 17, A1217.

The district court's holding is mistaken, and it threatens to impair the government's enforcement of the False Claims Act. The United States has a substantial interest in the proper interpretation and application of that statute, which is the government's primary tool to combat fraud and recover losses due to fraud in federal programs. The United States submits this amicus brief to provide the Court with the government's views as to the proper interpretation and application of the FCA. As explained below, the district court erred in its assessment of the impact of statutory or regulatory ambiguity on FCA liability. When a defendant advances a reasonable interpretation of an ambiguous federal statute or regulation, the court still must evaluate whether the defendant at least recklessly disregarded the correct interpretation of the provision. Notwithstanding the district court's error, however, this Court can properly affirm the judgment below on the alternative ground that relator has failed to adduce sufficient evidence at summary judgment to prove that defendant acted with the requisite scienter.

STATEMENT OF THE CASE

A. Statutory and Regulatory Background

1. The False Claims Act

The False Claims Act prohibits any person from "knowingly" presenting "a false or fraudulent claim for payment or approval" to the federal government. 31 U.S.C. § 3729(a)(1). A person "knowingly" submits a false claim not only when he or she "has actual knowledge of the information," but also when he or she "acts in deliberate ignorance" or "reckless disregard" of the truth or falsity of the information. *Id.* § 3729(b)(1)(A). No proof of specific intent to defraud is required. *Id.* § 3729(b)(1)(B). Any person who violates the FCA is liable to the United States for civil penalties and for three times the amount of the government's damages. *Id.* § 3729(a)(1).

2. "Medical Direction" Regulations

The Centers for Medicare and Medicaid Services (CMS) pay anesthesiology providers at four levels of reimbursement, depending on the anesthesiologist's involvement in the procedure. Appellants' Addendum (Add.) 4, A1204. To bill at the "medical direction" rate, which is at issue in this case, the anesthesiologist must direct a certified registered nurse anesthetist ("nurse anesthetist") in no more than four concurrent cases. 42 C.F.R. § 415.110(a). In each case, the anesthesiologist must satisfy additional payment conditions, including that the anesthesiologist "[p]ersonally

participate[] in the most demanding aspects of the anesthesia plan including, if applicable, induction and emergence." *Id.* § 415.110(a)(1)(iii). The definition of "emergence" is at issue in this case. Relator argues that "emergence" always begins and ends in the operating room, and does not extend to the recovery room; therefore, an anesthesiologist is not present for "emergence" when he or she examines the patient in the recovery room only, and not in the operating room. Add. 11, A1211; A33 (Am. Compl. ¶ 60). By contrast, defendant argues that "emergence" may include time in the recovery room. Add. 10, A1210; *see also* A607 (¶ 14), A610 (¶ 29). CMS has not issued guidance on the meaning of this term.

B. Factual Background and Prior Proceedings

1. John Donegan, the original relator in this *qui tam* action, was a nurse anesthetist employed by the defendant, Anesthesia Associates of Kansas City, P.C. A19 (Am. Compl. ¶ 7). Relator alleges that defendant submitted false claims to CMS by seeking reimbursement for anesthesiology services at the "medical direction" rate even when an anesthesiologist was not present for "emergence," in violation of CMS regulations. Add. 1, A1201; *see also* 42 C.F.R. § 415.110(a)(1)(iii). Relator claims that "under the broadest definition" of the term, "emergence" ends when "the patient is turned over to the staff of the recovery room" and thus does not include the patient's time in the recovery room. A33 (Am. Compl. ¶ 60). By contrast, defendant's

¹ Donegan is now deceased, and the district court substituted his estate as relator. Add. 1, A1201.

corporate compliance policy states that "emergence'...include[s] the recovery room." A638.

2. The United States declined to intervene in the case. A15. The parties filed cross-motions for summary judgment. Defendant argued that summary judgment was warranted because relator could not prove scienter. Defendant reasoned that the meaning of "emergence" was ambiguous, and that defendant reasonably understood "emergence" to extend to the recovery room. A622-27. In defendant's view, its reasonable interpretation of an ambiguous regulation precluded a finding of scienter.

In response, relator urged the court to consider defendant's state of mind at the time it submitted the false claims. Relator argued that defendant "had constructive notice that the Government interprets [the regulation] differently than [defendant]," A738, but failed to ask the government for clarification regarding the meaning of "emergence," A739. Therefore, relator argued, defendant recklessly disregarded the proper interpretation of the term. A742.

The United States filed a statement of interest to address the impact of ambiguity on FCA liability. Without taking a position on the ultimate question of liability, the government argued that scienter "depends on the surrounding facts as they existed at the time, not on whether [the defendant's] lawyers can point to ambiguities in regulatory language and advance plausible post hoc interpretations."

Al 121. The government argued that even when a defendant identifies an ambiguity,

"[t]he factfinder must evaluate the defendant's state of mind at the time the claims are submitted to the government." A1123. The United States relied on this Court's decision in *United States ex rel. Minnesota Ass'n of Nurse Anesthetists v. Allina Health System Corp.*, 276 F.3d 1032 (8th Cir. 2002), which held that a defendant may have the requisite knowledge even if a regulation is ambiguous. *Id.* at 1053. For example, scienter is established if a defendant "certifie[s] compliance with the regulation knowing that the [government] interpreted the regulations in a certain way and that [the defendant's] actions did not satisfy the requirements of the regulation as the [government] interpreted it." *Id.*

3. The district court entered summary judgment for defendant. The court rejected the fact-specific inquiry proposed by the United States. Add. 17-18, A1217-18. Instead, the district court adopted the sweeping rule that a defendant's reasonable interpretation of an ambiguous regulation precludes FCA liability, regardless of the defendant's state of mind. Add. 18, A1218. "This is true," the court explained, "even if the defendant's behavior is somewhat opportunistic." Add. 17, A1217. In support of its rule, the district court relied on two recent decisions of this Court, *United States ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825 (8th Cir. 2013), and *United States ex rel. Hixson v. Health Mgmt. Sys., Inc.*, 613 F.3d 1186 (8th Cir. 2010). The district court did not attempt to reconcile its rule, or these cases, with this Court's earlier decision in *Allina*.

In granting summary judgment to defendant, the court held that relator could not establish that defendant "knowingly" made false claims because the definition of "emergence" is ambiguous, and because defendant's interpretation is reasonable.

Add. 18-20, A1218-20. The court stated that "[e]mergence' is not defined by CMS, a National Coverage Determination, a binding Local Coverage Determination, or any national or state anesthesiology organization." Add. 18-19, A1218-19. The court observed that "there is no agreement on when [emergence] *ends.*" Add. 19, A1219. Rather, "anesthesiologists consider emergence to be a process that occurs over a period of time and may take an hour or more to complete, depending on the patient." *Id.* The court concluded that "[d]efendant's view that the regulation is satisfied by seeing the patient in the recovery room is a reasonable interpretation." *Id.* ²

ARGUMENT

A Defendant's Reasonable Interpretation of an Ambiguous Regulation Does Not Preclude Scienter

The district court erred in holding that a defendant's reasonable interpretation of an ambiguous regulation precludes scienter as a matter of law, regardless of whether the defendant acted with the requisite scienter. As explained below, however, this Court can nonetheless affirm the judgment on the alternative ground

² The district court also declined to consider several of relator's proposed facts, Add. 7, A1207, and refused to consider a separate theory of liability, Add. 14-15, A1214-15. The government takes no position on these rulings.

that relator has failed to demonstrate in this case that defendant actually knew of, deliberately ignored, or recklessly disregarded the correct interpretation of the rule.

A. The False Claims Act prohibits any person from "knowingly" presenting false or fraudulent claims to the government. 31 U.S.C. § 3729(a)(1). A person "knowingly" submits a false claim not only when he or she "has actual knowledge of the information," but also when he or she "acts in deliberate ignorance" or "reckless disregard" of the truth or falsity of the information. *Id.* § 3729(b)(1)(A).

In some cases, a federal statute or regulation may be susceptible to more than one interpretation. But the mere ambiguity of a federal law does not foreclose FCA liability, because a defendant may have submitted false claims with the requisite scienter. Liability will almost certainly exist when the defendant's interpretation of a statute or regulation is unreasonable. 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). And 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. 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); United States ex rel. Oliver v. Parsons Co., 195 F.3d 457, 464 (9th Cir. 1999) (requiring good faith); see also 31 U.S.C. § 3729(b)(1)(A). Either condition is sufficient

to satisfy the scienter requirement. If a defendant has notice of a contrary interpretation 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 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5272 ("[T]hose doing business with the Government have an obligation to make a limited inquiry to ensure the claims they submit are accurate.").

In *Allina*, this Court made clear that a defendant's actual knowledge, deliberate ignorance, or reckless disregard of the proper interpretation of an ambiguous regulation satisfies the scienter requirement. 276 F.3d at 1053-56. As this Court explained, "[i]f 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. Indeed, scienter may be established if "the defendants were on notice of the possibility" that the government interpreted ambiguous regulations differently. *Id.*

Applying these principles, this Court reversed the grant of summary judgment for defendants. The Court explained that defendants may be liable for false claims submitted during three relevant time periods, despite the alleged ambiguity of the relevant regulation. *Allina*, 276 F.3d at 1053-1056. In the first time period, advice

from in-house counsel put defendants "on notice of the possibility that" that their conduct violated the relevant regulation, creating "at least a question of fact as to their state of mind." *Id.* at 1053. In the last period, the government clarified its interpretation, giving defendants no plausible basis for adhering to their position. *Id.* at 1054. And even during the in-between period, when a "[government] memorandum could have been thought to" support defendants' interpretation, defendants' conduct was so egregious that "[n]othing... could have led [them] to think that they" were complying with the regulation. *Id.* at 1055. *Allina* establishes that a defendant's reasonable interpretation of an ambiguous regulation is not the end of the inquiry. Rather, a court must engage in a fact-specific inquiry to determine whether a defendant acted with the requisite knowledge of the proper interpretation.

Other courts are in accord. The D.C. Circuit has explained that the reasonableness of a defendant's interpretation "does not preclude a finding of knowledge." *United States ex rel. K & R Ltd. P'ship v. Massachusetts Hous. Fin. Agency*, 530 F.3d 980, 983 (D.C. Cir. 2008) (citing *Parsons*, 195 F.3d at 464). In *K & R*, the D.C. Circuit concluded that defendant had offered a plausible interpretation of ambiguous mortgage notes, but it nevertheless proceeded to consider whether the defendant "at least recklessly disregarded the falsity of its claims." *Id.* Because the relator failed to "point to anything that might have warned [defendant] away from the view it took," the court held that there was no genuine issue of material fact as to

whether the defendant acted with reckless disregard, and it affirmed summary judgment for the defendant. *Id.* at 984 (internal quotation marks omitted). This decision makes clear that a defendant's reasonable interpretation of an ambiguity does not automatically foreclose FCA liability; rather, the court must inquire into the defendant's state of mind at the time it submitted the claims.

Similarly, the Ninth Circuit has emphasized that when an ambiguous regulation is at issue, the reasonableness of defendant's interpretation 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.*

B. The district court erroneously held that a defendant's reasonable interpretation of an ambiguous regulation necessarily precludes FCA liability. Add. 18, A1218. The court explained that this rule applies regardless of the defendant's state of mind, and "even if the defendant's behavior is somewhat opportunistic." Add. 17, A1217. But this ruling cannot be squared with this Court's decision in *Allina*, which underscores the importance of considering whether the defendant's interpretation was reasonable *and* the defendant did not knowingly, deliberately or recklessly disregard the proper interpretation. 276 F.3d at 1053. The

district court's rule also undermines the FCA's important role in rooting out fraud in federal programs, because it absolves defendants of liability whenever they can justify their conduct with a plausible post-hoc interpretation of an ambiguous law. Given the ease with which post-hoc rationalizations can be constructed, the decision below threatens to preclude FCA liability in many cases involving an ambiguous federal law.

The district court relied on two recent decisions of this Court, which include language that focuses on the reasonableness of a defendant's interpretation. See United States ex rel. Ketroser v. Mayo Found., 729 F.3d 825, 832 (8th Cir. 2013); Hixson, 613 F.3d at 1190-91. But the district court failed to consider these cases against the background of this Court's earlier decision in *Allina*. Hixson and Ketroser are best understood as applications of Allina's general rule that a relator may prove the requisite scienter when a defendant's interpretation of an ambiguous federal law is unreasonable or when a defendant actually knows of, deliberately ignores, or recklessly disregards the proper interpretation. 276 F.3d at 1053-56. This Court held that summary judgment for defendants was improper in Allina, because there was evidence that defendants were on notice of the government's contrary interpretation, and because defendants' interpretation was unreasonable. By contrast, in *Hixson* and *Ketroser*, the relators did not plausibly allege that the defendants' interpretation was unreasonable or that they actually knew of, deliberately ignored, or recklessly disregarded the correct interpretation.

In *Hixson*, this Court affirmed the dismissal of an FCA complaint where defendants' interpretation of an ambiguous legal question was reasonable, and there was no indication that defendants had notice of the correct standard or otherwise acted in deliberate ignorance or reckless disregard of the truth. 613 F.3d at 1190-91. The Court explained that defendants' interpretation "is a reasonable interpretation, perhaps even the most reasonable one," observed that there was "no authoritative contrary interpretation of [the] statute," and suggested that "the relevant legal question was unresolved." Id. at 1190. The Court rejected the relator's reliance on a trial-court decision that arguably supported its interpretation, explaining that the decision involved a different context and had "no precedential value." Id. The Court also concluded that defendants were not bound by the State's interpretation in that case. *Id.* In sum, the relator offered no plausible basis for concluding that defendants deliberately ignored or recklessly disregarded the falsity of their claims. *Id.* This case stands in contrast with Allina, where there was evidence that the government had adopted a contrary interpretation, that "defendants were on notice" of that interpretation, and that defendants' conduct could not possibly satisfy the relevant standard. 276 F.3d at 1053-56.

In *Ketroser*, the Court similarly held that the scienter requirement was not satisfied where there was no support for the relators' view of the relevant regulation, and the defendants' interpretation of the law was "a reasonable interpretation, perhaps

even the most reasonable one." 729 F.3d at 832 (quoting *Hixson*, 613 F.3d at 1190). After considering relevant regulations, industry practice, and "common sense," this Court determined that "all Relators have plausibly alleged is their *desire*" to interpret the law in a certain way. *Id.* at 831. Given the absence of any plausible allegations supporting relators' interpretation, this Court held that relators "fail[ed] to state an FCA claim of knowing fraud." *Id.* Like *Hixson*, this case differs markedly from *Allina*, and it does not foreclose the possibility that defendants may act with the requisite scienter despite their reliance on a plausible interpretation of an ambiguous federal law.

This Court's precedents thus stand for the proposition that a relator may prove the requisite scienter when a defendant's interpretation of an ambiguous federal law is unreasonable or when a defendant actually knows of, deliberately ignores, or recklessly disregards the proper interpretation. In any event, to the extent that the district court perceived conflict in this Court's decisions, it should have followed the earlier decision in *Allina*. *See Mader v. United States*, 654 F.3d 794, 800 (8th Cir. 2011) (en banc) ("[W]hen faced with conflicting panel opinions, the earliest opinion must be followed[,] as it should have controlled the subsequent panels that created the conflict.") (internal quotation marks omitted).

C. Notwithstanding the district court's erroneous holding, this Court may affirm the judgment on alternative grounds. Under the proper legal standard, relator

failed to demonstrate that defendant acted with the requisite scienter by concluding that in at least some cases, "emergence" can extend beyond the operating room.³

Relator contends that defendant violated a bright-line rule that "emergence" has a definite end point in the operating room and does not extend into the recovery room. *E.g.*, Relator Br. 13; A33 (Am. Compl. ¶ 60). As the district court concluded, however, "there is no agreement on when [emergence] *ends*," and "it is uncontroverted that anesthesiologists consider emergence to be a process that occurs over a period of time and may take an hour or more to complete, depending on the patient." Add. 19, A1219. The timing of emergence varies based on the particular patient. Although this Court considered the meaning of "emergence" in *Allina*, it did not establish the bright-line rule that relator proposes, nor did it define this term. *Allina* merely held that summary judgment was improper because the district court failed to consider all of the evidence on this question. 276 F.3d at 1056. Therefore, *Allina* does not establish that defendant recklessly disregarded relator's contrary, bright-line interpretation.

³ The district court did not resolve the question of whether an anesthesiologist's failure to be present in the operating room for extubation violates the regulation, Add. 14-15, A1214-15, and the government takes no position on this question. *See* Relator Br. 44-53. In addition, the court made "no ruling on whether seeing a patient in the recovery room is a reasonable interpretation of step three's requirement to personally participate in the *most demanding aspects* of emergence," Add. 19 n.11, A1219, and the government also takes no position on this issue.

In light of the fact-specific inquiry that "emergence" requires, relator has failed to show that defendant acted with the requisite scienter by concluding that emergence extends into the recovery room in at least some cases. To the extent that there are specific circumstances in which emergence could not reasonably extend to the recovery room, relator has failed to present evidence of specific instances in which defendant knowingly violated the regulation by billing when emergence had ended in the operating room in a particular case.⁴

Because relator cannot show that defendant acted with the requisite knowledge, this Court may affirm the judgment on this basis. Alternatively, it would be appropriate to remand the case to the district court to consider the defendant's scienter under the proper standard.

⁴ The examples set forth in relator's amended complaint, A43-53, are mere allegations; they do not provide an adequate basis for surviving summary judgment. *See Robbins v. Becker*, 794 F.3d 988, 993 (8th Cir. 2015) ("In opposing summary judgment, a plaintiff may not simply point to allegations in the complaint, or rest on the hope of discrediting the movant's evidence at trial, but must identify and provide evidence of specific facts creating a triable controversy.") (internal quotation marks and citations omitted). If relator can point to such evidence, remand may be appropriate to allow the district court to consider the evidence in the first instance.

CONCLUSION

For the foregoing reasons, this Court should reject the district court's holding that a defendant's reasonable interpretation of an ambiguous law precludes scienter under the FCA.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Rules 29(c)-(d) and 32(a)(7)(C) of the Federal Rules of Appellate Procedure, I hereby certify that the foregoing brief was prepared using Microsoft Word and complies with the type and volume limitations set forth in Rules 29 and 32 of the Federal Rules of Appellate Procedure. I further certify that the font used is 14 point Garamond, for text and footnotes, and that the computerized word count for the foregoing brief is 3,702 words.

Pursuant to 8th Cir. R. 28A(h)(2), I hereby certify that the foregoing brief has been scanned for viruses and that no viruses were detected.

/s/ Tara S. Morrissey
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Appellate Case: 15-2420 Page: 22 Date Filed: 09/16/2015 Entry ID: 4317194

CERTIFICATE OF SERVICE

I hereby certify that on September 16, 2015, I electronically filed the foregoing with the Clerk of the Court by using the appellate CM/ECF system. Participants in the case who are registered CM/ECF users will be served by the CM/ECF system.

I further certify that some of the participants in the case are not CM/ECF users. I have mailed the foregoing document by First-Class Mail, postage prepaid, or have dispatched it to a third-party commercial carrier for delivery within 3 calendar days, to the following non-CM/ECF participants:

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Appellate Case: 15-2420 Page: 23 Date Filed: 09/16/2015 Entry ID: 4317194