UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

> No. 15-238 (L) (0:12-cv-03466-JFA)

UNITED STATES OF AMERICA, EX REL. BRIANNA MICHAELS AND AMY WHITESIDES

Petitioners-Respondents,

v.

AGAPE SENIOR COMMUNITY, INC.; AGAPE SENIOR PRIMARY CARE, INC.: AGAPE SENIOR SERVICES, INC.: AGAPE SENIOR, LLC; AGAPE MANAGEMENT SERVICES, INC.; AGAPE COMMUNITY HOSPICE, INC.; AND AGAPE NURSING AND REHABILITATION CENTER, INC. d/b/a AGAPE REHABILITATION OF ROCK HILL a/k/a AGAPE SENIOR POST ACUTE CARE CENTER - ROCK HILL a/k/a EBENEZER SENIOR SERVICES, LLC; AGAPE SENIOR FOUNDATION, INC.; AGAPE COMMUNITY HOSPICE OF ANDERSON, INC.; AGAPE HOSPICE OF THE PIEDMONT, INC.: AGAPE COMMUNITY HOSPICE OF THE GRAND STRAND, INC.; AGAPE COMMUNITY HOSPICE OF THE PEE DEE, INC.; AGAPE COMMUNITY HOSPICE OF THE UPSTATE, INC.; AGAPE HOSPICE HOUSE OF HORRY COUNTY, INC.; AGAPE HOSPICE HOUSE OF LAURENS, LLC; AGAPE HOSPICE HOUSE OF THE LOW COUNTRY, INC.; AGAPE HOSPICE HOUSE OF THE PIEDMONT, INC.; AGAPE REHABILITATION OF CONWAY, INC.: AGAPE SENIOR SERVICES FOUNDATION, INC.; AGAPE THERAPY, INC.; AGAPE HOSPICE; HOSPICE PIEDMONT; HOSPICE ROCK HILL; and CAROLINAS COMMUNITY HOSPICE, INC.

Respondents-Petitioners.

PARTIAL OPPOSITION TO PETITION FOR INTERLOCUTORY APPEAL

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INTRODUCTION

The district court certified the following two issues for interlocutory appeal pursuant to 28 U.S.C. § 1292(b): (1) whether the Government may unconditionally veto a settlement in a *qui tam* action in which it has not intervened; and (2) whether the district court abused its discretion in rejecting the use of statistical sampling to prove liability and damages in this case. On July 6, 2015, both the Petitioner-Respondents (hereinafter "Relators") and Respondent-Petitioners (hereinafter "Agape") petitioned this Court for review of the first issue.¹ The Relators have petitioned this Court for review of the second issue², and Agape submits this Response in Opposition to Relators' Petition to Appeal the district court's ruling that statistical sampling is inappropriate in this case.

This Court should deny the Relators' Petition for review of the statistical sampling issue. First, the statistical sampling issue is not a purely legal one; rather, it is a complex evidentiary ruling made within, and committed to, the sound discretion of the district court. Although the district court described the issue as a "pure question of law, not dependent on subsequent discovery," Ex. 2. p. 13, the

¹ As evidenced by Agape's Petition submitted on July, 6, 2015 (hereinafter "Agape's Petition"), Agape agrees with Relators that the first issue satisfies all elements § 1292(b) and should be reviewed on interlocutory appeal.

² On Pages 2 and 11 of Agape's Petition, Agape briefly noted its positon that the district court's statistical sampling was not appropriate for interlocutory review by this Court pursuant to § 1292(b).

court's rejection of proof by statistical sampling was nevertheless inextricably bound up with the particular circumstances of this case. Appellate review of this decision at this stage would require this Court to analyze the entire record to determine whether statistical sampling is an appropriate method of proof under the specific and unique facts and circumstances of this case. The district court's decision involves the application of the law to a complex set of facts in making a discretionary call concerning the introduction of a particular type of evidence--and generally, courts have found such discretionary rulings inappropriate for interlocutory review.³

Second, the statistical sampling decision does not involve or constitute a "controlling issue of law" as required by 28 U.S.C. § 1292(b). An appellate ruling on this issue will not terminate this litigation and, even in the unlikely event of a reversal, future developments in this case could moot the issue. *See* Wright & Miller § 3930 ("Immediate appeal may be found inappropriate if there is a good prospect that the certified question may be mooted by further proceedings."). Thus,

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³ See 16 Charles Alan Wright et. Al., Federal Practice & Procedure § 3930 (hereinafter "Wright & Miller) ("Appellate courts frequently note the inappropriateness of interlocutory review of most discretionary orders."); McFarlin v. Conseco Services, LLC, 381 F.3d 1251, 1258 (11th Cir. 2004) ("The term 'question of law' does not mean the application of settled law to fact"); Johnson v. Alldredge, 488 F.2d 820, 822 (3d Cir. 1973) (declining appeal, since the question "comprehends factual as well as legal matters, requiring a factual decision ... as well as a legal decision").

addressing it on interlocutory appeal will almost certainly fail to have any determinative impact on this case.

For example, in seeking a ruling on this issue pre-trial, it should be noted that the Relators failed to propose, proffer or otherwise offer an expert and/or methodology concerning this issue in the district court. Had the district court indicated a preliminary intention to rule in the Relators' favor, any expert and methodology eventually proposed by the Relators would still be subject to the reliability threshold mandated by Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579 (1993) and its progeny. Therefore, a subsequent ruling by the district court that either the expert or his methodology is unreliable would moot the issue. Further, even assuming that this Court reversed the district court and the district court rejected a Daubert challenge, the Relators might still fail to prove any liability as to the sample claims, rendering moot any projection of liability and/or damages on the larger universe of claims. Finally, should this Court reverse the district court's ruling on the first issue and hold that the Government's objection is subject to judicial review, an amicable settlement would likely be reached by Agape and Relators, yet again rendering the statistical sampling issue moot.

Finally, a ruling on the issue of statistical sampling would **not** materially advance the litigation as required by § 1292(b). As noted above, reversal of the statistical sampling issue could lead to further evidentiary issues, including a

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possible *Daubert* challenge. And, regardless of how Relators attempt to prove liability, Agape plans to defend each and every allegedly false claim on its own merits. In short, neither affirmance nor reversal on the statistical sampling issue will materially advance this litigation. In fact, an interlocutory appeal and reversal would likely prolong the litigation in both the district court and beyond, as the issue is likely to be subject to a second appeal, following final judgment, within the factual context of the evidence presented at trial.

Consequently, the issue of statistical sampling does not meet the necessary elements to justify the exceptional remedy of interlocutory review, and the Relators' Petition for Review should be denied in part as to the statistical sampling issue.

I. Factual Background

On December 7, 2012, this *qui tam* case was initiated by Relators on behalf of themselves and the United States claiming damages and other relief under the False Claims Act 31 U.S.C. § 3729, et seq. ("FCA"), the Anti-kickback Statute, 42 U.S.C. § 1320a-7b, et seq., and the Health Care Fraud Statute, 18 U.S.C. § 1347. While there are multiple issues raised in the complaint, the central issue on which this case has proceeded revolves around alleged fraudulent billings by Agape to Medicare for hospice patients. The allegations in the complaint encompass around 10,000 patients in Agape facilities for whom over 50,000 claims were submitted. Rather than review all (or indeed, many) of the claims covered by the Second Amended Complaint they drafted and offer evidence with respect to specific false claims, the Relators sought to short-cut their burden of proof through the use of statistical sampling. On August 22, 2014, Relators moved the district court to allow statistical sampling in this case. Agape filed a brief in opposition, and the Government filed briefs in support of the Relators' position. At a hearing held on October 10, 2014, the district court heard oral argument from the parties and the Government and took the matter under advisement. During hearings in late 2014, the district court indicated that it was inclined to deny the Relators' motion.

The district court subsequently issued a brief written Order denying Relators' motion on March 16, 2015 documenting its ruling on the statistical sampling issue, stating that "the Court believes that, based on the facts of this case, statistical sampling would be improper," so it denied the Relators' motion. Ex. 1 p. 2.

Thereafter, the district court ordered a "bellwether" trial as to the claims of a small universe of approximately 100 patients cherry-picked by the Relators. The district court indicated that it believed that such a trial might provide information to the litigants about the relative strengths and weaknesses of their cases—which

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might then result in a settlement of the remaining claims based on the results of trial. The Relators indicated that they would proceed with claims related to 95 they had selected; however, the Relators later reduced this number to 38 patients with trial to begin on May 5, 2015.

As noted on Pages 8-9 of Agape's Petition, Agape and the Relators negotiated and believed they reached a settlement. Shortly after being notified of the settlement, the Government notified Agape and Relators that it was objecting to the settlement because, in light of the Government's projected damages, the settlement amount was too small to justify a full release from the Government.⁴ After five months of negotiating the scope of the release with the Government, Agape moved to enforce the settlement over the Government's objection.

While acknowledging the potential unreasonableness of the Government's objection, the district court ruled that it was "constrained to deny the motion to enforce the settlement." Ex. 2 p. 9. The district court went on to certify both the question of whether the Government has an unreviewable veto right over all *qui*

⁴As the district court notes, this damage figure was reached, "by using an 'error rate' in the '20-60% range' derived from an expert review of what the [g]overnment refers to as 'cherry picked' claims. While the Government's methodology for evaluating this case is not altogether clear to this Court, suffice it to say that the [g]overnment has used some form of statistical sampling extrapolated to the universe of potential claims in its damages calculation." Ex. 2 p. 6.

tam settlements,⁵ and whether the Relators should be permitted to use statistical sampling to prove liability and damages. Ex. 2 p. 19.

The district court found the issue of statistical sampling to be interrelated due to the Government's reliance on statistical sampling in calculating its projected damages, which in turn was the basis for its objection to the settlement. Consequently, the district court certified both issues for interlocutory appeal noting that the Government's reliance "upon a damages model that this Court has rejected for purposes of trial, presents a unique factual development that cries out for interlocutory appeal in this case." Ex. 2 p. 18.

In its Order certifying issues for interlocutory appeal, the district court further explained its reasoning and analysis on the statistical sampling issue. Ex. 2 pp. 12-18. The district court began by noting that "this case is not one where the evidence has dissipated," making direct proof of damages impossible. Ex. 2 p. 13. Indeed, the district court specifically found just the opposite, that all of the evidence in this case is intact and available for review and analysis by each party. Ex. 2 p. 13. The district court then noted that it was persuaded by the analysis in *United States v. Freidman*, 1993 U.S. Dist. Lexis 21496 (D.Mass July 23, 1993), where the court declined to allow statistical sampling "based on the existence at

⁵ Whether this issue is appealable under § 1292(b), will not be discussed in this Response as Agape has fully addressed this issue in its July 7, 2015 Petition, and Agape concurs with the positions taken by Relators as to the appealability of this ruling.

trial of discrete claims that may be analyzed, discussed, and subject to crossexamination." Ex. 2 p. 14. Finally, the district court noted that its responsibility was to determine the "fairest course of action based upon the facts presented and the claims asserted in the case," and in doing so, the court found that this case's highly fact intensive inquiry as to medical necessity was not suited for statistical sampling. Ex. 2 pp. 17-18.

As noted above, Relators and Agape have both petitioned this Court for review of the district court's ruling that the Government has an unreviewable veto over settlements in *qui tams* where it has not intervened.⁶ However, Agape respectfully submits that interlocutory review of the statistical sampling ruling is not appropriate, as the issue does not satisfy the standard set forth in § 1292(b).

II. Argument

It is generally understood that § 1292(b) "should be used sparingly." *Myles v. Laffitte*, 881 F.2d 125, 127 (4th Cir. 1989). Under 28 U.S.C. § 1292(b), the party seeking immediate appeal of any interlocutory order *must* demonstrate: (1) the issue to be appealed involves "a controlling issue of law;" (2) "there is

⁶ The district court's order makes it clear that the district court itself was unhappy about the effects of its ruling, as it noted that were it able to review the Government's objection "a compelling case could be made here that the Government's position is not, in fact, reasonable." Ex. 2 p. 10.

substantial ground for differences of opinion;"⁷ and (3) an immediate appeal from the order may materially advance the termination of the litigation. *See In re Pisgah Contractors, Inc.,* 117 F.3d 133, 136-37 (4th Cir. 1997). Even if a district court certifies an issue for interlocutory appeal, an appellate court must exercise its own discretion in deciding whether it will grant permission to appeal the certified order. *See* § 1292(b) ("The Court of Appeals which would have jurisdiction of an appeal of such action may thereupon, **in its discretion**, permit an appeal to be taken from such order, if application is made to it within ten days after the entry of the order.") (emphasis supplied).

⁷Agape does not address this issue in detail here because there is no substantial disagreement among courts as to whether statistical sampling can be used to prove liability in an FCA case. In fact, Agape's research indicates that only four (4) district courts have ever allowed statistical sampling to prove any element of liability in a FCA action. See United States v. Robinson, 2015 WL 1479396 (E.D. Ky. Mar. 31, 2015); United States ex rel. Ruckh v. Genoa Healthcare, LLC, 2015 WL 1926417, at *3 (M.D. Fla. Apr. 28, 2015); United States ex rel. Martin v. Life Care Ctrs. of Am., Inc. 2014 U.S. Dist. Lexis 142660 (E.D. Tenn. Sept. 29, 2014); United States v. AseraCare, Inc., 2014 WL 6879254 (N.D. Ala. Dec. 4, 2014). Moreover, none of these cases stand for the broad proposition that statistical sampling can be used to establish liability in all FCA cases, let alone cases which rise and fall based on medical necessity. Agape has, in fact, located no case where any court has ever agreed that statistical sampling can be used to establish liability in a hospice case, and determinations as to whether a patient is eligible for hospice care requires an analysis as to specific facts which are unique to each patient. While there may be substantial disagreements amongst district courts as to whether statistical sampling may be used in FCA actions to prove damages, the Relators seek to use statistical sampling to prove both liability and damages. Given the minimal authority siding with Relators on the narrow issue, there is no substantial disagreement amongst the courts as to whether statistical sampling may be used in a case like this one.

A. The Issue that Relators Ask This Court to Review is **Not** a Controlling Issue of Law

A question of law is "controlling" when it is "serious to the conduct of the litigation, either practically or legally." *Katz v. Carte Blanche Corp.*, 496 F.2d 747, 755 (3d Cir. 1974) (citing 3 U.S.C.C.A.N. 5256 (1958)); *see also Kennedy v. St. Joseph's Ministries, Inc.*, 657 F.3d 189, 195 (4th Cir. 2011) (finding the "controlling question of law" criterion met since the Court was "faced with a pure question of law"). Courts will find an issue controlling where prompt appellate resolution of the question "might save time for the district court, and time and expense for the litigants." Wright & Miller § 3930.

The issue of whether statistical sampling may be used to prove liability and damages in this case is not a "controlling issue of law" because: (1) the issue is not a narrow issue of law, as it involves a factually intensive discretionary ruling by the district court; (2) further developments in this case could moot the issue; and (3) an interlocutory appeal of this issue will likely lead to successive appeals delaying the case further.

1. The Issue is Not a Pure Question of Law

"The kind of question best adapted to discretionary interlocutory review is a narrow question of pure law whose resolution will be completely dispositive of the litigation, either as a legal or practical matter, whichever way it goes." *Fannin v. CSX Transp., Inc.*, 873 F.2d 1438, *5 (table) (4th Cir. 1989). The idea of § 1292(b)

"was that if a case turned on a pure question of law, something the court of appeals could decide quickly and cleanly without having to study the record, the court should be enabled to do so without having to wait till the end of the case." *Ahrenholz v. Bd. of Trs. of Univ. of Ill.*, 219 F.3d 674, 677 (7th Cir. 2000). The issue of whether statistical sampling should be permitted to prove damages and liability in this case is far from a narrow issue of pure law.

A determination of the method in which proof may be presented at trial is a complex discretionary decision by the trial judge, and it will only be reversed upon an abuse of discretion. See United States v. Hedgepeth, 418 F.3d 411, 418-19 (4th Cir. 2005) ("A trial court possesses broad discretion in ruling on the admissibility of evidence, and we will not overturn an evidentiary ruling absent an abuse of discretion"); Creekmore v. Mary View Hosp. 662 F.3d 686, 690 (4th Cir. 2011) (admission of expert testimony is reviewed under abuse of discretion standard). Generally, decisions involving discretion of the lower court will not be reviewed on interlocutory appeal. See In re City of Memphis, 293 F.3d 345, 351 (6th Cir. 2002) (the admissibility of evidence is reviewed for abuse of discretion, and "does not create a legal issue under § 1292(b)."); White v. Nix, 43 F.3d 374, 377-378 (8th Cir. 1994) ("A legal question of the type referred to in § 1292(b) contrasts with a matter for the discretion of the trial court."). Moreover, the district court's ruling (which involves the application of law to the facts of this particular case) requires extensive review of the record so as to determine the appropriateness of that ruling under an abuse of discretion standard. As such, appellate courts have frequently found such questions inappropriate for § 1292(b) appeals. *McFarlin v. Conseco Services, LLC*, 381 F.3d 1251, 1258 (11th Cir. 2004) ("The term 'question of law' does not mean the application of settled law to fact"); *In re Vitamin C Antitrust Littig.*, 2012 WL 425234, at *2 (E.D.N.Y. Feb. 9, 2012) ("Review of this issue would require scrutiny of an extensive record; interlocutory appeal of this question is therefore denied"); *D.R. Horton, Inc. v. Travelers Indem. Co. of Am.*, 2013 WL 5878122, at *2 (D. Colo. Nov. 1, 2013) ("In order for the reviewing court to make a decision on appeal, the reviewing court would necessarily have to make an extensive review of the record. . .which is inconsistent with purpose and intent of a § 1292(b) interlocutory appeal.").

Finally, a decision concerning whether statistical sampling may be used to prove either liability or damages in a particular case rises and falls on the merits of that individual case. While the Relators cite to district court's statement that this question is a "pure question of law," this characterization is belied by the rest of the district court's order. In discussing the issue, the district court acknowledges that the individual facts of the case dictate whether statistical sampling is appropriate. In fact, the district court described a recent case where it **may** have found statistical sampling appropriate. As the court stated, in ruling on statistical sampling the court must "determine the fairest court of action **based upon the facts presented and the claims asserted in this case**." Ex. 2 p. 17 (emphasis supplied). Thus, it is not appropriate for interlocutory appeal.

2. Future Developments in the Case Could Moot the Issue.

An issue is controlling when it is "serious to the conduct of the litigation, either practically or legally." Katz, 496 F.2d at 755. An issue which could be rendered moot may have no effect on the litigation whatsoever and as such, is not a "controlling issue of law." Courts have recognized that issues which could be rendered moot by further proceedings should not be reviewed on interlocutory appeal. See In re City of Memphis, 293 F.3d at 351 (denying § 1292(b) appeal due to prospect of future developments rendering it moot); see also Stringfellow v. Concerned Neighbors in Action, 480 U.S. 370, 380 (1987) (interlocutory appeals "burden appellate courts by requiring immediate consideration of issues that may become moot or irrelevant by the end of trial."); Gen. Acquisition, Inc. v. GenCorp, Inc., 23 F.3d 1022, 1030 (6th Cir. 1994) ("The potential for a challenged ruling to be mooted by subsequent developments in the district court weighs against certification for interlocutory appeal.").

First, as noted in Agape's Petition, the crucial issue in this case, as it currently stands, is whether the Government (after declining to intervene) has unreviewable veto authority over the settlement reached by the parties. If this

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Court were to reverse the district court's *purely legal* ruling as to this issue, the district court would be free to proceed to act on its view that, given the facts of this case, "a compelling case could be made that the Government's position is not, in fact, reasonable." Ex. 2 p. 10. Thus, the district court would likely find the Government's objection unreasonable and enforce the settlement and end this case- rendering the statistical sampling issue moot.

Other future developments could also render a decision by this Court on the district court's evidentiary ruling concerning statistical sampling moot. As noted herein, Relators chose not to put forth an expert on the sampling issue nor did they propose any valid sampling methodology when moving the district court to permit statistical sampling in this case. As a result, even if this Court were to grant the Relators' Petition and reverse the district court's statistical sampling ruling, the Relators would still have to demonstrate that an expert and his sampling methodology are reliable under *Daubert*. If the Relators are unable to carry this burden, any interlocutory ruling on statistical sampling would be moot.

Second, even assuming that they survive a *Daubert* hearing, Relators still have to establish liability as to the sample claims before any liability could be extrapolated to the larger universe of claims. In the event that district court or the jury found that Relators failed to show Agape violated the FCA as to the sample

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claims, the use of sampling to estimate the number of false claims and damages in the larger universe would be moot.⁸

3. Granting the Relators' Petition for Review as to this Issue Could Lead to Successive Appeals

The granting of a petition for interlocutory review is also inappropriate when the issue sought to be appealed would have to be reviewed by the appellate court a second time following the judgment. *See Wright v. Linebarger Googan Blair & Simpson, LLP* 2012 U.S. Dist. Lexis 40948, at *20 (W.D. Tenn. Mar. 26, 2012) ("Concerns for efficiency must be balanced against the inefficiency of having the Court of Appeals hear multiple appeals in the same case.") (internal quotations and citations omitted); *Nat'l Asbestos Workers Med. Fund v. Philip Morris, Inc.*, 71 F. Supp. 2d 139, 148 (E.D.N.Y. 1999) ("[d]elaying appellate review until trial court proceedings are complete prevents multiple appeals that may ultimately prove unnecessary").

Simply put, if this Court grants the petition and overrules the district court based on the record before it, it will almost certainly be asked to review this issue again after trial. Thus, granting the Relators' petition for interlocutory appeal

⁸ Similarly, courts have denied interlocutory appeals on damages where liability has not been established. *See Gen. Acquisition, Inc.* 23 F.3d at 1031 ("Appellate review of a question of damages prior to any determination of liability puts the proverbial cart before the horse, and such certifications are clearly reversible under the law of this circuit.").

would add to, not alleviate, the time and expense of this case and place the very type of burden on this Court that the final judgment rule is intended to avoid.

B. An Appellate Decision on the Issue of Statistical Sampling Will Not Materially Advance the Litigation

The question of whether an interlocutory appeal may materially advance the termination of the litigation is "closely connected" to the question of whether there is a controlling question of law. Primavera Familienstifung v. Askin, 139 F. Supp. 2d 567, 569-570 (S.D.N.Y. 2001). In analyzing the element, courts will look to whether "early appellate review might avoid protracted and expensive litigation." North Carolina ex rel. Howes v. W.R. Peele, Sr. Trust, 889 F.Supp. 849, 852-53 (E.D.N.C. 1995); In re Va. Elec. & Power Co., 539 F.2d 357, 364 (4th Cir. 1976) (finding interlocutory appeal would advance the ultimate termination of the litigation because the decision would prevent needless waste of "much time, expense and effort"); see also White 43 F.3d at 377 ("When litigation will be conducted in substantially the same manner regardless of [the court's] decision, the appeal cannot be said to materially advance the ultimate termination of the litigation.").

Whether statistical sampling will or will not be permitted in this case will have little impact on the length or expense of this litigation. Assuming reversal of the district court, as noted earlier, Agape plans to defend each and every claim alleged as false by the Relators by calling witnesses and presenting evidence. Consequently, the trial will not be shortened even if the Relators are allowed to proceed by offering evidence of statistical sampling.

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III. Conclusion

For the foregoing reasons, Agape respectfully requests this Court deny Relators' Petition to Appeal the district court's ruling as to whether the use of statistical sampling to prove liability and/or damages is appropriate in this case. As noted above, this issue is in essence an evidentiary issue which is based on the application of law to a discreet set of facts; therefore, it is not appropriate for interlocutory appeal pursuant to 28 U.S.C. § 1292(b).

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 20, 2015, I electronically filed the foregoing Partial Opposition to Petition for Interlocutory Appeal using the Court's CM/ECF system, which constitutes service under the Court's rules. The non-participants below are being served by U.S. mail, postage prepaid and properly addressed on the 21st day of July, 2015.

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<u>s/ Mark C. Moore</u> Mark C. Moore

Exhibit 1

(Order Denying Motion to Permit the Use of Statistical Sampling)

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IN THE UNITED STATES DISTRICT COURT DISTRICT OF SOUTH CAROLINA ROCK HILL DIVISION

C/A No. 0:12-cv-03466-JFA United States of America ex rel. BRIANNA MICHAELS and AMY WHITESIDES, Relators, vs. AGAPE SENIOR COMMUNITY, INC.; AGAPE SENIOR PRIMARY CARE, INC.; AGAPE SENIOR SERVICES, INC.; AGAPE SENIOR, LLC; AGAPE MANAGEMENT SERVICES, INC.; AGAPE COMMUNITY HOSPICE, INC.; AGAPE NURSING AND ORDER REHABILITATION CENTER, INC. d/b/a AGAPE REHABILITATION OF ROCK HILL a/k/a AGAPE SENIOR POST ACUTE CARE CENTER - ROCK HILL a/k/a EBENEZER SENIOR SERVICES, LLC; AGAPE SENIOR FOUNDATION, INC.; AGAPE COMMUNITY HOSPICE OF ANDERSON, INC.; AGAPE HOSPICE OF THE PIEDMONT, INC.; AGAPE COMMUNITY HOSPICE OF THE GRAND STRAND, INC.; AGAPE COMMUNITY HOSPICE OF THE PEE DEE, INC.; AGAPE COMMUNITY HOSPICE OF THE UPSTATE, INC.; AGAPE HOSPICE HOUSE OF HORRY COUNTY, INC.; AGAPE HOSPICE HOUSE OF LAURENS, LLC; AGAPE HOSPICE HOUSE OF THE LOW COUNTRY, INC.; AGAPE HOSPICE HOUSE OF THE PIEDMONT, INC.; AGAPE **REHABILITATION OF CONWAY, INC.**; AGAPE SENIOR SERVICES FOUNDATION, INC.; AGAPE THERAPY, INC.; AGAPE HOSPICE: HOSPICE PIEDMONT; HOSPICE ROCK HILL; and CAROLINAS COMMUNITY HOSPICE, INC.,

Defendants.

Plaintiff has moved this Court to permit the use of statistical sampling in this *qui tam* action, ECF No. 166. The Court has carefully reviewed the briefs on the topic and researched the topic thoroughly. The Court heard extensive oral argument regarding statistical sampling on October 10, 2014. At the hearing, the Court took under advisement the instant motion.

After additional consideration and research on statistical sampling, the Court believes that based on the facts of this case, statistical sampling would be improper. Accordingly, the Court hereby DENIES Plaintiffs' Motion to Permit the Use of Statistical Sampling, ECF No. 166.

IT IS SO ORDERED.

March 16, 2015 Columbia, South Carolina

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Joseph F. Anderson, Jr. United States District Judge

Exhibit 2 (Redacted Order)

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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH CAROLINA ROCK HILL DIVISION

United States of America <i>ex rel.</i> , Brianna Michaels and Amy Whitesides,) C/A No. 0:12-3466-JFA)
Michaels and Amy Whitesides, Plaintiff-Relators, v. Agape Senior Community, Inc.; Agape Senior Primary Care, Inc.; Agape Senior Services, Inc.; Agape Senior, LLC; Agape Management Services, Inc.; Agape Community Hospice, Inc.; Agape Nursing and Rehabilitation Center, Inc. d/b/a Agape Rehabilitation of Rock Hill a/k/a Agape Senior Post Acute Care Center – Rock Hill a/k/a Ebenezer Senior Services, LLC; Agape Senior Foundation, Inc.; Agape Community Hospice of Anderson, Inc.; Agape Hospice of the Piedmont, Inc.; Agape Community Hospice of the Grand Strand, Inc.; Agape Community Hospice of the Pee Dee, Inc.;) C/A No. 0:12-3466-JFA)) ORDER RESOLVING TWO) INTERRELATED ISSUES AND) CERTIFICATION FOR) INTERLOCUTORY APPEAL) PURSUANT TO 28 U.S.C. § 1292(b))))))))
Agape Community Hospice of the Upstate, Inc.; Agape Hospice House of Horry)
County, Inc.; Agape Hospice House of Laurens, LLC; Agape Hospice House of the Low Country, Inc.; Agape Hospice House of the Piedmont, Inc.; Agape Rehabilitation	
of Conway, Inc.; Agape Senior Services Foundation, Inc.; Agape Therapy, Inc.; Agape Hospice; Hospice Piedmont; Hospice Rock Hill; and Carolinas Community)))
Hospice, Inc.,)
Defendants.)

)

On December 7, 2012, this *qui tam* action was initiated by Brianna Michaels and Amy Whitesides (the "Plaintiff-Relators") on behalf of themselves and the United States of America (the "Government") claiming damages and other relief under the civil False Claims Act, 31 U.S.C. § 3729, *et seq.*, the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, *et seq.*, and the Health Care Fraud Statute, 18 U.S.C. § 1347. The Government declined to intervene as a plaintiff in this action on March 5, 2013.

The Plaintiff-Relators were formerly employed at one or more of the institutions operated by the Defendants. The Defendants (collectively referred to herein as "AGAPE") consist of a network of twenty-four nursing homes located throughout South Carolina, each containing some form of "AGAPE" in their names. The Plaintiff-Relators allege that AGAPE orchestrated a widespread fraudulent scheme of submitting false claims to the federal healthcare programs of Medicare, Medicaid, and Tricare, seeking reimbursement for nursing home-related services.

At the risk of oversimplification, it can be stated that the claims asserted in this action center primarily on two types of reimbursements sought by AGAPE from the federal healthcare programs: payments related to hospice care, and payments related to what are known as "general inpatient services." As with virtually ever aspect of this case, the Plaintiff-Relators and AGAPE disagree on the total number of patients involved and the total number of claims submitted by those patients. Regardless of who is correct on this issue, the total number of claims involved in the trial will be staggering. AGAPE contends that there were 19,820 patients admitted to AGAPE's facilities during the applicable time period for

whom approximately 53,280 claims were submitted. Plaintiff-Relators contend that the patient population is only 10,166 patients, who filed a total of 61,643 claims. In any event, Plaintiff-Relators' counsel represents to the Court that they have retained two experts, each of whom receives \$400 per hour for file review. These experts estimate they spend between four and nine hours reviewing each patient's chart. Thus, the review of a single patient's services would cost between \$1,600 and \$3,600 dollars. Using the conservative figure submitted by Plaintiff-Relators (10,166 patients), this means that the total outlay for expert file review (not including depositions, trial testimony, and the like) is between \$16.2 million and \$36.5 million.¹

During discovery, it became necessary for the Court to rule on a pivotal issue regarding damages in the case. The issue involved the question of whether Plaintiff-Relators would be able to prove damages by using a statistical sampling method. This particular method would involve the careful examination of a specified percentage of randomly selected claims. If it could be proven that a certain percentage of those claims were in fact fraudulent, then Plaintiff-Relators would project that percentage on the total universe of claims submitted by AGAPE to the Government. This issue arose during discovery when the parties became engaged in a controversy regarding the designation of expert witnesses and the methodology to be used by those witnesses. It appeared to both the Court and the parties that a ruling on this critical threshold issue would significantly impact the parties' preparation for trial. Therefore, the Court received briefing on the issue, heard argument

¹ The precise figures are: at \$1,600 per patient = \$16,265,600; at \$3,600 per patient = \$36,597,600.

thereon, and concluded that it would not allow the Plaintiff-Relators to use statistical sampling in determining damages.

Shortly thereafter, the Court suggested that the parties consider conducting a "bellwether" trial as to 100 of the allegedly false claims. In a bellwether trial, a sample of cases large enough to yield reliable results is tried to a jury, after which the remainder of the case is tried to a separate jury. The outcome of the bellwether trial can often be beneficial for litigants who desire to settle such claims by providing information on the value of the remainder of the case as reflected by the jury verdict in the bellwether trial.

Use of a bellwether trial is particularly appropriate in this case because unlike large class actions, which most often involve a significant degree of overlap regarding common factual issues, each and every claim at issue in this case is fact-dependent and wholly unrelated to each and every other claim. For this reason, the representative sample of the claims associated with a smaller number of patients may easily be selected for a separate trial because those claims, and the claims assocrited in the remainder of the case, are independent of each other.

Both parties agreed to this approach, and claims relating to 95 AGAPE patients were identified for the bellwether trial. Plaintiff-Relators later voluntarily reduced this number to 38 patients. The bellwether jury trial was scheduled to begin May 5, 2015.

On November 25, 2014, the parties and the Government engaged in mediation efforts. In early January 2015, shortly before all expert reports were due, the parties again engaged in mediation, this time before United States Magistrate Judge Mary Gordon Baker. In the first mediation session, both the Government and the Plaintiff-Relators were allowed to participate. In the second mediation, the Government was not invited and did not participate.

In mid-January, the parties informed the Court that a settlement had been reached as to the entire case, with AGAPE paying the sum of

The Government promptly signaled its intention to object to the settlement, relying upon a statute, 31 U.S.C. § 3730(b)(1), which on its face gives the United States Attorney General the right to prevent a settlement even in a case where the Government has declined to intervene.

After the Government objected, the Court conducted several status conferences in an effort to see if there could be some type of amicable resolution to the matter. When these conferences proved unsuccessful, AGAPE moved to enforce the settlement. The Court heard extensive oral argument on AGAPE's motion (ECF No. 263) on June 16, 2015. The motion squarely presented the question of whether the Attorney General has an absolute, unreviewable veto over the settlement of False Claims Act cases for which the Government has declined to intervene.

During the aforementioned status conferences and during the debate on the motion to enforce the settlement, it became clear that the basis for the objection by the Government was its belief that the total potential damages to the Government in this case would be around \$25 million. The Government posits that the proposed settlement—representing percent of what the Government believes is the potential recovery at trial—is insufficient. The Government arrived at its potential recovery figure by using an "error rate" in the "20–60% range" derived from an expert review of what the Government refers to as "cherry picked" claims. While the Government's methodology for evaluating this case is not altogether clear to this Court, suffice it to say that the Government has used some form of statistical sampling extrapolated to the universe of potential claims in its damages calculation.

The Court is thus faced with a unique dilemma: The Government, claiming an unreviewable veto right over the tentative settlement in this case, objects to a settlement in a case to which it is not a party, using as a basis of its objection some form of statistical sampling that this Court has rejected for use at the trial of the case. It thus appears that these two issues—the question of veto authority of the Government, coupled with this Court's rejection of the statistical sampling model—should be certified for interlocutory appeal before the parties embark upon what could be a trial stretching as long as one year or more.

For the foregoing reasons, the Court will set out in this Order its rationale for denying AGAPE's motion to enforce the settlement, thus recognizing the Government's unreviewable veto authority, and disallowing statistical sampling as a method of proving liability or damages.

The Government's Rejection of the Proposed Settlement

The False Claims Act, 31 U.S.C. § 3729 *et seq*. ("FCA"), provides that "[An FCA *qui tam* action] may be dismissed only if the court *and the Attorney General* give written consent to the dismissal and their reasons for consenting." (emphasis added). The unambiguous language of § 3730(b)(1) thus makes the consent of the Attorney General a prerequisite to

the dismissal of an FCA action pursuant to a settlement between a relator and a defendant. The statute provides no limitation on the Attorney General's authority, and no right of this Court to review the Attorney General's objection for reasonableness. The Supreme Court has stated time and time again that "courts must presume that a legislature says in a statute what it means and means in a statute what it says there." *Dept. of Defense v. FLRA*, 510 U.S. 487, 503 (1994).

The only circuit court that has held that the Government's consent is not required after the Government declines to intervene in a case is the Ninth Circuit in *United States ex rel. Killingsworth v. Northrup Corp.*, 25 F.3d 715 (9th Cir. 1994). In *Killingsworth*, the Ninth Circuit held that the Government has unreviewable veto authority of a settlement only during the 60-day period following the filing of a *qui tam* action, during which the Government has the opportunity to elect whether to intervene. After that, according to the Ninth Circuit, the Government's veto over a *qui tam* action in which it has not intervened is subject to a reasonableness review by the court in which the action is pending. Since that decision, every circuit court to address the issue has expressly rejected *Killingsworth*.

In United States ex rel Searcy v. Philips Electronics N. Am. Corp., 117 F.3d 154, 159 (5th Cir. 1997), the Fifth Circuit found that "[t]he statutory language relied on by the government is as unambiguous as one can expect," and noted that "[u]nlike the *Killingsworth* court, we can find nothing in § 3730 to negate the plain import of this language." *Id.* Likewise, in *United States v. Health Possibilities*, *P.S.C.*, 207 F.3d 335,339 (6th Cir. 2000), the Sixth Circuit agreed with the *Searcy* court and held that a *qui tam* action cannot be settled

without the consent of the Government, even if the Government has declined to intervene. The Sixth Circuit noted that "[i]f Congress wanted to limit the consent requirement to the period before the United States makes its initial intervention decision, we presume that it knew the words to do so." *Id.* The court further stated:

"[t]here is absolutely no statutory authority for the proposition that simply because the government decides not to expend the resources to proceed with an action itself, it thereby authorizes the relator to settle the government's claims in whatever manner he wishes. Indeed, such a construction would only force the government to unnecessarily intervene in *qui tam* cases and thereby frustrate the efficacy of the *qui tam* framework."

Id. at 343 n.6.

The state of the law on this issue was concisely summarized in a recent district court decision, which also sided with the Fifth and Sixth Circuits. *United States ex rel. Landis v. Tailwind Sports Corp.*, _____F. Supp. 3d ____, No. 1:10-CV-00976 (CRC), 2015 WL 1623282 (D.D.C. Apr. 9, 2015). In *Tailwind*, the court declined to enforce a settlement over the Government's objection. In doing so, the court stated "[w]hile it might seem unfair for the Government to be able to force a relator to continue to litigate non-intervened claims that he would prefer to settle, the broader purposes of the FCA are served, at least to some extent, by a plain reading of section 3730's consent provision." *Id.* at *2. The court went on to note that, "*Killingsworth* has not fared well in the intervening years," that "[i]ts conclusion and reasoning have been expressly rejected by both the Fifth and Sixth Circuits," and that, "while neither the Supreme Court nor the D.C. Circuit has tackled the question head-on, both have indicated that the Government's consent is required for the voluntary dismissal of

non-intervened claims." *Id.* (citing *United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 932 (2009), and *Hoyte v. Am. Nat'l Red Cross*, 518 F.3d 61, 63 n.2 (D.C. Cir. 2008)).

The *qui tam* Plaintiff-Relators and AGAPE, former adversaries, have now joined together to urge the Court to accept the rationale employed in *Killingsworth*. They argue that because the Government declined to intervene in this case, any objection lodged by the Attorney General to the proposed settlement must be reviewed for reasonableness by this Court. And, according to these two former adversaries, the Government's position opposing the settlement is patently unreasonable, especially in light of the forecast by the Plaintiff-Relators that expert witness fees necessary to develop this case are between \$16.2 and \$36.5 million² for a case in which the potential recovery, according to the Government, is around \$25 million. Furthermore, the parties point out, that the Government has not offered to come forward to underwrite the cost of these expert witnesses in the forthcoming trial.

Because the statute under consideration is plain on its face and contains no limitation on the Attorney General's authority to object to a settlement in a *qui tam* action, even one in which the Government has not joined, the Court is constrained to deny the motion to enforce the settlement. In so doing, the Court adopts the rationale employed by the Fifth and Sixth Circuits in full and rejects the analysis provided in *Killingsworth*.

 $^{^{2}}$ As noted previously, the figures cited involve pretrial file review only; they do not include time for depositions and trial testimony.

Having made this determination, this Court's inquiry is at an end. It bears mention, however, that if this Court did have the authority to review an objection by the Attorney General for reasonableness in a case of this nature, a compelling case could be made here that the Government's position is not, in fact, reasonable.

As noted previously, this action has been pending since 2012. The primary attorneys for the *qui tam* Plaintiff-Relators, Terry E. Richardson, Jr., and J. Preston Strom, Jr., are both seasoned federal litigators, each having extensive experience practicing before this Court (more than 40 years for Mr. Richardson and more than 30 years for Mr. Strom, during which Mr. Strom served for several years as the United States Attorney for the District of South Carolina). They both have handled numerous class actions involving highly complex issues and national implications. Their firms are large enough to be equipped to handle the extensive discovery and myriad administrative matters presented by a case of this nature. To use the vernacular, they have both been around the litigation table long enough to "know when to hold 'em, [and] know when to fold 'em." For these reasons, the Court should not cavalierly reject their wise counsel regarding their valuation of this case.

Moreover, as noted above, this case presents between 53,000 and 61,000 individual non-related claims, each involving a fact intensive examination of the medical charts of between 10,000 and 20,000 nursing home patients. According to AGAPE, these files contain opinions of a treating physician and an in-house staff physician attesting to the medical need for the claim submitted to the Government in this case. AGAPE indicates that it may call as many as 65 physicians to testify at trial. For this reason, it will be necessary for the Plaintiff-

Relators to counter this expert physician testimony with an expert of their own, and it has been reported to this Court that the expert retained has estimated that it would require up to nine hours of review of each individual patient's file, at the rate of \$400 per hour, to adequately prepare for all of the claims in this case. If this is true, the Plaintiff-Relators could be looking at an expenditure of between \$16.2 million and \$36.5 million in pretrial preparation alone for a case that the Government values at \$25 million. The additional time required for expert depositions and trial testimony would easily push the expenses of the trial above the Government's assessment of the value of this case. And, as noted herein, at oral argument, the Government was steadfast that it should not be required to underwrite any of the costs of going forward with the trial that it demands take place.

AGAPE points to another factor which, although of less significance, bears mention here. Although the Government has not intervened in this case, it has been an active participant in the litigation from the beginning. On March 12, 2013, shortly after the Government declined to intervene in this action, a second case—*Susan Rush, et al. v. Agape Senior, LLC, et al.*, [3:13-666-JFA (D.S.C.)]—was filed in this District asserting many of the same claims asserted in this action. In *Rush*, the Government requested and received several extensions of time within which to investigate the case for the purposes of deciding whether to intervene. During this period, the Government interviewed numerous employees of AGAPE, obtained thousands of documents pursuant to Civil Investigative Demands, and opened a criminal investigation to run parallel to the civil investigation. In the *Rush* case, the Government requested permission to unseal the complaint to reveal the existence of the second *qui tam* action to Plaintiff-Relators Michaels and Whitesides in this case. That request by the Government prompted a barrage of motions by the parties in the first and second cases, each seeking to have the other dismissed on "first to file" and "public disclosure" grounds.

After the Court resolved those disputes by dismissing the *Rush* case, the Government remained actively involved in this case, attending court hearings, taking positions on various procedural matters, filing briefs on substantive issues to be decided by this Court, attending depositions, and requesting extensions of time.

AGAPE points out that even with the Government's extensive involvement in this case as outlined above, when pressed to be more specific as to how the Attorney General arrived at the potential verdict of \$25 million, the Government has declined to provide its calculations, suggesting that it is not a party to this case and is under no obligation to respond to discovery requests. The Court has reluctantly agreed with the Government that it should not be required to respond to AGAPE's motion for a precise calculation of damages, but it should be noted that, as indicated above, the Government has admitted that statistical sampling of the entire universe of claims played a major part in its calculation of the value of this case.

Plaintiff-Relators' Use of Statistical Sampling in Proving Liability and Damages

As noted previously, this issue—which in most cases would be a trial-related issue raised shortly before or during trial—presented itself to this Court when the parties became embroiled in a controversy regarding the opinions given by their respective expert witnesses. Because the question presented was a pure question of law, not dependent upon subsequent discovery, the Court proceeded to receive briefing and heard argument on the use of statistical sampling. The Court rejected the use of this damages model and held that the Plaintiff-Relators would be required to prove each and every claim based upon the evidence relating to that particular claim. The Court's rationale is as follows.

The question whether to allow the Plaintiff-Relators to prove damages using statistical sampling that has been recognized by some courts is by far the most difficult one presented in this case. After carefully canvassing the decisions on each side of the issue, and giving careful consideration to the nature of the claims asserted here, the Court has ultimately determined that statistical sampling should not be allowed.

At the outset, it should be noted that this case is not one where the evidence has dissipated, thus rendering direct proof of damages impossible. Indeed, this Court recently handled a totally unrelated *qui tam* action where statistical sampling represented the only way the plaintiff-relators could prove damages. In that case, the allegations were that a company employed to move the household belongings of army personnel had submitted fraudulent claims to the government by artificially bumping the weight of each shipment so as to fraudulently increase the amount charged for the shipment. Two employees of the defendant came forward to report the alleged weight bumping, and a quick investigation revealed some discrepancies with shipments then in process. The problem in that case, however, was that for the vast majority of the claims, the shipments had been completed and

the belongings unpacked, thus rendering it impossible to determine if weight bumping had occurred.

Moreover, the defendant had also packed, shipped, and stored on a long-term basis, the household belongings of military personnel overseas. This provided the parties with the opportunity to sample those long-term storage units and, assuming that the sampling was supported by appropriate expert testimony, extrapolating the percentage of weight bumping discovered in the sample to the universe of claims filed by the defendant.

That case settled before the Court was given the opportunity to rule on the statistical sampling question, but it suffices for an illustration of why statistical sampling is sometimes the only way for a *qui tam* plaintiff-relator to prove damages. To disallow statistical sampling in cases of that nature would allow widespread fraud to go unpunished.

By contrast, nothing has been destroyed or dissipated in this case. The patients' medical charts are all intact and available for review by either party.

In United States v. Friedman, No. 86-0610-MA, 1993 U.S. Dist. LEXIS 21496 (D. Mass. July 23, 1993), the court declined to allow statistical sampling "based on the existence at trial of discrete claims that may be analyzed, discussed, and subjected to cross-examination." This Court agrees with the analysis provided by the District Court in *Friedman*.

AGAPE has cited numerous cases where a court refused to allow statistical sampling and extrapolation to prove damages or liability in an FCA action. *See United States ex rel. Crews v. NCS Healthcare of Illinois, Inc.*, 460 F.3d 853, 857 (7th Cir. 2006) (rejecting relator's attempt to establish FCA liability based upon percentages rather than proof of actual false claims); *United States ex rel. El-Amin v. George Washington Univ.*, 533 F. Supp. 2d 12, 31 n.9 (D.D.C. 2008) (requiring the relators to set forth specific evidence for each individual claim); *United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25, 66 (D.D.C. 2007) (court held that it is "imperative for [R]elator[s] to produce real evidence to support [their] contention[s]. . . ."); *United States v. Medco Physicians Unlimited*, No. 98-C-1622, 2000 U.S. Dist. LEXIS 5843, at *23 (N.D. Ill. Mar. 15, 2000) (declining to allow statistical sampling and explaining that the parties provided "no case law or other authority to support such a request"); *United States ex rel. Trim v. McKean*, 31 F. Supp. 2d 1308, 1314 (W.D. Okla. 1998) (declining to allow a statistical sample "to find a percentage of false claims from *all* claims submitted by [defendant]....").

In contrast, the Plaintiff-Relators and the Government provided a number of cases where a court permitted statistical sampling and extrapolation to prove damages (and sometimes liability) in an FCA action.³ *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir.

³ Other cases exist outside the realm of *qui tam* actions. The Government cites to a number of cases to support statistical extrapolation for the recoupment of Medicare overpayments; however, the Court is unpersuaded by the cited recoupment cases because each case involved a Government audit that established the amount of overpayments. *Illinois Physicians Union v. Miller*, 675 F.2d 151, 152 (7th Cir. 1982); *Webb v. Shalala*, 49 F. Supp. 2d 1114, 1125 (W.D. Ark. 1999).

Health Care Financing Administration Ruling 86-1 "provides for the use of statistical sampling to project overpayments when claims are voluminous and reflect a pattern of erroneous billing or overutilization and when a case-by-case review is not administratively feasible." *Webb*, 49 F. Supp. 2d at 1120 (citing HCFA Ruling 86-1). When a provider receives Medicare reimbursements, the provider agrees to allow the government to audit these payments in order to "identify and correct Medicare improper payments through the efficient detection and collection of overpayments made on claims of health care services provided to Medicare beneficiaries." *Recovery Audit Program*, CENTERS FOR MEDICARE & MEDICAID SERVICES, http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/ (last visited June 23, 2015).

2008) (appellate court rejected the argument that the district court had to address each of the 1,812 claims at issue and held that "[s]tatistical analysis should suffice;" however, all 1.812 claims were objectively false); United States ex rel. Ruckh v. Genoa Healthcare, LLC, No. 8:11-CV-1303-T-23TBM, 2015 WL 1926417, at *3 (M.D. Fla. Apr. 28, 2015) (district court expressed an inclination to allowing statistical sampling and extrapolation by rejecting Friedman and explaining that Friedman does not stand for the proposition that statistical sampling cannot be used in large-scale qui tam cases); United States ex rel. Martin v. Life Care Ctrs. of Am., Inc., Nos. 1:08-cv-251, 1:12-cv-64, 2014 U.S. Dist. LEXIS 142660 (E.D. Tenn. Sept. 29, 2014) (same); United States v. Fadul, No. CIV.A.DKA 11-0385, 2013 WL 781614, at *2 (D. Md., Feb., 28, 2013) (finding the extrapolation method acceptable for Medicare and Medicaid claims under common law theory of payment by mistake); United States v. Chen, No. 2:04-cv-00859, 2009 WL 1683142 (D. Nev. 2009) (jury found physician liable under the FCA for submitting 3,544 false claims, but parties only analyzed 37 claims at trial after the physician conceded that the referral request and services provided were the same for each of these claims); United States ex rel. Loughren v. UnumProvident Corp., 604 F. Supp. 2d 259, 263 (D. Mass. 2009) (extrapolation is a reasonable method for determining the number of false claims so long as the statistical

Sampling used in the administrative context of a recoupment case is distinct from using sampling to prove an FCA claim. In a recoupment action by an administrative agency, the burden is on the recipient to prove entitlement to monies and recovery is limited to the amount overpaid and interest. The FCA places the burden of proof on the relator under 31 U.S.C. § 3731(d); the defendant is liable for up to three times the amount of damages proven by the relator plus civil penalties for each false claim under 31 U.S.C. § 3729(a)(1)(G). The bottom line of the relied upon recoupment cases is that the Government audit on the claims essentially established false claim liability in any subsequent *qui tam* action.

methodology is appropriate); *United States ex rel. Barron v. Deloitte & Touche, LLP*, Civil No. SA-99-CA-1093-FB, 2008 WL 7136869, *2 (W.D. Tex. Sept. 26, 2008) (in a *Daubert* hearing, the court excluded the statistician's testimony, but recognized the relevance of statistical evidence); *United States ex rel. Doe v. DeGregorio*, 510 F. Supp. 2d 877, 890 (M.D. Fla. 2007) (court relied on an extrapolated overpayment figure derived from a prior Government audit when calculating the pre-judgment remedy figure in the subsequent FCA action); *United States v. Cabrera-Diaz*, 106 F. Supp. 2d 234, 242 (D.P.R. 2000) (court entered default judgment against defendants for treble the damages sustained based off the estimated overpayments that a prior Government audit revealed); *United States v. Krizek*, 859 F. Supp. 5, 7 (D.D.C. 1994) *supplemented*, 909 F. Supp. 32 (D.D.C. 1995) *aff'd in part and remanded*, 111 F.3d 934 (D.C. Cir. 1997) (physician agreed upon sampling process to prove liability of the 8,002 potentially false claims, appellate court agreed that physician consented to sampling).

As can readily be seen, the cases are legion on each side of the issue, and ultimately, it is this Court's responsibility to determine the fairest course of action based upon the facts presented and the claims asserted in this case. Distilled to its essence, each claim asserted here presents the question of whether certain services furnished to nursing home patients were medically necessary. Answering that question for each of the patients involved in this action is highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patient. As the Court has acknowledged, some cases are suited for statistical sampling and, indeed, in many cases that method is the only way that damages may be proved. This civil action, however, is not such a case.⁴

The Need for Certification of These Two Interrelated Issues

As can be seen from the discussion in this Order, the question of whether the Government should be allowed to reject a settlement in a case for which it has not intervened, while relying upon a damages model that this Court has rejected for purposes of trial, presents a unique development that cries out for interlocutory appeal in this case. If the Attorney General's objection is overturned by the Court of Appeals and, upon remand, this Court determines that the objection is unreasonable, this case will end with an amicable settlement. If, on the other hand, the Government's veto is upheld by this Court, and the case proceeds without the use of statistical sampling in determining damages, the parties in this action face a trial of monumental proportions, involving a staggering outlay of expenses by the Plaintiff-Relators and a significant drain of the resources of this Court, which would possibly be unnecessary if this Court's determination to reject statistical sampling were to be reversed. It would be much more judicially efficient to have a ruling on both of the questions before, rather than after, such a monumental trial.

⁴ At oral argument on the motion relating to statistical sampling, Defendants argued that the use of such a procedure would deprive them of their constitutional right to a jury trial. They also served notice that, even if the Court allowed statistical sampling, in their case-in-chief, the Defendants would delve into the medical issues involved in each and every claim for which the Plaintiff-Relators seek recovery, thereby insuring that the statistical sampling would not significantly shorten the trial.

For the foregoing reasons, the Court will certify its ruling on the two questions addressed in this order, to wit: (1) the Government's right to reject a settlement in a *qui tam* action to which it has not intervened; and (2) the Plaintiff-Relators' use of statistical sampling to prove liability and damages, for interlocutory appeal, pursuant to 28 U.S.C.

§ 1292(b). That statute provides that:

When a district judge, in making in a civil action an order not otherwise appealable under this section, shall be of the opinion that such order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation, he shall so state in writing in such order. The Court of Appeals which would have jurisdiction of an appeal of such action may thereupon, in its discretion, permit an appeal to be taken from such order, if application is made to it within ten days after the entry of the order.

28 U.S.C. § 1292(b).

Pursuant to the above quoted provision of § 1292, this Court hereby certifies that its decision on the two issues addressed in this Order involve a controlling question of law as to which there is substantial ground for difference of opinion, and that an immediate appeal from this Order may materially advance the ultimate termination of this litigation.

The parties are implored to seek permission from the Fourth Circuit Court of Appeals to review these two issues within ten days from the date of this Order so as to promote the wise use of judicial resources and potentially avoid undue cost to the parties.

IT IS SO ORDERED.

June 25, 2015 Columbia, South Carolina

Joseph F. anderson, J.

Joseph F. Anderson, Jr. United States District Judge