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Client Alert Commentary

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Fourth Circuit Declines to Address Use of Statistical Sampling in False Claims Act Cases

Court of Appeals panel rules use of statistical sampling is inappropriate for interlocutory appeal, leaving FCA litigants without any direct appellate court guidance.

In the closely watched case *United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, the U.S. Court of Appeals for the Fourth Circuit declined to address a key issue for False Claims Act (FCA) litigants — whether plaintiffs may use statistical sampling and extrapolation to establish the extent of liability and/or damages in FCA cases. The use of extrapolation is hotly contested among FCA defendants and plaintiffs (which can either be the Department of Justice or private individuals known as relators) in cases involving a large number of claims or transactions. This controversial method allows FCA plaintiffs to "prove" liability or damages only for those claims in a sample, thus avoiding the burden of establishing liability for what could be thousands of other similar claims on a claim-by-claim basis. While beneficial for plaintiffs, this approach strips defendants of the power to contest allegations concerning claims outside the sample.

FCA defendants had hoped that the Fourth Circuit in *Agape* would affirm the district court's ruling that statistical sampling was inappropriate under the facts of that case, and perhaps hold more generally that the use of this methodology is inconsistent with the FCA. See Latham's *Client Alert*, Fourth Circuit May Address Use of Statistical Sampling in False Claims Act Cases. The Fourth Circuit's refusal to rule means that FCA defendants, plaintiffs and district court judges alike must continue to navigate this issue without any bright-line rules.

Fourth Circuit Ruling in *Agape*

In *Agape*, the Relators alleged that a network of nursing home facilities submitted claims for medically unnecessary services as part of a scheme to defraud the Government.[1] The Relators wanted to use statistical sampling to establish that more than 50,000 claims submitted to federal healthcare programs were false.[2] The Relators claimed reviewing patient charts related to every claim to identify which claims included medically unnecessary services would be time-consuming and cost-prohibitive.[3] The Relators told the district court their experts would require four to nine hours to review each chart. With experts charging US$400 per hour, the Relators estimated this effort would cost more than US$36 million.[4]

The U.S. District Court for the District of South Carolina ruled that while statistical sampling may be appropriate in certain circumstances, it was improper under the facts of this case.[5] The district court reasoned that each alleged false claim required a highly fact-intensive inquiry regarding whether the claim was medically necessary and relevant evidence for each claim had not dissipated or been destroyed.[6] The court recognized, however, that this ruling meant the Relators faced a "staggering" outlay of time and money and a trial of "monumental" proportions.[7]

Acting on its own, or "*sua sponte*," the district court decided that pre-trial appellate review of this ruling was needed.[8] Accordingly, the district court certified its decision for interlocutory appeal and the Fourth

Circuit accepted the appeal, raising expectations that a ruling on the propriety of statistical sampling evidence in FCA cases would be forthcoming.

The Fourth Circuit panel surprised many by dismissing the appeal as "improvidently granted." The court ruled that whether statistical sampling could be used in *Agape* was not an issue of controlling law, but instead a question of fact within the discretion of the district court.[9]

No Bright Lines for FCA Litigants or District Court Judges

With no bright-line rules, little appellate guidance on the issue,[10] and high stakes involved on both sides, the use of statistical sampling and extrapolation will remain hotly contested in FCA cases. For defendants, the use of sampling to establish FCA liability — and the potential for an exponential growth of damages and civil penalties — may encourage settlement of meritless cases to avoid the risk of massive financial liability. For FCA plaintiffs, prohibiting statistical sampling may require investing "staggering" proportions to develop the evidence needed to prevail at trial. This expense could lead relators to curtail their efforts or even walk away from meritorious cases.

District courts have been disinclined to rule broadly that statistical sampling is not permissible under the FCA, even though the FCA does not authorize a "trial by formula" and in fact, requires plaintiffs to prove the falsity of every claim and the resulting damage. Instead, district courts that have rejected attempts to use statistical sampling have focused on the facts of each case, such as whether essential evidence (*e.g.* a group of patient records) is available for use in a claim-by-claim review. Trial courts have also considered whether the medical services in question required the exercise of medical judgment. The district court in *Agape* ruled that while statistical sampling may be permissible in FCA cases, sampling was not permissible under the circumstances of that case. The fraud allegations were based on determinations of medical necessity that were highly fact-specific for each claim, requiring a review of the medical chart of each individual patient and expert medical testimony to determine whether care provided to a particular patient failed to meet relevant medical necessity requirements.[11] The court also recognized that patient records were available for review, stating that "nothing has been destroyed or dissipated in this case. The patients' medical charts are all intact and available for review by either party."[12]

The U.S. District Court for the Northern District of Texas acknowledged in *United States ex rel. Wall v. Vista Hospice Care, Inc*., that "[s]ome district courts have allowed extrapolation in similar circumstances"[13] but held that "[g]iven the nature of the underlying data, the nature of liability under the FCA, and [the expert's] failure to select a random sample or to account for relevant variables, [the expert's] extrapolation is unreliable, even if it is assumed to be generally allowable."[14] Statistical sampling "cannot establish liability for fraud in submitting [hospice benefit] claims for ineligible patients, as the underlying determination of eligibility for hospice is inherently subjective, patient-specific, and dependent on the judgment of involved physicians."[15] As such, the Relator's statistical evidence was not reliable for proving that false claims were submitted.[16] The court further held that if evaluating the patient charts for the 12,000 claims at issue were impracticable, the Relator could bring claims within a smaller scope. The court determined the Relator's choice to "pursue all potential false claims submitted in fourteen states over nearly a decade, of which she did not have personal knowledge"[17] did not reduce the Relator's burden to prove her case.

Other district courts addressing statistical sampling in the context of medical necessity cases have reached different conclusions. While recognizing the drawbacks of using statistical sampling, particularly at the liability phase, these courts nevertheless permitted the use of these techniques in light of the practical burdens a claim-by-claim review imposes. In *United States v. Life Care Centers of America, Inc*., the U.S. District Court for the Eastern District of Tennessee recognized that the use of "statistical

sampling to find liability for extrapolated claims could be in conflict with the Government's evidentiary burden to establish the elements of a FCA claim."[18] The court recognized certain individualized factors affect an analysis of each patient's care — such as age, gender, reason for hospitalization, etc. The court nonetheless concluded that the "the fact that these factors exist and are likely unique to each patient does not necessarily preclude the use of statistical sampling"[19] and that the "purpose of the FCA as well as the development and expansion of government programs as to which it may be employed support the use of statistical sampling in complex FCA actions where a claim-by-claim review is impracticable."[20]

In *United States v. AseraCare, Inc*., the U.S. District Court for the Northern District of Alabama permitted the Government's use of sampling to prove the falsity of hospice eligibility certifications, but emphasized that the jury should determine the appropriate "weight to be accorded ... the Government's statistical evidence."[21] At the trial, the district court further took the unusual step of bifurcating the trial into two phases — the first phase addressing only whether any of the claims in the sample were, in fact, false claims.[22] Thus, while certain courts have been willing to allow statistical sampling in the FCA context, they have recognized the importance of implementing procedural safeguards and providing opportunities for defendants to challenge the statistical sampling analysis as applied to their case.[23]

This case-by-case approach is consistent with the U.S. Supreme Court's recent ruling in *Tyson Foods, Inc. v. Bouaphakeo*, approving the use of statistical sampling to certify a class in a Fair Labor Standards Act class action lawsuit. There the Supreme Court rejected a broad categorical rule for using statistical evidence in class actions, holding instead that "the ability to use a representative sample to establish classwide liability will depend on the purpose for which the sample is being introduced and on the underlying cause of action."[24] If *Tyson Foods* is any indication of a future appellate ruling on sampling in the FCA context, no bright-line prohibition is in sight.

Conclusion

In the absence of direct appellate guidance, FCA litigants face an unpredictable future, subject to the exercise of discretion by a particular judge about whether the use of sampling will be permitted in a particular case. While we can expect the Government and relators to pursue statistical sampling to ease their burden, defendants, like those in *Agape*, should contest vigorously the use of statistical sampling, especially if liability turns on the individual circumstance of each claim and if ample evidence supporting the claims may be examined. Furthermore, defendants and potential defendants in FCA cases that could involve thousands of claims should closely monitor how district courts around the nation address this topic. Eventually, one of those cases will progress to an appeal and an appellate court will issue the guidance hoped for in *Agape*.

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Endnotes

[1] *United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. 15-2145, 2017 WL 588356, at *1 (4th Cir. Feb. 14, 2017).

[2] *Id.* at *2.

[3] Reply Brief of Intervenor-Appellee at 9-12, *United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. 15-2145, 2017 WL 588356 (4th Cir. Feb. 14, 2017).

[4] *Agape Senior Cmty., Inc.*, 2017 WL 588356 at *2.

[5] *United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. 0:12-3466-JFA, 2015 WL 3903675, at *8 (D.S.C. June 25, 2015), *order corrected*, No. 0:12-3466-JFA, 2015 WL 4128919 (D.S.C. July 6, 2015).

[6] *Id.* at *7-8.

[7] *Id.* at *8.

[8] *Id.* at *8-9.

[9] *Agape Senior Cmty., Inc.*, 2017 WL 588356 at *8 (citing 28 U.S.C. § 1292(b)).

[10] A few appellate decisions have discussed the use of statistical sampling and extrapolation in the context of the FCA, though only indirectly. In *United States v. Rogan*, the Seventh Circuit included a parenthetical approving its use by stating that the Defendant's "argument that the district judge had to address each of the 1,812 claim forms is a formula for paralysis. Statistical analysis should suffice." 517 F.3d 449, 453 (7th Cir. 2008). Yet two years earlier the Seventh Circuit affirmed the district court's ruling that the Relator failed to submit proof of a single false claim because she did not tie a single allegedly illegally recycled and redistributed pill to a claim submitted to a Government payor. *United States ex rel. Crews v. NCS Healthcare of Illinois, Inc.*, 460 F.3d 853, 857 (7th Cir. 2006). The Seventh Circuit rejected the Relator's attempt to avoid a claim-by-claim analysis, opining that this "argument…defies common sense and the plain language of the FCA," noting that this was not a circumstance where the Defendant purposefully destroyed the evidence.

[11] *Agape Senior Cmty., Inc.*, 2015 WL 3903675 at *8.

[12] *Id.* at *7.

[13] *United States v. Vista Hospice Care, Inc.*, No. 3:07-CV-00604-M, 2016 WL 3449833, at *11 (N.D. Tex. June 20, 2016).

[14] *Id.* at *14.

[15] *Id.* at *11.

[16] *Id.* at *13.

[17] *Id.*

[18] *United States v. Life Care Centers of Am., Inc*., 114 F. Supp. 3d 549, 563 (E.D. Tenn. 2014).

[19] *Id.* at 566.

[20] *Id.* at 571; *see also United States v. Robinson*, No. 13-CV-27-GFVT, 2015 WL 1479396, at *11 (E.D. Ky. Mar. 31, 2015) (permitting the Government to use statistical sampling to calculate damages, reasoning that "[t]o require the United States to present individual evidence on each one of the 25,799 claims at issue would be unreasonable, likely impossible, and a waste of resources" and "would frustrate the purposes of the FCA because it would likely encourage anyone who fraudulently submitted claims to Medicare to do so in extremely large quantities so as to prevent the Government from logistically being able to bring suit").

[21] *United States v. AseraCare Inc*., No. 2:12-CV-245-KOB, 2014 WL 6879254, at *10 (N.D. Ala. Dec. 4, 2014), *opinion vacated and superseded sub nom. United States v. AseraCare Inc.*, No. 2:12-CV-245-KOB, 2014 WL 12593996 (N.D. Ala. Dec. 19, 2014).

[22] *United States v. AseraCare, Inc.*, No. 2:12-CV-KOB, 2015 WL 12830401, at *2 (N.D. Ala. May 20, 2015).

[23] *United States ex rel. Guardiola v. Renown Health*, No. 3:12-CV-0295-LRH (VPC), 2014 WL 5780426, at *2 (D. Nev. Nov. 5, 2014) (allowing a statistical sampling plan in the discovery phase, but noting that "ruling on the admissibility or use of statistical sampling will no doubt be debated later at the pre-trial stage of this case"); Order on Motion to Exclude, *United States of America v. Prime Healthcare Services, Inc.*, No. CV-11-8214 PJW (C.D. Cal. Jan. 13, 2017) (denying the Defendant's motion to exclude the Government's statistical evidence to prove its case, but noting that the Defendant could renew its motion once it was clear how the Government intended to use such evidence).

[24] *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1040, 194 L. Ed. 2d 124 (2016).