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FEATURE COMMENT: Extrapolation In FCA Litigation: A Statistical Anomaly Or A Tactic Here To Stay?

On Sept. 29, 2015, the Fourth Circuit agreed to hear an interlocutory appeal in *U.S. ex rel. Michaels et al. v. Agape Sr. Cmty., Inc.*, No. 15-238 (L) (0:12-cv-03466-JFA) (4th Cir. Sept. 29, 2015), on the issue of whether extrapolation can be used to prove both damages and liability under the False Claims Act (FCA), 31 USCA § 3729 et seq. Extrapolation is a statistical method in which a sample of data is used to draw inferences about a larger population. Statistical sampling has been regularly used in other areas of complex litigation, such as mass torts, antitrust, voting rights and employment discrimination cases. Its use in FCA cases, however, has generally been limited to calculating damages. This changed in 2014, when the U.S. District Court for the Eastern District of Tennessee opened the door for plaintiffs to argue that sampling should be used not only to calculate damages but also for establishing the underlying FCA liability. *U.S. ex rel. Martin v. Life Care Ctrs.*, 2014 WL 10937088 (E.D. Tenn. Sept. 29, 2014).

The *Life Care* ruling has led to growing concern within the FCA defense bar that statistical sampling will relieve plaintiffs of the burden of proving the prima facie elements for each alleged false claim for payment. By agreeing to hear the *Agape* appeal, the Fourth Circuit will be the first appellate court to rule on this controversial issue. Even though the underlying facts in the *Agape* case arise out of the health care context, the Fourth Circuit's ruling will impact the procurement industry in cases where the volume of claims at issue makes individual

examination of claims impractical. For example, a plaintiff might use statistical sampling in a case where a contractor is alleged to have provided sub-standard products because parts were not tested in the manner claimed by the contractor. Because of the large number of Government contractors within its jurisdiction, the Fourth Circuit's ruling could have a profound impact on the procurement community, and the court's ruling has the potential to shape this unsettled area of the law.

The Origins of Extrapolation—The *Life Care* ruling caught the attention of FCA practitioners because it extends the historically accepted use of statistical sampling in garden-variety cases to the FCA, which attaches liability to every “false claim” that is submitted, thereby putting the burden on the plaintiff to prove the falsity of every claim that is submitted. The use of statistical sampling in non-FCA cases traces back to the 1920s when litigants first attempted to use sampling as evidence of liability. See *Elgin Nat'l Watch Co. v. Elgin Clock Co.*, 26 F.2d 376, 377 (D. Del. 1928).

Prior to the *Life Care* ruling, sampling has rarely been used in FCA cases, and it has never been used at trial—without the consent of the defendant—to prove liability. For example, one court relied on an extrapolated overpayment figure derived from a prior Government audit when calculating the pre-judgment writ of attachment. *U.S. ex rel. Doe v. DeGregorio*, 510 F. Supp. 2d 877, 890 (M.D. Fla. 2007). In another case, the defendant consented to the use of sampling at trial. *U.S. v. Krizek*, 859 F. Supp. 5, 7 (D.D.C. 1994), *aff'd in part and remanded*, 111 F.3d 934 (D.C. Cir. 1997). Lastly, sampling was used to determine damages in two cases where defendants did not contest liability. *U.S. v. Cabrera-Diaz*, 106 F. Supp. 2d 234, 240 (D.P.R. 2000) (calculating damages based on an extrapolation of audited claims following the entry of a default judgment); *U.S. v. Fadul*, 2013 WL 781614, at *8 (D. Md. Feb. 28, 2013) (allowing sampling to calculate the judgment against a defendant cardiologist who did not oppose the Government's

motion for summary judgment). In allowing the use of sampling to calculate damages, the *Fadul* and *Cabrera-Diaz* courts looked to the well-established use of sampling in the administrative context, where, for example, statistical sampling is used in administrative decisions regarding overpayments. See Office of the Inspector General of the U.S. Department of Health & Human Services, RAT-STATS Statistical Software, available for download at www.oig.hhs.gov/compliance/rat-stats/index.as?. While the *Fadul* and *Cabrera-Diaz* decisions allowed the use of sampling to determine damages, the *Life Care* decision changed the paradigm by concluding that sampling could be used not just for determining damages but for establishing the element of falsity at trial without the defendant's consent.

Divergent Rulings on Sampling—In *Life Care*, the Government alleged that the nursing home operator violated the FCA by inflating Resource Utilization Group classifications in order to charge Medicare for unnecessary services. The Government argued that the case involved too many claims to litigate on a claim-by-claim basis, and so the Government proposed using a random sample of 400 patient admissions to extrapolate the number of fraudulent claims across the total population of more than 150,000 claims. *Life Care* moved for partial summary judgment, arguing that the Government could not prove liability as to the claims outside the sample merely by extrapolation and that permitting extrapolation would violate its right to due process. *Life Care*, 2014 WL 10937088 at *17. In its opinion, the court recognized that “using extrapolation to establish damages when liability has been proven is different than using extrapolation to establish liability.” *Id.* at *11. Despite this recognized distinction, the court found that judicial precedent and the FCA's legislative history did not prohibit the use of statistical sampling to prove liability. The court denied defendant's motion for partial summary judgment and the subsequent motion for certification for interlocutory appeal. The trial is currently scheduled for June 2017.

Among the reasons for its decision to deny partial summary judgment, the court noted the public policy considerations that weigh in favor of statistical sampling. The court expressed concern that limiting FCA enforcement to a claim-by-claim review would “open the door to more fraudulent activity” because in some instances an individualized claim review would be impossible, and therefore the FCA's deterrent effect

would be circumscribed. *Id.* at *18. It is true that the expense of trying a case with a large volume of claims could dissuade relators from bringing a qui tam action that they might otherwise bring, but this concern may be over-stated because the statute entitles successful relators to recover costs associated with bringing the action. 31 USCA § 3730(d).

In *Agape*, the U.S. District Court for the District of South Carolina considered a similar fact pattern, but reached the opposite result on the issue of statistical sampling. *U.S. ex rel. Michales v. Agape Sr. Cmty., Inc.*, 2015 WL 3903675, (D.S.C. June 25, 2015). In that case, a chain of South Carolina nursing homes is alleged to have submitted fraudulent claims to Medicare and Medicaid for care that was not medically necessary. During discovery, relators argued that because of the large number of claims at issue, their experts should review a small percentage of the claims, determine what percentage of those claims were not medically necessary and extrapolate across the population of submitted claims to determine the total number of medically unnecessary claims to demonstrate both FCA liability and damages.

Unlike in *Life Care*, the court did not allow for sampling, and instead recommended that the parties conduct a bellwether trial using 100 of the allegedly false claims. The parties agreed to the bellwether trial, but settled the case for \$2.5 million before the start of trial. The Government, although it did not intervene, objected to the settlement on the grounds that it believed the case to be worth \$25 million, a number it determined by using statistical sampling. The relators then moved to enforce the settlement, and the court considered both the Government's rejection of the proposed settlement and the use of statistical sampling in proving liability and damages.

In rejecting the use of statistical sampling, the court emphasized the “highly fact-intensive inquiry” that an expert has to make when making a medical necessity determination. *Id.* at *8. Moreover, the court found that use of statistical sampling would not necessarily insure a shorter trial because even if the court allowed relators to use sampling in their case-in-chief, the defendant was entitled to introduce evidence about claims outside the sample. The court did not go so far as to say that sampling would never be appropriate and reasoned that statistical sampling would be proper in select circumstances such as cases in which “evidence has dissipated” and “direct proof of damages [is] impossible.” *Id.* at *6. But the court noted that the case before it did

not present a situation where the relevant evidence was unavailable and statistical sampling presented the only possible method of proof. Recognizing that the sampling issue was central to the case, the court certified its ruling for interlocutory appeal.

Litigating Cases with Sampling—Until this area of the law is settled, defendants should be prepared to challenge a plaintiff’s proposed use of statistical sampling at several stages of the litigation. At the pleading stage, defendants should consider making arguments under Federal Rule of Civil Procedure 9(b) that plaintiffs have failed to allege fraud with particularity by failing to identify the submission of *individual* false claims. The availability of this argument depends on where the case is being litigated because the circuits apply different standards in terms of the degree of particularity that must be pled about the submission of specific false claims, and at least one court has recognized that “in FCA cases involving complex fraud schemes pleading by statistical sample is permitted under Rule 9(b).” *U.S. ex rel. Head v. Kane Co.*, 798 F. Supp. 2d 186, 204, n.28 (D.D.C. 2011). But even if this argument falls short at the pleading stage, it lays the groundwork for summary judgment arguments that sampling subverts the individualized claim-by-claim proof required under the FCA. The success of this argument may turn in part on the availability of evidence as well as the number of claims at issue.

Even if FCA defendants fail to defeat sampling at the summary judgment stage, defendants get another bite at the apple in pretrial motions when they can mount evidentiary attacks by filing *Daubert* motions challenging the size, randomness, precision and representativeness of the plaintiff’s sampling plan. This point was underscored in the recent decision of *U.S. ex rel. Ruckh v. Genoa Healthcare LLC et al.*, 2015 WL 1926417 (M.D. Fla. April 28, 2015), in which the court stated that there is no universal ban on statistical sampling in *qui tam* actions but that *Daubert* motions could exclude an expert’s sampling analysis because of defects in the methodology or sample. Indeed, this approach proved successful in *U.S. ex rel. Loughren v. UnumProvident Corp.* when the defendant moved, under Federal Rule of Evidence 702, to exclude plaintiff’s proposed expert testimony by a statistician on the number of false claims. 604 F.Supp.2d 259, 263 (D. Mass. 2009).

If defendants are unsuccessful at excluding the sampling evidence, they will want to introduce competing testimony from their own statistical expert to

challenge the plaintiff’s methodology. In *Life Care*, the court highlighted the fact that it could not “control the weight that the fact finder may accord to the extrapolated evidence,” and noted that *Life Care* could challenge the Government’s use of extrapolation through cross-examination of the Government’s expert and by introducing competing testimony from *Life Care*’s own witnesses. 2014 WL 10937088, at *19.

Even if a court allows a plaintiff to use sampling, plaintiffs must still prove all the *prima facie* elements. For example, in *Life Care*, the Government represented that it intended to prove the scienter element by introducing pattern and practice evidence that *Life Care* knowingly caused the submission of the false claims within the sample. As such, defendants facing the use of statistical sampling to prove liability might consider the unorthodox tactic of moving for the bifurcation of issues, a motion granted by the court in *U.S. v. AseraCare Inc.*, No. 2:12-CV-245-KOB (N.D. Ala. May 20, 2015). In *AseraCare*, the court ruled that the Government’s proposal to present statistical evidence from a sampling of claims reviewed by an expert would provide sufficient evidence of falsity to defeat summary judgment and denied *AseraCare*’s motion for partial summary judgment. This pretrial ruling gave the Government an opening to put on evidence about a random sample of 123 patients drawn from a population of 2,181 patients. The Government, however, still needed to prove the elements of scienter and materiality and planned on introducing pattern and practice evidence about the company’s marketing practices that included some highly prejudicial internal communications about the need to fill hospice beds by “trolling” in poor neighborhoods to enroll patients. This led the court to make the unprecedented decision to bifurcate the falsity element and the remaining elements of scienter and materiality into two separate trials.

In bifurcating the trial, the court agreed that allowing information about the company’s marketing practices would be unduly prejudicial to *AseraCare* and ruled that the Government could not present evidence of general corporate practices during the phase one trial focused on falsity. A likely evidentiary concern underlying the bifurcation order was the court’s prior pretrial ruling authorizing the use of statistical sampling and extrapolation to prove falsity. The bifurcation order can be viewed as a measure to level the playing field by preventing the Government from introducing evidence—not relevant to falsity—

that could improperly affect the jury's determination of whether the claims within the sample were false. At the conclusion of the phase one trial, the jury found that false claims were submitted for 104 of these sample patients. Soon after, however, the court granted defendant's motion for a new trial, holding that it should have instructed the jury, as requested by defendant, that the FCA requires proof of an objective falsehood and that a mere difference of opinion among medical experts is not enough to show falsity. (*U.S. v. AseraCare Inc.*, 2015 WL 8486874 at *12 (N.D. Ala. Nov. 3, 2015).)

Conclusion— A ruling in the *Agape* case is expected by June 2016. If the Fourth Circuit affirms the district court's ruling, the FCA defense bar will surely welcome the precedent in this unsettled area of the law. If the Fourth Circuit reverses and allows sampling in cases where individualized evidence is available, it is likely that the Government and relators will bring more FCA cases as they will be able to rely on sampling to support their case-in-chief. In response, defendants will rely heavily on evidentiary motions to restrict the use of sampling and will put on competing expert testimony to undermine the weight afforded to the evidence by the jury. In short, the Fourth Circuit's decision could have a profound impact on the number and types of FCA cases brought and the way in which the cases are litigated.



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