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FEATURE COMMENT: Making Fuzzy Math Less Fuzzy—A Practical Guide For Litigating And Winning False Claims Act Cases Involving Statistical Sampling

The False Claims Act has become a powerful tool for recovering government payments from healthcare providers, federally insured mortgage originators, defense contractors, and other private businesses that engage in activities sponsored or regulated by the federal or state governments. Aggregate recoveries under the federal FCA have increased dramatically in the last decade. Press Release, Dept. of Justice, Justice Department Recovers over \$4.7 Billion from False Claims Act Cases in Fiscal Year 2016 (Dec. 14, 2016), www.justice.gov/opa/pr/justice-department-recovers-over-47-billion-false-claims-act-cases-fiscal-year-2016 (“An astonishing 60 percent of” FCA recoveries since the FCA was amended in 1986 “were obtained in the last eight years.”). For example, a single FCA settlement last year saw a pharmaceutical company agreeing to pay over \$784 million to federal and state health programs after allegedly overcharging for their beneficiaries’ heartburn medicine. Press Release, Dept. of Justice, Wyeth and Pfizer Agree to Pay \$784.6 Million to Resolve Lawsuit Alleging That Wyeth Underpaid Drug Rebates to Medicaid (Apr. 27, 2016), www.justice.gov/opa/pr/wyeth-and-pfizer-agree-pay-7846-million-resolve-lawsuit-alleging-wyeth-underpaid-drug-rebates. As recoveries have increased, so has the scale of evidence—and associated litigation expense—required to establish large-scale violations. See, e.g., *U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, 2015 WL 3903675, at *1 (D.S.C. June 25, 2015) (*Agape I*) (noting, in fact-

intensive case with potential for \$25 million in damages by Government’s estimate, 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”). Some courts have responded to these burdens by dabbling in statistical extrapolation, allowing relators and governments to litigate one or more critical elements of their FCA cases using a subset of alleged false claims, and then using the results to draw conclusions about the broader universes of claims at issue.

This article examines the phenomenon of statistical sampling in FCA litigation from two related perspectives. It first provides a survey of the legal disputes over whether and when courts should recognize statistical sampling and extrapolation as evidence of liability, as opposed to just evidence of damages. Then it discusses practical considerations that should inform any statistical analysis performed in such cases for purposes of FCA liability and damages.

Legal Status of Statistical Sampling and Extrapolation under the FCA—Courts generally allow Government plaintiffs and relators to proceed by sampling and extrapolating in FCA cases for limited purposes or under special circumstances. In a detailed and influential 2014 opinion in *U.S. v. Life Care Ctrs. of Am., Inc.*, Judge Mattice of the U.S. District Court for the Eastern District of Tennessee offered the explanation that “[i]n the context of the FCA, . . . statistical sampling has been generally limited to determine *damages*, rather than liability.” 114 F.Supp.3d 549, 560 (E.D. Tenn. 2014) (emphasis added). This, however, may be an oversimplification. Judge Mattice’s main examples of extrapolation of damages in FCA cases included one case in which an appellant failed to raise at trial the argument that an individualized review of all claims would be necessary, *U.S. v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008) (“([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. At all events, [defendant] didn’t

bother to provide information on that subject in the district court and has forfeited this position.”), cited in *Life Care*, 114 F.Supp.3d at 563, and another in which a court expressly declined to find the defendant liable under the FCA on summary judgment (due to a genuine issue of fact as to scienter) and instead used extrapolation to determine damages on a separate common-law count of overpayment by mistake of fact. *U.S. v. Fadul*, 2013 WL 781614 at *12 (D. Md. Feb. 28, 2013), cited in *Life Care*, 114 F.Supp.3d at 563. In support of its decision to employ extrapolation to determine damages, the court in *Fadul* cited two Government health program overpayment cases, neither of which was brought under the FCA. 2013 WL 781614 at *13–14.

The law on whether statistical sampling can be used to establish FCA liability is even more muddled than it is in the context of damages. In a few instances, trial courts have instead decided to allow establishment of FCA liability by extrapolation from a sample. But procedural idiosyncrasies have led subsequent courts to discount the opinions’ precedential force or even their persuasive value. For example, one defendant failed to appear in court, resulting in default judgment based, in part, on extrapolation. See, e.g., *U.S. v. Cabrera-Diaz*, 106 F.Supp.2d 234, 240 (D.P.R. 2000), discussed in *Life Care*, 114 F.Supp.3d at 563–64. In others, the parties consented to sampling. See, e.g., *U.S. v. Krizek*, 111 F.3d 934, 934 (D.C. Cir. 1997) (“[A]greement between psychiatrist, wife, and government during trial provided that liability for Medicare claims would be determined by using seven-patient sample . . .”), cited in *Agape I*, 2015 WL 3903675, at *7; see also *U.S. ex rel. Loughren v. UnumProvident Corp.*, 604 F.Supp.2d 259, 261 (D. Mass. 2009) (excluding expert’s contested testimony on extrapolation as unreliable, but stating in dicta that “extrapolation is a reasonable method for determining the number of false claims so long as the statistical methodology is appropriate,” after defendant challenged reliability of particular sample but not practice of sampling itself), discussed in *Life Care*, 114 F.Supp.3d at 564–65. These cases did not involve robust argument or judicial explanation as to whether extrapolating liability from a sample is consistent with due process or the design of the FCA. Future cases, hopefully, will provide more clarity and consistency as to whether statistical sampling can be used to establish liability under the FCA, notwithstanding its use for establishing damages.

Despite this muddle, the *Life Care* court broke new ground by squarely considering whether a claim of medical necessity can be false for purposes of the FCA without proof of each patient’s actual characteristics and medical record. *U.S. ex rel. Crews v. NCS Healthcare of Ill., Inc.*, 460 F.3d 853, 856 (7th Cir. 2006) (rejecting assumption that false claims must have been submitted because “basic math proves that 6% to 12% of recycled drugs would have been redistributed to Medicaid recipients” contrary to state Medicaid program rules “and thus rebilled to” program); see also *U.S. ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301 (11th Cir. 2002) (upholding dismissal of FCA complaint based in part on relator’s “failure to allege with any specificity if—or when—any actual improper claims were submitted to the Government”). Concerns such as variation within a body of claims, Judge Mattice asserted, were not enough to outweigh the practical value of evaluating the whole body of alleged false claims based on a sample; the finder of fact would simply need to decide how to weigh it like any other expert testimony. *Id.* at 560. Ultimately, the court was persuaded by what it viewed as the insurmountable hurdle that individualized assessment of claims would pose; its opinion noted that an alternative approach would not be “practical” or “practicable” at least seven times.

As of this writing, however, the *Life Care* approach to evaluating cases for sampling is far from settled law. In a more recent case, *U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, the district court surveyed many of the same cases cited in *Life Care* but reached the opposite conclusion. Because determining whether each claim was based on medical necessity would be a “highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patient,” the trial court in *Agape* felt that “the fairest course of action” would be to reject a sampling approach. *Id.* at *8. The court noted that the defendants planned to offer evidence of medical necessity for each and every claim, including those outside the relator’s sample, even if the relator was permitted to rely on extrapolation. *Id.* at *8 n.4. Judge Anderson further pointed out that key evidence was “intact and available for review by either party” to distinguish the case before him from “one where the evidence has dissipated, thus rendering direct proof of damages impossible.” *Agape*, 2015 WL 3903675, at *6–7. Though the opinion did not

say outright that extrapolation should be reserved only for those cases where individualized review of claims is strictly impossible, it seemed to reflect a much greater sensitivity to defendants' due process concerns than was evident in *Life Care*.

The *Agape* trial court, hoping to avoid a massive trial touching on every claim, certified its decision to interlocutory appeal sua sponte. *U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, 848 F.3d 330, 333 (4th Cir. 2017) (*Agape II*). The Fourth Circuit, however, ruled that the sampling issue was inappropriate for an interlocutory appeal. *Id.* The appeals court seized on the trial court's suggestion that some FCA suits—namely, suits where dissipated or destroyed evidence makes direct claim-by-claim evaluation impossible—are appropriate for proof of liability by extrapolation. *Id.* at 341. The opinion left unclear whether extrapolation for liability *can* be appropriate in some factually distinct FCA cases, even in cases in which *there is* evidence relating to the falsity of each and every claim. And it is unlikely the case will present further opportunity for elaboration on the law since it has been recently settled by the parties. On Aug. 23, 2017, the parties to the *Agape* case reached a settlement in principal. Order Dismissing Case, *U.S. ex rel. Michaels v. Agape Sr. Cmty., Inc.*, No. 0:12-03466-JFA, Dkt. No. 345 (Aug. 23, 2017). The parties report that the settlement is valued at \$275,000, a nearly ten-fold decrease from earlier settlement offers. See Press Release, dlbjzgnk95t.cloudfront.net/0957000/957059/press%20statement%20on%20settlement.pdf.

In the absence of meaningful appellate court guidance, a range of arguments remain available to FCA litigants. Defendants could argue, as in *Agape*, that extrapolating for liability is categorically inappropriate if analysis of each individual claim is possible, regardless of whether it is practicable. The Government and relators, on the other hand, might import general principles of sampling reliability stated in recent Supreme Court class action cases, bolstering their argument that extrapolation is an appropriate response to otherwise overly burdensome litigation, even if it is not the only way to prove their cases. See David L. Scher and R. Scott Oswald, *Biggest Test Yet for Statistical Sampling in FCA Cases*, LAW360 (Oct. 18, 2016, 12:16 PM), www.law360.com/health/articles/851303/biggest-test-yet-for-statistical-sampling-in-fca-cases (arguing, prior to Fourth Circuit's decision in *Agape*, that circuit court should

model decision in *Agape* on *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036 (2016), and allow sampling if it is “the ‘only practicable’ way,” rather than *only* way, of establishing liability). For now, factors that diminish the reliability of a sample—such as small sample size, high variability within the broader body of claims, and the need for reevaluation of subjective professional judgments, see *U.S. ex rel. Trim v. McKean*, 31 F.Supp.2d 1308, 1314 (W.D.Okla. 1998)—will likely persuade some courts to avoid extrapolation if at all possible, and strike others as nothing more than fodder for fact finders as they decide how much to trust statisticians' testimony. Future decisions may have profound effects not only on the fundamental character of FCA litigation but also on the parties' settlement negotiation positions. See Press Release, Dept. of Justice, Life Care Centers of America Inc. Agrees to Pay \$145 Million to Resolve False Claims Act Allegations Relating to the Provision of Medically Unnecessary Rehabilitation Therapy Services (Oct. 24, 2016), www.justice.gov/opa/pr/life-care-centers-america-inc-agrees-pay-145-million-resolve-false-claims-act-allegations.

So what is a defendant do if sampling or extrapolation is permitted in an FCA case it is defending? The answer to this question, like the legal issues described above, is not so simple. To the extent a short answer exists, it is that a defendant should consider case-specific factors to determine the optimal approach to the quantification of damages. Naturally, if the information, capabilities, and resources exist to analyze the entire population, then analyzing the entire population will provide the most accurate and defensible results. However, each FCA matter is unique and often quite complex, leading to many additional factors for consideration. Situations where statistical sampling may offer the best option for quantifying damages include, but are not limited to, the following circumstances:

1. The Data Necessary to Evaluate Potential Exposure Does Not Exist
 - In contrast to the conditions in *Agape* referenced above, if the full population of data necessary to evaluate the allegations throughout the applicable time period no longer exists, some form of statistical sampling from available data and extrapolation of the results may be the only suitable option to quantify exposure related to any gap period. Such situations could arise

for a variety of reasons, such as records retention requirements that expired prior to the allegations being raised, the loss of pertinent information during the migration of data to a new enterprise resource planning system, or the failure to transfer legacy data as part of an acquisition.

2. The Format and Magnitude of Data is Prohibitive
 - Allegations that require the review of terabytes of transactions do not pose an insurmountable challenge for qualified experts versed in data analytics, provided the data is in an analyzable format. However, if the data quality is poor and requires reconstruction, contains gaps, or is inconsistent in its capture of relevant information, that necessitates a more manual review of supplemental support (e.g., an assessment of individual claims). These conditions coupled with terabytes of transactions could render an analysis of the entire population impractical, similar to the *Life Care* case, leaving the door open to statistical sampling.
3. Financial Resources to Respond are Limited
 - The costs incurred to defend litigation are always a factor. Depending on the size of the case and the nature of the allegations, the costs to perform a review of the entire population of affected transactions may exceed the value of alleged damages or potentially impact a company's ability to continue operations due to cash flow constraints. Where the costs to respond are excessively punitive in comparison to the false claims exposure or the financial resources just are not available, statistical sampling may be the only option worth pursuing.
4. Time Afforded to Respond to Allegations Constrains the Approach
 - Like financial resources, time can also be an important facet of litigation and one that may preclude the ability to evaluate the entire population of impacted transactions. If it will take more time to analyze the full population due to the size and/or format of such data than has been allotted to respond, then statistical sampling may offer a more expedient result.

Practical Considerations for Statistical Sampling for FCA Litigation—Where statistical sampling is ultimately selected as the method of choice, presenting the most statistically sound analysis, especially given the ambiguity of existing court guidance, is paramount. To do so requires (1) the proper usage of statistical sampling and extrapolation techniques and (2) the ability to demonstrate that the data relied upon for the sample is of high quality and representative of the entire population. Though the nuances and technical considerations in statistical sampling are beyond the scope of the article, some of the key elements of statistical sampling taken into account include:

- **Sample Size**—The size of the subset of the population utilized relative to the whole.
- **Type of Sample**—The method used to select the sample from within the full population. Common examples include a random sample, a systematic sample and a stratified sample, each of which may be more appropriate for particular circumstances.
- **Confidence Interval**—An estimated result expressed as a range of values signifying the margin of error, or the amount of uncertainty in the result. This goes hand in hand with the confidence level below to establish the statistical significance of the results.
- **Confidence Level**—The probability (e.g., 95 percent confidence level) of generating similarly accurate confidence intervals from different samples.

In addition to these analysis steps and assumptions, the quality, completeness, and relevance of the data utilized is critical. Such key characteristics of the data underpin the credibility of the entire analysis. Nevertheless, obtaining the information is a necessary first step that often becomes a cumbersome and complex process to navigate. For example, in many instances, alleged false claims can arise from or persist due to a breakdown in communications and/or manual business processes among multiple functions within an organization. Each function may house different sets of compartmentalized data necessary for separate and distinct (though related) operations, which limits the benefit of certain automated controls otherwise found in more centralized systems. In these cases, before an analysis can be performed, a critical component of the damages quantification process is to obtain the necessary breadth of data across multiple systems to formulate a compelling analysis.

It is for all these reasons—the technical skills to select the sample and perform the analysis as well as extract the data, coupled with resource constraints and the high-stakes nature of FCA matters—that most engage third party experts in the form of accountants, consultants and statisticians, to assist. If chosen wisely, these individuals not only possess the skills needed to perform the actual analysis (whether based on statistical sampling or the full population), but also understand systems and the extraction of data to ensure the integrity of the information on which any calculations rely, and can help guide litigants through the steps necessary to bolster their case.

Consider, for example, responding to FCA allegations regarding the off-label marketing of a prescription drug. A pharmaceutical company may need to extract data from its:

1. Client Relationship Management Database—to evaluate the history of its sales forces interactions with doctors prescribing the drug.
2. Accounting System—to identify any alleged inducements provided to such doctors.
3. Sales Database—to determine if there was an uptick in sales that corresponded to such inducements.

This is notwithstanding the potential need to analyze external market data surrounding prescription and patient diagnosis activity to ascertain if any uptick was attributable to a broader market trend rather than the alleged inducements or claims data to quantify the portion of off-label prescriptions paid for by the Federal Government.

Rarely are companies' business systems configured to facilitate an analysis of Government allegations like this, nor would one necessarily expect otherwise given the cost of integration and limited benefit to daily operations. As a result, to respond to Government or relator allegations, companies are typically left with the effort to piece together relevant information from multiple sources and then perform either a deep dive of the data or utilize statistical sampling to quantify potential exposure.

Though every matter is unique, in order to navigate the many challenges typically encountered along the path of FCA litigation, below are some tips and best practices to consider:

1. Maintain data dictionaries for business systems. Data dictionaries serve as the best starting point for evaluating whether the transactional data available within a company's business systems

may be sufficient to respond to FCA allegations. These dictionaries provide insight into the data attributes that may exist, the reliability of such data in evaluating retrospective claims, as well as potential options for linking disparate data-sets. It takes minimal effort to maintain data dictionaries that are generally produced during the implementation of a business system, but it is not uncommon for these files to become out of date or misplaced over time, thereby increasing the level of effort necessary for a company to understand and evaluate its data.

2. Determine the root cause of the potential issues that resulted in false claims allegations, and be ready to walk through examples with outside attorneys and experts to provide greater insight into the controls that failed and the relevant data to be analyzed. In many instances, there are issues outside of those identified within the preliminary FCA allegations, which resulted from the same failure in controls. Identifying the root cause and proactively evaluating potential exposure related to all of the issues provides a company with a better understanding of its worst case liability, while potentially improving its negotiating position with the Government based on its good faith effort to identify and remediate the underlying cause of the issue(s).
3. Engage experts early and allow them to work directly with the appropriate stakeholders. The right experts can help save time and expense with the extraction of data necessary to perform the analysis, and by providing timely insights into the potential benefits and risks of statistical sampling as it relates to the particular case. To maximize efficiencies, it is best to reduce unnecessary bottlenecks between front-end business stakeholders who understand the business processes implicated within FCA allegations and the back-end information technology personnel who maintain the supporting business systems in which the data reside. While the context offered by business process owners is valuable in understanding operations and how such issues may have come about, providing experts with direct access to IT personnel generally expedites the analysis of such claims as they should know the specific data necessary to generate a response and the best course for extracting such data.

4. Unless absolutely necessary, do not attempt to limit or filter the data provided to experts performing the analysis. The right expert can efficiently weed out any extraneous data, and allowing them to do so ensures completeness and reduces the burden placed on internal resources. The most recent system backup of relevant data tables is generally the most efficient way to produce the data, and may also offer experts insight into information that proves useful in the future.
5. Perform distribution analysis of the data to obtain a high level understanding of the types of transactions included within the population. Private consulting firms regularly handle these types of matters and have experience working hand-in-hand with outside counsel to make sure the representative sample is pulled early, competently, and with the necessary protections typically afforded to corporate defendants during internal investigations led by outside counsel. Validating the data to be analyzed upfront to identify any potential gaps or inconsistencies early in the process before proceeding with analyses helps to confirm a representative sample has been pulled, while reducing the likelihood of costly efforts tracking down potential outliers.
6. Ensure the steps applied in preparing the statistical sample have not unduly excluded certain types of transactions or introduced any bias, whether real or perceived, into the evaluation process. Remember that statistical sampling is a tradeoff between precision and certain data or resource constraints. Relevant stakeholders should always consider whether the results of such an analysis will serve as a defensible basis for facilitating the negotiation and settlement of potential damages.
7. Assess the need to parse the data into more detailed groupings (e.g., a stratified sample) based on additional descriptors within the data. This can reduce the variability of outcomes used to extrapolate potential exposure within the sub-populations of relevant transactions and add to overall accuracy of the analysis. It also enables

the legal team to persuasively retreat to alternative negotiating positions when more aggressive positions fail.

8. Weigh the benefits and potential challenges of statistical sampling with outside counsel and third party experts often to ensure the highest chances of success. Facts and circumstances evolve and change throughout a given matter, and the direction strategized at the outset may warrant adjustment as new information comes to light.



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