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PERSPECTIVE

Statistical sampling on the rise in False Claims Act cases

By Matthew D. Benedetto

Since the 1920s, when the Elgin Watch Co. and Elgin Clock Co. pioneered the use of statistical sampling in a trademark dispute, attorneys have sought to introduce small samples into evidence to make the case for a much larger amount of proof. Statistical analysis has since become a recognized method of proof in certain types of litigation, including antitrust, employment discrimination and mass tort.

While it's been widely used in complex civil litigation, statistical sampling has been rarely used in federal False Claims Act litigation. Plaintiffs have used sampling in FCA actions but mostly to determine damages, not liability. That trend may be shifting, raising new concerns and issues for FCA practitioners.

The FCA penalizes any person who submits a false claim to the U.S. government for payment, and it has become the government's primary weapon to combat fraud across a number of programs, including procurement contracts, Medicare and Medicaid, and government-backed home mortgages. In large-scale actions spanning many years — for instance, Medicare reimbursements over a 10-year period — FCA plaintiffs will likely seek to prove that an enormous number of claims were false.

One federal court recently endorsed the use of statistical sampling to establish liability in such a large-scale FCA case. In *United States ex rel. Martin v. Life Care Centers of America*, a suit alleging Medicare fraud by a company that owns skilled nursing facilities, Judge Harry Mattice of the U.S. District Court for the Eastern District of Tennessee ruled on partial summary judgment that the government could employ statistical sampling to prove liability under the FCA, including the falsity and knowledge elements.

The government evaluated a random sample of 400 patients who received medical services at Life Care facilities to determine the number of claims it deemed false. It then extrapolated from this sample that 154,621 claims were false.

Life Care argued that such an extrapolation was improper under the FCA, and violated due process, for several reasons: The government would not need to identify any individual claim, much less a false claim, beyond the initial sample. The government would not be required to prove that therapy provided by Life Care was medically inappropriate for any particular patient in the extrapolated universe. And, relatedly, the government would be relieved of addressing the myriad subjective factors that inform therapeutic decisions made for the patients at issue.

Life Care also argued that the case for sampling fell short of the scenario in *United States ex rel. Loughren v. UnumProvident Corp.*, an FCA action in Massachusetts federal court where sampling was permitted to adjudicate a large number of disability claims. There, the district court first held a bellwether trial on a sample number of alleged false claims and then concluded that extrapolation was a reasonable method to determine the total number of false claims.

The government countered that an FCA action is no different than any other complex action, including fraud suits, where sampling has historically been permitted. It argued that sampling does in fact provide direct evidence that claims were false and that Life Care knew that they were.

The district court accepted the government's position. It found that the government *could* in fact, with unlimited resources and time, specify the claims it alleges are false, but that it would not be practicable or efficient to do so. Statistical sampling, it opined, is designed precisely for this type of instance in which the vast number of claims precludes a claim-by-claim offer of proof.

The court also rejected Life Care's argument that the individualized nature of patient care makes sampling improper. The court observed that all sampling raises the same issue: drawing an inference about a larger and not identical population of claims. If Life Care were right, the court reasoned, sampling would never be warranted or proper.

The court gave Life Care the option to use cross-examination and competing witnesses to expose the differences among claims. Life Care has sought interlocutory review in the 6th U.S. Circuit Court of Appeals.

The court's conclusion that statistical evidence can be used to establish liability raises several important issues for FCA practitioners, especially in healthcare cases involving therapeutic decision-making, including:

• The ruling allows a set of unidentified, extrapolated claims to be the basis for liability. Although the court ruled on partial summary judgment, its conclusion also implicates pleading strategy under Federal Rule of Civil Procedure 9(b), which requires plaintiffs in FCA actions to allege fraud with particularity. Defendants in large-scale cases should anticipate early on these evidentiary hurdles and attack the complaint under Rule 9(b) if it fails to identify false claims with requisite specificity. Recognizing that the circuits disagree as to what plaintiffs must show at the pleading stage to satisfy Rule 9(b), Defendants should press that plaintiffs bear the burden to identify and prove the submission of individual false claims.

• The court proposed a stringent challenge of the government's statistical expert, which means the venue for arguments about statistical sampling in FCA cases may shift from summary judgment to *Daubert* proceedings, where defendants have their last chance to attack the validity of statistical sampling as a matter of law before a jury is given the final word. Defendants should thus raise sampling concerns early in the process and perhaps with a tandem filing of summary judgment and Daubert motions to characterize sampling as legally insufficient to prove liability under the FCA and also as unreliable as expert evidence under Federal Rule of Evidence 702.

• The ruling dismisses, without any substantive explanation, Life Care's arguments regarding the individualized nature of medical decision-making. Beyond endorsing the general mathematical principles that underpin sampling itself, the decision does not explain how sampling accounts for the many factors that are at play in a therapeutic scenario. It does not adequately respond to Life Care's position that sampling eviscerates the government's obligation to establish that individual therapeutic decisions were rendered in violation of the controlling "medically reasonable and necessary" standard. It thus raises real concerns about the threshold for proving falsity under the FCA in the healthcare context.

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