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Client Alert Commentary

Latham & Watkins Healthcare & Life Sciences Practice

July 21, 2015 | Number 1858

Fourth Circuit May Address Use of Statistical Sampling in False Claims Act Actions

Court has the opportunity to assess the use of statistical sampling/extrapolation as a method to prove FCA liability or damages.

Courts require that plaintiffs prove each element of a legal claim with evidence — mere suggestion is not enough. Extrapolation *suggests* what damages or liability may be based on a statistical sample but does not tell anyone what damages or liability *actually are.* Not surprisingly, therefore, extrapolation is a controversial issue for the civil False Claims Act (FCA)[1] bar because extrapolation allows government authorities and whistleblowers alike to prove damages, or even liability, without the claim-by-claim proof typically required in highly fact-dependent civil cases. On June 25, 2015, in *United States ex rel. Michaels v. Agape Senior Community, Inc.*, the District of South Carolina certified an interlocutory appeal to the Fourth Circuit to answer two questions related to a *qui tam* action brought under the FCA: (1) does the Government have a right to reject a settlement in a *qui tam* action to which it has not intervened; and (2) can a relator use statistical sampling to prove liability or damages in an FCA action?[2] This Client Alert discusses the second question, which will be addressed for the first time by an appellate court if the Fourth Circuit accepts the appeal petition.

Statistical Sampling Inconsistent with the FCA

The FCA prohibits any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government. Generally, FCA claims may be false for a number of reasons, such as when services provided were not medically necessary despite certification by the provider as to medical necessity, or when claims for payment were otherwise tainted because the service provider submitted claims in violation of another federal statute (*e.g,* the federal Anti-Kickback Statute). At bottom, each claim for payment — whether for healthcare services or for other items or services — emanates from a specific set of deliverables provided to the federal government which either were, or were not properly provided. Notably, the FCA imposes penalties for each and every "false claim" submitted, which ordinarily means that plaintiffs must prove the falsity of *every claim* — including damage suffered as a result of the false claim.

In recognition of the fact-dependent nature of every claim for payment, federal legislators affirmatively adopted a burden of proof standard for the FCA almost 30 years ago with the so-called "1986 amendments" to the FCA. Now, as it has for decades, the FCA makes clear that every essential element of an FCA claim, including damages and, of course, overall liability, must be proven by a "preponderance of the evidence."[3] Yet, the government and many relators have attempted to prove damages and, in some cases, liability, by presenting evidence only with respect to a sample of allegedly false claims and then extrapolating findings for that group of sample claims to a larger universe of allegedly false claims. For example, if a relator can show that a sample of 25 claims out of a group of 100 (or 25% of claims) should be judged false, that relator may then be able to argue that, when extrapolated, 15,000 claims out of a total universe of 60,000 similar claims should also be judged false.

The key questions the Fourth Circuit may address are:

- When a plaintiff attempts to prove damages under the FCA through extrapolation, has that plaintiff proven damages with respect to every false claim?
- Can a plaintiff plausibly carry her burden of proof when no one has reviewed or analyzed underlying support (or lack thereof) for many (or most) of the claims for which damages are sought?

Using the extrapolation method, plaintiffs could prove liability or damages without ever submitting evidence relating to the majority of claims for payment at issue. In the healthcare setting, individual claims for payment are based on unique services provided to unique patients in unique circumstances, and it is therefore difficult to generalize across claims given the high degree of individuality present in every claim.

Unsettled Territory Worth Watching

Proponents of extrapolation in FCA cases argue that the method is more efficient and cost-effective than subjecting each and every allegedly false claim to proof requirements –failure to extrapolate requires expensive expert analysis and testimony. Further, extrapolation keeps the bar for bringing FCA claims for whistleblowers and others appropriately low, encouraging deterrence of fraud. On the other hand, many parties and observers, including a number of federal judges, have concluded that extrapolation is unfair to defendants and, more importantly, prohibited by statute because extrapolation allows plaintiffs to prove false claims act liability (or damages) without providing evidence for each specific false claim alleged by a plaintiff.

Recently some courts have allowed use of the statistical sampling and extrapolation method for determining damages and liability in FCA cases.[4] In *United States ex rel. Martin v. Life Care Centers of America, Inc*., a 2014 case addressing allegedly false claims based on the medical necessity of services provided to nursing home patients, the Eastern District of Tennessee approved of statistical sampling not only to prove damages, but also to prove liability in the first instance — an expansion of the use of the method in FCA cases.[5] The court recognized that the use of statistical sampling in FCA cases has been limited, but after an analysis of the history of both the FCA and the use of statistical sampling in litigation, the court recognized no explicit prohibition against the practice. The court focused on the large number of claims for reimbursement usually submitted by a provider to the Medicare program and highlighted the practical burdens imposed by claim-by-claim review. According to the court, without the use of statistical sampling, the door would be open to more fraudulent activity, especially for large-scale perpetrators, because the deterrent effect of prosecution would be constrained. Instead of prohibiting statistical sampling evidence altogether, the court noted that a defendant's compelling arguments against statistical sampling should be considered by fact finders.

However, a number of other courts, including the District of South Carolina last month in *United States ex rel. Michaels v. Agape Senior Community, Inc*., have rejected statistical sampling and extrapolation as a method for providing liability or damages because it gives plaintiffs an "end around" an otherwise far more complex burden of proof.

The relator in *Agape* alleges that a network of nursing home facilities submitted more than 60,000 claims for medically unnecessary services as part of a scheme to defraud the government. The parties conducted a so-called "bellwether trial" on a small number of claims to help frame a possible settlement and ultimately agreed on a settlement of US$2.5 million. The government — though it had previously declined intervention in the case — objected to the settlement amount as "too low" given the volume of claims at issue and the government's estimate of Agape's exposure.

Despite pressure from the government to allow the relator to prove damages through extrapolation (in part due to the relator's estimate that it would need to spend more than US$16 million on expert analysis and testimony to prove its case), the court concluded that every claim at issue in the case was "fact-dependent and wholly unrelated to each and every other claim" and, therefore, not susceptible to

extrapolated findings. The court acknowledged that some circumstances warrant extrapolation, such as when underlying documentation has been destroyed or is otherwise unavailable. However, the court concluded in this instance that "the patients' medical charts are all intact and available for review by either party."

In contrast to the court in *Martin*, the court in *Agape* recognized the fact-specific nature of the FCA fraud allegations. Where the allegations of fraud were based on claims that the services provided to patients were not medically necessary, the court noted that answering the question of medical necessity involves an inquiry into medical testimony after a thorough review of the medical chart of each patient. This individual, fact-specific viewpoint taken by the *Agape* court is arguably more consistent with the underpinnings of the FCA than the approach the court took in *Martin.*

Conclusion

Agape is a perfect opportunity for the Fourth Circuit to provide guidance on this important issue for future FCA actions. If the Fourth Circuit accepts the appeal, this will be the first and only appellate decision addressing extrapolation in the FCA context and will therefore affect FCA litigations and settlements across jurisdictions. For example, to the extent the Fourth Circuit accepts the appeal and endorses extrapolation, relators and the government will be emboldened to bring complex cases knowing that they will have to prove damages only for a narrow subset of the overall set of claims at issue in a case. To the extent the Fourth Circuit limits the use of extrapolation, we expect FCA plaintiffs will face new challenges bringing cases due to the more significant cost outlay that will be required to articulate a realistic basis for damages in complex FCA actions.

If you have questions about this *Client Alert*, please contact one of the authors listed below or the Latham lawyer with whom you normally consult:

Roger S. Goldman
roger.goldman@lw.com
+1.202.637.2253
Washington, D.C.

Katherine A. Lauer
katherine.lauer@lw.com
+1.858.523.5451
San Diego, CA

Michael K. Fee
michael.fee@lw.com
+1.617.880.4600
Boston, MA

Daniel Meron
daniel.meron@lw.com
+1.202.637.2218
Washington, D.C.

Anne Robinson
anne.robinson@lw.com
+1.202.637.2161
Washington, D.C.

David C. Tolley
david.tolley@lw.com
+1.657.880.4610
Boston, MA

Kasey P. Branam
kasey.branam@lw.com
+1.858.523.5419
San Diego, CA

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Endnotes

1 31 US Code § 3730.

2 Order Resolving Two Interrelated Issues and Certification for Interlocutory Appeal, Case No. 0:12-cv-03466-JFA (June 25, 2015).

3 31 US Code § 3731 (d). Note also that courts were previously split as to whether the proper burden of proof standard in FCA cases should be "clear and convincing evidence" or a "preponderance of the evidence."

4 *See, e.g., United States ex rel. Ruckh v. Genoa Healthcare*, *LLC*, No. 8:11-cv-1303-T-23TBM, 2015 U.S. Dist. LEXIS 55384 (M.D. Fla. Apr. 28, 2015) (allowing statistical sampling expert analysis be submitted).

5 *United States ex rel. Martin v. Life Care Centers of America, Inc.,* No. 08-cv-251, 2014 WL 4816006 (E.D. Tenn. Sept. 29, 2014).