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Courts Examine Use of Statistical Sampling in False Claims Act Cases

The *False Claims Act* (FCA) continues to grow in strength as the federal government and relators increase their use of the law to recover billions of dollars from companies that violate the Act's provisions. Developments in the application and interpretation of the FCA, particularly in regard to the issue of statistical sampling in proving damages, may significantly influence the regulatory risk to healthcare enterprises, in light of the significant volume of recoveries received by the government under this law for healthcare fraud and abuse violations.[1] In recent months, interpretation of the FCA influenced the outcome of two prominent healthcare fraud and abuse cases: (1) *U.S. ex rel. Michaels v. Agape Senior Community* (*Agape*), originating in the U.S. District Court for the District of South Carolina and heard by the U.S. Court of Appeals for the 4th Circuit; and, (2) *U.S. ex rel. Ruckh v. Genoa Healthcare Consulting, Inc.* (*Genoa*), in the U.S. District Court for the Middle District of Florida. The cases, both of which explored the utilization of statistical sampling in proving damages under the FCA, leave unclear the standards associated with the admissibility of expert testimony in this context. This *Health Capital Topics* article will summarize the *Agape* and *Genoa* cases, and discuss the role that statistical sampling may play in future FCA actions.

In *Agape*, the relators, former *registered nurse* (RN) case managers, alleged that Agape Senior, LLC, and its subsidiaries engaged in fraudulent billing practices related to its patients, including:

(1) Certification of patients for hospice care without the approval of a physician;[2]
(2) Backdating of certification of patients for hospice care;[3]
(3) Inadequate documentation within the medical record supporting the need for hospice care;[4] and,
(4) "*Inappropriate referrals to [Agape's] GIP [general inpatient] care*" in order to receive higher reimbursements from payors.[5]

The relators alleged that Agape and its subsidiaries "*knowingly presented…and continue to present*" such claims for reimbursement to federal program payors in violation of the FCA and the *Anti-Kickback Statute* (AKS).[6] Notably, the relators alleged that such billing practices are pervasive throughout all Agape enterprises, based on their experience as RNs at a limited number of Agape facilities:

> "*Relators have discovered so many instances of fraud that they believe the marketing, false certifications, false recertifications, and fraudulent billing of federal health care benefit programs for care to unqualified patients, as well as billing for care and services not provided, among other things, are* ***widespread, systematic practices*** *of [Agape].*"[7] [Emphasis Added]

In an effort to prove the extent to which Agape engaged in fraudulent billing activity, the relators sought to introduce expert testimony to quantify the extent of damages across the enterprise, which involved the potential examination of 61,643 claims over a six year period.[8] Instead of examining each individual claim, the relator's expert witnesses sought to determine damages by performing two main tasks: (1) an examination of a "*specified percentage of randomly selected claims*" to determine if fraudulent billing practices occurred; and, (2) upon discovery of fraud, a "*project[ion of] that percentage on the total universe of claims submitted by Agape to the Government.*"[9] The U.S. District Court for the District of South Carolina initially denied utilization of statistical sampling as described above, but later allowed the parties to conduct a "*bellwether trial*," i.e., the examination of "*a sample of cases large enough to yield reliable results*," of approximately 100 randomly selected claims to provide an indication "*on the value of the remainder of the case*" to support settlement negotiations.[10] The parties ultimately reached a settlement agreement; however, the government rejected the settlement, claiming that the undisclosed damages amount was "*insufficient*" as related to its estimated damages of $25 million.[11] In support of its position, the government utilized a form of statistical sampling previously rejected by the district court, to which Agape raised objections in an effort to enforce the settlement.[12]

Although the district court, as well as the U.S. Court of Appeals for the 4th Circuit, held that the FCA contains "*no limitation on the Attorney General's authority to object to a settlement in a qui tam action*," the district court reaffirmed its earlier refusal to utilize statistical sampling when proving damages in the case.[13] The

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district court stated that unlike other *qui tam* actions, *Agape* was not a case "*where the evidence has dissipated, thus rendering direct proof of damages impossible*."[14] Instead, the district court noted that the patient medical records, necessary to review in determining "*medical necessity*" as part of the examination into the existence of fraudulent billing practices by Agape, were "*all intact and available for review by either party*."[15] The 4th Circuit affirmed the district court's ruling on the issue, stating that the lower court, as the fact finder, has "*broad latitude in ruling on the admissibility of evidence, including expert opinion*."[16]

In contrast to *Agape*, the U.S. District Court for the Middle District of Florida, in *Genoa*, allowed for the utilization of statistical sampling to determine damages under the FCA. In *Genoa*, the relator, an RN who worked for two of the 53 nursing homes owned or operated by four companies in the State of Florida, alleged that the defendant nursing home owners and operators violated the FCA by:

(1) "*Fraudulently inflat[ing] the RUG [Resource Utilization Group] levels*" of patients in claims submitted for public payor reimbursement;
(2) Not completing required care plans for nursing facility patients; and,
(3) Inappropriately certifying the medical necessity of certain treatment plans by using non-RN staff instead of the required RN.[17]

Similar to the relator in *Agape*, the relator in *Genoa* alleged that the defendant nursing home owners and operators engaged in fraud across multiple facilities, and "*cultivated a work culture that focused on maximizing profits at the expense of resident care and that systematically incentivized and pressured employees to resort to any means – including fraud – to increase profits.*"[18] Additionally, similar to the relator in *Agape*, the relator in *Genoa* sought to determine damages through the utilization of statistical sampling techniques that extrapolate data derived from a sample of claims across the entire dataset of claims.[19] The district court upheld the utilization of statistical sampling in *Genoa*, noting in two separate orders that (1) "*no universal ban on expert testimony based on statistical sampling applies in a qui tam action*";[20] and, (2) "*a comparatively small sample size typically is not dispositive in excluding expert opinion otherwise formulated in accord with established principles and techniques*."[21]

The examinations by the courts in *Agape* and *Genoa* into the admissibility of expert testimony utilizing statistical sampling to determine damages under the FCA underscore the uncertainty in determining the risk of potential damages faced by healthcare providers for fraud and abuse violations. Plaintiff relators argue that statistical sampling makes litigating FCA actions more efficient, in that investigation is not required for each claim, but rather can be extrapolated based on the sample size.[22] Defendants retort that statistical sampling finds arbitrary amounts of claims and inflates small issues into large damage awards without the requirement of "*developing robust, individualized proof*."[23] Legal commentators hoped that the 4th Circuit in *Agape* would provide a bright-line rule on this issue; however, the 4th Circuit opinion did not provide such clarity.[24] Instead, the issue may continue to create significant uncertainty for healthcare providers regarding their risk exposure under the FCA. Considering that the jury in *Genoa* found the defendants liable for over $115 million in damages,[25] which the judge tripled to over $345 million in damages[26] (an award that was recently postponed by the presiding judge in the case),[27] healthcare providers and their professional advisors may find it prudent to continue monitoring developments on this topic.

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3 *Ibid*, p. 17.
4 *Ibid*, p. 21.
5 *Ibid*, p. 30-31.
6 *Ibid*, p. 41.
7 *Ibid*, p. 16.
8 "U.S. ex rel. Michaels v. Agape Senior Cmty, Inc" Case no. 0:12-cv-03466-JFA (D.S.C., June 25, 2015), Order Resolving Two Interrelated Issues and Certification for Interlocutory Appeal, p. 2-3; "U.S. ex rel. Michaels v. Agape Senior Cmty, Inc" Case no. 0:12-cv-03466-JFA (D.S.C., August 22, 2014), Plaintiff's Memorandum in Support of Motion to Permit the Use of Statistical Sampling, Exhibit A, p. 3.
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10 *Ibid*, p. 4.
11 *Ibid*, p. 5.
12 *Ibid*, p. 6.
13 *Ibid*, p. 9, 13; "U.S. ex rel. Michaels v. Agape Senior Cmty, Inc" Case no. 0:12-cv-03466-JFA (U.S. App. 4 Cir. February 14, 2017), Opinion.
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16 "U.S. ex rel. Michaels v. Agape Senior Cmty, Inc" Case no. 0:12-cv-03466-JFA (U.S. App. 4 Cir. February 14, 2017), Opinion, p. 26.
17 "U.S. ex rel. Ruckh v. Genoa Healthcare Consulting, LLC, et al." Case no. 8:11-cv-1303-T-23TBM (M.D. Fla. June 3, 2013), Relator's Revised Second Amended Complaint and Demand for Jury Trial, p. 3-5.
18 *Ibid*, p. 32.
19 *Ibid*, p. 5.
20 *Ibid*, p. 9.
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26 *Ibid* p. 3.

27 *Ibid*, p. 4.

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