Courts Remain Skeptical Of FCA Statistical Arguments

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On March 30, a federal court in Massachusetts dismissed without prejudice an action brought under the False Claims Act.[1] The dismissal is noteworthy because it highlights courts' continued skepticism of using statistics and other evidence (i.e., not the submission of actual claims) to establish liability under the FCA. The decision is particularly important since it comes from the First Circuit, a jurisdiction where the FCA's pleading standards, although ostensibly based in Rule 9(b), are relaxed relative to other regional circuits in certain situations.

The prevailing narrative is that courts permit statistical extrapolation only in those FCA cases where liability is already established for the limited purpose of determining the extent of damages and penalties.[2] Liability itself, in contrast, should be adjudged only through the identification and examination of individual claims submitted to the government.[3]

Some courts, however, have permitted relators to narrow their focus to a sample of claims, from which the falsity of other claims outside the sample can supposedly be estimated, because of the complexity of the case or large number of claims at issue.[4] The difficulty of proving liability in such cases is demonstrated by certain health care cases, where tens of thousands of claims for payment may have been submitted to the federal government.[5] To date, no federal appellate court has squarely addressed whether this is a valid application of the FCA.[6]

The leading case on the use of statistics is the Fourth Circuit's decision in Agape. There, the district court rejected the use of sampling, but certified the issue for interlocutory appeal. The appeals court seized on the trial court's suggestion that some FCA suits — namely, suits where dissipated or destroyed evidence makes direct claimby-claim evaluation impossible — are appropriate for proof of liability by extrapolation.[7] 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 the matter was settled on Aug. 23, 2017. Agape is important because it leaves open the possibility that liability can be established using statistical sampling, but, as mentioned above, does not definitively resolve the issue one way or the other.

Agape comes on the heels of other decisions in which statistical sampling to establish liability had been permitted by agreement of the parties or had been suggested permissible in dicta.[8] The takeaway from these decisions is that, in the absence of definitive resolution from the appellate courts, relators will continue to push for broader acceptance of statistics and other evidence at the liability stage.

As the relators bar attempts to expand the use of statistical sampling and other nonclaim evidence, it will face significant headwinds in form of the Rule 9(b) pleading standards. In most FCA cases, pursuant to Rule 9(b), relators are required to "provide details that identify particular false claims for payment that were submitted to the government."[9] But in the First Circuit, under a case known as Duxbury, a relator may present details of a scheme paired with "reliable indicia that lead to a strong inference that claims were actually submitted" when the relator's complaint alleges that a third party has been induced to file false claims. Such "factual or statistical evidence" must "strengthen the inference of fraud beyond possibility without necessarily providing details as to each false claim."[10]

These pleading standards set the stage for a federal court in Massachusetts to decide whether statistics and other evidence would be permitted in a case that did not involve fraudulent inducement. Luckily for defendants, the district court's March 30, 2018, Wollman decision did not go so far.

In Wollman, a former anesthesiologist with <u>Massachusetts General Hospital</u> (MGH) filed an FCA suit against the hospital alleging that MGH, a physician group practicing there, and Partners Healthcare System would bill government payors for multiple, temporally overlapping surgical procedures supposedly performed by the same teaching physician, but actually performed by residents and fellows under such physician's supervision whose services were ineligible for reimbursement.[11] Dr. Lisa Wollman also alleged that certain procedures lacked medical necessity and questioned the reasonableness of the defendants' use of anesthesia and whether patients had given valid consent to treatment by nonphysicians.[12] Wollman argued that providing significant detail about the provision of certain overlapping surgeries and the Medicare/Medicaid eligibility of particular patients should be sufficient to establish "reliable indicia that lead to a strong inference that claims were actually submitted" under Duxbury.

The court noted that Wollman, based on her alleged personal observations as an anesthesiologist serving MGH's orthopedic surgery department, "provide[d] notable detail with respect to the commonplace occurrence of overlapping surgeries at MGH, including the date, surgeon, start time, location, duration, and type of surgery for numerous procedures."[13] In addition:

To strengthen the inference of fraud, [the relator] submits that ... Medicare was the primary payor for 63.3% of total knee replacements and 58.2% of total hip replacements in 2000, 54.7% of total knee replacements in 2009, and 52.8% of total hip replacements in 2009; and ... MGH's orthopedic surgeons performed concurrent surgeries that involved patients who, because they were aged 65 or older, were likely to be covered by Medicare and/or Medicaid. She further asks that the Court take judicial notice of the fact that more than 43 million people aged 65 or older were covered by Medicare in 2012, which allegedly results in nearly universal coverage for that age demographic. MGH also had a policy ... implying that MGH bills the government for at least some concurrent surgeries. Relator attached to her opposition brief additional exhibits to show that Medicare paid MGH approximately \$766 million for 33,702 inpatient and 752,283

outpatient claims for services provided to beneficiaries during 2010 and 2011, and approximately 2,218 Medicare in-patients underwent orthopedic surgery at MGH in 2016.[14]

Yet, as the court observed, none of the relator's narratives and numbers rose to the level of detail required "with respect to the actual submission of claims; no dates, identification numbers, amounts, services, individuals involved, or length of time are provided for a single claim on any overlapping surgery."[15] Wollman argued that this should be of no moment because, under the First Circuit's more flexible Duxbury pleading standard, Wollman provided "reliable indicia that lead to a strong inference that claims were actually submitted" and lacked access to, and therefore should not be required to plead, specific claims data, particularly in light of the significant demonstration of patients' Medicare/Medicaid eligibility and the frequency with which Medicare and Medicaid pay claims.[16] In a footnote, however, U.S. District Judge Allison Burroughs took care to reject the relator's efforts to substitute a showing of Medicare eligibility for evidence that claims were actually submitted.[17] Citing a line of First Circuit cases, the district court recognized the clear distinctions between eligibility and actual coverage, and between coverage and actual claims submission.[18]

It is only a matter of time until the appellate courts begin to decide how courts should grapple with the tension between the rigorous pleading standards associated with the False Claims Act and relators' insistence that statistics and other evidence be used to establish liability in difficult-to-prove cases. In the meantime, it appears that, post-Escobar, the courts, citing Rule 9(b), remain skeptical of FCA actions constructed from statistics and evidence other than actual false claims.

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[1] See Robert T. Rhoad, Matthew W. Turetzky, Sean M. Cuddihy, and Aaron Raddock, "FEATURE COMMENT: Making Fuzzy Math Less Fuzzy—A Practical Guide For Litigating And Winning False Claims Act Cases Involving Statistical Sampling," The Government Contractor (Sept. 27, 2017) ("The Government Contractor Comment" hereinafter); U.S. ex rel. Wollman v. The Gen. Hospital Corp., No. 15-cv-11890-ADB, slip op. at 1–2 (D. Mass. Mar. 30, 2018).

[2] See, e.g., U.S. v. Life Care Ctrs. of Am., Inc., 114 F.Supp.3d 549, 560 (E.D. Tenn. 2014); but see The Government Contractor Comment at 288–89 (reexamining cases cited therein).

[3] See, e.g., U.S. ex rel. Crews v. NCS Healthcare of Ill., Inc., 460 F.3d 853, 856 (7th Cir. 2006) (rejecting relator's reliance on "basic math" to determine how many Medicaid-funded prescription fills had likely included improperly recycled pills).

[4] E.g. Life Care, 114 F.Supp.3d at 560.

[5] For example, in the Tuomey Health Care case, the jury found that Tuomey had submitted over 21,000 claims for reimbursement. The number of claims at issue made it so half of the \$243 million judgment entered following a jury's verdict was comprised of civil penalties, which at the time were worth \$5,500 per claim. See https://www.justice.gov/opa/pr/united-states-resolves-237-million-false-claims-act-judgment-against-south-carolina-hospital (DOJ settlement press release).

[6] See U.S. ex rel. Michaels v. Agape Senior Cmty., Inc., 848 F.3d 330, 333 (4th Cir. 2017) (dismissing as improvidently granted (that is, declining to address on merits) interlocutory appeal from partial summary judgment against extrapolation evidence).

[7] ld.

[8] United States 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."); United States 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).

[9] Wollman, slip op. at 13, quoting U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 226 (1st Cir. 2004), abrogation on other grounds recognized by U.S. ex rel. Gagne v. City of Worcester, 565 F.3d 40, 45 (1st Cir. 2009).

[10] Id. at 14–15 (quoting U.S. ex rel. Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13 (1st Cir. 2009) (internal quotation marks omitted)).

[11] Id. at 1–2.

[12] Id. at 6.

[13] Id. at 16.

[14] Id. at 17 (internal citations omitted).

[15] ld.

[16] Id. at 20.

[17] Id. at 19 n.4.

[18] Id. (citing Hagerty ex rel. U.S. v. Cybertronics, Inc., 844 F.3d 26, 29, 33 (1st Cir. 2016); D'Agostino v. <u>ev3</u>, Inc., 845 F.3d 1, 11 (1st Cir. 2016)).