IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA, et al. ex rel. Ruckh, et al.	)	
Plaintiff,	)	No. 8:11-cv-1303-T-23TBM
v.	)	
CMC II, LLC, et al.	)	
Defendants.	)	

THE UNITED STATES' STATEMENT OF INTEREST

Pursuant to 28 U.S.C. § 517 and the Court's March 23, 2015 order (Doc. 184), the United States submits the following Statement of Interest to respond to certain arguments raised in Defendants' Response to Relator's *Motion in Limine* to Admit Expert Statistical Sampling Testimony (Doc. 179). Federal courts have regularly approved of the use of sampling as evidence in a variety of contexts, including both criminal and civil fraud cases. Defendants, however, contend that statistical sampling and extrapolation cannot from the basis for liability in a False Claims Act case. Doc. 179 at 12-15.

For the reasons stated below, Defendants' position is contrary to established case law. Indeed, allowing the use of statistical sampling evidence is not only routine but essential in False Claims Act cases where the defendants' conduct caused the submission of more false claims and records than could reasonably be tried before a court on a claim by claim basis.

In this filing, the United States clarifies its position with respect to the following issues raised in Defendants' response to Relators' *Motion in Limine*: (1) whether statistical sampling is an admissible, valid, and essential method of proof in complex cases, including False Claims Act cases; (2) whether the False Claims Act requirement of proof of false claims precludes the use of statistical sampling; (3) whether statistical sampling is appropriate where each patient or claim involves unique characteristics; and (4) whether the False Claims Act requires proof, on a claim by claim basis, of a defendant's knowledge that it was submitting, or causing the submission of, false claims. The United States takes no position as to whether Relator's motion is premature or whether the Court should conduct a *Daubert* hearing to address the sample design set forth by Relator's expert, Constantijn Panis, Ph.D.[1]

[1] The United States notes, however, that the court in *United States ex rel. Martin v. Life Care Centers of America, Inc.*, Civ. No. 1:08-cv-251, 1:12-cv-64, 2014 WL 4816006, (E.D. Tenn. Sept. 29, 2014), addressed the admissibility of the government's expert's sample design well before the close of discovery (which is ongoing in that case) and before the medical review, upon which the expert statistician would base his estimates, was completed. *See. id.* at *16 ("Because the medical review has not yet been completed, the precision of the estimates attained from [the government's expert's] sample design is unknown.") Moreover, the *Life Care* court considered and rejected the same arguments from the same expert, Mr. Stefan Boedeker, that Defendants propound here. Specifically, the court in *Life Care* rejected arguments that the government's expert's methodology was somehow flawed because he "did not perform a probe sample, calculate a sample size, account for any variable, set precision requirements up front, and address issues with the medical review." *Id.* at *13, 17-18 ("Defendant's arguments merely distinguish other approaches that [the government's expert] could have taken rather than identifying significant flaws in the sampling plan.").

Without citing support from any statistical authorities, Defendants also argue that the sample design is "woefully inadequate" because the sample is a small percentage of the population from which it was drawn. Doc. 179 at 17. The absence of statistical support for such a statement, however, is unsurprising

BACKGROUND

Sampling is a common, mathematically proven technique by which estimates of a characteristic of a population can be made based on a sample of that population. *United States v. Rosin*, 263 Fed. Appx. 16, 29 (11th Cir. 2008) ("The purpose of statistical sampling is to provide a means of determining the likelihood that a large sample shares characteristics of a smaller sample."); *In re Countrywide Fin. Corp. Sec. Litig.*, 984 F. Supp.2d 1021, 1038 (C.D. Cal. 2013) ("[T]he purpose of using a sample is to extrapolate results from a small sample to a large population."). "The essence of the science of inferential statistics is that one may confidently draw inferences about the whole from a representative sample of the whole. The applicability of inferential statistics have [sic] long been recognized by the courts." *In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1019-20 (5th Cir. 1997). Indeed, as even the public is well aware during election cycles, surveys of a small number of voters can predict the electoral winner. *See United States v. Ukwu*, 546 Fed. Appx. 305, 308 (4th Cir. 2013) ("[I]n many elections, a sample of 1,000 Americans can show, with enough certainty to satisfy the preponderance of the evidence standard, what is likely to happen in an election involving over 100 million voters.") (upholding the use of statistical sampling to prove amount of loss in tax fraud case).

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because "[p]opulation size . . . usually has little bearing on the precision of estimates for the population average." David H. Kaye and David A. Freedman, *Reference Guide on Statistics*, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 211, 214 (Fed. Judicial Ctr., 3d ed. 2011). In other words, as even Mr. Boedeker has previously testified in the *Life Care* case, "the universe size has a relatively small impact on the sample size necessary to achieve the same results in terms of confidence and precision." *See United States ex rel. Martin v. Life Care Centers of America*, Case No. 1:08-cv-251, 1:12-cv-64, Boedeker Dep. at 186:16-18, Doc. 151-4 (attached as Exhibit A).

ARGUMENT

I. Sampling is an Established Method of Proof in Complex Litigation and False Claims Act cases

Statistical sampling and extrapolation have been widely accepted by federal courts and used in various types of litigation. *See, e.g*., *Rosin*, 263 Fed. Appx. at 21, 29 (finding no error in the admission of testimony in a criminal health care fraud case of a statistical expert who selected a statistically valid random sample of biopsy slides that were reviewed by medical experts and extrapolated a preliminary loss figure from the defendant physician's conduct based on the medical review); *Republic Svcs., Inc. v. Liberty Mut. Ins. Co.*, No. Civ.A. 03–494–KSF, 2006 WL 2844122, at *3 (E.D. Ky. Oct. 2, 2006) (accepting statistical sampling in case alleging mismanagement of workers' compensation program); *Blue Cross & Blue Shield of N.J. v. Phillip Morris, Inc.*, 113 F. Supp. 2d 345, 372-75 (E.D.N.Y. 2000) (in RICO case, stating that "[t]he use of statistical evidence and methods in the American justice system to establish liability and damages is appropriate").

Courts have approved of the use of statistical sampling and extrapolation where an individualized claim-by-claim-review of the elements in a case would be unfeasible or extremely costly and where the challenging party is afforded an opportunity to rebut the results. *See, e.g., Chaves County Home Health Serv. v. Sullivan*, 931 F.2d 914, 919 (D.C. Cir. 1991) (observing that statistical sampling has been allowed in a wide range of contexts "to determine whether there has been a pattern of overpayments spanning a large number of claims where case-by-case review would be too costly"); *United States v. Fadul*, Civil Action No.

DKC 11-0385, 2013 WL 781614 at *14 (D. Md. Feb. 28, 2013) (explaining that "[c]ourts have routinely endorsed sampling and extrapolation as a viable method of proving damages in cases involving Medicare and Medicaid overpayments where a claim-by-claim review is not practical").

In *Fadul*, for example, the court considered statistical extrapolation for damages after finding that a medical practice was liable for the improper Medicare and Medicaid payments it had received under the common law theory of payment by mistake. Based on a medical expert's review of a sample of the improper claims, the court awarded damages based on an extrapolation of the results of that review. 2013 WL 781614 at *12, 14. In doing so, the court determined that the use of statistical extrapolation in such circumstances is firmly established. *Id*. at 14 (citing cases).

Moreover, courts have repeatedly upheld the use of statistical sampling in Medicare and Medicaid overpayment cases as a valid means by which the Department of Health and Human Services may determine the amount of overpayment by Medicare and Medicaid to health care providers.[2] In *Califano*,

[2] *See Balko & Assocs. v. Sec'y,* 555 Fed. Appx 188, 194 (3d Cir. 2014) (upholding use of extrapolation in review of Medicare overpayments); *Ratanasen v. State of Cal., Dep't of Health Servs.*, 11 F.3d 1467, 1471 (9th Cir. 1993) (joining other circuits in "approving the use of sampling and extrapolation as part of [Medicare] audits . . . provided the aggrieved party has an opportunity to rebut such evidence"); *Yorktown Med. La., Inc. v. Perales,* 948 F.2d 84, 89-90 (2d Cir. 1991) (approving the use of sampling and statistical evidence to determine Medicaid overpayment); *Ill. Physicians Union v. Miller*, 675 F.2d 151, 155 (7th Cir. 1982) ("The use of statistical samples to audit claims and arrive at a rebuttable initial decision was reasonable where the number of claims rendered a claim-by-claim review a practical impossibility."); *Miniet v. Sebelius*, No. 10-24127-CIV, 2012 WL 2930746, at *6 (S.D. Fla. July 18, 2012) (in medical necessity case, propriety of statistical extrapolation to determine the amount of overpayment is "undisputed," and "the sampling utilized need not be based on

for example, the Department of Health, Education and Welfare ("HEW"), based on a review of statistically random samples of Medicaid claims paid by the state of Georgia, determined that Georgia had overpaid doctors $1,614,788 of federal funds. 446 F. Supp. at 406-07. Georgia challenged this finding as "arbitrary and capricious because the amount of overpayment was determined by use of a statistical sample rather than individual claim-by-claim review." *Id*. at 409. In rejecting Georgia's challenge to HEW's finding, the *Califano* court held that "[p]rojection of the nature of a large population through a review of a relatively small number of its components" has been approved by federal courts and "mathematical and statistical methods are well recognized as reliable and acceptable evidence in determining adjudicative facts." *Id*.

When asked to address the use of statistical sampling evidence in False Claims Act cases, courts have generally found such evidence admissible. *See, e.g., United States v. AseraCare, Inc*., Civ. Action No. 2:12-CV-245-KOB, 2014 WL 6879254, at *3, 10, 12-13 (N.D. Ala. Dec. 4, 2014); *United States v. Halifax Hosp. Med. Ctr.*, No. 6:09-cv-1002-ORL-31TBS, 2014 WL 68579 at *1-2 (M.D. Fla. Jan. 8. 2014) (denying a motion to exclude Relator's statistical expert); *United States ex rel. Martin v. Life Care Centers of America*, Case No. 1:08-cv-251, 1:12-cv-64, 2014 U.S. Dist. LEXIS 142660 (E.D. Tenn. Sept. 29, 2014); *United States v. Cabrera-Diaz*, 106 F. Supp. 2d 234 (D.P.R. 2000).

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the most precise methodology, just a valid methodology"); *Pruchniewski v. Leavitt*, No. 8:04-CV-2200-T-23TMB, 2006 WL 2331071 at *7 & n.9 (M.D. Fla. Aug. 10, 2006) (Merryday, J.); *Webb v. Shalala*, 49 F. Supp. 2d 1114, 1123 (W.D. Ark. 1999); *Georgia v. Califano*, 446 F. Supp. 404, 409 (N.D. Ga. 1977); *see also Mile High Therapy v. Bowen*, 735 F. Supp. 984, 986 (D. Colo. 1988) (rejecting speech and physical therapy provider's challenge to HHS' use of sampling in Medicare overpayment case).

In *AseraCare*, the United States contends that the defendant hospice submitted false claims to Medicare for hospice care which was not medically necessary. 2014 WL 6879254, at *2. The United States seeks damages based on an extrapolation of the results of a medical review of two statistically valid random samples selected from two universes of the hospice's patients. *Id*. at 3. The *AseraCare* court ruled that "statistical evidence *is* evidence" regarding the claims which the hospice submitted for patients within the universes from which the samples were selected, but not included within the samples, and denied the hospice's motion to exclude the United States' statistical expert and its motion for partial summary judgment. *Id*. at *3, 10, 12-13.

The *Life Care* court also recently affirmed the admissibility of statistical sampling and extrapolation in a False Claims Act case involving allegations against another skilled nursing facility chain. 2014 U.S. Dist. LEXIS 142660. In *Life Care*, the United States alleges that the defendant, which owns over 200 skilled nursing facilities, knowingly caused the submission of claims to Medicare and TriCare for therapy services that were medically unnecessary and unreasonable in violation of the False Claims Act. *Id.* at *5-19. The United States disclosed a statistical expert who selected a statistically valid random sample of patient admissions from a population of the defendant's patients within certain facilities during a certain time frame. *Id.* at *20; 2014 WL 4816006, at *5. The United States also disclosed that its statistical expert will extrapolate the number of false claims which Defendant caused to be submitted for patients in the population and the amount Medicare and TriCare overpaid Defendant for

patients in the population based on the results of expert review of the medical records for patients within the sample. 2014 U.S. Dist. LEXIS 142660, at *20; 2014 WL 4816006, at *19.

In denying Defendant's motion for partial summary judgment to bar the United States' use of statistical sampling with respect to its False Claims Act allegations, the *Life Care* court observed that "a claim-by-claim review is often impractical" in cases involving numerous potential false claims and that the exclusion of statistical sampling and extrapolation in False Claims Act cases "would open the door to more fraudulent activity because the deterrent effect of the threat of prosecution would be circumscribed." 2014 U.S. Dist. LEXIS 142660, at *63. Finding that "[t]he language and the history of the FCA do not suggest that statistical sampling is an improper vehicle by which to litigate FCA claims," the *Life Care* court held that "statistical sampling may be used to prove claims brought under the FCA involving Medicare overpayment." *Id*. at *62, 64.

In *Cabrera-Diaz*, the United States alleged that the defendant, Dr. Cabrera, knowingly submitted claims for anesthesia services at a local hospital that "overstated, falsely reported, undocumented, and/or unsupported" his anesthesia time. 106 F. Supp. 2d at 237. The United States selected a statistically valid random sample of 230 claims filed by Dr. Cabrera in 1994, and 231 claims filed by him in 1995. *Id.* The United States determined that all but six of the 461 claims were not supported by the underlying medical records. *Id.* The United States further determined that damages for the sampled claims and

records were $75,338.78 for the 1994 claims and $56,448.99 for the 1995 claims. *Id.*

Based on these results from its review of the sampled claims, the United States, through extrapolation to the universe of claims, determined that the total amount overpaid to Dr. Cabrera was $237,600.39 in 1994 and $211,773.89 in 1995. *Id.* After Dr. Cabrera failed to appear, the United States moved for a default judgment. *Id.* at 238. The district court granted that motion, holding that the United States had proven all of the elements of the False Claims Act. *Id.* Finding ample precedent in the Medicare and Medicaid overpayment context, the district court awarded the United States three times the amount of the extrapolated overpayment as damages. *Id.* at 240-41.

II. The False Claims Act Requirement of Proof of False Claims Does Not Preclude the Use of Statistical Sampling

The purpose of statistical sampling and extrapolation is to permit reasonable inferences about a universe of claims from a sample of that universe. In a case involving allegations that defendants submitted, or caused to be submitted, thousands of false claims to the Medicare program for medically unnecessary therapy services, sampling permits a fact finder to reasonably infer, based on the extrapolated results of a medical review of a sample of a universe of the defendants' patients, the amount that the government overpaid as a result of the false claims that the defendants submitted, or caused to be submitted, for patients within the universe of patients.

Defendants, in opposing Relator's *motion in limine*, contend that "statistical sampling evidence and extrapolation cannot form the basis for liability

in a FCA case due to a lack of individual proof" because it "eliminates the opportunity for Defendants to present factual and expert evidence that the therapy actually provided to individual patients was medically necessary." Doc. 179 at 12. Courts, however, have rejected the argument that statistical sampling evidence and extrapolation cannot be relied on in a False Claims Act case because of the need for "individual proof." *See Life Care*, 2014 U.S. Dist. LEXIS 142660, at *44-46 (rejecting that argument because "the purpose of statistical sampling is precisely for these types of instances in which the number of claims makes it impracticable to identify and review each claim and statement"); *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008) (rejecting the argument that "the district judge had to address each of the 1,812 claim forms" at issue and holding that "[s]tatistical analysis should suffice"); *see also Yorktown Med. Lab.,* 948 F.2d at 89 (rejecting argument, in an overpayment case, that sampling improperly prevented doctor from contesting "unidentified unacceptable practices"). Indeed, in rejecting these very arguments, the *Life Care* court explained:

> [T]he fact that [individualized] factors exist and are likely unique to each patient does not necessarily preclude the use of statistical sampling. Statistical sampling has been used in litigation for decades, and Defendant's argument regarding the individuality of each claim in the sample is not unique to this litigation. *See State of Ga., Dep't of Human Res.*, 446 F. Supp. at 409. In fact, Defendant's argument highlights the very nature of statistical sampling: that a smaller portion of claims will be used to draw an inference about a larger, not entirely identical, population of claims. *In re Countrywide Fin. Corp. Mortgage-Backed Sec. Litig.*, 984 F. Supp. 2d at 1033. If all of the claims were exactly the same in every respect, there would be no need for statistical sampling and extrapolation in litigation because each individual unit would be identical, and it

> would be relatively simple to formulate a mathematical calculation for a large number of claims.

2014 U.S. Dist. LEXIS 142660, at *49.

Defendants rely primarily on *United States v. Friedman*, 1993 U.S. Dist. LEXIS 21496 (D. Mass. July 23, 1993), to support their assertion that statistical sampling and extrapolation cannot form the basis for liability in a False Claims Act case because of the need of individual proof. Doc. 179 at 12-13. As discussed by the *Life Care* court, the *Friedman* case did not address the question whether statistical sampling and extrapolation can be used in a case where it is "impracticable for the Court to review each claim individually" because of the number of claims potentially at issue in the case. *Life Care*, 2014 U.S. Dist. LEXIS 142660, at *32-33, 45-46. Thus, *Friedman* does not support the proposition that statistical sampling and extrapolation cannot support a cause of action under the False Claims Act.

In *Friedman*, the United States alleged that the defendant submitted false claims for reimbursement for psychiatric services over a two year period. 1993 U.S. Dist. LEXIS 21496, at *2, 5-6. Over that time period, defendant submitted a total of 676 total claims for the procedure codes at issue. *Id*. at *5-6. At trial, the United States presented expert medical testimony on a random sample of 350 of the 676 total claims. *Id*. at *9 n.1. While recognizing "the validity of the mathematical and statistical projections based on a review of a small number of claims," the *Friedman* court refused to extrapolate the results of the expert review of the 350 claim sample to the universe of 676 total claims. *Id*. The *Friedman*

court, however, cited no case law or other authority in support of its ruling on statistical sampling evidence.

In denying Defendants' motion for partial summary judgment as to the United States' proposed use of statistical sampling, the *Life Care* court observed that the *Friedman* case differed from a False Claims Act case where potentially thousands of claims are at issue "because there was a sufficiently limited universe of claims [in *Friedman*] for the court to review each one individually rather than relying on extrapolation." *Life Care*, 2014 U.S. Dist. LEXIS 142660, at *45. The *Life Care* court further found that "the court in *Friedman* recognized the validity of statistical sampling even though it was not applied in that case, indicating that the case does not stand for the proposition that statistical sampling cannot be used in large scale FCA cases." *Id*. at *33. The Life Care court also noted that "the court in *Friedman* cited no case law in support of its position, nor did it explain its reasoning for declining to use statistical extrapolation in detail." *Id.* at *46.

Moreover, a court in the District of Massachusetts, in a case subsequent to *Friedman*, also recognized that sampling can be used to support a False Claims Act case. *United States ex rel. Loughren v. Unumprovident*, 604 F. Supp. 2d 259, 261 (D. Mass. 2009). In *Loughren,* the relator alleged that the defendant insurance company caused its insureds to file disability applications with the Social Security Administration that falsely stated that the claimants were unable to work. *Id.* at 260. There were 468,641 applications at issue. *Id.* at 263. The relator sought to introduce expert testimony regarding the use of "statistical

techniques to extrapolate the number of false claims within a sample of claims to an estimation of the total number of false claims filed." *Id.* at 260. Defendant challenged the reliability of the extrapolation. *Id*. While excluding relator's statistical expert based on a determination that the sampling methodology was flawed, the *Loughren* court held that "extrapolation is a reasonable method for determining the number of false claims so long as the statistical methodology is appropriate." *Id.* at 261, 269 (citations omitted).

III. Statistical Sampling is Appropriate in a False Claims Act Case Where Each Patient or Claim Involves Unique Characteristics

Defendants' opposition to Relator's *motion in limine* also suggests that use of statistical sampling is inappropriate specifically because this case involves issues of medical necessity. Doc. 179 at 13-14. Defendants contend that the determination of whether therapy provided to a particular patient for a specific time period was medically necessary involves unique factors about the needs and care of the particular patient "including, without limitation, the 'subjective' health care professional assessment of the individual's particular needs." *Id.* at 13. Because medical necessity determinations are based on unique factors for each patient, Defendants assert that Relator cannot "carry her burden of proof by presenting an across the board extrapolation of unidentified residents with unidentified medical problems." *Id*. at 13-14.

This argument reflects a misunderstanding of the science of statistical extrapolation itself and should be rejected. The purpose of statistical sampling and extrapolation is to permit reasonable inferences about a universe of claims from a sample of that universe. *See In re Chevron U.S.A., Inc.,* 109 F.3d at

1019-20. Such reasonable inferences can be drawn from a random sample of a universe even where the universe of claims are not identical. *See Life Care*, 2014 U.S. Dist. LEXIS 142660, at *49 (holding that the "very nature of statistical sampling [is] that a smaller portion of claims will be used to draw an inference about a larger, not entirely identical, population of claims."). Indeed that is the whole point of sampling. If there was no variability in the universe being considered, there would be no need for sampling. *Id*. ("If all of the claims were exactly the same in every respect, there would be no need for statistical sampling and extrapolation in litigation because each individual unit would be identical, and it would be relatively simple to formulate a mathematical calculation for a large number of claims.").

The *Life Care* court specifically addressed the issue of whether the uniqueness of patients within universes of Medicare skilled nursing facility patients precludes the use of statistical sampling and extrapolation in a False Claims Act case. *Id*. at *46-50. Life Care contended "as the Government will only rely on statistical sampling and will not present evidence concerning patients' actual conditions, diagnoses, clinical needs, the nature of therapy, or the extent of therapy, the Government cannot establish that the therapy provided to each patient was medically unnecessary." *Id*. at *47.

While recognizing that the medical necessity of therapy for individual patients within the universe from which the sample was selected depends on factors unique to the individual patients, the *Life Care* court held that "as long as the statistical sample is a valid sample that is representative of the universe of

claims, the natural disparity between the claims does not preclude sampling and extrapolation as evidence of the total number of claims for non-covered services." *Id.* at *50. A defendant still has the ability to present evidence contesting the inference from a sample to the universe from which the sample was selected even where statistical sampling and extrapolation evidence is permitted. As the *Life Care* court recognized, if a defendant "wishes to challenge the weight that a fact finder may attribute to the extrapolation, it can employ cross-examination and competing witnesses and testimony to highlight the disparity between claims." *Id*. at *49-50.

In addition, the Southern District of New York considered and rejected an argument similar to that of Defendants in a case involve securities backed by home equity loans. In *Assured Guar. Mun. Corp. v. Flagstar Bank, FSB*, 920 F. Supp. 2d 475 (S.D.N.Y. 2013), the plaintiff alleged that Flagstar misrepresented the suitability of thousands of loans. *Id.* at 477. The loans were underwritten by numerous employees of the defendant on an individual, loan-by-loan basis. *Id.* at 481. Based on these facts, the defendant "argues that the fact determination of material breach [of representations of suitability of a loan] in any given instance requires consideration of an entire loan file[,]" and that this fact "renders the loans ill-suited to proof by statistical sampling." *Id.* at 512.

The *Assured Guaranty* court, however, found the defendant's argument "unpersuasive," explaining that "[t]he very purpose of creating a representative sample of sufficient size is so that, despite the unique characteristics of the individual members populating the underlying pool, the sample is nonetheless

reflective of the proportion of the individual members in the entire pool exhibiting any given characteristic." *Id.; see also Mass. Mut. Life Ins. Co.* 989 F. Supp.2d 165, 173 (D. Mass. 2013) (permitting sampling where ultimate question of liability was a binary one, where defendants argued that sampling was inappropriate because "the four major inquiries [at issue] depend on complex and subjective analyses and cannot be reduced to simple 'yes-no' formulations").

There is simply nothing inherently unique about medical reviews, or medical reviews in the context of rehabilitation therapy in skilled nursing facilities, that would somehow render them inappropriate for sampling. Indeed, under the logic of Defendants' argument, even medical reviews to determine whether services billed for complied with Medicare's rules and regulations in the administrative context would not be appropriate for extrapolation. This is patently absurd and would undermine the government's efforts to protect the integrity of Medicare.[3]

IV. The False Claims Act Does Not Require Proof, On a Claim-by-Claim Basis, of Defendants Knowledge That it Was Submitting, or Causing the Submission of, False Claims

Under the False Claims Act, the United States must prove that a defendant submitted, or caused the submission of, false claims with "actual knowledge", "deliberate ignorance," or "reckless disregard" of the truth or falsity of the information in the claims. 31 U.S.C. § 3729(b)(1)(A). The False Claims

[3] *See* Medicare Program Integrity Manual, Chapter 1 – Medicare Improper Payments: Measuring, Correcting, and Preventing Overpayments, available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c01.pdf, Medicare Program Integrity Manual, Chapter 8 – Administrative Actions and Statistical Sampling for Overpayment Estimates, available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c08.pdf.

Act is clear that proof of specific intent to defraud is not required to establish the "knowing" submission of false claims. 31 U.S.C. § 3729(b)(1).

In opposing Relator's *motion in limine*, Defendants contend that "[t]he statistical methodology also eliminates Defendants' opportunity to present evidence and testimony from nurses and therapists who provided services to individual residents, where such testimony could inform the jury decision as to whether the therapy was medically necessary, as well as whether the mental state of such met the FCA element of scienter." Doc. 179 at 14. To the extent Defendants are arguing that the plaintiff, in a False Claims Act case alleging that a corporate entity has submitted, or caused the submission of, false claims, must prove that the corporate entity's knowledge of the falsity of particular claims on a claim by claim basis, or that the specific individuals who provided services connected with specific claims had particular knowledge of the falsity of claims, they are incorrect.

Courts have rejected the argument that a plaintiff in a False Claims Act action must prove, on a claim-by-claim basis, that a defendant had knowledge of the particulars of each claim submitted. *See United States ex rel. Jordan v. Northrop Grumman Corp.*, No. CV 95–2985 ABC (Ex), 2002 WL 34251040, at *17 (C.D. Cal. Aug. 5, 2002) ("'[I]f [defendant] knew that its actions would result in a number of false claims, the FCA penalizes it for each false claim.'") (characterizing the holding of, and quoting, *United States ex rel. Garibaldi v. Orleans Parish Sch. Bd.*, 46 F. Supp. 2d 546, 555 (E.D. La. 1999)) (alteration in original); *see also United States v. Chen*, 402 Fed. Appx. 185, 188-89 (9th Cir.

Oct. 28, 2010) (where doctor conceded he engaged in similar practice with respect to all claims, government need not prove the particulars of all 3,544 claims). Rather, courts have recognized that a defendant's scienter, for the purposes of the False Claims Act, can be proven through evidence that, as a result of a defendant's corporate practices or pressure, it "knew" that false claims would be submitted, without requiring individualized evidence as to each and every claim.[4]

Moreover, the Eleventh Circuit has recognized that the determination of whether a corporate entity acted with the requisite scienter when submitting, or causing the submission of, false claims, should not be based on the knowledge of any single employee of the corporate entity who has connection with a

[4] *See AseraCare*, 2014 WL 6879254, at *9 (holding in a False Claims Act case alleging that a hospice knowingly submitted false claims for hospice care that "[t]he Government can use testimony of former employees and documentary evidence to give rise to an inference from which the jury could conclude that [the hospice's] business practices resulted in the knowing or reckless disregard that it billed CMS for patients whose medical records did not contain clinical information and other documentation to support a certification that the patient was terminally ill"); *United States v. Wells Fargo Bank, N.A.*, 972 F. Supp. 2d 593, 602, 620 (S.D.N.Y. 2013) (allegations that bank engaged in reckless business practices to increase federally insured loans without regard to whether the loans complied with HUD regulations, including pressuring loan officers to issue loans, paying employees a bonus based on the number of loans, and inadequately training employees, along with other allegations, pleaded False Claims Act scienter with sufficient particularity under Fed. R. Civ. P. 9(b)); *United States ex rel. Landis v. Hospice Care of Kansas,* 2010 WL 5067614, at *2-3, 5-6 (D. Kan. Dec. 7, 2010) (holding, when denying a motion to dismiss in a False Claims Act case, that a complaint alleging that defendant hospice companies engaged in a number of business practices that could lead to the submission of false claims and were informed of concerns by both employees and outside consultants that one of the hospice companies "was at risk of admitting patients ineligible for hospice" sufficiently pleaded under Fed. R. Civ. P. 9(b) "how the defendants used their business practices to allegedly violate the FCA" and "the conduct that lead to the violation, including specific policies and actions taken by their employees").

particular claim. In *Grand Union Co. v. United States*, 696 F.2d 888 (11th Cir. 1983), the court reversed the district court's grant of summary judgment to a defendant grocery store that allegedly violated the False Claims Act by redeeming food stamps for ineligible items because of the head cashier's testimony that she did not know, and had no reason to know, that any cashier had accepted payment for ineligible items with food stamps when she submitted the food stamps to the government for payment. *Id*. at 890.

Holding "in cases brought under the False Claims Act that the knowledge of an employee is imputed to the corporation when the employee acts for the benefit of the corporation and within the scope of his employment," the *Grand Union* court ruled that the district court "erred when it focused solely on the head cashier's knowledge" and did not consider the evidence that the defendant's cashiers knew that they were redeeming food stamps for ineligible items*. Id*. at 891; *see also United States ex rel. Christiansen v. Everglades College, Inc.*, Case No. 12-60185-CVDIMITROULEAS/SNOW, at 9 (S.D. Fla. May 6, 2014) (attached as Exhibit B) (holding in a False Claims Act case against a corporate defendant that "[t]he question, therefore, is not whether a specific individual acting on behalf of [defendant] knowingly submitted false claims; rather, the question is whether [defendant], as an entity, knowingly submitted false claims"); *United States v. Kaman Precision Prods., Inc*., No. 6:09-cv-1911-ORL-31, 2011 WL 3841569, at *5 n.14 (M.D. Fla. Aug. 30, 2011) ("A corporation can be held liable under the FCA even if the verifying employee was unaware of the wrongful conduct of other employees").

In sum, this case law establishes that Defendants are incorrect that a False Claim Act plaintiff, in a case alleging that a corporate entity submitted, or caused to be submitted, false claims, must prove the knowledge of any specific individual of the falsity of the claim on a claim by claim basis. Thus, Defendants' reference to the scienter requirements in a False Claims Act case have no bearing on the admissibility of statistical sampling evidence.

CONCLUSION

Defendants ask this Court, in their Response to Relator's *Motion in Limine* to Admit Expert Statistical Sampling Testimony, to ignore well-established precedent from this and other circuits regarding the admissibility of statistical sampling and extrapolation evidence. Use of statistical sampling is supported by established case law and is essential in False Claims Act cases where a defendant's conduct caused the submission of more false claims and records than could practicably be tried on a claim-by-claim basis. A refusal to permit sampling and extrapolation evidence to support a cause of action under the False Claims Act would have the perverse effect of incentivizing fraud by making widespread fraudulent practices less enforceable.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, LACY R. HARWELL, Jr., hereby certify that on April 7, 2015, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system which will send an electronic notification of such filing to counsel for the relators and defendants.

/s LACY R. HARWELL, JR.
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