The Allowance of Statistical Sampling in False Claims Act Cases

Danielle Senn

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I. Health Care Fraud & The False Claims Act: How the Government Responds to the Pervasive Problem of Fraud within the U.S. Health Care System

Health care fraud is a pervasive problem and the False Claims Act (FCA) is an influential means for the government to recover funds and prevent future fraudulent behavior and actions by health care providers.¹ The National Health Care Anti-Fraud Association (NHCAA) estimates that health care fraud results in billions of dollars in losses for Americans every year.² Fraud in the health care industry is easily spread across multiple programs, public and private, which make it difficult to consistently detect.³ Health care fraud is not a victimless crime it results in higher premiums and expenses, reduced coverage, the performance of unnecessary procedures, unsafe diagnosis and unsafe procedures performed on patients, and compromised medical files.⁴ The Government Accountability Office (GAO) estimated that in fiscal year 2017 there was almost $52 billion in improper payments for Medicare.⁵ In order to combat this fraud involving government funds, the Department of Justice successfully uses the FCA.

The FCA was enacted due to the massive amount of fraud perpetrated against the United States during the Civil War.⁶ The purpose of the FCA was to reclaim payments falsely made by wrongdoers and to protect the government from further fraud by deterring false payment

³ Id.
⁴ Id.
submissions.\textsuperscript{7} The FCA deters and punishes fraudulent behavior using damages.\textsuperscript{8} Defendants are subject to repayment of claims found to be false (single damages), plus additional damages calculated at two or three times the amount of false payments, and penalties of $11,181 to $22,363 per claim.\textsuperscript{9}

In fiscal year 2017 the U.S. Department of Justice (DOJ) received over $3.7 billion from judgments and settlements through the FCA.\textsuperscript{10} Fiscal year 2017 was also the eighth consecutive year that the DOJ has received over $3.0 billion.\textsuperscript{11} In fiscal year 2018, the total recovered by the DOJ in civil judgments and settlements was $2.8 billion,\textsuperscript{12} down from the prior year total. The largest recovery area is health care fraud, followed by the financial services industry.\textsuperscript{13} Besides health care and financial services the DOJ receives damages from other industries including defense, energy, and telecommunications.\textsuperscript{14}

According to a 2017 report by the Department of Health and Human Services and the Department of Justice Health Care Fraud and Abuse Control Program, during that fiscal year the Federal government recovered $2.4 billion in judgments and settlements.\textsuperscript{15} In fiscal year 2018 the total recovered was $2.5 billion from the health care industry.\textsuperscript{16} In fact since 2010, the Civil Division’s Commercial Litigation branch has brought in over $2.0 billion every year through

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\item[7] ERIC M. CARLSON, LONG-TERM CARE ADVOCACY, § 10.06 (Matthew Bender 2018); JOEL M. ANDROPHY & REBECCA L. GIBSON, FEDERAL FALSE CLAIMS ACT AND QUI TAM LITIGATION § 6.01, (ALM Media Prop. 2019).
\item[8] CARLSON, supra note 7.
\item[12] Justice Dep’t. Recoveres Over $2.8 Billion from False Claims Act Cases in Fiscal Year 2018, supra note 6.
\item[13] Bloom et al., supra note 11.
\item[14] Id; Justice Dep’t. Recoveres Over $3.7 Billion from False Claims Act Cases in Fiscal Year 2017, supra note 10.
\item[15] HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FISCAL YEAR 2017, supra note 1.
\item[16] Justice Dep’t. Recoveres Over $2.8 Billion from False Claims Act Cases in Fiscal Year 2018, supra note 6.
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judgments or settlements. The fiscal year 2017 Agency Financial Report from The Department of Health and Human Services reported that the Medicaid improper payment rate was 10.10%, which amounts to “$36.73 billion in gross improper payments.”

Recoveries from the health care industry accounted for sixty-seven percent of the total funds received by the federal government from FCA cases in fiscal year 2017. Additionally, claims from health care fraud represented sixty-eight percent of new matters in 2017. FCA settlements and judgments in the health care industry involve both individuals and companies, working within the pharmaceutical industry, at medical device manufacturers, hospitals, pharmacies, laboratories, and nursing homes. From 2010 to 2017 under the FCA the DOJ recovered $20.4 billion from the health care industry. Since the amendments to the FCA in 1986 through fiscal year 2018 the DOJ has recovered in civil judgments and settlements $59 billion.

The government is increasingly turning towards statistical sampling due to the size of the universe of claims involved in FCA health care cases, the costs associated with individual reviews of each claim, and the lack of documentation. The universe of claims (and patients) will continue to rise as the population ages and by the year 2030 the U.S. Census Bureau

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17 Id.
18 HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FISCAL YEAR 2017, supra note 1, at 54.
19 Bloom et al., supra note 11.
20 Bloom et al., supra note 11.
21 Justice Dep’t. Recovers Over $2.8 Billion from False Claims Act Cases in Fiscal Year 2018, supra note 6; see also Bloom et al., supra note 11.
22 Bloom et al., supra note 11.
23 Justice Dep’t. Recovers Over $2.8 Billion from False Claims Act Cases in Fiscal Year 2018, supra note 6.
26 Id. at 18-19.
estimates that 1 out of every 5 Americans will be age 65 or older.\textsuperscript{27} Also, since the 1986 amendments to the FCA the health care industry has been impacted by the rise in technology, this is predicted to continue.\textsuperscript{28} Some Courts have been willing to allow the use of statistical sampling as the quantity of claims has increased and the cost of reviewing claims has risen.\textsuperscript{29}

Currently there remains an open controversy of whether statistical sampling can or should be used by the government in health care FCA cases. District Courts have ruled for and against the use of statistical sampling, but to date no Court of Appeals has answered the specific question of whether statistical sampling is allowable or not allowable. Many commenters and legal analysts have framed the cases into two basic groups: those pro-statistical sampling and those anti-statistical sampling. In complex cases, such as those involving health care fraud, and the complexity of statistical sampling, the facts and circumstances of each case and analysis make the issue itself more complicated than simply a favorable or unfavorable view of statistical sampling.

\textbf{II. FCA Elements and Damages}

\textbf{A. FCA Elements}

The False Claims Act provides under 31 U.S.C. S. § 3729(a)(1):

\begin{quote}
(A) “any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;” or (B) “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim” is liable to the U.S. Government.\textsuperscript{30}
\end{quote}

\textsuperscript{29} United States ex rel. Martin, 114 F. Supp. 3d at 560; see also JOEL M. ANDROPHY & REBECCA L. GIBSON, FEDERAL FALSE CLAIMS ACT AND QUI TAM LITIGATION § 9A.04, (ALM Media Prop. 2019).
In order to meet their burden under the FCA, the government must prove that the person had knowledge, that the claim was false (falsity), and that the claim was material (materiality).\textsuperscript{31} Knowing or knowing is also defined by the statute as meaning that a person: “(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information.”\textsuperscript{32} Further, there is no requirement that the person have the specific intent to defraud the government.\textsuperscript{33}

Falsity requires that the government show that the claim filed was false.\textsuperscript{34} The issue of falsity is separate from proving that the defendant had knowledge of the fraud or acted recklessly.\textsuperscript{35} The government has the burden in FCA cases to prove that the claim itself was false.\textsuperscript{36} Material, as defined by statute, means “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.”\textsuperscript{37} The claim must be material, if a claim is not material then there is no FCA liability. For a claim to be material, as defined above by the statute, it must influence the payment for a claim, if there is no influence upon payment then the claim is not material. \textsuperscript{38} So, if the government pays a claim while knowing that the claim has violated certain requirements, this can be evidence that the violated requirement was not material and therefore no liability.\textsuperscript{39}

Under the FCA there is a direct link to liability and damages by statutory provision. The FCA states:

\textsuperscript{31} United States ex rel. Martin, 114 F. Supp. 3d at 565-69.
\textsuperscript{32} 31 U.S.C. S. § 3729 (b) (1) (A) (2009).
\textsuperscript{33} 31 U.S.C. S. § 3729 (b) (1) (B) (2009).
\textsuperscript{34} 31 U.S.C. S. § 3729 (b) (1) (A) (2009).
\textsuperscript{36} Id.
\textsuperscript{37} 31 U.S.C. S. § 3729 (b) (4) (2009).
\textsuperscript{38} 31 U.S.C. S. § 3729 (b) (4) (2009); see also United States ex rel. Martin v. Life Care Ctrs. of America, Inc., 114 F. Supp. 3d 549, 569 (E.D. Tenn. 2014).
\textsuperscript{39} CARLSON, supra note 7.
In general. Subject to paragraph (2), any person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than $ 5,000 and not more than $ 10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.\(^{40}\)

Once the government has met their burden of proving that a defendant knowingly submitted false claims that were material, then the government is entitled to damages.

As the total quantity of claims has increased along, with rising costs of claim-by-claim review, the government has attempted to utilize statistical sampling and extrapolation to prove liability and calculate the total amount of damages.\(^{41}\) When a health care provider has submitted hundreds or thousands of claims, the use of statistical sampling will save both the time and cost of conducting an individual claim-by-claim review.\(^{42}\) In some of the recent court cases where the government has attempted to utilize statistical sampling the number of claims submitted by a defendant has ranged between 25,000 to almost 155,000 claims.\(^{43}\) With such large universes of claims there would be great expenditures of time and resources to prove each claim false.\(^{44}\) Further, the cost of reviewing claims by medical experts has risen. In one nursing home case, in which the government attempted to use statistical sampling, the government’s estimate was that one expert would need four to nine hours to adequately review a patient’s file and the expert’s

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\(^{44}\) United States ex rel. Martin, 114 F. Supp. 3d at 565.
fee was $400 per hour which totaled between $1,600 to $3,600 per patient.\textsuperscript{45} In that individual case the total expense would range “between $16.2 million and $36.5 million.”\textsuperscript{46} The lack of documentation also drives the government’s attempts to use statistical sampling.\textsuperscript{47} In addition to using statistical sampling to establish liability and damages with larger universes of claims and increased resource devotion, the government has attempted to establish knowledge and falsity using sample claims and then extrapolating.\textsuperscript{48} Given that many providers are now larger organizations that have multiple locations and multiple physicians making determinations, it is more practical for the government to use statistical sampling and extrapolation.\textsuperscript{49} Over time there have been changes to government programs which increased the total number of individuals covered, as well as the creation of anti-fraud programs and incentives by the Centers for Medicare and Medicaid.\textsuperscript{50} These changes have impacted the desire to utilize statistical sampling. Lastly, the statutory language of the FCA does not prevent the government, or any party, from using statistical sampling.\textsuperscript{51}

\textbf{III. Federal Rules of Evidence and the Daubert Standard}

The use of statistical sampling will involve the use of expert evidence and therefore must comply with Federal Rules of Evidence, specifically rule 702, which outlines four elements that guide the Court in admission of expert evidence: “(a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact

\textsuperscript{45} United States \textit{ex rel.} Michaels, 2015 U.S. Dist. LEXIS 82379, at *3.
\textsuperscript{46} \textit{Id.} at *3-4.
\textsuperscript{47} \textit{Id.} at *19.
\textsuperscript{48} United States \textit{ex rel.} Martin, 114 F. Supp. 3d at 565-68.
\textsuperscript{51} United States \textit{ex rel.} Martin, 114 F. Supp. 3d at 571.
in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.\textsuperscript{52} Rule 702 was amended to codify the factors outlined by the Supreme Court in \textit{Daubert v. Merrell Dow Pharmaceutical, Inc.}\textsuperscript{53} The \textit{Daubert} Factors for assessing expert evidence include: (1) whether the theory or technique in question can be and has been tested; (2) whether it has been subjected to peer review and publication; (3) its known or potential error rate; (4) the existence and maintenance of standards controlling its operation; and (5) whether it has attracted widespread acceptance within a relevant scientific community.\textsuperscript{54}

Reliable expert testimony using statistical sampling requires that the underlying methodologies be based on widely and generally accepted methods.\textsuperscript{55} Courts have critiqued several factors within statistical sampling based upon the analysis of the data, the presentation, or the accumulation of the data that impacts the reliability of the methodologies.\textsuperscript{56} These factors include:

The selection of an inappropriate control population for comparison with the test population. The inclusion of irrelevant data. The use of a data base that is too small. The improper combination of categories into a single category, to create an impression at odds with the actual results of the study. The failure to account for potential systemic errors, such as selective recall in respondents providing the data base that the statistician analyzed.\textsuperscript{57}

Based on statutory elements and Supreme Court guidance, expert evidence such as statistical sampling and testimony by the experts who perform such analysis will have to comply with those elements and be admitted by the Court. The government/relator has the

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\textsuperscript{52} \textit{Fed. R. Evid.} 702.
\textsuperscript{54} \textit{Daubert v. Merrell Dow Pharm., Inc.}, 509 U.S. 579, 592-95 (1993).
\textsuperscript{55} \textit{Jack B. Weinstein \& Margaret A. Berger, Weinstein’s Federal Evidence}, \textsection 702.06 (Mark S. Brodin, ed., Matthew Bender 2 ed. 2019).
\textsuperscript{56} \textit{Id.}
\textsuperscript{57} \textit{Id.}
burden of proving that their expert evidence and expert witness are reliable.58 Defendants can challenge experts reliability using the Daubert factors.59

IV. Statistical Sampling in the Law

Statistical sampling has been used in a wide variety of cases outside of health care fraud, such as “antitrust, employment discrimination, toxic torts, and voting rights cases.”60 Statistical analysis and expert testimony has been used in many cases to prove:

[F]acially neutral practices had a disparate impact on a protected class in employment discrimination cases . . . That the pricing and sales activities of competitive distributors of chlorine indicated circumstantially that they were engaged in collusive bidding and pricing in violation of the antitrust laws. That the amount of pseudoephedrine products purchased by defendant for resale in his convenience store, compared to the expected legitimate consumer demand, tended to show that he was engaged in criminal activity, rather than legitimate retail sales. That defendant drug manufacturer’s fraudulent marketing campaigns to physicians causally affected their prescribing of defendant’s drug for off-label uses.61

Expert witness testimony by statistical experts is admissible when the expert witness is “qualified to give expert testimony in the field of statistics (see § 702.04), the testimony will be helpful to the trier of fact (see § 702.03), and the testimony is reliable and “fits” the case (see § 702.05).”62 Expert testimony for statistical analysis will be allowed only if it is probative on the issue that is determinative for the trier of fact.63 Many times the battle over the use of statistical sampling in legal cases will be over the weight given rather than admissibility, but studies may be inadmissible because they were poorly executed, the method was inappropriate, or the sampling utilized data that is not reasonably relied upon by experts.64 Generally though statistical

58 United States ex rel. Loughren, 604 F. Supp. 2d at 269.
61 Weinstein, supra note 55.
62 Weinstein, supra note 55.
63 Weinstein, supra note 55.
64 Kaye, supra note 60, at 214.
studies will be admitted if they address material issues and fully comply with the Federal Rules of Evidence which allows for admission.\(^{65}\)

A sound statistical analysis should ensure that measurements are reliable, valid, and that the sample is representative of the population as a whole.\(^{66}\) In order to avoid selection bias samples should be randomized, and if there is bias the statistician will need to find a model that is better suited for the data or make changes to their design model.\(^{67}\) When working with data that spans a lengthy period of time the statistician should verify what, if any, changes have been made to collection of the data over that period of time or whether definitions that directly impact data collection have been updated.\(^{68}\) In health care fraud cases diagnosing criteria and medical definitions will be especially important when reviewing data and determining variables over any extended period of time.

Sampling was statutory authorized in 2003 when Congress passed the Medicare Prescription Drug, Improvement and Modernization Act which established the Medicare Integrity Program.\(^{69}\) This program allows Medicare contractors to request medical records, supporting documentation, and allows for extrapolation of sampling to determine the total amount of overpayments by Medicare in certain circumstances.\(^{70}\) Currently statistical sampling within the health care context has expanded from its long history of use in the administrative setting to use within federal Courts under the FCA.\(^{71}\)

\(^{65}\) Kaye, *supra* note 60, at 214.
\(^{67}\) Kaye, *supra* note 60, at 225-46.
\(^{68}\) Kaye, *supra* note 60, at 231.
\(^{69}\) Katie Pawlitz and Greg Russo, *Proactively Responding to Government Investigations using Data Analytics: An Examination of Data Considerations in the Post-Acute Context*, 29 HEALTH LAYERS 23 (June 2017).
\(^{70}\) Id.
\(^{71}\) Id.
Statistical sampling and extrapolation in administrative cases is statutorily authorized when “there is a sustained or high level of payment error” or “documented educational intervention has failed to correct the payment error.” Judicial review of administrative agency actions is governed by the Administrative Procedure Act (APA). The standard of review is deferential to the agency’s expertise and allows the court to only set aside agency decisions that are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” The court may not substitute its own judgement for that of the administrative agency. Allowing the use of statistical sampling and extrapolation in an administrative sampling does not simply transfer to using statistical sampling in FCA cases that are heard directly by District Courts. A District Court hearing an FCA case will have to apply its own judgment and will have to follow the Federal Rules of Civil Procedure in evaluating claims, not follow the APA standard for judicial review.

If an expert witness is relying on a statistical analysis a Court should inquire as to the use of the analysis in the case at hand and why a particular model was chosen. The Court needs to consider whether it has enough information and details about the model and methodology that the analysis could be replicated and whether the Court can determine that the expert’s choices were reasonable. In addition to the model chosen the Court should inquire about the variables included, since the Court decides if a model is appropriate. The Court should question which variables were included, why certain models include or do not include certain variables, and

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76 Id.
77 Kaye, supra note 60, at 271.
79 Kaye, supra note 60, at 272.
whether any variables included were tainted.\textsuperscript{80} The expert should be prepared to explain to the Court why they chose that particular model and if there are any other suitable models from which they could have chosen.\textsuperscript{81} In order to minimize disputes over statistical analysis an expert should provide the Court with: clearly stated objectives, definitions of variables, the sample parameters, what methods were utilized in calculating a sample, any deficiencies with the data or method, and measurements over error calculations.\textsuperscript{82}

It is a matter of law whether or not the Court will allow the government or the defendant to use statistical sampling in a case.\textsuperscript{83} but once allowed the fact finder decides which experts to believe and which evidence to give more weight. Given the technical nature of health care fraud cases and the science behind statistical analysis multiple experts will be the norm in these cases\textsuperscript{84} and the jury will, as they do in other types of cases, give weight to testimony and the evidence presented.

V. History of FCA Cases Using Statistical Sampling

In the past few years there have been several cases where the government or relator has attempted to use statistical analysis in an FCA case before a District Court. Some District Courts have allowed the use of statistical sampling, while others have not allowed the use of statistical sampling.

A. Cases that Have Not Allowed Statistical Sampling

The following District Court cases have not allowed statistical sampling in FCA claim cases. A 2016 case in Texas, \textit{United States ex rel. Wall v. Vista Hospice Care, Inc.}, involved the

\textsuperscript{80} Kaye, \textit{supra} note 60, at 272.
\textsuperscript{81} Rubinfeld, \textit{supra} note 78, at 317.
\textsuperscript{82} Rubinfeld, \textit{supra} note 78, at 331-32.
\textsuperscript{83} ANDROPHY § 9A.04, \textit{supra} note 29.
\textsuperscript{84} Kaye, \textit{supra} note 60, at 215.
determinations by physicians employed by the hospice care facility of whether a patient was eligible for Medicare’s hospice benefit, the requirement for such benefit being that the individual is terminally ill.85 A patient is terminally ill if their life expectancy is six months or less.86 The Centers for Medicare and Medicaid Services (CMS) have advised physicians that determining life expectancy is not exact and that there is no risk to the physician for certifying a patient for hospice care so long as the physician believes the patient is terminally ill.87 The patient population was identified by the statistician hired by the relator as consisting of 12,000 patients over an eight year period.88 The statistician then selected a sample of 291 patients for the expert in hospice and palliative care to review.89 The relator argued that the sampling and extrapolation were “sufficient to show both damages and liability” in this case, but the court came to the opposite conclusion that it could not establish liability for fraud.90 The Court concluded that statistical sampling is appropriate when the sample data can prove the elements of the specific claim reliably.91 Here the Court found the expert witness and the statistical methodology were “fundamentally flawed” since variables identified as important were not controlled nor was the sample randomly selected.92 Further the Court stated that proof regarding one individual claim does not give rise to proof that other claims were false due to the differences in claims based on individual patient’s condition, treatment, and physician.93 The Court did acknowledge other cases where variables were controlled, and that the statistician in this case could have done the

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86 Id.
87 Id. at *9.
88 Id. at *31.
89 Id. at *32.
90 Id. at *35.
91 Id. at *40-41.
92 Id. at *42-43.
93 Id. at *42.
same but did not. Based upon the lack of reliability of the statistical sampling, since the sample was not randomized based on the whole population and variables were not controlled, the nature of the subjective determinations for hospice placement, and that the statistical sampling would need to prove all elements of a FCA claim, the Court did not allow extrapolation.

In a similar case also involving hospice care and inpatient services at a nursing home, the Court did not allow the use of statistical sampling to prove liability for damages. In *United States ex rel. Michaels v. Agape Senior Community, Inc.*, the Court felt that determining whether services for nursing home patients were medically necessary was a highly-fact intensive inquiry that involved review of patient files individually. The relators in this case claimed that Agape submitted false claims for hospice related services. The defendants claimed that during the period in question there were 53,280 claims submitted for 19,820 patients. The relator claimed that there were 61,643 claims for 10,166 patients. The relator also informed the Court that it would cost “between $16.2 million and $36.5 million” to have two experts review each patient’s chart for anywhere from four to nine hours, at a hourly rate of $400. The Court separated this case from another recent non-health care case where the evidence was no longer available and therefore statistical sampling was the only way for the government/relator to prove damages. Further, the Court did not find that statistical sampling could not be used in other cases, simply that this case was not “suited for statistical sampling.”

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94 *Id.* at *46-47.
95 *Id.* at *47.
97 *Id.* at *24.
98 *Id.* at *2.
99 *Id.* at *3.
100 *Id.*
101 *Id.*
102 *Id.* at *18-19.
103 *Id.* at *24.
In *United States v. AseraCare, Inc.* the government argued that AseraCare violated the FCA by presenting false claims for payment when certifying patients for hospice care.\(^{104}\) The defendant operated hospice care facilities in nineteen states and the defendant’s sixty facilities accounted for almost 10,000 patient admissions each year.\(^{105}\) During the relevant period it was determined that the universe of patients was 2,181 patients.\(^{106}\) The government hired an expert to review 233 of the patient claims and found that 124 of the 233 claims were false.\(^{107}\) The government sought to extrapolate the sampling finding to the entire universe.\(^{108}\) The Court initially found that statistical evidence was evidence that the jury should evaluate and the jury should accord the weight to be given to both the government’s evidence and the defendant’s evidence.\(^{109}\) However, the case quickly became centered on whether using only the expert witness’ testimony over his sampling of the 233 claims was enough to prove falsity without more objective evidence.\(^{110}\) Eventually the defendant was granted summary judgment since the government did not use any other testimony other than one clinician’s opinion on whether the patients were eligible for hospice care.\(^{111}\) The Court found that as a matter of law mere “contradiction based on clinical judgment or opinion alone cannot constitute falsity under the FCA.”\(^{112}\)

In *United States ex rel. Trim v. McKeen*, a medical coding company was charged with submitting false claims to a Pennsylvania Medicare administrative program along with Medicaid


\(^{105}\) Id. at *8-10.

\(^{106}\) Id. at *8.

\(^{107}\) Id.

\(^{108}\) Id.

\(^{109}\) Id. at *25-26.

\(^{110}\) United States v. AseraCare, Inc., 153 F. Supp. 3d 1372, 1381 (N.D. Ala. 2015)

\(^{111}\) Id. at 1284-85.

\(^{112}\) Id. at 1286
programs in Arizona and Oregon. The Court found that the audits were insufficient to form a statistical sample of the universe of claims, that the audits were not reliable nor an accurate representation of the universe of claims, and therefore the court was unwilling to extrapolate the audit findings. Considering that the charts, largely handwritten and illegible, in Pennsylvania were not representative of the universe of claims the Court was unwilling to use that audit to extrapolate. The Oregon audit was tainted by the opportunity for false claims to be recovered once they were notified of the current lawsuit, the Court was concerned with the objectiveness of the audit. The experts who were responsible for the Arizona audit did not testify, which factored into the Court’s decision to not extrapolate based on that audit.

A defendant’s motion to exclude the government’s expert testimony over its statistical sampling was allowed in United States ex rel. Loughren v. UnumProvident Corp. In Loughren, the plaintiff claimed that the corporation urged claimants to file for Social Security Disability benefits that the corporation knew they did not qualify for based upon the statutory requirements for disability. The claims took place in a ten year span from January 1997 to July 2007 and include 468,641 claims. The Court concluded that providing the statistical methodology was reliable, then extrapolation was reasonable since there was enough evidence at trial that a jury could reasonably find that the corporation violated the FCA. However, the

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114 Id.
115 Id.
116 Id.
117 Id.
119 Id. at 260.
120 Id.
121 Id. at 261.
Court went on to find that the statistical sampling was unreliable due to overlapping cohorts and lack of secondary resources or peer reviewed literature to support the methodology utilized.\textsuperscript{122}

In \textit{United States ex rel. El-Amin v. George Washington Univ.}, the Court did not allow the relator to try the case using statistical sampling. The complaint alleged that over six years the defendant submitted false claims to Medicare for anesthesia services that had been performed by licensed physicians, but had instead been performed by other staff members.\textsuperscript{123} Of particular concern to the court was the fact that the relator was unable to determine the universe of claims, instead offering that it could be between 5,000 and 15,000 claims.\textsuperscript{124} The Court ended up denying the motion to use statistical sampling because there was a lack of a definite universe of claims, plus the motion was filed in 2008 after a long discovery period that began when the case was filed in 1995.\textsuperscript{125} The Court also noted that the decision to use statistical sampling so close to trial would be unfair to the defendant who, like the relator, has not secured an expert witness nor determined the universe of claims.\textsuperscript{126}

\textbf{B. Cases that Have Allowed Statistical Sampling}

While some courts have not allowed a relator or the government to proceed with their statistical sampling, other courts have found it appropriate. In considering summary judgment of the government’s use of statistical sampling only, the Court in \textit{United States ex rel. Martin v. Life Care Ctrs. Of America, Inc.} denied the defendant’s motion.\textsuperscript{127} The government asserted that the defendant up-coded and also billed for medically unnecessary services.\textsuperscript{128} At issue were 54,396 patient admissions that total 154,621 claims that occurred at eighty-two facilities between

\begin{footnotesize}
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\item\textsuperscript{122} \textit{Id.} at 269.
\item\textsuperscript{123} \textit{United States ex rel. El-Amin v. George Washington Univ.}, 533 F. Supp. 2d 12, 18 (D. D.C. 2008).
\item\textsuperscript{124} \textit{Id.} at 29.
\item\textsuperscript{125} \textit{Id.} at 50-51.
\item\textsuperscript{126} \textit{Id.}
\item\textsuperscript{127} \textit{United States ex rel. Martin v. Life Care Ctrs. of America, Inc.}, 114 F. Supp. 3d 549, 550 (E.D. Tenn. 2014).
\item\textsuperscript{128} \textit{Id.} at 554.
\end{enumerate}
\end{footnotesize}
January 2006 until January 2012.\textsuperscript{129} The Government wanted to use a random sample of 400 admissions and then extrapolate those findings to the universe of claims.\textsuperscript{130} The Court concluded that preventing statistical sampling and relying only upon individual claim-by-claim review under the FCA would not deter fraudulent behavior, which is inconsistent with the purpose and history of the FCA.\textsuperscript{131} The evidence is best left to the jury to determine the weight to be given to the government’s statistical sampling, extrapolation, and the defendant’s evidence.\textsuperscript{132}

In \textit{United States v. Cabrera-Diaz}, the defendant never responded nor appeared in the case in which he was charged with over billing Medicare for anesthesia time.\textsuperscript{133} An audit for two years, 1994 and 1995, revealed that in the first year the defendant physician over billed for 77,899 minutes and in the second year billed Medicare another 69,943 minutes of “overstated, falsely claimed, unsupported or undocumented anesthesia time.”\textsuperscript{134} The Medicare contractor in this case, based upon the Medicare guidelines for methodology, selected a random sample of 230 claims from 1994 and 231 claims from 1995.\textsuperscript{135} The results from these two samples were then extrapolated to the universe of claims.\textsuperscript{136} The final result of the extrapolation was a total of $237,600.39 of overpaid time in 1994 and $211,773.89 for 1995.\textsuperscript{137} The court cited to other cases that allowed the use of statistical sampling and ultimately used the sampling and extrapolation figures when entering default judgment against the defendant physician.\textsuperscript{138}

\begin{itemize}
\item \textsuperscript{129} \textit{Id.} at 556.
\item \textsuperscript{130} \textit{Id.}
\item \textsuperscript{131} \textit{Id.} at 571.
\item \textsuperscript{132} \textit{Id.}
\item \textsuperscript{133} \textit{United States v. Cabrera-Diaz}, 106 F. Supp. 2d 234, 236 (D. P.R. 2000).
\item \textsuperscript{134} \textit{Id.} at 237.
\item \textsuperscript{135} \textit{Id.} at 240
\item \textsuperscript{136} \textit{Id.}
\item \textsuperscript{137} \textit{Id.} at 237.
\item \textsuperscript{138} \textit{Id.} at 240-244.
\end{itemize}
In *United States v. Robinson*, the physician, an optometrist, and his company were charged with claims under the FCA for submitting claims for medically unnecessary or unreasonable services or for services not actually provided.\(^{139}\) Dr. Robinson traveled to fourteen nursing homes and provided services to patients every four to six weeks.\(^{140}\) The universe of claims was determined to be 25,779 claims for the relevant period and the government’s expert witness reviewed a random sample of 30 examination files.\(^{141}\) The government sought to use statistical sampling and extrapolation, but the defendant argued that the use was improper as a matter of law.\(^{142}\) The Court concluded that the use of statistical sampling and extrapolation were not improper as a matter of law and that the jury should determine the weight given to the evidence presented over the statistical analysis.\(^{143}\)

In *United States v. Fadul*, the physician and his mobile diagnostic business were charged with submitting false claims under Medicare and Medicaid for nursing home patients.\(^{144}\) The company’s billing system would bill for two codes when one imaging service was performed.\(^{145}\) So when a technician logged an abdominal ultrasound, the company billed the patient’s insurance for both an abdominal and retroperitoneal ultrasound.\(^{146}\) Additionally, when a technician logged a bilateral lower extremity venous study or a unilateral lower extremity venous study the company would bill for both a venous duplex ultrasound, bilateral and the non-invasive physiologic study of extremity veins.\(^{147}\) During the time from 2004 to 2009 the physician and his company received $145,010.99 from Medicare and $11,544.24 from Medicaid for services under


\(^{140}\) *Id.* at *1.

\(^{141}\) *Id.* at *2-5.

\(^{142}\) *Id.* at *10.

\(^{143}\) *Id.* at *11.


\(^{145}\) *Id.* at *5-6.

\(^{146}\) *Id.* at *6.

\(^{147}\) *Id.* at *8.
the retroperitoneal ultrasound that was not performed.\textsuperscript{148} Additionally, the defendant received $588,521.61 from Medicare and $17,433.47 from Medicaid for the double coding of the venous studies.\textsuperscript{149} The Court did not grant summary judgment for the FCA claims against the physician, but did grant judgment for a claim for payment by mistake of fact.\textsuperscript{150} The court accepted the government’s calculation of damages based upon statistical sampling and extrapolation as 152 of the 551 claims could not be obtained.\textsuperscript{151}

In \textit{United States ex rel. Doe v. DeGregorio}, the defendant was charged with filing false and fraudulent claims to Medicare that resulted in over $17 million in payments to the company.\textsuperscript{152} The Court allowed the evidence done by audits and small samples to suffice in holding the defendant’s property to pay his debts.\textsuperscript{153}

\textbf{VI. Analysis of Successes and Failures of Statistical Sampling in FCA Health care cases}

\textbf{A. Why Statistical Sampling Has Succeeded in Some Cases}

To date, some District Courts have allowed statistical sampling to be used in proving falsity, liability, damages, defended against due process concerns, and balanced concerns over methodology and clinical judgment. In \textit{United States ex rel. Martin v. Life Care Centers of America, Inc.}, the government claimed that Life Care Centers of America, Inc. increased patients therapy time during assessment periods and billed for unnecessary services.\textsuperscript{154} In \textit{Martin}, the Court found that the government could specify the individual claims, but that the universe of claims was large and would be burdensome on the government to do so for each and every

\begin{footnotesize}
\textsuperscript{148} \textit{Id}. at *7.  
\textsuperscript{149} \textit{Id}. at *12.  
\textsuperscript{150} \textit{Id}. at *47-48  
\textsuperscript{151} \textit{Id}. at *46.  
\textsuperscript{153} \textit{Id}. at 32-36.  
\textsuperscript{154} \textit{United States ex rel. Martin v. Life Care Ctrs. of America, Inc.}, 114 F. Supp. 3d 549, 554-55 (E.D. Tenn. 2014).
\end{footnotesize}
Further the Court did not find that falsity could not be established nor that each claim needed to be individually reviewed. The Court did not find the argument persuasive that each of the fifteen plus factors identified as part of an analysis of the patient’s care were unique to each patient and therefore the use of statistical sampling was precluded. The Court concluded that statistical sampling was appropriate for such a situation, if all claims were identical then there would be no need for statistical sampling. During a trial the defense can cross-examine the government’s expert witness on qualifications, statistical method used, acceptable methods from which to choose, and research to support opinions. The defense can also call their own witnesses and present their own statistical sampling and analysis for liability and damages. Further, while Courts decide on whether statistical sampling can be used, the fact finder decides on the credibility of the witnesses and evidence offered by both parties.

When the defendant in United States v. Robinson challenged the use of statistical sampling to extrapolate for both liability and damages as improper as a matter of law, the Court found that the use of statistical sampling nor using a sample to extrapolate was improper as a matter of law. Further, in that case the Court found that to use statistical sampling the sample must be representative and the methodology must be valid, but the defendant had not challenged the sampling methodology. The Court determined that “proof of an objective falsehood is not the only means of establishing an FCA claim.” In quoting United States ex rel. Wall, the Court

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155 Id. at 565.  
156 Id. at 566-567.  
157 Id. at 566.  
158 Id.  
159 Id. at 570.  
160 Id.  
163 Id. at *10.  
164 Id. at *5.
stated that falsity can be proved “by an express false certification or it can also be established through a theory of implied certification,” when the defendant did not comply with the regulatory requirements when billing. Here, the government has to show that the defendant did not comply with the statute when submitting payments. Having the government’s medical expert review the sample of patient files is more properly framed as whether it creates an “issue of material fact” that should go to the jury not whether it proves falsity when moving for summary judgment. The defendant could cite to no authority that stated that expert medical opinions were not sufficient evidence when determining whether medical treatment was necessary.

In *United States v. Cabrera-Diaz*, the Court used statistical sampling in an audit of the defendant’s submissions for Medicare payment for anesthesia services. The results of the audit where extrapolated to the entire universe of claims to determine the amount of overpayment due to Medicare. The Court went on to use the amounts of overpayment and total number of claims determined from the extrapolation of the statistical sample to the total universe of claims to determine the total amount of damages. The Court effectively used statistical sampling and extrapolation to find both liability and damages.

Statistical sampling has been allowed to calculate damages in many types of cases, including health care fraud cases using the FCA when it is not practical to conduct a claim-by-claim review. In *United States v. Fadul*, the Court found that statistical sampling and

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165 *Id.*
166 *Id.*
167 *Id.* at *6.
168 *Id.*
170 *Id.* at 237.
171 *Id.* at 243-44.
172 *Id.* at 240-41.
extrapolation is “a viable method of proving damages in cases . . . where a claim-by-claim review is not practical.” In Fadul, the Court allowed the use of statistical sampling and extrapolation to grant summary judgment for the common law claim of “payment by mistake of fact” while not granting summary judgment on the FCA claims. In United States ex rel. Doe v. DeGregorio, the Court allowed audits and extrapolation to calculate total potential damages when the Court issued Prejudgment Writs of Attachment and Sequestration on property owned by the defendant.

B. Why Statistical Sampling Has Failed in Some Cases

In United States ex rel. Wall v. Vista Hospice Care, Inc., the Court would not allow the relator to establish liability under the FCA since the underlying facts of the case involved a physician’s subjective judgment on hospice care based upon an individual patient’s medical file. The Court concluded that statistical sampling is appropriate when the sample data can prove the elements of the specific claim reliably, but that was not the situation in the present case. Further, the Court found the expert witness and the statistical methodology were flawed and stated that proof regarding one individual claim does not give rise to proof that other claims were false due to the differences in claims based on individual patient’s condition, treatment, and physician. Here the Court did not believe that the expert selected the “relevant variables” nor did he “select a random sample.” The Court acknowledged that variables, such as individual patient conditions, treatment, physician, etc., could be controlled, but in this case had not been

174 Id.
175 Id. at *38-47.
178 Id. at *40-41.
179 Id. at *42.
180 Id. at *46-47.
and along with the underlying subjective nature of the clinical determination extrapolation was not allowed.\textsuperscript{181} Further, the Court did not allow the government to prove falsity with only another expert’s clinical judgments, instead requiring evidence of an objective fact that was false.\textsuperscript{182} When explaining what might be an objective fact at odds with the use of clinical judgment, “a relator could present evidence that a certifying physician was not in fact, exercising the physician’s clinical judgment when certifying a patient’s medical condition, nor saw the patient, or that the physician did not actually believe that if the patient’s disease ran its normal course, the patient had a prognosis of six months or less.”\textsuperscript{183}

In a similar case also involving hospice care and inpatient services at a nursing home, a Court again did not allow the use of statistical sampling to prove liability for damages.\textsuperscript{184} In \textit{United States ex rel. Michaels v. Agape Senior Community, Inc.}, the Court felt that determining whether services for nursing home patients were medically necessary was a highly-fact intensive inquiry that involved review of patient files individually.\textsuperscript{185} Further, the Court did not find that statistical sampling could not be used in other cases, simply that this case was not “suited for statistical sampling.”\textsuperscript{186}

In \textit{United States v. AseraCare}, the Court took issue with proving falsity using only difference of opinion by different medical experts in a case involving the certification of hospice patients for Medicare.\textsuperscript{187} The Court found “that contradiction based on clinical judgment or opinion alone cannot constitute falsity under the FCA as a matter of law.”\textsuperscript{188} The Court

\textsuperscript{181} \textit{Id.}
\textsuperscript{182} \textit{Id.} at *55-57.
\textsuperscript{183} \textit{Id.} at *56.
\textsuperscript{185} \textit{Id.} at *24.
\textsuperscript{186} \textit{Id.} at *24.
\textsuperscript{188} \textit{Id.} at 1286.
highlighted other ways that the government could have proven falsity other than simply relying on the expert witness testimony, including providing evidence that information in patient files was false or that the physicians withheld information when certifying a patient for hospice.\textsuperscript{189} It is important that both the \textit{Vista Hospice Care} and \textit{AseraCare} Courts did not strictly prohibit statistical sampling or the use of expert testimony, but simply refused to allow only expert witness testimony to prove liability and falsity with the particular facts of their respective cases.\textsuperscript{190}

In a non-FCA case, \textit{United States v. Paulus}, the government was able to overcome a subject judgment classification. In \textit{Paulus}, the defendant physician was found guilty by a federal jury of making false statements and committing fraud when interpreting angiograms to show higher percentages of blockage.\textsuperscript{191} By interpreting the angiograms at a higher blockage percentage, of at least 70\%, the physician did not need to complete any additional tests prior to inserting a stent.\textsuperscript{192} The District Court, after a guilty verdict by the jury, had granted the defendant’s motion for acquittal and a new trial, holding that the government did not prove intent and falsity.\textsuperscript{193} The District Court came to the conclusion that the “degree of stenosis” was a “subjective medical opinion” by an individual physician which cannot be confirmed or contradicted.\textsuperscript{194} The Sixth Circuit reversed the acquittal, reinstated the jury verdict and remanded the case, finding that “the degree of stenosis is a fact capable of proof or disproof,” it is not strictly a “subjective medical opinion” that cannot be proven or disproven.\textsuperscript{195} Stating that a

\textsuperscript{189} \textit{Id.} at 1285.


\textsuperscript{191} \textit{United States v. Paulus}, 894 F.3d 267, 270 (6th Cir. 2018).

\textsuperscript{192} \textit{Id.} at 271.

\textsuperscript{193} \textit{Id.} at 274-275.

\textsuperscript{194} \textit{Id.}

\textsuperscript{195} \textit{Id.}
doctor who deliberately inflates the blockage he sees on an angiogram has told a lie; if he does so to bill a more expensive procedure, then he has also committed fraud.\textsuperscript{196} Opinions and clinical judgments are not immune from being false if the person holding that belief knows that the facts do not support the opinion.\textsuperscript{197} The jury is the trier of fact and submitting the governments evidence to the jury is the appropriate method of determining proof.\textsuperscript{198} It is up to the jury to determine the weight to give the government’s evidence.\textsuperscript{199} The jury members were free to come to the conclusion that the physician had acted in good faith in reading angiograms or had not acted in good faith.\textsuperscript{200} The jury determines how reliable the expert witness is and how believable their testimony is for any given piece of evidence, each member of the jury can prevent a verdict in either direction.\textsuperscript{201} According to the Sixth Circuit, in this case the defendant was convicted for misrepresenting facts, he lied about the interpretations of the angiograms and then billed for unnecessary procedures.\textsuperscript{202} The Court stated that the time to challenge expert testimony is at a \textit{Daubert} motion or during trial and here the defendant had multiple times to challenge the government’s evidence, which he did, and any one juror who had reasonable doubt could have prevented his conviction.\textsuperscript{203}

In \textit{United States ex rel. Loughren v. Unum Provident Corp.}, the Court found that the expert evidence and expert witness were unreliable since the expert’s report did not cite to any text that could support the methodology utilized nor could the expert, while testifying over his methodology, identify any peer-reviewed literature to support his approach.\textsuperscript{204} Further, in \textit{United

\begin{footnotes}
\item[196] Id.
\item[197] Id.
\item[198] Id.
\item[199] Id.
\item[200] Id. at 275-76.
\item[201] Id. at 277.
\item[202] Id.
\item[203] Id. at 277-78.
\end{footnotes}
States ex rel. Loughren, the defense expert was able to credibly counter the government/relator’s expert witness which lead the Court to not trust the results.\textsuperscript{205} The Court quoted the First Circuit’s stance on Daubert, “as long as an expert’s scientific testimony rests upon “good grounds, based on what is known,” it should be tested by the adversary process – competing expert testimony and active cross-examination – rather than excluded from jurors’ scrutiny.

…\textsuperscript{206} In United States ex rel. Trim v. McKeans, the Court did not extrapolate the findings of the audits to the universe of all claims because the Court found that the audits were “not a reliable or accurate representation of all . . . claims.”\textsuperscript{207} In Trim, the Court found the claims in Pennsylvania were not representative of the universe of claims since the charts were largely handwritten and illegible.\textsuperscript{208} The Oregon audit was unreliable since it was started in response to a lawsuit with the potential to recover claims.\textsuperscript{209} The Arizona audit was also unusable since the experts who were responsible for the audit did not testify.\textsuperscript{210}

In United States ex rel. El-Amin v. George Washington University, the Court did not allow statistical sampling because the discovery period was closed and the trial was starting.\textsuperscript{211} The Court in El-Amin, found two issues with the government/relator’s request to use statistical sampling, (1) the timing and (2) unfairness to the defendant.\textsuperscript{212} The government/relator in that case had failed to raise the issue of statistical sampling during the discovery period which was now closed, failed to raise the issue in their pretrial statement as well as not raising the issue during a pretrial conference.\textsuperscript{213} Further, given that the trial was starting the defendant would be at

\textsuperscript{205} Id. at 269.  
\textsuperscript{206} Id. at 265.  
\textsuperscript{208} Id.  
\textsuperscript{209} Id.  
\textsuperscript{210} Id.  
\textsuperscript{212} Id.  
\textsuperscript{213} Id.
a disadvantage since they had not prepared for a trial using statistical sampling, had not sought out their own experts, nor determined the universe of claims.\textsuperscript{214}

In many cases, such as \textit{United States ex rel. Wall}, \textit{United States ex. Rel. Michaels}, and \textit{United States ex rel. Loughren}, the Court has found the statistical method to be unreliable or unrepresentative. In \textit{United States ex rel. Loughren}, the defendant was successful in attacking the government’s expert witness and his methods.\textsuperscript{215} The government’s expert witness did not direct the Court to any peer-reviewed literature in support of his methodology, therefore the Court was left with the defense expert witness’ criticisms of the methods utilized in the statistical sampling by the government.\textsuperscript{216} As indicated by the Court in \textit{AseraCare}, the defendant can attack whether the government has met their burden and demand more than a simple battle of the experts in terms of establishing the requisite factors.\textsuperscript{217}

\textbf{VII. Why Statistical Sampling Should be Allowed in health care FCA Cases}

The allowance of statistical sampling in FCA cases is beneficial to all parties since modern cases of health care fraud involve increasingly larger quantities of claims and there are high costs associated with individual claim-by-claim reviews.\textsuperscript{218} The FCA has been amended over time to ensure that the government can adequately fight fraudulent conduct.\textsuperscript{219} Allowing the use of statistical sampling is a furtherance of that goal to ensure that those receiving funds from the U.S. government are not engaging in fraudulent behaviors. Further, Statistical sampling

\begin{itemize}
\item \textsuperscript{214} \textit{Id.}
\item \textsuperscript{215} \textit{United States ex rel. Loughren v. Unum Provident Corp.}, 604 F. Supp. 2d 259 (D. Mass. 2009).
\item \textsuperscript{216} \textit{Id.} at 266.
\item \textsuperscript{217} \textit{United States v. AseraCare, Inc.}, 176 F. Supp. 3d 1282, 1286 (N.D. of Ala. 2016).
\item \textsuperscript{218} \textit{United States ex rel. Martin v. Life Care Ctrs. of America, Inc.}, 114 F. Supp. 3d 549, 560 (E.D. Tenn. 2014); \textit{United States ex rel. Michaels v. Agape Senior Comty., Inc.}, No. 0:12-3466-JFA, 2015 U.S. Dist. LEXIS 82379, at *3-4 (S.C. June 25, 2015).
\end{itemize}
should be allowed in FCA cases so long as the government is able to meet their burden and prove that a defendant(s) engaged in fraudulent behavior.

In several cases the Courts have found that the sampling methods or the samples themselves were not adequate and therefore would not allow the usage of the statistical sampling in the case.\textsuperscript{220} When a government/relator wants to use statistical sampling, they need to be prepared to prove that their expert witness is reliable and that the methodology utilized is reliable and credible in accordance with the Federal Rules of Evidence and the \textit{Daubert} Factors. If a government/relator’s expert has based their methodologies and testimony off sufficient facts or data, the methods used are reliable because they have been tested and subjected to peer review, and variables have been controlled, then the expert testimony over statistical sampling should go to the fact finder to assess.\textsuperscript{221}

The government’s burden of proving that fraudulent actions have occurred is not minimalized by using statistical sampling. While the Courts do decide as a matter of law whether to allow statistical sampling, the weight given to the expert testimony, the statistical analysis, and the defendant’s or other witness’ testimony, belongs to the fact finder.\textsuperscript{222} In FCA cases the government/relator has the burden of proving their substantive theories, especially on falsity.\textsuperscript{223}

Using statistical sampling is a reasonable solution if the government can specify falsity for each claim. If done with the appropriate methodology and care an audit and a representative sample will suffice to show fraudulent acts. Using statistical sampling methods to control for certain variables, such as patient conditions, caregivers, facilities, etc. that arise in any given


\textsuperscript{221} United States \textit{ex rel.} Loughren, 604 F. Supp. 2d at 265.

\textsuperscript{222} ANDROPHY § 9A.04, \textit{supra} note 29.

\textsuperscript{223} Rubinfeld, \textit{supra} note 78, at 319. As stated in the Reference Guide on Statistics, statistical sampling will not prove a substantive theory, but it can assist the trier of fact.
universe of claims, ensures that the appropriate parameters are factored into the analysis, therefore if the sample, using appropriate variables, proves falsity then extrapolation is logical. 224

With the right parameters it would be reasonable to use statistical sampling in a case where the government/relator is proving that there was a systematic disregard for the truth. In such cases, statistical sampling is useful since the expert can control the analysis for many variables. A statistical sample that is representative of the universe of claims, in which different experts can testify to those factors does not defy what would occur with a case-by-case review. Using a representative sample, the government should be allowed to show that consistently altering your patient’s prognosis is fraudulent. The government needs to be prepared to connect evidence of objective falsehoods with the use of expert witness testimony in order to meet their burden of proof. 225 If the government is claiming that a physician or care organization repeatedly and systematically saw one condition and repeatedly billed for another then the government should be able to call their own experts and present statistical analysis. The jury should decide which experts and testimony they believe are more reliable. Further, if you allow statistical sampling to be used to calculate damages under the FCA then to some extent you are also using it to prove liability. So, there is no reason why you should not be able to use statistical sampling if you can use it to collect damages.

The use of statistical sampling does not shift the burden of proving FCA elements to the defendant. Statistical sampling is based off a representative sample that can be utilized by both parties to show why or why not the required factors were met. There are several procedural safeguards that are available to a defendant to challenge the government’s use of statistical sampling. The defense can challenge the expert witness’ credentials and experience, the

methodology utilized, the results themselves and also present their own evidence.\textsuperscript{226} When using \textit{Daubert} motions or requesting summary judgment the defendant can challenge whether the sample itself is representative as well as challenge if the methods utilized were valid and representative of the universe of claims.\textsuperscript{227}

In addition to the multiple options of what a defendant can challenge there are several points during the litigation process that concerns can be raised, including during the pleading stage, pretrial hearings, and during the trial.\textsuperscript{228} A defendant has abundant opportunity to challenge the credibility of the government/relator’s witness and to present their own case including expert testimony, which ensures that their due process is protected despite using statistical sampling.\textsuperscript{229} As the provider of care, the defendant should be prepared to utilize their own data and have a good understanding of what data and information they have available to use in defending themselves.\textsuperscript{230} Once a defendant has notice provided in pleading, they can run their own analysis and evaluate their patient files.\textsuperscript{231} They have unlimited access to their own data and patient files to build their own case and develop their own analysis.

It is reasonable for the Court to allow the use of extrapolation to determine the total quantity of claims and the volume of damages, once the government/relator’s burden is met. Health care fraud will frequently involve numerous smaller claims, more so than other types of fraud cases under the FCA. When dealing with a large universe of claims it is reasonable and economical for both the government/relators and defendants to utilize some form of statistical sampling and extrapolation.

\textsuperscript{226} United States \textit{ex rel.} Martin, 114 F. Supp. 3d at 570.
\textsuperscript{228} United States \textit{ex rel.} Martin, 114 F. Supp. 3d at 570.
\textsuperscript{229} \textit{Id.}
\textsuperscript{230} Pawlitz, \textit{supra} note 69.
\textsuperscript{231} \textit{Id.}
As with any type of scientific data the key to using statistical sampling is the methodologies and data utilized. Statistical sampling that is valid, reliable, and credible should allay the Courts’ concerns. Health care fraud will continue to be an issue due to an aging population and changes in technology and medical care. In order to combat fraudulent behavior or to defend oneself when charged, statistical sampling should be part of the litigation toolbox and accepted by the Courts.

232 U.S. CENSUS BUREAU, supra note 27; Deloitte, supra note 28.