SHOULD STATISTICAL SAMPLING BE USED TO PROVE LIABILITY UNDER THE FALSE CLAIMS ACT IN HEALTHCARE FRAUD?

MILENE VEGA, R.N.*

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* Executive Online Editor, Southern California Law Review, Volume 91. J.D. Candidate 2018, University of Southern California Gould School of Law; B.A. Nursing 2015, Florida International University; A.S. Nursing 2014, Miami-Dade College. I would like to thank my note advisor, Professor Alexander Capron. I would also like to thank my husband, Austin Stack, and my parents, Rafael and Leticia Vega, whose sacrifices and unending support have made this possible. Finally, I owe an immense debt of gratitude to the editors of Volume 91 of the Southern California Law Review for their outstanding editing and feedback, especially Eli Tarlow, Justin Bongco, and James Salzmann.
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INTRODUCTION

In recent years the False Claims Act ("FCA")¹ has become the
Department of Justice’s ("DOJ") favorite tool to combat large-scale fraud—
particularly healthcare fraud. In fact, from 2009 to 2016 alone, the DOJ
recovered over $19.3 billion in health care fraud²—"more than half the
health care fraud dollars recovered since the 1986 amendments to the False
Claims Act."³ In general, the statute prohibits (1) knowingly submitting false
claims to the federal government or causing another to submit a false claim,

² Press Release, Office of Pub. Affairs, U.S. Dep’t of Justice, Justice Department Recovers Over
opa/pr/justice-department-recovers-over-47-billion-false-claims-act-cases-fiscal-year-2016 [hereinafter
U.S. Dep’t of Justice 2016].
³ Press Release, Office of Pub. Affairs, U.S. Dep’t of Justice, Justice Department Recovers Over
$3.5 Billion from False Claims Act Cases in Fiscal Year 2015 (Dec. 3, 2015), https://www.justice.gov/
opa/pr/justice-department-recovers-over-35-billion-false-claims-act-cases-fiscal-year-2015 [hereinafter
U.S. Dep’t of Justice 2015].
(2) knowingly creating a false record or statement to get a false claim paid by the federal government, and (3) retaining funds improperly received from the federal government.4

Although the FCA originated during the Civil War, Congress has periodically strengthened the FCA through amendments, which have converted it into a “modern weapon” that the DOJ and whistleblowers use to punish providers who knowingly submit false claims or false records or retain funds improperly received from the government.5 The amendments have permitted larger damages, which in turn have incentivized whistleblowers and the DOJ to use whatever means available to prove liability in as many false claims as possible. During the last five years in particular, that has meant turning away from proving liability for each individual claim and instead using statistical sampling as proof of liability for a much larger number of claims.6

While many courts have consistently approved statistical sampling to calculate damages, they have not resolved whether statistical sampling is sufficient to establish liability under the FCA.7 Some district courts have held that plaintiffs must prove the falsity of each individual claim, while others have held that falsity and liability may be established for thousands of Medicare and Medicaid claims from only a relatively small sampling.8 This controversy has recently come to the fore in United States ex rel. Michaels v. Agape Senior Community, Inc.,9 the first instance in which a circuit court has considered this issue. Notably, the government, despite refusing to intervene in the underlying action, filed a brief concerning the use of statistical sampling once the case was appealed,10 suggesting its intent to continue using statistical sampling to prove liability.

Ultimately, the combination of the FCA’s trebling of damages and the civil penalties it imposes per false claim means that billions of dollars in

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8. See infra Part II.
potential damages hinge on how courts use statistical sampling. This paper will (1) consider how district courts have treated the use of statistical sampling to prove liability in FCA cases concerning healthcare fraud, (2) analyze the outcome of Michaels, and (3) consider the effect of the courts’ decisions on future FCA and qui tam litigation. This paper will then criticize the courts’ decisions and propose that a more reasonable approach would be to use a bellwether trial to determine whether there is sufficient evidence to prove a generalized fraudulent practice and the likelihood of commonality between the claims. Only after preliminary liability has been established in such a way through a bellwether trial could statistical sampling then be used to establish liability for the remainder of claims, when it would otherwise be infeasible to prove the elements of liability for each individual claim.

I. BACKGROUND

The FCA originated in 1863, as a way to deter fraud against the government during the Civil War. It targeted Union suppliers who were defrauding the United States, incentivizing private citizens to bring actions against suppliers at a time when the government lacked resources to investigate and prosecute such fraud. Since then, the FCA has undergone several revisions, most recently in 2010 as part of the Patient Protection and Affordable Care Act (“ACA”). Despite its 155-year history, the FCA is certainly not a war relic; today it remains more relevant than ever, with some scholars calling it a “modern nightmare for the health care industry.” The FCA continues to serve as the federal government’s safeguard against being overcharged or provided “shoddy goods or services.” In fact, FCA actions have significantly increased since 2009, with the DOJ recovering more than $3.5 billion in fiscal year 2015, more than $4.7 billion in 2016, and $3.7 billion in 2018—the eight consecutive year in which over $2 billion of yearly settlements were awarded.

11. See, e.g., U.S. Dep’t of Justice 2016, supra note 2 (providing examples of recent settlements that range from $125 million to $784.6 million).
13. Robin Page West, Advising the Qui Tam Whistleblower: From Identifying a Case to Filing Under the False Claims Act 2 (2d ed. 2009).
14. Laemmle-Weidenfeld, supra note 4, at 133.
17. U.S. Dep’t of Justice 2015, supra note 3.
recoveries were from the healthcare industry—and there are no signs of a slowdown. Indeed, the former head of the Justice Department’s Civil Division has called the FCA the “government’s most effective civil tool to ferret out fraud.”

Today, most FCA litigation is originated by whistleblowers (called “relators”) under the statute’s qui tam provisions. A typical claim at issue in healthcare fraud cases under the FCA is a request by a provider for reimbursement of services or items, submitted to the Centers for Medicaid & Medicare Services (“CMS”) or a state Medicaid agency. A claim may be submitted individually or as part of annual cost reports presented to CMS or a state agency. However, because the healthcare industry is so highly regulated, there are “an innumerable variety of issues [that] can cause claims to be false or fraudulent.”

Generally, the issues can be categorized into claims that are factually false and claims that are legally false. Factually false claims include misrepresentations of services provided, such as (1) when a service occurred in a different location than the one stated (for example, a service was provided at a physician’s office but is billed as having been provided at an ambulatory care center); (2) when service was not performed at all or a different service was performed; and (3) when a claim indicates that a physician performed a service, but in reality it was performed by unlicensed personnel. Another type of factually false claim is for a service that CMS deems not medically necessary for a specific patient. If a claim indicates that a service was medically necessary, but according to CMS it was not, the claim is false even if the services were provided and the treating physician is of the opinion that the service was necessary.

On the other hand, legally false claims are those that, despite being factually accurate (for example, the services were provided as stated in the


22. Id. at 146–47.

23. Id. at 147.

24. Id.

25. See id. at 147–48.

26. Id. at 147.

27. Id. (“Medicare has issued significant amounts of guidance in the form of regulations, national coverage decisions, and other less formal means indicating what criteria must be met in order for particular items and services to be medically necessary.”).

28. See id.
claim), have failed to meet a condition for payment under a “federal healthcare program.” Such claims can be as simple as a patient failing to qualify under specific eligibility criteria or failing to meet a requirement under one of the federal government’s complicated payment rules. Legally false claims also include claims resulting from a violation of the Anti-Kickback Statute or the Stark Law. Further, under the implied false certification theory upheld by the Supreme Court in 2016, a claim for payment “impliedly certifies compliance with all conditions of payment.” Therefore, if such a claim fails to disclose a violation of “material statutory, regulatory, or contractual requirement . . . it has made a misrepresentation that renders the claim ‘false or fraudulent’” under the FCA. Regardless of whether it is a legally or factually false claim, plaintiffs must first prove liability and then, separately, damages.

A. PROVING LIABILITY UNDER THE FCA

An individual or entity is liable under the FCA for (1) submitting a “false or fraudulent claim for payment or approval” or causing another person or entity to submit a false claim for payment or approval; (2) submitting a “false record or statement material to a false or fraudulent claim;” or (3) possessing or controlling funds improperly received. Thus, not only does the statute prohibit actively submitting fraudulent claims or information, it also prohibits failing to pay back an overpayment within a specified timeframe, in what is sometimes referred to as the reverse false claims provision.

One of the most important aspects of the FCA from a liability perspective is that a plaintiff must prove scienter. To prove scienter, the government or a relator must prove either “actual knowledge,” “deliberate ignorance,” or “reckless disregard.” However, specific intent to defraud is not required. In other words, for there to be liability based on “actual

29. See id. at 148.
30. Id.
31. Id. at 148–51. See also 42 U.S.C. §§ 1320a–7(b), 1395nn (2012).
33. Id.
34. 31 U.S.C. § 3729(a)(1)(A)–(B), (D). See also Laemmle-Weidenfeld, supra note 4, at 133–34.
35. Laemmle-Weidenfeld, supra note 4, at 134, 147–48. See also 42 U.S.C. § 1320a-7k(d).
36. See Laemmle-Weidenfeld, supra note 4, at 135.
37. 31 U.S.C. § 3729(b)(1)(A) (“the terms “knowing” and “knowingly”—(A) mean that a person, with respect to information—(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”).
38. Id. § 3729(b)(1)(B)).
knowledge,” an individual or entity must have “known” at the time that they were submitting a claim or statement that it was false or, in the case of improper retention of money, that they were not entitled to those funds. Nonetheless, scienter can also be proved if the violator acted with “reckless disregard” or “deliberate ignorance.” As such, to avoid liability an individual or entity must still establish reasonable safeguards to protect against filing inaccurate claims.

B. DAMAGES UNDER THE FCA

While the stakes are already extremely high for providers, who risk being excluded from federally funded programs such as Medicare and Medicaid for losing at trial on just one FCA claim, once liability is established, FCA damages are particularly large. The FCA not only issues a civil penalty between $5,000 and $10,000 per false claim but also awards treble damages to a successful plaintiff-relator. To put this in perspective, in United States v. Krizek, despite having only $245,392 in actual damages, the government sought $81 million in total damages as a result of treble damages and civil penalties of $10,000 for each of the 8,002 separate claims. Additionally, violators are liable for the legal costs incurred by the government or plaintiff-relator.

The FCA does, however, permit reduced damages if certain conditions are met. First, the violating party must provide the investigating officials with “all information known to such person about the violation within 30 days” of obtaining the information. Second, the violating party must fully cooperate with the investigation. Third, when the violating party provides the information, there must be no actions regarding the violation (criminal, civil, or administrative) commenced against them under the FCA, and the violating party must “not have actual knowledge of the existence of an investigation into such violation.” Even the reduced damages, however, are

39. See id. § 3729(b)(1)(A); Laemmle-Weidenfeld, supra note 4, at 135.
40. Id.
41. See United States v. United Healthcare Ins. Co., 848 F.3d 1161, 1169 (9th Cir. 2016).
42. See Laemmle-Weidenfeld, supra note 4, at 135–36 (citing 42 U.S.C. §§ 1320a-7(b)(7), -7a(a)(1)(B)) (explaining that the Department of Health and Human Services can exclude providers from participating in federal healthcare programs if providers submit false claims).
43. Id. at 135.
44. 31 U.S.C. § 3729(a)(1).
46. 31 U.S.C. § 3729 (a)(3); Laemmle-Weidenfeld, supra note 4, at 146.
47. Id. § 3729 (a)(2)(A).
48. Id. § 3729 (a)(2)(B).
49. Id. § 3729 (a)(2)(C).
to be assessed at no less than two times the amount sustained by the government.\textsuperscript{50} Because the damages at stake are so incredibly high, the method by which plaintiff-relators can prove liability for each claim is a major point of contention in FCA cases: the lower the burden to prove liability, the higher the number of claims and subsequent damages.

C. STATISTICAL SAMPLING AND THE FCA

Statistical sampling is one of the methods that ultimately reduces the burden of proving liability in FCA cases. While the FCA does not statutorily authorize statistical sampling, it also does not prohibit it.\textsuperscript{51} FCA cases, as courts have acknowledged, present a particular challenge, because for especially large fraud schemes it becomes prohibitively expensive and impractical for qui tam relators and the government to pursue and prove each individual claim.\textsuperscript{52} As a result, starting in 1991 with \textit{Chaves County Home Health Service, Inc. v. Sullivan,}\textsuperscript{53} courts have allowed statistical sampling and extrapolation to be used to establish damages once liability has already been proven.\textsuperscript{54}

Despite its past use, until recently\textsuperscript{55} statistical sampling was generally limited to establishing damages.\textsuperscript{56} In other words, plaintiffs had to prove liability through other evidence, as courts recognized that “establish[ing] damages when liability has been proven is different than using extrapolation to establish liability.”\textsuperscript{57} In recent years, though, district courts have taken different approaches in determining whether statistical sampling can be used to establish liability.\textsuperscript{58} However, no circuit court has yet resolved the issue, and the one time the issue has been certified for appeal, the court declined to

\textsuperscript{50} \textit{Id.} § 3729 (a)(2).
\textsuperscript{54} \textit{See United States v. Cabrera-Diaz, 106 F. Supp. 2d 234, 240–42 (D.P.R. 2000) (outlining cases that have allowed statistical sampling to establish damages).}
\textsuperscript{55} \textit{Markey & Sarola, supra note 6.}
\textsuperscript{56} \textit{Martin,} 114 F. Supp. 3d at 560.
\textsuperscript{57} \textit{Id.} at 563.
\textsuperscript{58} \textit{See United States \textit{ex rel.} Wall v. Vista Hospice Care, Inc., No. 3:07-cv-00604-M, 2016 U.S. Dist. LEXIS 80160, at *37 (N.D. Tex. June 20, 2016) (“No circuit has resolved whether statistical sampling and extrapolation can be used to establish liability in an FCA case where falsity depends on individual physicians' judgment regarding individual patients.”).
As such, the question remains whether statistical sampling is sufficient evidence to establish liability under the FCA. Additionally, as will be discussed in greater detail, courts frequently conflate statistical sampling for liability and damages, even when they claim to only be using statistical sampling to calculate damages. Thus, it is important to understand how statistical sampling can be used in practice to establish liability and to determine damages, clearly highlighting the differences between the two uses.

1. How Statistical Sampling Would Establish Liability

The following example demonstrates how statistical sampling would typically be used to establish liability in an FCA case. Assume that the government brings suit against a healthcare provider for allegedly false claims submitted to Medicare between 2012 and 2015. During that period, the healthcare provider submitted 100,000 claims. It would be highly impractical for the government to carefully review each of the 100,000 claims and bring suit on every single claim found to be false. Instead, the government reviews a statistically valid random sample of 500 claims. Upon completing its review, the government has proof that of these 500 claims, 250 (50 percent) are false under the FCA. Accordingly, based on this statistical sampling, the government claims that 50 percent of the total number of claims, or 50,000, are false. If the court were to allow statistical sampling to establish liability, the healthcare provider could be held liable for 50,000 claims, even though the government definitively proved the falsity and knowledge elements of only 250 claims.

Using statistical sampling to establish liability would require using statistical sampling to establish damages almost by default. In the example above, liability for 50,000 claims means little without corresponding damages. However, since the government could only establish the exact amount of damages for 250 claims, the government would have no choice but to rely on statistical sampling to also calculate damages for the remaining 49,750 claims.

2. How Statistical Sampling Would Establish Damages

In theory, it is possible to use statistical sampling only to calculate damages (and not to establish liability in any way). For example, a defendant healthcare provider could admit that every single time they submitted certain

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types of claims to Medicare, they knew the claims were false. The
government could then determine that 3,000 of these types of claims were
submitted and decide that it would be impractical to determine the exact
amount of damages for each one. Instead, the government could review a
statistically valid sample of 300 of these 3,000 claims. If based on its review
the government calculates an average damage amount of $250 per false
claim, then the government could be awarded $750,000 in damages (or
$2,250,000 after trebling) for the 3,000 false claims, despite having only
reviewed 300 of them.

In practice, however, such situations are exceedingly rare in FCA
litigation. Given the FCA’s trebling of damages and how its civil penalties
are levied on each individual claim, defendants have virtually no incentive
to admit liability on claims the government is unable or unwilling to
thoroughly review, and they have a strong incentive to challenge the alleged
falsity of such claims. Accordingly, even when a court claims that it is using
statistical sampling solely to determine damages, unless liability has already
been proven for every single claim, the court is actually using statistical
sampling to establish liability.60

Having discussed how statistical sampling could feasibly be used to
establish liability and damages separately, this Note turns now to an
overview of the legal precedent surrounding the use of statistical sampling.

D. LEGAL PRECEDENT FOR THE USE OF STATISTICAL SAMPLING

1. Daubert Generally Permits Use of Statistical Methods

Statistical sampling evidence is typically introduced through expert
testimony. Generally, the Federal Rules of Evidence allow for the admission
of an expert’s testimony if certain requirements are met.61 Those
requirements, provided in Rule 702, are that (1) the expert’s knowledge will
help the trier of fact to better understand evidence in the case or make a
factual determination; (2) the testimony is sufficiently based on facts or data;
and (3) the testimony both results from, and properly applies to, the facts of
the case and reliable principles and methods.62 Accordingly, a court must
first determine that an expert is testifying as to specialized knowledge and
that this knowledge will be helpful to the trier of fact.63

60. See infra Part I.C.1.
61. See Vista Hospice Care, 2016 U.S. Dist. LEXIS 80160, at *42 & n.108.
62. Id. (citing FED. R. EVID. 702).
63. Id.
Under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, a court must determine not only if evidence is relevant but also whether it is reliable. The court, acting as gatekeeper, must consider the following factors, commonly known as the "Daubert factors":

1) whether the expert’s scientific technique or theory can be, or has been, tested; 2) whether the technique or theory has been subject to peer review and publication; 3) the known or potential rate of error of the technique or theory when applied; 4) the existence and maintenance of standards and controls; and 5) whether the technique or theory has been generally accepted in the scientific community.

It follows then, under *Daubert*, that an expert can testify as to extrapolated data so long as the methodology is appropriate and the data is “randomly selected” and “representative of the whole.” However, the *Daubert* factors are not exclusive, and the court is ultimately given considerable leeway in determining whether evidence is admissible. Additionally, the proponent of the expert testimony must establish by a preponderance of the evidence that the testimony satisfies the admissibility requirements.


One of the main legal precedents for the use of statistical sampling comes from the landmark case *Wal-Mart Stores, Inc. v. Dukes*, in which the Supreme Court refused to allow trial by statistics. However, the Court did not close the door to the use of statistical sampling during the damages phase. In *Wal-Mart*, respondents attempted to certify a class of 1.5 million female employees by alleging that local managers pervasively discriminated against women in the workplace, favoring male employees for promotions and higher pay, and that Wal-Mart had refused to restrain the managers’...
discretion in these decisions.\textsuperscript{72} To certify the class,\textsuperscript{73} respondents had to prove that “‘questions of law or fact [were] common to’ all the women of Wal-Mart.”\textsuperscript{74} To satisfy this requirement, they attempted to use anecdotal testimony of 120 women, the expert testimony of a sociologist, and statistical evidence showing pay and promotion disparities between male and female employees.\textsuperscript{75}

The Court disregarded the expert testimony, finding that the anecdotal evidence was too weak.\textsuperscript{76} The statistical evidence consisted of a regression analysis showing a disparity between the number of women promoted to management positions and the total number of available employees.\textsuperscript{77} The Court found that the evidence did not raise an inference of a company-wide discriminatory policy, and “merely proving that the discretionary system has produced a racial or sexual disparity \textit{is not enough}.”\textsuperscript{78} The Court noted that a defendant is “entitled to litigate its statutory defenses to individual claims”\textsuperscript{79} and has “a right to contest the fact of its liability to each claimant, including the fact of the claimant’s injury.”\textsuperscript{80} The Court reversed the Ninth Circuit, holding that “individualized determinations of each employee’s eligibility for backpay” could not be replaced by “Trial by Formula.”\textsuperscript{81}

In the post-Wal-Mart period, courts have typically allowed statistical sampling to prove damages but not aspects such as liability or commonality of issues.\textsuperscript{82} For example, in \textit{Dailey v. Sears, Roebuck & Co.}, the court held that plaintiffs in a class action could not use statistical sampling to show

\begin{itemize}
\item \textsuperscript{72} \textit{Wal-Mart}, 564 U.S. at 343–45.
\item \textsuperscript{73} See Fed. R. Civ. P. 23(a) (listing class certification requirements).
\item \textsuperscript{74} \textit{Wal-Mart}, 564 U.S. at 346 (quoting Fed. R. Civ. P. 23(a)(2)).
\item \textsuperscript{75} Id.
\item \textsuperscript{76} See id. at 353–55, 358.
\item \textsuperscript{77} Id. at 356.
\item \textsuperscript{78} Id. at 356–57. “Information about disparities at the regional and national level does not establish the existence of disparities at individual stores.” Id. (quoting Dukes v. Wal-Mart Stores, Inc., 603 F.3d 571, 637 (9th Cir. 2010) (Ikuta, J., dissenting)).
\item \textsuperscript{79} Id. at 367.
\item \textsuperscript{80} Tidmarsh, \textit{supra} note 71, at 1474 (emphasis omitted).
\item \textsuperscript{81} \textit{Wal-Mart}, 564 U.S. at 366–67. The Court explained the proposed trial by formula: “A sample set of the class members would be selected, as to whom liability for sex discrimination and the backpay owing as a result would be determined in depositions supervised by a master. The percentage of claims determined to be valid would then be applied to the entire remaining class, and the number of (presumptively) valid claims thus derived would be multiplied by the average backpay award in the sample set to arrive at the entire class recovery—without further individualized proceedings.” Id. at 367.
\item \textsuperscript{82} See Tidmarsh, \textit{supra} note 71, at 1459–77 (discussing \textit{Wal-Mart’s} effects on statistical sampling).
\end{itemize}
commonality of issues for class certification.83

3. Tyson Foods: Admissibility of Statistical Sampling Turns on Reliability

In 2016, the Supreme Court revisited the use of statistical sampling evidence in Tyson Foods, Inc. v. Bouaphakeo.84 Here, the Court rejected bright-line rules regarding statistical sampling, instead preferring a case-by-case approach.85 In Tyson Foods, a class action suit was filed against an employer. The suit alleged that the employer failed to compensate employees for the time it took to put on and take off protective gear, resulting in unpaid overtime wages in violation of the Fair Labor Standards Act (“FLSA”).86 To establish the amount of unpaid time, the plaintiffs relied on an expert study that reviewed evidence concerning only a sample of class members, such as videotaped observations of the time it took some employees to put on and take off the protective gear.87 Based on the review of the sample, the expert determined that one category of employees averaged eighteen minutes a day putting on and taking off the gear, while another averaged twenty-one minutes and fifteen seconds.88 Since the employer did not maintain records tracking this time for each individual, the plaintiffs calculated the damages for each affected member of the class based on the averages from the sample.89 The employer did not move for a hearing to determine the validity of the study under Daubert or attempt to discredit the expert’s testimony with a rebuttal expert, but rather argued that the study overstated the average times and that the actual differing times it would take each individual to put on and take off the protective gear “made the lawsuit too speculative for classwide recovery.”90 In affirming the damages awarded, the Court recognized that statistical sampling is just another piece of evidence that can “establish or defend against liability”91 and is at times “the only practicable” approach to prove liability, and thus under the circumstances of the instant case sampling could be used.92

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86. Tyson Foods, 136 S. Ct. at 1042.
87. Id. at 1042–44
88. Id. at 1043–44.
89. Id.
90. Id. at 1044.
91. Id. at 1046.
92. Id. (emphasis added) (quoting MANUAL FOR COMPLEX LITIGATION (FOURTH) § 11.493
Despite both parties and their respective amici urging the Court to establish “broad and categorical rules governing the use of representative and statistical evidence,” the Court refused to do so.93 The Court instead concluded that whether statistical sampling is appropriate depends on “the degree to which the evidence is reliable in proving or disproving the elements of the relevant cause of action”94 and the “facts and circumstances particular” to each case.95 The opinion in Tyson extends well beyond the FLSA and class actions and has been hailed by some legal practitioners as the new roadmap to FCA claims.96

E. SAMPLING IN OTHER TYPES OF LITIGATION

Statistical sampling is also used in other types of litigation, and the breadth of its use as appears to be expanding. For example, statistical sampling is frequently used in antitrust, equal employment opportunity, discrimination, voting rights, product liability, trademark, fairness in sentencing, and mass tort cases (including environmental cases such as toxic torts).97 In 2010, statistical sampling was also permitted in MBIA Insurance Corp. v. Countrywide Home Loans, Inc., a notable mortgage securities case.98

II. ANALYSIS

As Tyson Foods indicates, courts, including the Supreme Court, are reluctant to establish clear, general rules regarding the use of statistical sampling in litigation, and this is no different in cases involving the FCA. As such, parties involved in FCA litigation and courts deciding FCA claims

(2004)).

93. Id. at 1049.
94. Id. at 1046.
95. Id. at 1049.
must rely on the sometimes-conflicting reasoning of previous decisions regarding the use of statistical sampling. Accordingly, an overview of frequently cited and relied-upon cases addressing the use of statistical sampling in FCA claims is necessary in order to fully understand the legal arguments made for and against their use. Having already reviewed the background of the FCA and established the legal precedents for the use of statistical sampling evidence, this Note will now analyze how district courts have approached the use of statistical sampling to prove liability in FCA cases pertaining to healthcare fraud.

The following is an overview and survey of the sixteen most cited and relevant cases. This Part of the Note extracts their fundamental legal principles concerning statistical sampling and categorizes and discusses them as follows: Section A, courts allowing the use of statistical sampling to prove liability; Section B, courts not allowing the use of statistical sampling to prove liability; Section C, courts that likely would have allowed statistical sampling if data had been reliable or the timing was proper; and Section D, courts that did not decide the issue determinatively. Section E provides an in-depth discussion of Michaels v. Agape Senior Community, Inc., given the magnitude of its importance as the only case concerning statistical sampling and FCA liability to reach an appellate court.

TABLE 1. Healthcare Fraud Cases with Statistical Sampling for Liability

<table>
<thead>
<tr>
<th>Case</th>
<th>Venue</th>
<th>Year</th>
<th>Statistical Sampling Allowed for Liability?</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States ex rel. Martin v. Life Care Centers. of America, Inc.</td>
<td>E.D. Tenn.</td>
<td>2014</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>United States v. Robinson</td>
<td>E.D. Ky.</td>
<td>2015</td>
<td>Y</td>
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<tr>
<td>United States v. Aseracare Inc</td>
<td>N.D. Ala.</td>
<td>2014</td>
<td>Y</td>
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<td>United States ex rel. Ruckh v. Genoa Healthcare, LLC</td>
<td>M.D. Fla.</td>
<td>2015</td>
<td>Y</td>
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<td>Case</td>
<td>Venue</td>
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<td>Statistical Sampling Allowed for Liability?</td>
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<td>United States ex rel. Wall v. Vista Hospice Care, Inc.</td>
<td>N.D. Tex.</td>
<td>2016</td>
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<td>United States v. Medco Physicians Unlimited</td>
<td>N.D. Ill.</td>
<td>2000</td>
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<td>United States ex rel. Guardiola v. Renown Health</td>
<td>D. Nev.</td>
<td>2014</td>
<td>Y*</td>
<td>Only allowed statistical sampling in discovery; did not rule as to trial phase.</td>
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<tr>
<td>United States v. Fadul</td>
<td>D. Md.</td>
<td>2013</td>
<td>Y*</td>
<td>Addressed statistical sampling only with regard to common law claim, not FCA claim.</td>
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<tr>
<td>United States v. Friedman</td>
<td>D. Mass.</td>
<td>1993</td>
<td>N*</td>
<td>Acknowledged validity in general of statistical sampling but only referred to statistical sampling regarding damages.</td>
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<tr>
<td>Case</td>
<td>Venue</td>
<td>Year</td>
<td>Statistical Sampling Allowed for Liability?</td>
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<td>United States ex rel. Michaels v. Agape Senior Community, Inc.</td>
<td>D.S.C.</td>
<td>2015</td>
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<tr>
<td>United States ex rel. Michaels v. Agape Senior Community, Inc. (^p)</td>
<td>4th Cir.</td>
<td>2017</td>
<td>N*</td>
<td>*Held that it was inappropriate to review issue through an interlocutory appeal.</td>
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\(^a\) United States ex rel. Martin v. Life Care Ctrs. of Am., Inc., 114 F. Supp. 3d 549, 572 (E.D. Tenn. 2014).


\(^p\) Michaels, 848 F.3d at 341.
A. CASES ALLOWING THE USE OF STATISTICAL SAMPLING

The following are cases in which the court allowed the use of statistical sampling to prove liability in FCA litigation. These summaries demonstrate that courts arrive at this decision primarily based on (1) the FCA’s purpose of combating large scale fraud, (2) the impracticability of the government or a relator proving each one of thousands of claims, and (3) the lack of authority that would disallow the use of statistical sampling.

First, in United States ex rel. Martin v. Life Care Centers of America, Inc., the defendants argued that “the Government cannot satisfy its burden of proof through evidence based on statistical sampling and extrapolation.”99 The court, finding that no legal precedent was determinative,100 held that statistical sampling could be used by a plaintiff to attempt to prove liability in FCA litigation.101 The court reasoned that the purpose of the FCA—to fight large-scale fraud against the government—would be undermined were it not to allow statistical sampling, because it would be impractical to review individual claims on a large scale.102 Notably, however, the court ruled that the fact finder must determine how much weight is given to the statistical evidence.103

Similarly, in United States v. Robinson, the court denied the defendant’s motion for summary judgment, finding the defendant had not proven that the use of extrapolated data was inappropriate.104 Agreeing with Martin, it held that, with “over 25,000 claims at issue,” it would be impracticable to require a plaintiff to present evidence of each claim individually and that it would defeat the purpose of the FCA.105

Additionally, the court in United States v. Aseracare Inc., found that “statistical evidence is evidence” and deferred to the fact finder as to the weight such evidence should receive.106 Notably, the court did not

100. Id. at 564.
101. Id. at 570–71.
103. Martin, 114 F. Supp. 3d at 572.
105. See id. at *17, 29 (citing Martin, 114 F. Supp. 3d at 554 and Mich. Dep’t of Educ. v. U.S. Dep’t of Educ., 875 F.2d 1196, 1205 (6th Cir. 1989)).
distinguish between the use of statistical sampling at the damages stage and at the liability stage, although it did ask the plaintiffs whether they were using sampling to establish liability or damages.  

In another example, United States ex rel. Ruckh v. Genoa Healthcare, LLC, the relator moved to admit expert testimony on statistical sampling before any sampling had been done. The defendant argued that the expert testimony was inadmissible, citing United States v. Friedman (discussed infra in Part II.D). The court was not persuaded by the defendant’s arguments and, quoting Martin, explained that even though Friedman did not allow statistical sampling for the case at hand, it did “not stand for the proposition that statistical sampling cannot be used” at all. Instead, the court “recognized the validity of statistical sampling” in general and held that no testimony was excludable solely because it was statistical sampling.

Finally, in United States ex rel. Loughren v. UnumProvident Corp., the court concluded that statistical sampling was adequate to determine the number of false claims. Notably, however, it only did so after a bellwether trial, during which testimony was presented that the defendant had a generalized policy of coercing its insureds to file for Social Security disability benefits when it “knew or should have known that these insureds did not meet the statutory definition of disability required to qualify.” While the court ultimately granted the motion to exclude the expert’s testimony, it did so only because it found the statistical sampling and expert testimony to be unreliable.


107. Reporter’s Official Transcript of Motion Hearing at 223–26, AseSacare, 2014 U.S. Dist. LEXIS 167970 (No. 305). See also infra Part IV.A (discussing how some courts do not seem to distinguish between liability and damages and their respective requirements when analyzing the use of statistical sampling).


109. Id. at *8–9.

110. See id. at *9–10 (quoting Martin, 114 F. Supp. 3d at 561).

111. Id. at *9 (quoting Martin, 114 F. Supp. 3d at 561).

112. Id. at *12–13.


114. Id. at 260–61.

115. See id. at 269.
B. CASES NOT ALLOWING THE USE OF STATISTICAL SAMPLING

The following two cases are examples of courts disallowing statistical sampling in FCA litigation and the typical reasoning behind that decision. Courts arrive at this decision primarily based on (1) the claims at issue involving subjective medical judgment, (2) the plaintiff’s burden in establishing falsity and scienter for each claim, and (3) the lack of authority that would allow the use of statistical sampling.

In United States ex rel. Wall v. Vista Hospice Care, Inc., a case involving patient eligibility for hospice care, the court struck expert statistical sampling testimony.\(^{116}\) The court reasoned that statistical sampling was insufficient to prove liability in an FCA claim when the “underlying determination of eligibility for hospice is inherently subjective, patient-specific, and dependent on the judgment of involved physicians.”\(^{117}\) While the court recognized the general validity of statistical sampling, it noted that it is not always permissible and instead turns on “the degree to which the evidence is reliable in proving or disproving the elements of the relevant cause of action.”\(^{118}\) In fact, the court argued that any ruling that extrapolation and sampling are always reliable, no matter the “nature of the data and the nature of the claim,” is incorrect in light of Wal-Mart, which requires “a particularized analysis of . . . whether extrapolation from a particular data set can reliably prove the elements of the specific claim.”\(^{119}\)

In arriving at its decision the court also noted how the facts were analogous to those in Michaels v. Agape Senior Community, Inc., in that each claim involved subjective decision-making based on the facts and circumstances surrounding each individual patient.\(^{120}\) The court then differentiated the case at hand from several decisions that did permit sampling, because those cases did not involve a physician’s necessary “subjective clinical judgment” in predicting an individual’s life expectancy.\(^{121}\) Further, one of the cases, Robinson, dealt with only a single optometrist, as opposed to Vista Hospice Care, which involved many physicians at different locations.\(^{122}\) These points were particularly important because even if there were sufficient proof in one particular claim requiring

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117. See id. at *35.
118. Id. at *36 (quoting Tyson Foods, Inc. v. Bouaphakeo, 136 S. Ct. 1036, 1046 (2016).
119. Id. at *40.
120. See id. at *37–38.
121. Id. at *40 (emphasis omitted).
122. Id.
subjective judgment, such a finding could not impact the burden of proof for a different claim requiring subjective judgment involving "different patients, different medical conditions, different caregivers, different facilities, different time periods, and different physicians." 123

Ultimately, the court determined that an FCA claim based on the exercise of a physician’s subjective clinical judgment “must be predicated on the presence of an objectively verifiable fact at odds with the exercise of that judgment," and not simply question the subjective judgment.124 An example of such a claim involving an “objectively verifiable fact” would be a physician not actually exercising clinical judgment where he neither reviewed a patient’s medical condition nor saw the patient.125 Accordingly, an FCA claim cannot rely solely on an expert’s disagreement with a certifying physician’s subjective conclusion.126

Separately, the court emphasized that the FCA’s scienter requirement is independent of the requirement to show the falsity of records or claims.127 In other words, showing that a defendant operated with reckless disregard for falsity does not in itself prove actual falsity under the FCA.

In an older case, United States v. Medco Physicians Unlimited, the plaintiff asked the court to extrapolate from an expert review of sixteen of the defendant’s patients that the defendant had fraudulently billed for all of its patients.128 The court declined because the plaintiff had failed to cite any authority supporting extrapolation, or even to provide evidence sufficient to prove fraudulent billing for the sixteen reviewed patients, let alone the rest.129

C. COURTS THAT LIKELY WOULD HAVE ALLOWED STATISTICAL SAMPLING IF DATA HAD BEEN RELIABLE OR TIMING WAS PROPER

FCA cases sometimes discuss the issue of statistical sampling but refuse to allow it for reasons specific to the case at hand. However, if these case-specific issues had been corrected, statistical sampling would likely have been allowed. As demonstrated in the summaries that follow, courts have refused to permit the use of statistical sampling to prove liability when

123. Id. at *41–42.  
124. Id. at *54.  
125. Id. at *55–56.  
126. See id. at *56–57.  
127. Id. at *64.  
129. Id. at *23–24.
(1) the data or methodology used in conducting the sample was flawed, (2) the plaintiff raised the issue of statistical sampling after an unreasonable delay, or (3) the plaintiff failed to properly establish the parameters of the sample.

In United States ex rel. Trim v. McKean, the court rejected the use of audits as statistical data for extrapolation because the data was “tainted.”\(^1\)\(^3\)\(^0\) The court appeared to take issue with the method and factual circumstances surrounding the performance of the audit and not necessarily the use of extrapolated statistical data in FCA claims generally.\(^1\)\(^3\)\(^1\) In fact, it found that the audit was “persuasive evidence of false claims.”\(^1\)\(^3\)\(^2\)

In United States ex rel. El-Amin v. George Washington University, the court denied the relators’ motion for “trial by representative sample” because the litigation had been pending for eleven years, and at no point had the relators raised the issue of statistical sampling.\(^1\)\(^3\)\(^3\) In addition to the practical inconveniences presented by this last-minute argument, the relators were unprepared to even define the universe of claims, instead merely providing an estimate of somewhere between 5,000 to 15,000 claims.\(^1\)\(^3\)\(^4\) It seems very likely, however, that the court would have allowed statistical sampling had the issue been raised by the relators in a timely matter, given the court’s emphasis on the injustice of allowing the case to be converted to a trial by representative sample so late into the litigation and its mention that the “[r]elators [had not] taken the preparatory steps that would give them the proper foundation to try this case by statistical sample.”\(^1\)\(^3\)\(^5\)

D. COURTS THAT DID NOT DECIDE THE ISSUE DETERMINATIVELY

Finally, some courts discuss the issue of statistical sampling but refuse to rule on the matter. As demonstrated by the following summaries, courts have failed to decide the issue of statistical sampling when they (1) deferred

\(^1\)\(^3\)\(^1\). See id.
\(^1\)\(^3\)\(^2\). Id.
\(^1\)\(^3\)\(^4\). Id.
\(^1\)\(^3\)\(^5\). Id. at 50–51 (“In short, the Relators’ failure to take even the most basic steps in preparing for a trial by representative sample proves fatal to the instant motion because, as the Defendant convincingly argues, the time for trial preparation is over. . . . It would be unfair to the Defendant at this stage of the litigation and on the eve of trial to permit the Relators to convert this case to a trial by representative sample. The Defendant, like the Relators, has not consulted an expert statistician and, like both the Relators and this Court, cannot even identify the universe of allegedly fraudulent claims. In light of these practical considerations, the motion is denied.”).
the decision to a later stage of the litigation that never occurred; (2) decided the matter on a motion for default judgment or the defendants agreed to the use of a sample; (3) addressed statistical sampling outside of the FCA context, even though the opinion also addressed FCA claims; and (4) recognized the general validity of statistical sampling but opted to award damages only on claims the court was able to actually examine. It is worth noting, however, that each of these cases, in some way, acknowledges the validity of statistical sampling.

In *United States ex rel. Guardiola v. Renown Health*, the court allowed statistical sampling in the discovery phase but did not make a ruling on admissibility of statistical sampling, reserving it instead for the “pre-trial stage.”136 While the case settled before trial, the judge’s willingness to allow statistical sampling at the discovery phase suggests that he would likely have permitted it in pre-trial motions.

In another case, *United States v. Cabrera-Diaz*, the court granted the plaintiff’s motion for default judgment, finding—based on statistical sampling—that the defendants had violated the FCA by knowingly “caus[ing] to be presented false or fraudulent claims to the United States.”137 However, *Cabrera-Diaz* is exceptional, as the *Martin* court argued, in that it was decided on a motion for default judgment.138 Because the physician was not present to oppose the motion, liability was proven not by the use of statistical sampling but instead as a result of the defendant’s failure to answer.139 As such, given that the outcome was determined by a “procedural mechanism,” the court’s reasoning should not be viewed as determinatively binding.140 While one cannot say with certainty what the outcome would have been had the defendants responded to the motion, the opinion still reflects a willingness to accept statistical sampling to prove liability.

A similarly unique case is *United States v. Krizek*, in which the court conducted a trial based on seven patients and 200 claims “that the government believed to be representative” of 8,002 reimbursement

139. See *id.*
140. See *Martin*, 114 F. Supp. 3d at 564 (“Without evidence and argument opposing the government’s position, the Court cannot view the result in *Cabrera-Diaz* as anything other than an unopposed remedy suggested by the government, which was granted through a procedural mechanism to obtain judgment from unresponsive parties.”).
claims. This decision resulted from the defendants’ motion to quash a subpoena seeking office records, on the grounds of patient confidentiality. Apparently for the purposes of protecting such confidentiality, the court decided to move forward with a smaller sample trial based on the seven patients’ records that the government already possessed. The opinion noted, however, that the defendants had agreed “that a determination of liability” on the smaller trial would then extend the liability to the remaining 8,002 claims. Because the defendants had agreed, the court did not explain its rationale or the legal precedent for using a sample to establish liability; therefore this opinion cannot be used as binding precedent for the use of statistical sampling to prove liability in FCA claims.

Another case, United States v. Fadul, is often cited by defendants and courts to reject the use of statistical sampling to prove liability in FCA claims. Nonetheless, while Fadul technically addressed statistical sampling, it did not address statistical sampling in the context of an FCA claim. In Fadul, the government moved for summary judgment on both the FCA and common law claims. The court determined, however, that summary judgment on the FCA claim was inappropriate because there were discrepancies in the record regarding scienter and because of the “general preference for allowing the issue of scienter to be decided by a fact finder.”

Thus, the court never addressed statistical sampling in the context of the government’s FCA claim.

Rather, statistical sampling came up only when determining damages for the common law claim based on payment by mistake of fact relating to improper Medicare and Medicaid coding. The court made clear that, “[n]otably, ‘[k]nowledge of falsity is not a requisite for recovery under the mistake doctrine.’ . . . Thus, even where it cannot establish that a defendant acted knowingly for purposes of the False Claims Act, the Government may be entitled to recovery under the alternative theory of payment by mistake of

143. See id. at *3.
146. See id. at *23–39.
147. Id. at *21.
148. Id. at *37–38.
149. Id. at *44–45.
Accordingly, Fadul provides no insight as to whether statistical sampling is appropriate in FCA claims.

Another case frequently cited as precedent for rejecting statistical sampling to prove liability is United States v. Friedman. There, however, the court did not outright reject statistical sampling to prove liability. Instead, it “recognize[d] the validity of the mathematical and statistical projections based on a review of a smaller number of claims” but noted that it was “reluctant to accept a statistical sampling” in that particular case because it had the opportunity to scrutinize discrete claims and wanted the opportunity to do the same for the remaining claims. The court referred to the use of statistical sampling in calculating damages but did not delve into its admissibility for purposes of proving liability.

E. UNITED STATES EX REL. MICHAELS V. AGAPE SENIOR COMMUNITY, INC.

All of the cases summarized above are district court cases. Michaels is the only case involving statistical sampling in FCA litigation to reach a circuit court. For this reason, a thorough summary of the district court opinion and the arguments made to the Fourth Circuit is appropriate, as the arguments may serve as a guide for future litigants.

1. The District Court Case

In Michaels, the plaintiff-relators alleged that their former employer, an entity owning twenty-four nursing homes, had engaged in a widespread fraud by submitting false claims for reimbursement of home healthcare services. The number of claims at issue was approximately between 53,280 and 61,643.
During discovery, the court ruled that statistical sampling could not be used to determine damages.157 The case later settled before trial, but the government objected to the settlement, believing that it represented only 10 percent of the potential damages of the case, which it estimated to be around $25 million.158 As a result, the defendants filed a motion to enforce the settlement.159 During oral argument it was revealed that the government had relied on statistical sampling in arriving at its estimated damages, despite the previous order from presiding Judge Joseph F. Anderson, Jr. rejecting such use in the instant case.160 Given the voluminous number of claims, and the great expense and time involved were the case to continue to trial, Judge Anderson detailed his reasoning for denying the use of statistical sampling for the purpose of certifying the issue for interlocutory appeal.161

Judge Anderson affirmed the reasoning of the court in Friedman,162 denying the use of statistical sampling because the claims at issue were distinct and based on evidence that should be subject to individual examination in court.163 He made a distinction between the case at hand, in which all relevant medical records were available to the parties, and cases in which evidence was no longer available and thus statistical sampling was the only way that the case could be tried.164 Denying the use of statistical sampling in those cases would "allow widespread fraud to go unpunished."165 Here, however, because the claims at issue concerned medical records and patient information that varied from patient to patient, the case was not conducive to statistical sampling.166 The court carefully noted numerous cases cited for and against the use of statistical sampling before certifying the decision for interlocutory appeal.167

It is worth noting that the court seemed to conflate the use of statistical sampling in proving liability and in establishing damages. At no point did the court distinguish between the two.168

157. Id. at *4.
158. Id. at *6–7.
159. Id. at *7.
160. Id. at *1, *7–8.
161. Id.
164. Id. at *18–19.
165. Id. at *19.
166. Id. at *24.
168. See infra Part IV.
2. The Circuit Court Case

On appeal, the government relied heavily on Martin and argued that statistical sampling was essential to these types of cases. In turn, the defendants argued that as hospice eligibility is subjective and individualized, statistical sampling would not be an appropriate method for establishing liability. The defendants also emphasized that statistical sampling is typically used to calculate damages once liability has been conceded or is indisputable. Additionally, they argued that scienter could not be proved through statistical sampling, making an analogy to Fadul, in which the court found that collective knowledge of employees/agents was insufficient to prove scienter. Thus, Agape posited that aggregate data from sampling is not sufficient to prove scienter.

Amicus briefs were also filed in support of the defendants-appellees by Savaseniorcare Administrative Services, LLC (“Savaseniorcare”); the American Hospital Association (“AHA”) and the Catholic Health Association of the United States (“CHA”); and the American Health Care Association (“AHCA”). These amici provide a glimpse into what the arguments against statistical sampling could look like should this issue reach the Supreme Court in the future—as some practitioners have suggested it might—and thus are worthy of detailed review.

Savaseniorcare argued that whether a treatment is reasonable or necessary, and thus appropriately reimbursable, cannot be decided by a mathematical formula. These decisions are necessarily subjective, involving complex circumstances that require individualized medical judgment. Additionally, it noted that “reasonable disagreement of professional opinion” is insufficient to establish liability under the FCA, the conduct must
instead be objectively false. As such, it would be inappropriate to conduct a trial by formula when the relevant conduct consisted of subjective medical decisions concerning whether a patient should be admitted to hospice care. Further, it emphasized that FCA liability does not attach to an “underlying fraudulent scheme” but rather only attaches when there is an actual claim for payment. Therefore, trial by formula would be insufficient, since it would not provide proof that each individual claim was false.

Savaseniiorcare also noted that the government had been trying to avoid appellate review in both the case at hand and Martin because the government is accustomed to using the threat of statistical sampling to obtain large settlements from providers. It urged the court to recognize the government’s assertion that the inability to use statistical sampling would allow large-scale fraud to run rampant and unpunished is nothing more than a scare tactic. It then argued that the court should not sidestep the decision, given how often the issue arises in healthcare fraud litigation and FCA cases in general, and that it is a controlling question of law.

The AHA and CHA made similar arguments, but they also focused heavily on the plaintiff’s burden of proof, arguing that it would be illogical and counter to the purpose of the FCA to shift the burden to defendants. Doing so would essentially make way for “financially motivated relators to attempt to collect large judgments . . . by second guessing doctors’ medical judgments.” They also relied heavily on United States ex rel. Nathan v. Takeda Pharmaceuticals North America, Inc. to assert that if “statistical allegations” are insufficient to plead a cause of action, they should be insufficient to find liability.

a material and false statement.”).

178. Id. (citing United States ex rel. Wilson v. Kellogg Brown & Root Servs., Inc., 525 F.3d 370, 376 (4th Cir. 2008)).
179. Id. at 5–7, 10.
180. Id. at 11–12 (quoting United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc., 707 F.3d 451, 456 (4th Cir. 2013)).
181. See id.
182. See id. at 23–25.
183. Id. at 4, 20–21.
184. Id. at 24–25.
185. See AHA/CHA Brief, supra note 174, at 7–8. The burden of proof would shift to defendants if statistical sampling were allowed: plaintiff-relators would not have to prove the falsity of each individual claim, but defendants potentially would have to sift through each claim to disprove allegations of falsity. See id.
186. Id.
187. Id. at 13–14 (citing United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc., 707 F.3d 451, 459 (4th Cir. 2013)).
AHA and CHA also contended that arguments regarding whether statistical sampling is appropriately conducted under the Daubert standard have no bearing as to whether statistical sampling should be used to establish liability in the first place. In other words, it is ultimately irrelevant whether the statistical sampling is reliable under Daubert because statistical sampling should not be used to establish liability, even if it is reliable. Further, they suggested that since relators can recuperate reasonable fees under the FCA, including expert fees, it is particularly unjustified that liability standards should be relaxed: if what the relators allege is true, and they prove each claim, then they will be able to recuperate the expenses incurred in satisfying their burden of proof. They also argued that the district court cases that the relators and the government relied upon only address the issue of proving damages, not the issue of proving liability. Finally, they argued that the approval of statistical sampling to establish liability would prove catastrophic to the healthcare industry, ultimately resulting in increased healthcare costs.

Similar to the AHA and CHA, the AHCA espoused concern over the burden of proof. It also argued, however, that the use of statistical sampling to prove liability would violate the Due Process Clause. Given the FCA’s treble damages allowance, amounting to “essentially punitive damages,” due process rights would be violated if defendants were not permitted to defend their liability for each specific claim. Finally, it emphasized the practical effects of allowing statistical sampling to prove FCA liability, namely, continued pressure for providers to settle meritless cases.

During oral argument, the Fourth Circuit judges seemed uninterested in the statistical sampling arguments, commenting that the district court had the ability to decide whether statistical sampling was appropriate for each individual case given the factual context. Instead, the court was more
interested in the government’s veto power over the settlement.\textsuperscript{197}

Ultimately, the Fourth Circuit dismissed the statistical sampling portion of the relators’ appeal as improvidently granted, finding that it was not a pure question of law and, as such, was not appropriate for interlocutory review under 28 U.S.C. § 1292(b).\textsuperscript{198} The court noted that the relators themselves presented the issue as whether the statistical sampling was properly conducted under the \textit{Daubert} standard, not whether it could be used at all.\textsuperscript{199} Thus, the question at issue was whether the district court had discretion to allow the relators to “use statistical sampling to prove [the] case.”\textsuperscript{200} The court emphasized that there was a difference “between a question of law, which will satisfy § 1292(b), and a question of fact or matter for the discretion of the trial court,” concluding that the statistical sampling issue in \textit{Michaels} was a factual matter subject to the abuse of discretion standard and thus inappropriate for interlocutory appeal.\textsuperscript{201} Through its emphasis that the issue as presented was a factual one, the circuit court was careful to avoid comment as to whether the use of statistical sampling is appropriate for proving liability as a matter of law. Despite passing on the issue for the moment, the decision in practice allows district courts to continue to use discretion in determining whether statistical sampling is appropriate for a particular case.\textsuperscript{202}

With the resolution of the interlocutory appeals, \textit{Michaels} settled and was dismissed in August 2017.\textsuperscript{203} While \textit{Michaels} did not ultimately provide the answer practitioners were looking for, other circuits will likely have to determine in the near future whether statistical sampling can be used to prove liability. As such, this Note turns now to the impact a more definitive ruling would have.

\textsuperscript{197} See id.
\textsuperscript{198} \textit{Michaels}, 848 F.3d at 341.
\textsuperscript{199} Id.
\textsuperscript{200} Id.
\textsuperscript{201} Id. (quoting McFarlin v. Conseco Servs., LLC, 381 F.3d 1251, 1258 (11th Cir. 2004)).
III. IMPACT

A. CONSEQUENCES OF REJECTING STATISTICAL SAMPLING FOR LIABILITY

Should a circuit court decide to reject the use of statistical sampling to prove liability, FCA discovery would become significantly more burdensome given the increase in the number of claims that must be proven.204 Whistleblowers also argue that the costs would be so significant that “combat[ing] large scale fraud through whistleblower litigation” would become much harder,205 potentially defeating the very purpose of the FCA. They argue that attorney’s fees would increase insurmountably, and cases would take much longer to settle. A rejection of statistical sampling would also reduce the potential recovery of damages, since litigants would have to prove each individual claim and would be unable to collect damages from as many claims as they would if statistical sampling was allowed. Ultimately, this would greatly reduce the incentive for whistleblowers to file suit. Arguably more importantly, it would also reduce the incentive—and possibly make it prohibitively expensive—for attorneys to take on contingent whistleblower litigation cases.

Additionally, some may argue that this significantly increased discovery would also burden courts through an increase in pre-trial motions.206 However, this argument fails to recognize that the burden would also be borne by prosecutors and whistleblowers who, as a result, could only pursue claims that they could individually prove, likely decreasing in the number of actions filed. Further, the number of claims would also decrease because of the reduced financial incentive for attorneys and whistleblowers, as discussed above, thereby negating the increased burden on courts.

B. CONSEQUENCES OF PERMITTING STATISTICAL SAMPLING FOR LIABILITY

On the other hand, a circuit court allowing the use of statistical sampling to prove liability would have its own significant consequences. First, such a result would significantly increase the pressure providers feel to settle FCA actions—even in instances where they did little or nothing wrong. Defendants could risk going bankrupt if they do not settle, due to the potentially devastating financial effects that the FCA’s civil penalties and treble damages207 could have if only a small sample of false claims were to

204. Topor, supra note 7.
205. Id.
206. See, e.g., id.
207. See supra text accompanying note 44.
establish wide liability

Additionally, since the use of statistical sampling would significantly increase the financial risk to any provider receiving reimbursements from the federal government (such as providers accepting Medicare and Medicaid), the use of statistical sampling would reduce the number of providers accepting patients covered by federal programs. There is already a shortage of primary care providers willing to accept Medicare and Medicaid, and the population eligible for these programs has significantly increased under the Affordable Care Act.\footnote{See Kevin Murphy, \textit{Advanced Practice Nurses: Prime Candidates to Become Primary Caregivers in Relation to Increasing Physician Shortages Due to Health Care Reform}, 14 \textit{J. NURSING L.} 117, 117–19 (2011).} Allowing statistical sampling to establish liability would, therefore, exacerbate the shortage problem. Ultimately, this decision would negatively affect access to care for those who are most needy and ill. Without access to preventative care through a primary care doctor, a large portion of this population will develop serious illnesses that could have otherwise been prevented or managed—and taxpayers will have to foot the hospital bills.

IV. \textbf{A SOLUTION AND A SUGGESTED OUTCOME}

To provide a workable solution regarding the use of statistical analysis to establish liability in FCA cases, the problems with previous court decisions must be addressed and corrected. In this Part, Section A highlights and describes common problems and potential flaws in the judicial reasoning regarding the use of statistical liability in FCA litigation. Section B takes these criticisms into consideration as it recommends a general framework for the proper use of statistical sampling in such cases, helping litigants and courts to balance the negative consequences of always either allowing or disallowing the use of statistical sampling to establish liability.

A. \textbf{CRITICISMS AND POTENTIAL FLAWS IN JUDICIAL REASONING}

1. Courts Conflate the Use of Statistical Sampling in Proving Liability and Establishing Damages

As briefly described above, a common problem in statistical sampling cases is conflating the use of statistical sampling to prove liability with use to establish damages. Take, for example, \textit{Michaels}.\footnote{See United States \textit{ex rel.} Michaels v. Agape Senior Cmty., Inc., No. 0:12-3466-JFA, 2015 U.S. Dist. LEXIS 82379, at *4, *17–18, *20 (D.S.C. June 25, 2015), \textit{aff’d in part and dismissed in part}, 848 F.3d 330 (4th Cir. 2017).} At first, the court...
discussed the matter as a damages issue (that is, whether statistical sampling could be used to prove damages). Later, in the same opinion, the court said it is a liability and damages issue. At no point did the court distinguish between the elements to prove liability versus the requirements for damages. Under the FCA, however, plaintiffs must prove several elements: falsity, scienter, material conduct, and actual damages.

The court in Robinson did the same. It began by discussing the defendant’s claim that it is inappropriate to use statistical sampling to extrapolate liability and damages. The court then proceeded to rule that the results of the statistical sampling, per the evidence submitted, could be submitted to a jury, primarily because such methods “have been accepted in the Sixth Circuit and in other jurisdictions as reliable and acceptable evidence in determining facts related to FCA claims.” The court did not go into detail about whether the results of the statistical sampling could be used for the purpose of determining damages, establishing liability, or both, and instead ruled that “[t]he weight to be given to such statistical evidence is necessarily one which must be considered by the fact finder in light of the practical difficulties in obtaining a claim-by-claim review.” Thus, by permitting the statistical sampling without providing any guidance for the fact finder (or future cases) as to its permissible uses, the court either confused or ignored the difference between use to establish damages and use to establish liability.

The danger of purportedly using statistical sampling only for damages, without establishing liability, can be illustrated by looking instead at a Medicaid overpayment case, which parties have cited in FCA cases to support the validity of statistical sampling for purposes of proving damages. In Goldstar Medical Services, Inc. v. Department of Social Services, the government conducted an audit of a sample of ninety-three out

210. Id.
211. See id. at *20–24.
214. Id. at *28–29.
215. Id. at *32 (quoting Mich. Dep’t of Educ. v. U.S. Dep’t of Educ., 875 F.2d 1196, 1205 (6th Cir. 1989)).
Based on the ninety-three sample claims, the government determined that sixty-nine, or 74%, contained errors resulting in an excess reimbursement from Medicaid. The government then extrapolated that from the entire universe of 3,496 claims, the defendant’s excess reimbursements totaled $261,303.45. The court recognized that “it is well established that proof of damages through the use of statistics and statistical sampling has been endorsed in numerous cases involving Medicare and Medicaid overpayments” and upheld the government’s use of statistical extrapolation. Since this was an appeal from an administrative judge’s ruling on a post-payment Medicaid audit, it is not subject to the elements of an FCA claim. However, assume instead that the claims were FCA claims and the court was alleging that the statistical sampling was only being used to establish damages. In that situation, the court would implicitly be using the sampling to establish both liability and damages. While definitive proof was found regarding the sixty-nine claims, no such proof was found or presented for any claims outside of the ninety-three-claim sample. Accordingly, to extrapolate damages regarding claims outside of the sample, the court would have to accept that the defendant was liable for errors that the government established solely through statistical data.

Instead, courts should recognize that the analysis as to whether statistical sampling is appropriate for establishing liability requires looking at the individual elements of liability under the FCA. That analysis differs from—and requires a different legal foundation than—the analysis regarding statistical sampling for damages. First, the scienter element of the FCA must be proved. If scienter is being proved through actual knowledge, it must be proven that the defendant knowingly submitted a false claim. Establishing through statistical sampling that a certain number of false claims were likely submitted does not address scienter here. Furthermore, even if relators were able to prove an “underlying fraudulent scheme” to satisfy scienter through deliberate ignorance or reckless disregard, this, although likely evidence of fraud and liability, is not alone sufficient. This is because a defendant

218. Id.
219. Id. at 31.
220. Id.
221. Id. at 22–23; see, Anna Grizzle & Julia Tamulis, Medicare and Medicaid Audits, in AN INTRODUCTION TO HEALTH LAW LITIGATION BASED ON CONTRACT AND GOVERNMENT CLAIMS 84, 99, 102–05 (Aaron Krauss ed., 2016).
could maintain fraudulent records, and even prepare fraudulent claims, but never actually submit a false claim to the government. Thus, it would still be necessary to establish that a false claim was actually presented for payment to satisfy the falsity element of the FCA.

Additionally, muddling the requirements for establishing liability and for calculating damages would effectively remove one of the few protections that the FCA provides defendants. The FCA’s requirement that the falsity and scienter of each specific claim be proved safeguards against abuse by potential plaintiffs. This is of particular importance because the FCA allows for treble damages, which could be devastating in cases where thousands of claims are at issue.

2. Evidentiary Burden

Another problem with using statistical sampling to prove liability is the plaintiff or government’s “evidentiary burden to establish the elements of a FCA claim.” While the government often argues that forbidding the use of statistical sampling would allow large-scale fraud to go unpunished, this ignores a critical point: permitting the use of statistical sampling to establish liability creates a perverse incentive for relators—who already have a significant pecuniary incentive to bring suit—to allege large-scale fraud with little or no proof. In this instance, the larger the fraud that one alleges, the lower the burden of actually having to prove the fraud; as long as the plaintiff can use statistical sampling, the government no longer has the burden of establishing proof of falsity and scienter for each individual claim. Instead, the government or plaintiff can establish proof of falsity and scienter for only a subset of cases and claim that they have satisfied their burden for hundreds, if not thousands, of other unexamined claims. Defendants would effectively have the burden of discrediting the statistical evidence or proving that each claim in the claims universe was actually valid.

Courts, like those in Martin and Aseracare, that take the approach that due process is satisfied so long as defendants can rebut the evidence at trial and through cross-examination fail to recognize that this approach shifts the burden of proof. Although these courts state that statistical sampling is the only practical way for the government and relators to logistically and cost-effectively try large FCA claims, they ask defendants to bear the very cost

\[223. \text{ See AHA/CHA Brief, supra note 174, at 6.}\]
\[224. \text{ United States ex rel. Martin v. Life Care Ctrs. of Am., Inc., 114 F. Supp. 3d 549, 563 (E.D. Tenn. 2014).}\]
\[225. \text{ See supra text accompanying note 44.}\]
that they are shielding plaintiffs from. In effect, the courts require defendants to individually sift through thousands of claims to combat statistical evidence obtained cost-effectively by plaintiffs. As a result, wise defendants are likely to perform a cost-benefit analysis to determine whether the costs of document review for thousands of claims and the associated legal fees are worth combating the litigation, or whether it is more cost-effective to settle. It is also worth noting that some defendants who are single practitioners may not have the means to hire a law firm or expert to conduct such an analysis. Thus, this shifting of the burden creates the opportunity for the government to impose (or extort) settlement from providers. This outcome is not true to the statutory purpose of the FCA, and it contradicts Congress’s express desire to place the burden of proof on the government.

3. Many Medical Decisions Are Subjective, and Medical Opinions Can Differ

One of the issues plaguing the use of statistical sampling in FCA cases involving the healthcare industry is that many of the claims being reviewed for fraud result from a treating physician’s clinical judgment—a subjective decision. These decisions are made on a “patient-by-patient basis” and are not an exact science.226 Thus, it would be inappropriate to draw conclusions from a small sampling for claims based on clinical judgments because the samples could not possibly account for the subjective nature of such decisions for the entire universe of claims.

For example, in Vista Hospice Care, the relator claimed that the defendants had submitted fraudulent claims to the government when it admitted patients who were ineligible for hospice into hospice care and then submitted claims for reimbursement.227 Determining whether a patient is eligible for hospice care, however, is a subjective clinical decision.228 Under Medicare regulations, “terminally ill” patients are eligible for hospice care,229 and a “terminally ill” person is one whose life expectancy is “[six] months or less if the illness runs its normal course.”230 A bystander without clinical or medical experience might assume that determining whether a person has six months to live is a simple process, based on some sort of scientific clinical criteria. The truth is far from that. While Medicare has

228. Id. at *8–9.
230. Id. § 418.3.
published guidelines for hospice admissions. These “guidelines are not necessarily accurate in predicting death within six months.”

To make a prediction concerning life expectancy, a provider must first determine what exactly qualifies as a terminal condition and then assess, using subjective and objective symptomatology, whether that specific patient has less than six months to live. And while providers may look to Medicare’s guidelines to assist them with their decisions, these guidelines are not necessarily accurate in determining life expectancy, and the decision is ultimately subjective. It stands to reason, then, that if doctors must make an individualized and subjective clinical judgment, reasonable medical minds can differ as to whether the person could qualify for hospice care.

Therefore, if we had a case involving 50,000 claims concerning hospice eligibility, it would be inappropriate to use statistical sampling of, say, 1,000 claims to prove liability for a percentage of all 50,000 claims. To do so would be making not only the assertion that a proportionate number of claims in the universe of claims were false, but also that the provider’s clinical judgment was incorrect in all of those cases—a highly illogical conclusion considering the subjectivity of the field of medicine as a whole and the subjective determinations that a provider has to make in forming clinical judgments. In other words, it would be inappropriate to use a sample in this context because it would be almost impossible to establish a truly representative sample given the unique circumstances surrounding each and every claim.

As illustrated above, it is particularly difficult to justify the argument that scienter and falsity can be proved via statistical sampling for FCA claims concerning subjective clinical decisions. In essence, we would be saying that a provider knew that thousands of clinical judgments were false and such clinical judgments actually were false simply because a small sample of those judgments were incorrect (or in many instances, just inconsistent with an expert witness’s clinical judgment). While this may seem practical, it also seems starkly unjust in light of the significant consequences of the FCA and

the nature of the decisions involved. After all, reasonable minds can differ.

4. Is Justice Being Served?

Part of the issue also centers on justice—it is not fair to determine knowledge as to thousands of claims from a small sampling. This is especially so in the realm of healthcare, not only because decisions are often times subjective, but also because they pertain to different patients and circumstances. Unlike in cases dealing with uniform products, healthcare providers frequently deal with many different patient scenarios, and because no two patients are alike, neither are two claims. Further, it seems particularly unjust to assume liability from just a small sampling when the corresponding damages are trebled.

On the other hand, not allowing statistical sampling to prove liability could lead to abuse by providers who know of the disallowance, which is also not in the interest of justice. However, it seems ultimately more unjust that some providers should suffer such severe consequences as treble damages and civil penalties for thousands of claims, potentially bankrupting their practice, just because there is the potential for abuse.

Additionally, while many would say that not allowing statistical sampling would frustrate the government’s ability to sue,234 this is simply not the case. The government would still be able to sue, but it would have to focus its efforts on the claims it can actually prove. It would accordingly focus on the meritorious cases, instead of attempting to sue for as many claims as possible by bundling them and seeking to bypass its evidentiary burden. Limiting the government’s ability to use statistical sampling to establish liability would therefore not frustrate its ability to sue under the FCA, but it would protect defendants from potential governmental abuse. This is because if statistical sampling is generally permitted to establish liability, the government can pressure defendants to settle for arguably unjustifiably large amounts, due to the prospect of their being held liable for even greater amounts on top of the costs of defending against the statistical sampling.235


235. See, e.g., U.S. Dep’t of Justice 2015, supra note 3 (listing several examples of recent large settlements). See also Laemmle-Weidenfeld, supra note 4, at 146 (“As a practical matter, the vast majority of FCA cases settle . . . .”).
B. A MORE REASONABLE APPROACH

An approach more reasonable than broadly allowing or disallowing statistical sampling to establish FCA liability in the healthcare industry would be to limit its use to cases where there is sufficient evidence of a company-wide policy that results in the submission of false claims. This could be accomplished through a bellwether trial to determine whether there is sufficient evidence of a generalized policy of fraud. If there are sufficient findings following the bellwether trial, then the court could proceed to use statistical sampling to extrapolate and establish liability for the universe of claims.

A model case is UnumProvident, in which there was sufficient evidence of liability in the eyes of the fact finder before using statistical sampling. This was accomplished through a bellwether trial that uncovered a generalized fraudulent policy. Another model case is Fadul, in which the court did not rely solely on statistical evidence to prove falsity and scienter. The court in Fadul relied on significant evidence, including expert reports, employee testimony, and an audit to establish liability. Only after liability was properly established was statistical sampling used to establish liability for a universe of claims and to determine the total amount of damages.

However, the approach used in UnumProvident and Fadul would still be insufficient in my suggested framework. Similar to the approach used in those cases, evidence of liability would need to be provided prior to the use of statistical sampling. Unlike those cases, though, I suggest that the use of statistical sampling to extrapolate liability in FCA cases concerning healthcare fraud should be limited to cases where evidence is presented (again prior to the use of statistical sampling) indicating a known company-

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236. A bellwether trial used by a judge to try a smaller number of cases that are representative of the sample. Alexandra D. Lahav, Bellwether Trials, 76 GEO. WASH. L. REV. 576, 577 (2008). The verdicts are then used “as a basis for resolving the remaining cases.” Id. These types of trials are commonly used to value cases in mass tort litigation and have been used to resolve human rights class actions. Id. at 577–78.

237. Alternatively, should sufficient evidence be presented at summary judgment, the permissibility of statistical sampling could be decided at that point.


239. Id.


242. Id.
wide procedure or policy that results in the systematic submission of false claims. For example, the government or plaintiff might submit evidence of a standard policy or procedure that any time an abdominal scan was performed on a Medicare or Medicaid patient, a claim would instead be submitted for a full-body scan, generating a larger reimbursement. Statistical sampling to establish liability in such an arrangement would therefore be appropriate because the government or plaintiff could approximate the total number of incorrectly submitted scans in a given timeframe based on a representative sample of claims, and there would be an acceptably high level of certainty that the defendant should be held liable for—and pay damages on—every single one of the extrapolated number of claims. This outcome would be a just and reasonable middle ground.

Furthermore, these cases would not be subject to the criticisms surrounding the subjective nature of most healthcare decisions. For example, this framework would not apply to the situation in Vista Hospice Care, in which the issue centered around a particularly subjective matter, hospice-care eligibility. Additionally, this proposed outcome would accommodate the government’s reasonable assertion that in cases involving tens of thousands of claims, statistical sampling is the only efficient way to avoid wasting judicial resources. However, it would subject only defendants who violate the FCA in a particularly egregious manner to the burdens of statistical sampling to establish liability. This would result in plaintiffs being able to more easily collect large amounts of damages in cases involving such violations, thereby deterring egregiousness, while also protecting the vast majority of defendants from potential abuse by the government. In turn, this could help increase the number of healthcare providers who accept Medicare or Medicaid.

While opponents may point to judicial economy to argue against this proposed approach, given the additional resources required to conduct bellwether trials, we must weigh judicial economy against the interests of justice. When billions of dollars per year in damages are potentially at stake, it is the courts’ responsibility to make sure they justly establish liability for those damages. Fulfilling this responsibility requires a certain amount of time and resources. Here, such additional resources are warranted. In any event, it is difficult to judge if these concerns are even valid, given that limiting the use of statistical sampling will likely lead to an overall decrease in the number of claims filed.
CONCLUSION

Statistical sampling and its use in FCA cases remains a “hotly contested issue” and one that may eventually have to be decided by the Supreme Court, should circuits split on its use for establishing liability.243 Despite the Fourth Circuit’s refusal to rule on whether statistical sampling could be used to prove liability in *qui tam* litigation,244 circuit courts will inevitably be faced with the decision—likely in the near future—as the government continues to combat large-scale fraud. Given the subjective nature of the medical field and the negative effects a decision may have on the healthcare system as a whole, however, courts considering whether statistical sampling should be used to establish FCA liability in healthcare cases should carefully weigh the interests of justice and judicial efficiency.
