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“Statistical Sampling to Establish Liability under the False Claims Act: A Liberty Deprivation and a Due Process Violation”

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I. Introduction

The health care industry is no stranger, nor have courts been averse to, statistical sampling being used to prove damages in the context of a False Claims Act claim.¹ The streamlining darling known as statistical sampling eases the weight of dockets around the United States, spares the judicial system precious time, and saves litigants substantial amounts of discovery costs.² The issue becomes, then, whether courts are ready to allow this queen of efficiency – statistical sampling – to be used to prove False Claims Act liability, as opposed to damages.

As we shall examine, the implications of taking statistical sampling from the damages arena to the liability arena are significant and at the very least, pose serious constitutional questions, if not violate the Due Process Clause altogether. For orientation purposes, this paper will examine the interrelationship among the False Claims Act, statistical sampling, and the Fifth Amendment Due Process Clause of the United States Constitution.

We shall first consider these three components individually so as to facilitate a better understanding of how they do, or as my argument goes, how they do not, function in harmony with one another. Specifically, the disconnect among the False Claims Act, statistical sampling, and the Fifth Amendment Due Process Clause can be attributed to the use of statistical sampling, and the extrapolation of the findings through statistical sampling to prove False Claims Act liability, giving rise to a violation of one's Fifth Amendment Due Process rights through a deprivation of a liberty interest.

¹ See U.S. *ex rel.* Ruckh v. Genoa Healthcare, LLC, No. 8:11-CV-1303-T-23TBM, 2015 WL 1926417, at *3 (M.D. Fla. Apr. 28, 2015) (citing U. S. v. Robinson, 2015 WL 1479396, at *10 (E.D. Ky. Mar. 31, 2015)) (finding that “statistical sampling methods and extrapolation have been accepted in the Sixth Circuit and in other jurisdictions as reliable and acceptable evidence in determining facts related to [False Claims Act] claims as well as other adjudicative facts”).

² See U.S. v. Cabrera-Diaz, 106 F. Supp. 2d 234, 240 (D.P.R. 2000) (discussing the court's limited resources as well as general feasibility concerns should the court proceed without using statistical sampling).

A. The False Claims Act: The Statute, Its Purpose, and Its History

Before we turn to the basics of statistical sampling, it is necessary to examine briefly the False Claims Act's history and purpose. First, the text of the statute. Pursuant to 31 U.S.C.A. § 3729:

(a) Liability for certain acts.--

(1) In general.--Subject to paragraph (2), any person who--

- (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
- (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
- (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)...

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...plus 3 times the amount of damages which the Government sustains because of the act of that person.³

For our purposes, subparagraphs (D), (E), (F), and (G), by their nature, are not of prominent importance to the statistical sampling discussion. What is important, however, is the guidance the False Claims Act provides as far as the language it uses. The statute states in pertinent part as follows:

(b) Definitions.--For purposes of this section--

(1) 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; and
- (B) require no proof of specific intent to defraud...⁴

With this necessary backdrop, we next turn to the purpose and history behind the False Claims Act. Congress passed the False Claims Act during the Civil War to prevent fraud from

³ The False Claims Act, 31 U.S.C.A. § 3729 (Westlaw 2015).

⁴ *Id.*

being perpetrated against the United States Government.⁵ Needless to say, the False Claims Act has had a profound impact on the health care industry. In a December 2015 Department of Justice press release, Principal Deputy Assistant Attorney General Benjamin C. Mizer announced that for the fiscal year ending September 30, 2015, the Department of Justice obtained more than \$3.5 billion in settlements and/or judgments stemming from False Claims Act litigation.⁶

The years 2014, 2013, 2012, and 2011 also saw the Department of Justice exceed \$3.5 billion in False Claims Act recoveries.⁷ In fact, from January 1, 2009 to September 30, 2015, the Department of Justice obtained \$26.4 billion in False Claims Act recoveries.⁸ Of the \$3.5 billion recovered in fiscal year 2015, \$1.9 billion was related to health care fraud, and of the \$26.4 billion recovered since the beginning of 2009, \$16.5 billion was health related.⁹

Mizer went on to laud the False Claims Act, calling the statute “the government’s most effective civil tool” in its ongoing efforts to prevent fraud against its programs.¹⁰ Emphasizing the False Claims Act’s significance in the context of Medicare and Medicaid, Mizer noted the statute’s central role in safeguarding “the integrity of vital government programs that provide health care to the elderly and low income families.”¹¹ In other words, the False Claims Act is a powerful ally of the government, and the stakes are astronomical.

⁵ Mann v. Heckler & Koch Def., Inc., 630 F.3d 338, 342 (4th Cir. 2010).

⁶ The U.S. Dep’t of Just., *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>.

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Id.*

B. Statistical Sampling: What It Is, Its Purpose, and Its Emergence in the Health Fraud and Abuse Context

Statistical sampling represents a potential mechanism through which the government can more efficiently establish False Claims Act liability. So, if the False Claims Act is the cannon in the battle against health care fraud and abuse, think of statistical sampling as a – but not the – cannon ball. It is merely one way for the government to attempt to win its continuous battle. So what is statistical sampling?

As a preliminary disclaimer, this paper will in no way attempt to analyze the steps or methods of the various forms of statistical sampling which exist. Such an attempt would be better suited for an evidentiary-based argument, as opposed to a constitutionally-based argument. Where differentiation will become worthwhile, however, is when we look at the different contexts in which prosecutors may employ statistical sampling to prove liability under the False Claims Act.

While delving into the various forms of statistical sampling is not a central focus of this paper, understanding how statistical sampling generally works will prove useful. First, though, a brief overview of how False Claims Act cases are prosecuted. In order to satisfy the statutory elements of a claim under the False Claims Act, the government must establish that the defendant submitted a claim for payment to the federal government; such claim was false or fraudulent; and the defendant had actual knowledge of the claim's falsity or acted in reckless disregard of the claim's validity.¹² Prosecutors generally establish the elements of a claim under the False Claims Act in a claim-by-claim manner.¹³ An alternative offered by statistical sampling would allow this first element to be established without the resource constraints that come with

¹² U.S. v. Life Care Ctrs. of Am., Inc., 114 F. Supp. 3d 549, 559 (E.D. Tenn. 2014).

¹³ *Id.* at 571.

claim-by-claim review.¹⁴ The government, by way of statistical sampling, presents expert analysis of a random portion of, for example, Medicare or Medicaid claims from the defendant provider's pool of total claims.¹⁵ The experts calculate the percentage of fraud within the selected portion and extrapolate, or transfer that percentage, to the provider's total pool of claims.¹⁶ The government's position is that this extrapolated result represents the total amount of fraud committed by the defendant provider.¹⁷ Thus, statistical sampling seeks "to provide a means of determining the likelihood that a large sample shares characteristics of a smaller sample."¹⁸

On the flip side, defendants will (and should) argue that statistical sampling is an unfair advantage to the government, as it functions as a shortcut in the prosecutorial process. The defendant will argue that the results of statistical sampling are not necessarily indicative of the entire pool being sampled.¹⁹ Thus, the defendant will contend that its rights have been abridged in the sense that it cannot defend against unidentified claims of fraud.²⁰ Specifically, the argument goes somewhat like this: by utilizing statistical sampling, the government is essentially skipping several crucial steps of the prosecutorial process by making an assumption which is based on nothing more than an educated guess that because a certain number of fraudulent, say Medicare claims, have been submitted to the government for payment, a certain number of other

¹⁴ *Id.*

¹⁵ Carol C. Lam, *Assessing Loss in Health Care Fraud Cases*, 10 FED. SENT. REP. 145, 148 (1997).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ U.S. v. Rosin, 263 F. App'x 16, 29 (11th Cir. 2008).

¹⁹ Lester J. Perling, *Challenging the Use of Statistical Sampling in Overpayment and False Claims Cases*, Apr. 2, 2003, AHLA-PAPERS P04020364.

²⁰ *Id.*

claims submitted to the government must have been fraudulent as well.²¹ This argument is best served to be evaluated against the backdrop of the Fifth Amendment's Due Process Clause.

C. A Closer Look at the Fifth Amendment's Due Process Clause

The Fifth Amendment of the United States Constitution provides that “No person shall...be deprived of life, liberty, or property, without due process of law.”²² Therefore, in order to prevail in making an argument that one's Fifth Amendment due process rights have been violated, one must first adequately demonstrate that he or she was in possession of “a protected interest in life, liberty or property.”²³ Courts have previously rejected the argument that a defendant was unconstitutionally deprived of a property interest (i.e., withheld payments to the provider by the government) by way of statistical sampling.²⁴ With this losing argument in mind and because a life interest is not applicable, we shall look to the third option under the Fifth Amendment Due Process Clause: liberty.

In order to successfully assert a loss of a liberty interest, a party must satisfy a four-pronged test: [1] “a charge impugns honesty or morality,” [2] “the accuracy of the charge is contested,” [3] “there is some public disclosure of the charge,” and [4] “the charge is made in connection with the termination of employment or the alteration of some legal right.”²⁵

Once having established the existence of a liberty interest, the defendant must show that he had a “legitimate claim of entitlement” to that interest, and must make the showing that “the procedures attendant upon that deprivation were constitutionally insufficient.”²⁶

²¹ *Id.*

²² U.S. CONST. amend. V.

²³ *ABA, Inc. v. D.C.*, 40 F. Supp. 3d 153, 165 (D.D.C. 2014).

²⁴ *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84, 89 (2d Cir. 1991).

²⁵ *Cleanmaster Indus., Inc. v. Sandra Shewry*, 491 F. Supp. 2d 937, 942 (C.D. Cal. 2007).

²⁶ *ABA*, 40 F. Supp. 3d at 167.

The second step for a person asserting a claim under the Due Process Clause of the Fifth Amendment is to make the demonstration that “government officials knowingly, and not merely negligently, deprived him of that interest without notice and an opportunity to be heard at a meaningful time and in a meaningful manner.”²⁷

Behind this critical pillar of American law is the understanding that while the Due Process Clause is perhaps a challenging one to definitively and consistently define and explain across all legal avenues, the core of due process has proven to be an enduring one.²⁸ The Supreme Court has noted that the Due Process Clause can be read to “imply a conformity with natural and inherent principles of justice.”²⁹ More specifically, the Due Process Clause functions as a “...heightened protection against government interference with certain fundamental rights and liberty interests.”³⁰

In order to carry out its function, due process depends on fairness.³¹ The Supreme Court has noted that fairness, in fact, is “the essence of due process.”³² In assessing fairness, a court will not be limited in its analysis to a “fixed standard” purporting to be applicable in all situations before it.³³ Rather, the standard by which to analyze whether due process was or was not satisfied is supposed to be a versatile one, in which various factors and circumstances are taken into the court’s consideration.³⁴ Accordingly, due process protections are to be put in place “as the particular situation demands.”³⁵

²⁷ *Id.*

²⁸ *Holden v. Hardy*, 169 U.S. 366, 390 (1898).

²⁹ *Id.*

³⁰ *Washington v. Glucksberg*, 521 U.S. 702, 720 (1997).

³¹ *Galvan v. Press*, 347 U.S. 522, 530 (1954).

³² *Id.*

³³ *Furey v. Temple Univ.*, 884 F. Supp. 2d 223, 246 (E.D. Pa. 2012).

³⁴ *Id.*

³⁵ *Morrissey v. Brewer*, 408 U.S. 471, 481 (1972).

Before proceeding further, it is worth noting here that a central focus of this paper is not on what type of process would be due to those against whom statistical sampling is utilized in False Claims Act cases. Thus, the well-known “Mathews” test for procedural due process as laid out by the Supreme Court³⁶ is not an essential component of this paper. Rather, the focus is narrowly confined to the basic argument that the use of statistical sampling, and the extrapolation of the findings through statistical sampling, violates one’s Fifth Amendment Due Process rights in one way: through a deprivation of a liberty interest.

II. A Look at the Inconsistencies in the Case Law: Several Courts Have Held that the Use of Statistical Sampling in the Context of False Claims Act Litigation Does Not Violate a Defendant’s Due Process Rights – So Where Does this Leave Us?

The case law in the area of the False Claims Act, statistical sampling, and the relationship both have with due process is by no means extensive. Litigators’ increasing reliance on algorithmic data analysis, however, requires that the issue receive meaningful exploration. There are a few key cases central to the discussion of the False Claims Act and statistical sampling.

First, *United States v. Cabrera-Diaz* is relevant to the discussion of whether statistical sampling adheres to due process when used to prove False Claims Act liability because it is the perfect prototype of a fair use of statistical sampling. Thus, when juxtaposed with the facts from other cases, *Cabrera-Diaz* dramatically accentuates their due process shortcomings. The remaining cases highlight the non-uniform approaches which courts have taken when confronted with cases involving statistical sampling in the context of the False Claims Act. For instance, the court in *United States ex. rel. Loughren v. UnumProvident Corp.*, appears to focus its attention on the adequacy of the methods of sampling in analyzing whether statistical sampling may be

³⁶ *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976).

utilized.³⁷ Other courts, such as the Eastern District of Tennessee in *United States ex rel. Martin v. Life Care Centers of America, Inc.*, have permitted statistical sampling to be used to establish liability under the False Claims Act.³⁸

At the same time, courts like the D.C. Circuit Court appear to be less sure of themselves, seemingly wrestling with which specific kinds of fraud, such as improper upcoding or the provision of medically unnecessary services, warrant the use of statistical sampling to establish liability under the False Claims Act.³⁹ Finally, in holding that statistical sampling is an impermissible means by which to establish liability under the False Claims Act, the court in *U.S. ex rel. Michaels v. Agape Senior Community, Inc.* based its analysis on the type of fraud being alleged, lack of medical necessity,⁴⁰ while also noting that the relevant evidence was indeed available to be examined.⁴¹ In short, the approaches taken by the courts throughout the country have been, on the whole, wildly inconsistent.

A. The Statistical Sampling Gold Standard: United States v. Cabrera-Diaz

United States v. Cabrera-Diaz involves a case in which the federal district court in Puerto Rico permitted statistical extrapolation to calculate damages.⁴² The defendant, Dr. Cabrera, was

³⁷ See *U.S. ex rel. Loughren v. UnumProvident Corp.*, 604 F. Supp. 2d 259, 261 (D. Mass. 2009) (concluding that “extrapolation is a reasonable method for determining the number of false claims so long as the statistical methodology is appropriate”).

³⁸ See *U.S. v. Life Care Ctrs. of Am., Inc.*, 114 F. Supp. 3d 549, 571 (E.D. Tenn. 2014) (noting that the False Claims Act’s language and legislative history are not consistent with “a legislative disinclination regarding the use of statistical sampling in FCA cases”).

³⁹ See *U.S. v. Krizek*, 111 F.3d 934, 941 (D.C. Cir. 1997) (citing and affirming the propriety of the District Court’s decision to allow statistical sampling to be used in the improper coding context but noting that more discovery could be needed to establish liability in the provision of unnecessary services context).

⁴⁰ See *U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. CA 0:12-3466-JFA, 2015 WL 3903675, at *8 (D.S.C. June 25, 2015) (noting that medical necessity is a “highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patient”).

⁴¹ See *Id.* at *6 (commenting that “this case is not one where the evidence has dissipated, thus rendering direct proof of damages impossible”).

⁴² *U.S. v. Cabrera-Diaz*, 106 F. Supp. 2d 234, 240 (D.P.R. 2000).

an anesthesiologist in Puerto Rico who submitted claims to Medicare in 1994 for over \$400,000 and in 1995 for over \$300,000.⁴³ Medicare's Part B carrier, Triple S, Inc., conducted an audit of Dr. Cabrera's claims by sampling 461 claims, tied to 73 patients, for the years 1994 and 1995.⁴⁴ The hospital where Dr. Cabrera performed his services provided Triple S, Inc. with the patients' operation reports, anesthesia records, and nursing notes, but did not provide the patients' medical records.⁴⁵ Using these documents, Triple S, Inc. reviewed the "actual (real) anesthesia time" in minutes.⁴⁶ The audit performed by Triple S, Inc. revealed results which were staggering: of the 461 claims in the sample, 455 were determined to have been "overstated, falsely reported, unsupported or undocumented" in terms of the time Dr. Cabrera claimed in his bills to have devoted to providing anesthesia services.⁴⁷

More specifically, Dr. Cabrera billed for 99,270 minutes of anesthesia time in 1994, while actually providing only 21,371 minutes, and billed for 90,930 minutes of anesthesia time in 1995, while actually providing only 20,987 minutes.⁴⁸ The end result was that, based on this sample size alone, Dr. Cabrera received \$131,787.74 in overpayments as a result of his fraudulent submissions for the years 1994 and 1995 combined.⁴⁹ The findings of the sample size were then extrapolated to all of the claims Dr. Cabrera submitted to Medicare for the years 1994 and 1995, resulting in approximately \$237,600.39 in alleged unearned overpayments in 1994 and \$211,773.89 in alleged unearned overpayments in 1995.⁵⁰

⁴³ *Id.* at 236.

⁴⁴ *Id.* at 237.

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Cabrera-Diaz*, 106 F. Supp. 2d at 237.

⁴⁹ *Id.*

⁵⁰ *Id.*

The court briefly addressed a due process argument in the context of damages, and in rejecting it, cited impracticability with regard to resources, feasibility with regard to the number of potential claims, and noted that the alternative was unnecessary.⁵¹ The court also said that the use of statistical sampling to arrive at a damages estimate was “not improper.”⁵² Unsurprisingly, the court did not engage in a discussion of due process, probably because no advocate against statistical sampling, no matter how ardent, could seriously argue that results from the sample taken in this case – 455 claims out of 461 total were determined to be in violation of the False Claims Act – depicted an unfair representation of Dr. Cabrera’s body of work.

B. One Approach to the Uncertain Statistical Sampling Landscape: How Reliable is the Sampling?

In *United States ex. rel. Loughren v. UnumProvident Corp.*, a qui tam action out of Massachusetts, the government argued that the defendant, UnumProvident Corp., convinced its clients/insureds to apply to the Social Security Administration for disability benefits under the guise that they were “unable to work” or were “disabled,” despite that the defendant “knew or should have known that these insureds did not meet the statutory definition of disability required to qualify.”⁵³ All told, between January 1997 and July 2007, the government contended that UnumProvident Corp. had 468,641 of its insureds apply for Social Security Disability Insurance benefits.⁵⁴

The court’s reaction to the proposed usage of statistical sampling will look familiar. The court noted, “Given the enormous number of claims and the significant time and resources it would take to determine if a single claim were false, the plaintiff understandably deemed it

⁵¹ *Id.* at 240.

⁵² *Id.*

⁵³ U.S. *ex rel.* Loughren v. UnumProvident Corp., 604 F. Supp. 2d 259, 260 (D. Mass. 2009).

⁵⁴ *Id.*

impractical to examine each one by one, and so turned to statistical sampling and extrapolation.”⁵⁵ After considering UnumProvident Corp.’s challenges to the proposed use of statistical sampling and the subsequent extrapolation thereof, the court concluded that “...extrapolation is a reasonable method for determining the number of false claims so long as the statistical methodology is appropriate.”⁵⁶ However, despite the court’s recognition that statistical sampling is warranted in some circumstances as described above, it then engaged in an in-depth analysis of the sampling method which was used in the case before it, and ultimately allowed the defendant’s motion to exclude the plaintiff’s sampling testimony.⁵⁷

While this paper is not intended to provide an in-depth analysis of the specifics behind certain sampling techniques or processes, a brief examination of how this court evaluated the appropriateness of a statistical methodology is not without value, especially in light of due process. First, the court noted that the Dr. Mercurio, retained by the government to produce a statistical sample, failed to “cite to any texts or articles that support the reliability of using his method of extrapolation from overlapping cohorts.”⁵⁸ Secondly, Dr. Mercurio “failed to cite any peer-reviewed literature to support his novel approach to overlapping cohorts.”⁵⁹ Once the court requested the same, the Dr. Mercurio furnished “pages of incomprehensible formulae,” which clearly only exacerbated the court’s frustration.⁶⁰ When presented with the testimony of Dr. Hayne, who was retained by the defendant, that the sampling method sought to be used was unreliable, Dr. Mercurio responded only by saying that his fellow expert was wrong, but did not

⁵⁵ *Id.*

⁵⁶ *Id.* at 261.

⁵⁷ *Id.* at 269.

⁵⁸ *Id.* at 266.

⁵⁹ *UnumProvident*, 604 F. Supp. 2d at 266.

⁶⁰ *Id.*

explain why.⁶¹ After considering all of the expert testimony, the court ultimately decided that the flaws in the plaintiff's sampling method were too many to overcome and excluded it as a result.⁶²

C. A Second Approach Confirms Statistical Sampling's Ability to Establish the Elements of the False Claims Act and Rejects the Defendant's Due Process Argument: But Was the Analysis Superficial?

In *United States ex rel. Martin v. Life Care Centers of America, Inc.*, the United States District Court for the Eastern District of Tennessee denied the defendant's motion to prevent the government from using statistical sampling and the extrapolation thereof to prove its False Claims Act case.⁶³ The factual gist of the case was that separate qui tam actions were brought by two relators who formerly worked for a corporation called Life Care Center (here after, "Life Care"), which consisted of more than two-hundred nursing homes and facilities.⁶⁴ The U.S. Government then intervened as plaintiffs.⁶⁵ From January 2006 through December 2011, Life Care received more than \$4.2 billion in Medicare payments.⁶⁶ In the consolidated complaint, the government alleged that Life Care treated its patients with therapy which was not "medically reasonable or necessary," billed Medicare for services which were "medically unreasonable, unnecessary, and unskilled," and had knowledge that the payment claims it was submitting to Medicare were indeed for "unreasonable, unnecessary, and unskilled services."⁶⁷

As for statistical sampling, the government's plan was to take the time period of January 1, 2006 through October 31, 2012, which altogether saw Life Care admit 54,396 patients and submit 154,621 claims to the government for payment, and draw a random sample of 400

⁶¹ *Id.* at 268.

⁶² *Id.* at 269.

⁶³ *U.S. v. Life Care Ctrs. of Am., Inc.*, 114 F. Supp. 3d 549, 571 (E.D. Tenn. 2014).

⁶⁴ *Id.* at 551.

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.* at 554–555.

admissions from that pool.⁶⁸ Following extrapolation, that number would assist in formulating “estimates on the total number of claims which were submitted for non-covered services and the total amount of overpayments by Medicare.”⁶⁹ As indicated above, the entire sample universe to which the sampled results of the 400 admissions would be extrapolated was 54,396 admissions, comprising 154,621 claims. In other words, the estimate would be used for False Claims Act liability purposes.

The court in *Life Care*, in citing *Cabrera-Diaz*, where the defendant defaulted on the liability part of the case,⁷⁰ noted that statistical sampling in False Claims Act cases has generally been limited to calculating damages, rather than determining liability.⁷¹ The court next addressed *United States v. Friedman*, a 1993 case from a district court in Massachusetts, which disallowed the government from using statistical sampling to prove liability.⁷² The court noted that the *Friedman* case involved only 676 claims, and thus, the opportunity for claim-by-claim review existed, rendering statistical sampling, in effect, unnecessary.⁷³ The court was also sure to note that even in refusing to permit statistical sampling, the *Friedman* court still “recognized the validity of statistical sampling.”⁷⁴ In any event, the *Friedman* case, in the eyes of the *Life Care* court, “provides little analysis regarding the propriety of statistical sampling in a FCA case.”⁷⁵

The *Life Care* court then made quick work of the second case which the defendant attempted to argue was similar to its own situation, *United States ex rel. Trim v. J.D. McKean*, from the Western District of Oklahoma. There, the court determined that the audits which were

⁶⁸ *Life Care*, 114 F. Supp. 3d at 556.

⁶⁹ *Id.*

⁷⁰ *Cabrera-Diaz*, 106 F. Supp. 2d at 243.

⁷¹ *Life Care*, 114 F. Supp. 3d at 560.

⁷² *Id.* at 561.

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.*

under consideration to be used as part of a statistical sample were “insufficient” because they involved conflicts of interests and lacked testimony as to the reliability of the auditor or the auditing process itself, as well as because of the subjective nature of the physician coding, and because the sampling size was too small.⁷⁶ Other problems with these audits were that a portion of the charts in question were “completely illegible and, in some cases, [did not] appear to be written in English.”⁷⁷ The *Life Care* court noted that none of these issues were present before it, and as such, found *Trim* to be inapplicable.⁷⁸

While the *Life Care* court was quick to differentiate between the situation before it and scenarios in which statistical sampling had been rejected by other courts, it was also careful to distinguish administrative cases in which extrapolation is permitted because appellate courts analyze them under a different standard of review.⁷⁹ An administrative decision to implement statistical sampling will be cast aside only if the reviewing court “finds that the actions were arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.”⁸⁰ Outside of the administrative context, a plaintiff must establish the elements of a False Claims Act case by a preponderance of the evidence.⁸¹

The *Life Care* case in particular is helpful in highlighting the tension parties share over the issue of whether statistical sampling may be used to prove the elements of the False Claims Act. The court considered the viability of statistical sampling in establishing these four elements

⁷⁶ *Id.* (citing U.S. ex rel Trim v. McKean, 31 F. Supp. 2d 1308, 1314 (W.D. Okla. 1998)).

⁷⁷ *Life Care*, 114 F. Supp. 3d at 561 (citing U.S. ex rel Trim v. McKean, 31 F. Supp. 2d 1308, 1314 (W.D. Okla. 1998)).

⁷⁸ *Id.* at 562.

⁷⁹ *Id.*

⁸⁰ *Id.* (citing Dressman v. Costle, 759 F.2d 548, 555 (6th Cir.1985)).

⁸¹ *Id.*

in order: identification of specific claims submitted or statements made, falsity, knowledge, and materiality.⁸²

First, with respect to the identification of specific claims submitted or statements made, the differing positions are quite simple: the defendant argued that individualized proof of specific claims or statements made could not be accomplished through statistical sampling, while the government countered that statistical sampling was not a blockade to satisfying this first element.⁸³ The court agreed with the government, noting that while the government could technically engage in a claim-by-claim review, such identification and review of each claim defeats the very purpose of statistical sampling.⁸⁴ The defendants cited *Friedman* in reliance on their position, but the court rejected such reliance by distinguishing the relatively small number of claims in *Friedman* as compared to its own case (676 claims in *Friedman* as compared to 154,621 in *Life Care*), as well as by emphasizing the impracticability of such an extensive review, especially in light of the “limited resources” at the court’s disposal.⁸⁵

The second element over which the parties argued was falsity. In arguing that statistical sampling cannot be used to establish falsity, the defendants sought to underscore the “fact-intensive, subjective determinations by scores of different physicians, therapists, and other professionals” which are inherent in deciding whether a specific treatment is medically necessary.⁸⁶ In other words, the defendant argued, in effect, that statistical sampling cannot satisfy the falsity element because “the determination of whether therapy is medically necessary for a particular patient requires an individual assessment of the patient’s clinical condition,” a

⁸² *False Claims Act - Proof of Liability - Eastern District of Tennessee Rules That Statistical Extrapolation May Suffice to Prove Liability - United States ex rel. Martin v. Life Care Centers of America, Inc., Nos. 1:08-cv-251, 1:12-cv-64, 2014 U.S. Dist. LEXIS 142660 (E.D. Tenn. Sept. 29, 2014)*, 128 HARV. L. REV. 2074, 2076 (2015).

⁸³ *Life Care*, 114 F. Supp. 3d at 565.

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ *Id.*

determination which statistical analysis alone cannot account for.⁸⁷ According to the defendant, without evidence of the “patients’ actual conditions, diagnoses, clinical needs, the nature of therapy, or the extent of therapy,” the government cannot establish unnecessary medical treatment, and therefore, cannot establish falsity.⁸⁸

In its response, the government argued simply that statistical sampling is “routinely used in the medical necessity context” and that its planned review of the statistical sample for medical necessity prior to extrapolation would be sufficient to fulfill its legal obligation to satisfy the falsity element.⁸⁹ The court essentially took the position that the defendant’s argument was its own undoing: by citing all of the different possibilities with respect to a patient’s possible situation concerning medical necessity, the defendant only provided more ammunition for using statistical sampling, because statistical sampling is used “to draw an inference about a larger, not entirely identical, population of claims.”⁹⁰ Furthermore, according to the court, statistical sampling is not helpful in situations where all claims are identical, because in such a scenario “it would be relatively simple to formulate a mathematical calculation for a large number of claims,” and thus, there would “be no need for statistical sampling and extrapolation.”⁹¹

The third element which the *Life Care* court walks through is knowledge. Unsurprisingly, the defendant argued that statistical sampling does not suffice to establish knowledge because in order to establish knowledge, the government must demonstrate that “a particular employee or agent acted knowingly with respect to the alleged false claims.”⁹² The government maintained that statistical sampling, just as it covers the falsity element, satisfies the knowledge requirement

⁸⁷ *Id.* at 566.

⁸⁸ *Id.*

⁸⁹ *Life Care*, 114 F. Supp. 3d at 566.

⁹⁰ *Id.*

⁹¹ *Id.* at 566–67.

⁹² *Id.* at 567.

as well.⁹³ The court refers back to the definition of “knowingly” under the False Claims Act and, at the same time, cautions that “negligent actions or innocent mistakes” do not amount to knowledge within the meaning of the statute.⁹⁴

The court then noted that the “collective knowledge theory,” which the defendant alleged the government was asserting, cannot be used within the context of the False Claims Act.⁹⁵ This theory provides that a plaintiff “need not prove that any one individual employee of a corporate defendant also acted with scienter” and that “proof of a corporation’s collective knowledge and intent is sufficient.”⁹⁶ As to why courts have not allowed this theory to be used in False Claims Act cases, the court noted that such use would produce the unintended consequence of permitting plaintiffs “to prove scienter by piecing together scraps of ‘innocent’ knowledge held by various corporate officials, even if those officials never had contact with each other or knew what others were doing in connection with a claim seeking government funds.”⁹⁷ In order to circumvent this theory, the government planned to bring forth evidence pertaining to Life Care’s scienter “as to the claims identified within the sample.”⁹⁸ The court addressed this strategy and in no uncertain terms said that this course of action does not fall under the “collective knowledge theory” because the government, in perfect alignment with the purpose of statistical sampling, would “be attempting to meet the scienter element in each submitted claim and then extrapolate the total number of claims to the relevant universe.”⁹⁹

Finally, the court analyzed the fourth element under the False Claims Act: materiality. This is defined as “having a natural tendency to influence, or be capable of influencing, the

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *Life Care*, 114 F. Supp. 3d at 567.

⁹⁶ *Id.* at 567–68.

⁹⁷ *Id.* at 568.

⁹⁸ *Id.*

⁹⁹ *Id.*

payment or receipt of money.”¹⁰⁰ The defendant posited that statistical sampling cannot be used to prove materiality, while the government responded that the claims are material “by definition” because they involve claims for which the government refused to pay.¹⁰¹ In making its determination on this element, the court noted that it would look to “the potential effect of the false statement when it is made, not on the actual effect of the false statement when it is discovered.”¹⁰² Specifically, the defendant argued that the materiality element would only be satisfied “if the patient would be re-classified into a lower [Resource Utilization Group] category [with a corresponding lower reimbursement rate] after subtracting the number of allegedly unnecessary therapy minutes from the total number of therapy minutes for the assessment period.”¹⁰³ The court unequivocally rejected this argument, noting that such an arrangement still had the “potential to affect any ultimate payment” by the government.¹⁰⁴ In addition, the court found the argument speculative in nature and felt that materiality was best served to be evaluated by the fact-finder.¹⁰⁵

The defendant in *Life Care* did make the argument that allowing the government to establish liability by way of statistical sampling would violate its due process rights.¹⁰⁶ Prior to addressing the defendant’s due process argument, the court noted again that False Claims Act plaintiffs must prove the elements of a false claim by a preponderance of the evidence, which it defined as “such evidence as, when considered and compared with that opposed to it, has more

¹⁰⁰ *Id.* at 569.

¹⁰¹ *Life Care*, 114 F. Supp. 3d at 568.

¹⁰² *Id.* at 569.

¹⁰³ *Id.*

¹⁰⁴ *Id.* at 570.

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

convincing force and produces in [one's] mind...belief that what is sought to be proved is more likely true than not true.”¹⁰⁷

Despite acknowledging that “using extrapolation when liability has been proven is different than using extrapolation to establish liability” and also recognizing the distinct possibility that using statistical sampling to establish liability “could be in conflict with the Government’s evidentiary burden” to establish the elements of the False Claims Act, the court rejected the due process argument outright.¹⁰⁸ In so doing, the court noted that due process would be satisfied through the defendant’s ability to depose any expert the government proffers, retaining its own expert, and presenting its own evidence throughout the course of the trial.¹⁰⁹

D. Added Turbulence: Statistical Sampling’s Usage Depends on What Type of Fraud the Provider is Allegedly Committing?

The circumstances present in *United States v. Krizek* are slightly different, although no less concerning. In discussing the proceedings in the District Court, the D.C. Circuit Court noted that Dr. Krizek, a Washington D.C.- based psychiatrist, along with his wife, whom Dr. Krizek employed, were held “presumptively liable” for violations of the False Claims Act.¹¹⁰ Between January 1986 and March 1992, according to the government, Dr. Krizek submitted 8,002 “false or unlawful requests for reimbursement” totaling more than \$245,392.00.¹¹¹ Specifically, the government asserted that Dr. Krizek provided “medically unnecessary” services and that he had “upcoded,” or exaggerated the degree of the services that he had actually performed, some of the requests for reimbursement.¹¹²

¹⁰⁷ *Life Care*, 114 F. Supp. 3d at 562.

¹⁰⁸ *Id.* at 563.

¹⁰⁹ *Id.* at 570.

¹¹⁰ *U.S. v. Krizek*, 111 F.3d 934, 938 (D.C. Cir. 1997).

¹¹¹ *Id.* at 936.

¹¹² *Id.*

The District Court decided it would use a seven-patient sample in order to determine the liability under the False Claims Act, a decision which was arrived at with an agreement of the government and the Krizeks in place and effecting the same.¹¹³ According to that court, in light of the practicality, or lack thereof, of assessing whether approximately 8,000 claims submitted by the Krizeks were medically necessary, "...it was decided that this case should initially be tried on the basis of seven patients and two-hundred claims that the government believed to be representative of Dr. Krizek's improper coding and treatment practices."¹¹⁴ Following the evaluation of this 200 claim sample, the same court noted that "a determination of liability on Dr. Krizek's coding practices would be equally applicable to all 8,002 claims in the complaint."¹¹⁵

While the Krizeks unsuccessfully attempted to show that they did not agree to this arrangement, the District Court did note that "...as to the allegations of performance of unnecessary services, it may be that further discovery will have to take place to establish liability for the other patients and claims alleged by the government."¹¹⁶ In somewhat puzzling fashion, the District Court then enforced the agreement between the government and the Krizeks, despite its acknowledgment that more discovery could be needed on some of the liability issues.¹¹⁷ Thus, the District Court appeared willing to allow statistical sampling to establish liability in the improper upcoding context, yet in the same breath, it appeared to be reluctant to permit statistical sampling to establish liability in the performance of medically unnecessary services context.¹¹⁸ The D.C. Circuit Court, on appeal, ruled that the Krizeks were indeed "bound by their agreement at trial."¹¹⁹ In doing so, the Circuit Court, despite the District Court's apparent indecisiveness as

¹¹³ *Id.* at 940.

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ *Krizek*, 111 F.3d at 941.

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Id.*

to which specific types of fraud will be allowed to be established by way of statistical sampling and extrapolation, did not substantially address the differences between upcoding and medical necessity as they apply to statistical sampling.

E. More Guidance On the Way: Fourth Circuit Poised to Weigh In

Finally, the most recent consideration of statistical sampling and its relationship with the False Claims Act occurred in *U.S. ex rel. Michaels v. Agape Senior Community, Inc.*, a 2015 case out of the District Court in South Carolina, and currently pending before the Fourth Circuit Court of Appeals. This qui tam action was brought by two former employees of defendant Agape, which consisted of twenty-four nursing homes throughout South Carolina.¹²⁰ The plaintiffs alleged that Agape submitted false claims to Medicare, Medicaid, and Tricare for various payments related to hospice care and “general inpatient services.”¹²¹ The plaintiffs and Agape disputed the number of potential claims involved, with the plaintiffs arguing that the False Claims Act was implicated by 61,643 claims tied to 10,166 patients, while the defendants maintained that 53,280 claims were submitted in connection with 19,820 patients.¹²²

Despite this voluminous pool of claims, in this case, the court did not even permit statistical sampling to be used to establish damages.¹²³ Eventually a settlement was reached, although the government had not participated in mediation discussions.¹²⁴ When the government was made aware of the terms of the settlement, it objected to it, arguing that the settlement fell about \$23 million short of what potential damages could be.¹²⁵ The District Court certified two

¹²⁰ *U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. CA 0:12-3466-JFA, 2015 WL 3903675, at *1 (D.S.C. June 25, 2015).

¹²¹ *Id.*

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Id.* at *2.

¹²⁵ *Id.* at *2.

issues for interlocutory appeal: whether the government can veto the settlement in a situation where it did not intervene in the litigation, and the court's decision not to permit statistical sampling to be used to prove damages or liability.¹²⁶

In reaching its decision not to allow statistical sampling to be used to prove damages or liability, the District Court cited its "responsibility to determine the fairest course of action based upon the facts presented and the claims asserted."¹²⁷ Because the basis of the alleged False Claims Act violations in this case involved whether the services rendered to Agape's nursing home patients were "medically necessary," the court emphasized that it was a situation in which a "highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patient" was required.¹²⁸

Furthermore, according to the court, such review of each patient's medical chart(s) is possible, because there is no dispute that the evidence is available for examination.¹²⁹ The court agreed with the Massachusetts District Court's reasoning in *United States v. Friedman* that statistical sampling would not be permitted "based on the existence at trial of discrete claims that may be analyzed, discussed, and subjected to cross-examination."¹³⁰ Thus, due to the nature of the inquiry at the heart of the lawsuit and the ready availability of the evidence, the court, while acknowledging that statistical sampling may be appropriate in cases where it is the only way to avoid fraudulent activity from going unpunished, concluded that statistical sampling would not be permitted in this instance.¹³¹

¹²⁶ U.S. *ex rel.* Michaels v. Agape Senior Cmty., Inc., No. CA 0:12-3466-JFA, 2015 WL 3903675, at *3 (D.S.C. June 25, 2015).

¹²⁷ *Id.* at *8.

¹²⁸ *Id.*

¹²⁹ *Id.* at *7.

¹³⁰ *Id.*

¹³¹ *Id.* at *8.

III. The Equalizer: The Use of Statistical Sampling to Establish False Claims Act Liability Does Not Align with the Due Process Clause

In order to make out a constitutionally viable claim specific to due process, a party must overcome four main hurdles: first, it must satisfy the four-pronged test articulated in *Cleanmaster Industries, Inc. v. Sandra Shewry* for a violation of the Due Process Clause by way of a deprivation of a liberty interest; second, it must show that it had a “legitimate claim of entitlement” to that interest; third, it must establish that “the procedures attendant upon that deprivation were constitutionally insufficient”; and finally, it must make the demonstration that “government officials knowingly, and not merely negligently, deprived him of that interest without notice and an opportunity to be heard at a meaningful time and in a meaningful manner.”¹³²

A. A Deprivation of Liberty and a Violation of Due Process

Returning to the test articulated in *Cleanmaster Industries, Inc. v. Sandra Shewry* for a violation of the Due Process Clause by way of a deprivation of a liberty interest, a party must first satisfy the following four elements: first, “a charge impugns honesty or morality”; second, “the accuracy of the charge is contested”; third, “there is some public disclosure of the charge”; and finally, “the charge is made in connection with the termination of employment or the alteration of some legal right.”¹³³

Now, we shall apply the use of statistical sampling in the context of False Claims Act to this four-pronged test. First, an allegation against a defendant that he has violated the False Claims Act clearly calls into question that defendant’s honesty. After all, a complaint alleging a violation of the False Claims Act, by definition, involves the allegation that a defendant has

¹³² *ABA*, 40 F. Supp. 3d at 165–166.

¹³³ *Cleanmaster*, 491 F. Supp. 2d at 942.

“knowingly presented or caused to be presented a false or fraudulent claim for payment or approval to the government,” or has “knowingly made, used, or caused to be made or used a false record or statement material to a false or fraudulent claim,” or has “conspired” to do such.¹³⁴ Thus, the defendant’s honesty in his dealings with the government is at issue.

Secondly, the requirement that the accuracy of the charge must be contested is also met. The very essence of False Claims Act litigation, and indeed what liability under the False Claims Act ultimately boils down to, is whether the defendant has submitted a false claim to the government for payment. The government will argue that a false claim has in fact been submitted, while the defendant will argue that any claim submitted to the government was not false. Thus, the heart of the litigation is the dispute over whether or not the defendant actually submitted a false claim.

Third, any trial would lend itself to public accessibility, thereby satisfying the public disclosure of the charge element. Finally with respect to the four-pronged test, while on the surface the fourth requirement that “the charge is made in connection with the termination of employment or the alteration of some legal right” may seem far-fetched, in reality, it is anything but an attenuation. In light of the nature of False Claims Act, the stigma attached to such litigation for any defendant, and the potentially career-ending consequences, financially and otherwise, associated with a finding of liability, an argument can be made that a charge of a violation of the False Claims Act could be the functional equivalent of a “termination of employment” for purposes of this analysis.

Once the defendant has made the showing that he had a liberty interest in not having statistical sampling used against him in the liability context, and was entitled to not have this

¹³⁴ 31 U.S.C.A. § 3729 (Westlaw 2015).

liberty interest deprived of him by the government's use of statistical sampling to prove liability under the False Claims Act, the argument that "the procedures attendant upon that deprivation were constitutionally insufficient" becomes easy to make. The False Claims Act explicitly provides, under the heading "Liability for certain acts," that liability shall attach when one "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim" or "conspires" to do the same.¹³⁵ The False Claims Act provides that the word "knowingly" can be defined as any of the following: having "actual knowledge of the information," acting "in deliberate ignorance of the truth or falsity of the information" or acting "in reckless disregard of the truth or falsity of the information."¹³⁶

Therefore, the knowledge component, either direct or indirect, is by no means excused under the False Claims Act. Herein lies the problem for those wishing to argue that the use of statistical sampling is in harmony with due process. First of all, nowhere in the False Claims Act is there any mention of the use of statistical sampling as being a permissible method to prove liability. This notable omission from the statute aside, even more telling is the language highlighted above which is included in the False Claims Act. Quite simply, the use of statistical sampling and the plain language included in the False Claims Act are in direct contrast with one another.

It just does not follow that because "claim A" is false, "claim B" must also be false. Mere estimates cannot magically bridge the gap between one claim which has been proven to be false, and another claim that is purportedly false. The attenuation in such logic is far too pronounced. Moreover, the language of the False Claims Act, albeit indirectly, does not permit such a method

¹³⁵ *Id.*

¹³⁶ *Id.*

of proof. The False Claims Act requires that a defendant “knowingly” – albeit with various degrees of knowledge – submit a false claim.¹³⁷ While statistical sampling may be an effective way to calculate damages, it by no means can serve as a method to calculate liability. It is one thing to have the liability issue settled and say that a pattern of results has developed within a portion of the false claims, and then extrapolate those results to the remaining pool of claims to determine damages. It is quite another matter to have the liability issue unresolved as to all the claims and then to predict that because liability has been established in a certain number of claims, other claims must be subject to liability, as well.

In essence, statistical sampling is mathematical formula. While such a formula may be useful to solve a question of math, such as calculating damages, it would be inappropriate for such a formula to solve a question of law, such as liability. In order to prove that one knowingly submitted a false claim to the government for payment, the circumstances surrounding such submission would need to be examined. If statistical sampling in the context of the False Claims Act would be permitted to establish liability, the knowledge requirement would be completely negated. Of course, if the False Claims Act were to be revised to provide that a certain threshold percentage of false claims from a selected sample would satisfy the knowledge requirement for the remaining pool of claims, we would find ourselves having a completely different discussion. As of now, however, the False Claims Act is written as it is and as has been outlined above, with knowledge of a claim’s falsity being a central requirement and there being nothing to indicate that the same requirement is subject to any exceptions.

The fourth and final hurdle for a person asserting a due process violation, “government officials knowingly, and not merely negligently, deprived him of that interest without notice and

¹³⁷ *Id.*

an opportunity to be heard at a meaningful time and in a meaningful manner,” is also not a difficult one to overcome in the liability via statistical sampling context. First, the government’s decision to employ statistical sampling at trial is a tactical one, and thus, the government is knowingly depriving the defendant of its liberty interest. Moreover, we must ask: how can a person be on notice of which purportedly fraudulent claims have been allegedly submitted if the government does not identify them? Therefore, statistical sampling would appear to fail to pass muster under the “meaningful time and in a meaningful manner” language, as well.

In other words, by only making blanket assertions under the guise of statistical sampling, the defendant is left between a rock and hard place: he is being accused of a violation of the False Claims Act, yet is left in the dark completely as to which supposedly false claims he is specifically being accused of submitting, and he is therefore rendered defenseless. Even assuming that the defendant was somehow on notice, any opportunity to be heard following such notice could hardly be said to be “meaningful.” It would be quite difficult to be heard on unidentified claims. Put simply, one cannot defend against allegations in the abstract.

B. Concerns Stemming from the Case Law

The foundation of the Due Process Clause is fairness. The current approaches taken by American courts to whether statistical sampling may be used to establish the elements of the False Claims Act, and in turn establish False Claims Act liability, are anything but fair. They are unpredictable, irreconcilable, and above all, incredibly frustrating. Litigants are left at the mercy of their jurisdiction’s view on the issue, a fate seemingly left up to chance itself.

In *United States v. Life Care Centers of America, Inc.*, the court noted that due process would be satisfied through the defendant’s ability to depose any expert the government proffers,

retaining its own expert, and presenting its own evidence throughout the course of the trial.¹³⁸

Yet, the court seemed to ignore the target of the defendant's challenge. The defendant was not claiming that it could not put forth some defense, or that it was afraid due process would be absent in the courtroom procedures following the government's use of statistical sampling. Rather, the court arguably missed the boat entirely by not recognizing that the defendant was actually challenging whether it was deprived of due process by way of the government's use of statistical sampling in the first place.

In response to the defendant's assertion that its due process rights were being violated, the court noted that the defendant "will be afforded due process by having the opportunity to depose the Government's expert, challenge the qualifications of the Government's expert, retain its own expert, and to present all of this evidence at trial."¹³⁹ Perhaps the defendant is arguing, in light of the risks of statistical sampling, that it should not have to engage in any of this at all. Of course the defendant will have a chance to rebut the government's evidence at trial. The defendant's more likely concern is whether that point should ever be reached, given the due process concerns surrounding the utilization of statistical sampling as a mechanism for establishing liability.

Furthermore, the *Life Care* court, despite its acknowledgement that statistical sampling to prove damages is different from statistical sampling to prove liability, "did not meaningfully address a longstanding contrast between judicial acceptance of uncertain or probabilistic evidence to establish damages and judicial reluctance to allow this evidence to prove liability."¹⁴⁰

¹³⁸ *Life Care*, 114 F. Supp. 3d at 570.

¹³⁹ *Id.*

¹⁴⁰ *False Claims Act - Proof of Liability - Eastern District of Tennessee Rules That Statistical Extrapolation May Suffice to Prove Liability - United States ex rel. Martin v. Life Care Centers of America, Inc., Nos. 1:08-cv-251, 1:12-cv-64, 2014 U.S. Dist. LEXIS 142660 (E.D. Tenn. Sept. 29, 2014), supra note 83, at 2076.*

Perhaps this was a calculated omission in an effort to avoid due process pushback. After all, in *Life Care*, the sample the government wished to use, 400 out of 54,396, comprised less than one-percent (1%) of the total pool of admissions. The defendant did agree that the government would not have to prove liability by going case by case.¹⁴¹ This concession by the defendant aside, there is a common sense argument to be made that a sampling size of less than one-percent (1%) may very well not reflect accurately the status of more than ninety-nine percent (99%) of the total pool of admissions and resulting claims for payment. Thus, grave concerns as to whether the sample aligns with due process are implicated.

While *Life Care* emphasized the defendant's opportunity to rebut statistical evidence, the court in *United States ex. rel. Loughren v. UnumProvident Corp.* elected to examine the precise nature of the statistical sample and excluded such evidence after a somewhat exhaustive scientific review of what went into the government's expert's proffered statistical sample.¹⁴² The *Krizek* court, meanwhile, did not place heavy emphasis on expert testimony or the nuts and bolts of the statistical samples; instead, it chose to distinguish between types of fraud in discussing whether statistical sampling may be appropriate.¹⁴³ The court seemed open to permit statistical sampling to establish liability in the upcoding context, yet was hesitant to say that statistical sampling should be permitted to establish liability in dealing with issues of medical necessity.¹⁴⁴

The court in *U.S. ex rel. Michaels v. Agape Senior Community, Inc.* also based part of its analysis on the type of fraud being alleged, lack of medical necessity.¹⁴⁵ This court added a new

¹⁴¹ *Life Care*, 114 F. Supp. 3d at 556.

¹⁴² *UnumProvident*, 604 F. Supp. 2d at 269.

¹⁴³ *Krizek*, 111 F.3d at 940–941.

¹⁴⁴ *Id.*

¹⁴⁵ *U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. CA 0:12-3466-JFA, 2015 WL 3903675, at *8 (D.S.C. June 25, 2015).

wrinkle to the discussion, as well, as it noted that the availability of evidence to be examined is also a key factor in deciding whether statistical sampling to prove liability should be allowed.¹⁴⁶

In essence, from a lawyer's perspective, there is no clear blueprint for litigating this issue. As this paper has sought to demonstrate, and which has hopefully been shown by way of the differing analyses that the courts have engaged in, perhaps the wrong questions are being asked. Perhaps the questions should not be whether a defendant can rebut statistical evidence in court, what type of fraud has allegedly been committed, how many claims are at issue, or whether or not evidence is available. If we take a step back, perhaps the question which should be asked first is whether statistical sampling truly does conform to due process. Only once this issue has been legitimately addressed should courts consider the other points of contention which have been discussed above.

IV. Conclusion

The *Life Care* court noted that a defendant seeking to challenge the use of statistical sampling "is not without tools at its disposal to attack the weight to be accorded to any extrapolated evidence."¹⁴⁷ Respectfully, with that court's view notwithstanding, the Fifth Amendment Due Process Clause remains the biggest tool of all. While courts have consistently reminded us that it may not be practicable to perform a claim-by-claim review of all claims submitted to the government for payment, we must also remember that the extreme alternative – permitting statistical sampling and the extrapolation thereof – may not be a fair solution, either.

It goes without saying that the goal of this paper is not to make it easier for perpetrators of fraud to go unpunished or for fraudulent activity to go unscathed. At the same time, the courts would be wise to remain cognizant that due to the nature of False Claims Act claims and the

¹⁴⁶ *Id.* at *7.

¹⁴⁷ *Life Care*, 114 F. Supp. 3d at 571.

financial incentives inherent in qui tam actions, defendants must be afforded protection in a fair manner. In addition, none of this is to say that any of the defendants in the above-mentioned cases are or were not liable under the False Claims Act. Nor is it to say what type of due process is warranted in each of the respective circumstances. That issue should be left up to the relevant court. All this paper is suggesting is that the use of statistical sampling, and the extrapolation thereof, violates a defendant's Fifth Amendment due process rights, as it deprives him of a constitutionally protected liberty interest.

One cannot prove that someone "knowingly" submitted one purportedly false claim based on the fact that the same person "knowingly" submitted another false claim. Breach of the False Claims Act is a serious matter. The severe consequences stemming from liability under the False Claims Act need to be imposed in a manner other than statistical sampling, which is, quite simply, the equivalent of glorified, educated guesswork. Liberty depends on it, and the Due Process Clause of the Fifth Amendment, the cornerstone of American jurisprudence, demands it.