

THE EXTRAPOLATION CONUNDRUM: FINDING A UNIFIED THEORY FOR THE USE OF STATISTICAL SAMPLING IN MEDICARE FRAUD CASES BROUGHT UNDER THE FALSE CLAIMS ACT

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I. INTRODUCTION

Healthcare fraud has become one of the federal government's costliest problems. The government spends over one trillion dollars every year on Medicare and Medicaid.¹ Total spending on healthcare in America is around 2.7 trillion dollars, roughly seventeen percent of the nation's gross domestic product.² Despite—or perhaps, because of—the massive amounts spent on healthcare, Medicare and Medicaid “have become a sitting duck for fraudulent activity.”³ In spite of constant attempts by both the FBI and the Department of Justice, Medicare and Medicaid fraud continues to cost the government—and thus taxpayers—billions of dollars.⁴ Indeed, though estimates vary, fraud and systematic overcharging are estimated to cost the government roughly sixty billion dollars every year, totaling roughly ten percent of Medicare's annual costs.⁵

This widespread fraud stems in large part from the fact that the Medicare and Medicaid systems are, by their very nature, vulnerable to fraudulent activity conducted by dishonest practitioners. Indeed, the United

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¹ *The \$272 Billion Swindle*, THE ECONOMIST (May 31, 2014), <http://www.economist.com/news/united-states/21603078-why-thieves-love-americas-health-care-system-272-billion-swindle>.

² *Id.*

³ *Medicare: A System Ripe for Fraud*, MEDICARE & MEDICAID FRAUD REPORTING CENTER, <http://www.medicarefraudcenter.org/medicare-fraud-information/11-medicare-a-system-ripe-for-fraud.html> (last visited Oct. 30, 2015) [hereinafter *Medicare Fraud Reporting Center*].

⁴ Merrill Matthews, *Medicare and Medicaid Fraud is Costing Taxpayers Billions*, FORBES (May 31, 2012, 3:08 PM), <http://www.forbes.com/sites/merrillmatthews/2012/05/31/medicare-and-medicare-fraud-is-costing-taxpayers-billions/>.

⁵ Reed Abelson & Eric Lichtblau, *Pervasive Medicare Fraud Proves Hard to Stop*, N.Y. TIMES (Aug. 15, 2014), http://www.nytimes.com/2014/08/16/business/uncovering-health-care-fraud-proves-elusive.html?_r=0.

States Government Accounting Office has labeled both the Medicare and Medicaid programs “high-risk programs.”⁶ Much of the problem stems from the fact that “the government pays [Medicare and Medicaid bills] on an honor system, requiring only electronic submission to claim for services or goods provided by a health care provider.”⁷ The relative ease with which health care providers can file a claim was originally designed to provide quick and efficient payment to doctors who could then treat the poor and the needy; but, in more recent times, this lack of oversight has made it all too easy for dishonest health care providers to exploit the system.⁸ To make matters worse, “[no] built-in checks and balances or due diligence exists to protect the Medicare giant from the onslaught of [fraudulent activity].”⁹ The sheer volume of health care claims submitted each year under Medicare and Medicaid only adds to the problem, as the government faces the seemingly unfeasible task of sorting out proper claims from fraudulent ones in a pool of millions of claims submitted by millions of Americans.¹⁰

With executive, administrative, and institutional efforts failing to prevent widespread health care fraud, the government increasingly relies on an old, though still very useful tool: the False Claims Act.¹¹ For many years, the federal government has considered the False Claims Act (FCA) to be its primary instrument in preventing fraud against the government.¹² Today, private actions brought under the FCA play a “vital role” in fighting Medicare fraud.¹³ In 2014 alone, the Department of Justice recovered over two billion dollars in health care-related FCA actions.¹⁴

But the FCA is not without its drawbacks. Health care fraud cases brought under the FCA are often large, unwieldy affairs involving thousands of claims.¹⁵ Faced with the practical impossibility of sorting through such a

⁶ *High Risk List*, U.S. GOV'T ACCOUNTABILITY OFF., <http://www.gao.gov/highrisk/overview> (last visited Apr. 23, 2016).

⁷ See *Medicare Fraud Reporting Center*, *supra* note 3.

⁸ *Id.*

⁹ *Id.*

¹⁰ *Medicare Program*, U.S. GOV'T ACCOUNTABILITY OFF., http://www.gao.gov/highrisk/medicare_program/why_did_study (last visited Mar. 19, 2017); *Medicaid Program*, U.S. GOV'T ACCOUNTABILITY OFF., http://www.gao.gov/highrisk/medicaid_program/why_did_study (last visited Mar. 19, 2017).

¹¹ 31 U.S.C. § 3729 (2012).

¹² See S. REP. NO. 99-345 at 1 (1986).

¹³ See *Medicare Fraud Reporting Center*, *supra* note 3.

¹⁴ Press Release, Department of Justice, Justice Department Recovers Nearly \$6 Billion from False Claims Act Cases in Fiscal Year 2014 (Nov. 20, 2014) <http://www.justice.gov/opa/pr/justice-department-recovers-nearly-6-billion-false-claims-act-cases-fiscal-year-2014>.

¹⁵ Jeanne A. Markey & Raymond M. Sarola, 4th Cir. *FCA Statistical Sampling Case is One to Watch*, LAW360 (Oct. 8, 2015, 10:33 AM), <http://www.law360.com/articles/712001/4th-circ-fca-statistical-sampling-case-is-one-to-watch>.

large volume of claims, the government and private relators have turned to statistical sampling—sometimes called “extrapolation”—as an efficient way to determine the characteristics of large sets of data.¹⁶ Statistical sampling is an economically efficient and scientifically accepted mathematical method for drawing inferences and generalizations about a large set of data based on a subset data.¹⁷ Furthermore, it has long been established that statistical sampling is a viable method for proving damages in FCA cases, and most courts have allowed its use for this limited purpose.¹⁸

In recent years, the government has pushed towards using statistical sampling not only for proving damages, but for proving liability as well.¹⁹ Courts have split on the issue; some have allowed statistical sampling for proving liability, some have allowed it only for proving damages, and still others have not allowed it at all.²⁰ Yet there remains no unified theory for when and how statistical sampling should be implemented. The courts that have addressed the issue have held for one approach or the other without espousing a guiding framework that can be applied on a case-by-case basis. Furthermore, courts addressing statistical sampling have taken ostensibly extreme approaches, allowing either an uninhibited use or, alternatively, a restricted approach that prohibits its use in almost every instance.²¹

This Comment will argue for a middle ground between these extreme approaches while developing a single, unified framework for determining whether statistical sampling should be permitted in a given case. Part II will provide a more detailed overview of the history and development of the FCA and the use of statistical sampling. Part III will provide an analysis of the reasons courts have provided for allowing the use of statistical sampling, while Part IV will analyze the reasons courts have given for prohibiting the use of statistical sampling. Finally, Part V will put forth a unified framework for the use of statistical sampling in FCA cases, while also explaining the

¹⁶ See *id.*

¹⁷ See generally Laurens Walker & John Monahan, *Sampling Evidence at the Crossroads*, 80 S. CAL. L. REV. 969 (2007) (providing the history and scientific background of statistical sampling).

¹⁸ See *United States v. Cabrera-Diaz*, 106 F. Supp. 2d 234, 240 (D.P.R. 2000) (establishing that statistical sampling is generally permitted for establishing damages and providing an overview of cases that have permitted it).

¹⁹ Matthew D. Benedetto, *Statistical Sampling on the Rise in False Claims Act Cases*, L.A. DAILY J. (Nov. 20, 2014), https://www.wilmerhale.com/uploadedFiles/Shared_Content/Editorial/Publications/Documents/statistical-sampling-on-the-rise-in-false-claims-act-cases.pdf.

²⁰ For concise arguments on both sides of the issue, compare *United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. 0:12-3466-JFA, 2015 U.S. Dist. LEXIS 82379 (D.S.C. June 25, 2015) (prohibiting statistical sampling), *interlocutory appeal dismissed*, 848 F.3d 330 (4th Cir. 2017), with *United States ex rel. Martin v. Life Care Ctrs. of Am., Inc.*, 114 F. Supp. 3d 549 (E.D. Tenn. 2014) (allowing statistical sampling).

²¹ See *infra* Parts III, IV.

framework's origins and various rationales.

As a preliminary matter, this Comment only addresses the issue of when statistical sampling should be used for proving liability. It is well settled, with perhaps a few outliers, that statistical sampling is generally agreed to be permissible for calculating damages.²² Furthermore, this Comment will address only the use of statistical sampling in health care fraud cases brought in federal court under the FCA, and will not address statistical sampling in other contexts, such as mass tort cases, or in administrative rulings.²³

In attempting to create a unified framework for statistical sampling, this Comment will endeavor to reconcile the various cautions, concerns, and principles that have led courts to come out on different sides of the issue. This unified framework will provide for a cautionary approach to the use of statistical sampling for proving liability in FCA cases. In particular, it will require the party proposing to use statistical sampling to show some legitimate reason for why the use of statistical sampling will be necessary. The effect will be to create what is in essence a rebuttable presumption²⁴ against the use of statistical sampling for proving liability, which can be overcome by a showing of hardship on the party proposing to use statistical sampling, or where claim-by-claim review is a practicable impossibility. The ultimate result of this approach will be a legal framework that allows the government and private relators to have access to statistical sampling in cases where it is necessary to prevent large-scale fraud, while also preventing its use in smaller cases where the benefits are slight and there is a large potential for abuse.

II. A BRIEF HISTORY OF THE FCA AND STATISTICAL SAMPLING

A. *The Humble Origins and Modern Power of the False Claims Act*

The FCA imposes liability on any person who knowingly presents the United States with a false or fraudulent claim for payment.²⁵ Under the FCA, private individuals, legally known as “relators,” are permitted to bring suits in the government’s name, known as *qui tam* suits, for fraudulent conduct committed against the United States.²⁶ The FCA was originally

²² See *Cabrera-Diaz*, 106 F. Supp. 2d at 240.

²³ *United States ex rel. Martin*, 114 F. Supp. 3d at 562 (“Appeals from administrative agency decisions are distinguishable from [cases brought under the FCA] because they are considered by an appellate court under a different standard of review.”).

²⁴ The term “rebuttable presumption” in this sense means a presumption against the legitimacy of statistical sampling in a given case that can be overcome by a showing of additional facts that warrant its use. See BLACK’S LAW DICTIONARY 1267 (6th ed. 1990).

²⁵ 31 U.S.C. § 3729 (2012).

²⁶ See 31 U.S.C. § 3730(b) (2012).

implemented during the Civil War as a way for the federal government to control fraud on the part of defense contractors.²⁷ But as the federal government's involvement in the national economy continued to grow throughout the Twentieth Century, and as pervasive fraud became ever more present, the once innocuous FCA began to take a more central role in the government's attempts to prevent fraud.²⁸ In the 1980s, against a backdrop of national efforts to encourage whistleblowing against health care fraud,²⁹ the FCA took on its current form.³⁰ As currently constructed, the FCA imposes severe penalties on violators, including a provision for treble damages and fines of up to ten thousand dollars per claim.³¹ Private relators, for their part, receive substantial rewards ranging from between fifteen and thirty percent of the proceeds of the action or settlement of the claim.³² Together, this system of penalties and rewards, which came to full fruition through the enactment of the 1986 amendments to the FCA, lay at the heart of an increasingly aggressive government scheme to root out fraudulent activity.³³

The aggressive enforcement scheme prompted by the 1986 amendments to the FCA has fallen heavily—perhaps even disproportionately—in the field of health care.³⁴ Indeed, the modern FCA has become a “nightmare for the health care industry,” as “[h]ealth care providers have discovered that billing errors once viewed as mistakes in need of correction, are now attacked as crimes that compel million dollar settlements.”³⁵ The focus on health care fraud has also come in conjunction with a massive rise in litigation brought under the FCA since the enactment of the 1986 amendments.³⁶ As an example, there were twelve *qui tam* cases brought under the FCA in 1987, compared to two hundred and twenty brought in 1994.³⁷ Over seven hundred *qui tam* actions have been brought under the FCA in every year since 2010.³⁸

²⁷ See Patricia Meador & Elizabeth S. Warren, *The False Claims Act: A Civil War Relic Evolves Into a Modern Weapon*, 65 TENN. L. REV. 455, 458 (1998).

²⁸ See *id.* at 459–61.

²⁹ See Elletta Sangrey Callahan & Terry Morehead Dworkin, *Do Good and Get Rich: Financial Incentives for Whistleblowing and the False Claims Act*, 37 VILL. L. REV. 273, 275–83 (1992).

³⁰ See Meador & Warren, *supra* note 27, at 461.

³¹ 31 U.S.C. § 3729(a)(1)(G) (2012).

³² § 3730(d)(1)–(2).

³³ See Meador & Warren, *supra* note 27, at 460.

³⁴ See Frank LaSalle, *The Civil False Claims Act: The Need for a Heightened Burden of Proof as a Prerequisite for Forfeiture*, 28 AKRON L. REV. 497, 502 (1995).

³⁵ See Meador & Warren, *supra* note 27, at 456.

³⁶ See *id.*; LaSalle, *supra* note 34, at 500–02.

³⁷ LaSalle, *supra* note 34, at 500–02.

³⁸ 2014 Year-End False Claims Act Update, GIBSON DUNN (Jan. 7, 2015),

With health care fraud now standing front and center in cases brought under the FCA, and with litigation on the rise, it is perhaps not surprising to find that the government is willing to push the boundaries of permissible methods of proving liability. Statistical sampling now stands at the forefront of one of the largest and most important areas of federal litigation, and its fate as a tool for proving liability will have a massive effect in shaping the future of health care fraud litigation.³⁹

B. *The History and Development of Statistical Sampling*

Statistical sampling is not a new evidentiary method. On the contrary, and perhaps surprisingly, it has been used in litigation since as early as the 1920s.⁴⁰ And while statistical sampling has been used—if not always accepted—in litigation for nearly a century, it has been recognized as a legitimate mathematical methodology in the world of science for even longer.⁴¹ Statistical sampling was first permitted in a trademark case in 1940, and it had “gained full acceptance in trademark law” by 1963.⁴² By 1990, statistical sampling had made its way into mass tort cases.⁴³ Today, courts and legal scholars generally recognize statistical sampling as a viable evidentiary method, and statistical reasoning and analysis is routinely used in “antitrust, employment discrimination, toxic torts, and voting rights cases.”⁴⁴

In general, statistical sampling is a methodology whereby a small sample of data is used to determine the characteristics of a much larger set of data.⁴⁵ While the specific process sometimes differs based on a variety of complex factors, statisticians tend to adhere to several basic principles in order to minimize bias and ensure the highest degree of accuracy possible.⁴⁶ To put the matter succinctly, “a good survey defines an appropriate population, uses a probability method for selecting the sample, has a high

<http://www.gibsondunn.com/publications/pages/2014-Year-End-False-Claims-Act-Update.aspx>.

³⁹ See Benedetto, *supra* note 19.

⁴⁰ See *Elgin Nat. Watch Co. v. Elgin Clock Co.*, 26 F.2d 376, 377–78 (D. Del. 1928) (disallowing the use of statistical sampling in a trademark dispute).

⁴¹ See Walker & Monahan, *supra* note 17, at 974 (“Sampling came to law later than to science.”).

⁴² *Id.* at 975.

⁴³ *Id.* at 976.

⁴⁴ David H. Kaye & David A. Freedman, *Reference Guide on Statistics*, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 211, 213 (3d ed. 2011).

⁴⁵ See, e.g., *id.* (explaining the methodology and process behind the use of statistics in litigation); Walker & Monahan, *supra* note 17, at 970–79 (providing a history and general background on statistical sampling).

⁴⁶ See generally Kaye & Freedman, *supra* note 44 (providing an in-depth explanation of statistical sampling methodology).

response rate, and gathers accurate information on the sample units. When these goals are met, the sample tends to be representative of the population. Data from the sample can be extrapolated[.]”⁴⁷

To be sure, statistical sampling is not a matter of simple number crunching. In fact, parties seeking to use statistical sampling in a particular case, even if just as a calculation of damages, will usually require the use of a statistician as an expert witness for purposes of developing the appropriate statistical method for the given facts and making the appropriate calculations for extrapolating the sample to the entire universe of claims.⁴⁸ In health care fraud cases in particular, statistical sampling often involves complicated methods for determining “the population of interest” from among thousands of claims, while also “identify[ing] a data source from which the sample will be drawn” to fit into a “sampling frame” which “comprehensively reflect[s] the population.”⁴⁹ With such complex calculations, and with so many variables in play, statistical sampling inevitably involves at least some margin for error.⁵⁰

While statistical sampling is a generally accepted evidentiary method, there is a large difference between the way in which statistical sampling has traditionally been used and the proposal for using statistical sampling as a means of proving liability in health care fraud cases brought under the FCA. Historically, statistical sampling has been used as a method either for determining damages or for demonstrating the external characteristics or beliefs of a population subset.⁵¹ For instance, in trademark cases, where statistical sampling first made its mark on the law, it was used primarily in regard to surveys as a means of demonstrating market confusion.⁵² In the context of mass torts, it has typically been used as a way to calculate damages and streamline large class-action cases involving similarly situated plaintiffs.⁵³ But, “[w]hile it’s [sic] been widely used in complex civil

⁴⁷ *Id.* at 226.

⁴⁸ *See, e.g.*, United States *ex rel.* Michaels v. Agape Senior Cmty., Inc., No. 0:12-3466-JFA, 2015 U.S. Dist. LEXIS 82379 (D.S.C. June 25, 2015), *interlocutory appeal dismissed*, 848 F.3d 330 (4th Cir. 2017); United States *ex rel.* Martin v. Life Care Ctrs. Of Am., Inc., 114 F. Supp. 3d 549 (E.D. Tenn. 2014).

⁴⁹ United States *ex rel.* Ruckh v. Genoa Healthcare, LLC, No. 8:11-cv-1303-T-23TBM, 2015 U.S. Dist. LEXIS 55384, at *7–8 (M.D. Fla. Apr. 28, 2015).

⁵⁰ Kaye & Freedman, *supra* note 44, at 243–46.

⁵¹ *See* Walker & Monahan, *supra* note 17, at 974–77.

⁵² *See, e.g.*, Elgin Nat. Watch Co. v. Elgin Clock Co., 26 F.2d 376, 376–78 (D. Del. 1928) (discussing how the plaintiff attempted to use expert witness testimony to show that there was market confusion concerning the name “Elgin” based on a survey of two thousand consumers); Zippo Mfg. Co. v. Rogers Imps., Inc., 216 F. Supp. 670, 681 (S.D.N.Y. 1963) (discussing how a random sample of five hundred people showed market confusion in relation to Zippo brand lighters).

⁵³ *See* Walker & Monahan, *supra* note 17, at 976–77.

litigation, statistical sampling has been rarely used in federal False Claims Act litigation.”⁵⁴ Traditionally, where statistical sampling has been used in FCA cases, it has been used for determining damages and not for proving liability.⁵⁵

The application of statistical sampling for proving liability in FCA cases would thus be a fairly large step in the evolution of the use of statistical sampling in litigation. In essence, using statistical sampling to prove liability in a health care fraud case brought under the FCA would involve taking a small sample of the total number of claims brought against the defendants, determining liability in the small sample of claims, and then, through the use of an expert witness statistician, extrapolating liability to the total universe of claims.⁵⁶ This methodology, which involves proving liability through what is essentially a mathematical formula—and without any individual, claim-by-claim review—would be an extraordinary step in FCA litigation. Statistical sampling thus warrants a cautionary approach.

III. CRITIQUE AND ANALYSIS OF THE REASONS COURTS HAVE GIVEN FOR ALLOWING STATISTICAL SAMPLING

Courts that have allowed the use of statistical sampling have typically done so on the principle that statistical sampling and extrapolation are viable and accurate scientific methods with a long tradition of use in complex litigation.⁵⁷ Other courts go further, reasoning that statistical sampling is the only viable way of determining liability and ensuring proper recovery in large-scale *qui tam* actions.⁵⁸ These courts tend to see no reason why the basic methodology cannot be extended to proving liability, especially in cases involving a large number of claims.⁵⁹ It is somewhat striking, however, that several of the courts that have allowed statistical sampling have endorsed an almost uninhibited use of statistical sampling, implying that the government and private relators should be free to use it whenever possible as a means of proving liability.⁶⁰ This perhaps goes too far, as there are

⁵⁴ See Benedetto, *supra* note 19.

⁵⁵ *Id.*

⁵⁶ See, e.g., *United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. 0:12-34466-JFA, 2015 U.S. Dist. LEXIS 82379 (D.S.C. June 25, 2015) (explaining the basic methodology), *interlocutory appeal dismissed*, 848 F.3d 330 (4th Cir. 2017); *United States ex rel. Martin v. Life Care Ctrs. of Am., Inc.*, 114 F. Supp. 3d 549 (E.D. Tenn. 2014) (same).

⁵⁷ See, e.g., *United States ex rel. Loughren v. UnumProvident Corp.*, 604 F. Supp. 2d 259, 261 (D. Mass. 2009); *Martin*, 114 F. Supp. 3d at 560. See also *infra*, Part III.B.

⁵⁸ See, e.g., *Martin*, 114 F. Supp. 3d at 571. See also *infra*, Part III.A.

⁵⁹ See *Loughren*, 604 F. Supp. 2d at 261 (noting that statistical sampling can be a “reasonable method” for proving liability); *Martin*, 114 F. Supp. 3d at 563.

⁶⁰ See, e.g., *Loughren*, 604 F. Supp. 2d at 261 (suggesting that statistical sampling is suitable for proving liability so long as the “statistical methodology is appropriate”).

various drawbacks to its use.

A. Statistical Sampling as a Practical Necessity

The primary argument for allowing statistical sampling as a means of proving liability is that it is necessary to allow the government and private relators to efficiently prove liability. As the court in *United States ex rel. Martin v. Life Care Centers of America, Inc.* stated succinctly: “[g]iven the large number of claims that can be submitted by a single entity to be reimbursed by Medicare, it is often not practicable to do a claim-by-claim review of each allegedly false claim in a complex FCA action.”⁶¹ Furthermore, “[t]he purpose of the FCA as well as the development and expansion of government programs as to which it may be employed support the use of statistical sampling in complex FCA actions where a claim-by-claim review is impracticable.”⁶² This sentiment was echoed in *United States ex rel. Ruckh v. Genoa Healthcare, LLC*, in which the court stated that it would allow the use of statistical sampling because, “[c]onsidering the large universe of allegedly false claims in the instant case, it would be impracticable for the Court to review each claim individually.”⁶³ Economic considerations also played a part in this determination, as the court in *Martin* stated: “if the Court were to individually review each allegedly false claim or statement in this action, it would consume an unacceptable portion of the Court’s limited resources.”⁶⁴

These concerns may well be true in large cases, where there are thousands of claims under review. In *Martin*, for instance, the defendant health care provider owned and operated more than two hundred nursing home facilities throughout the United States, and there were over one hundred thousand claims of fraud at issue.⁶⁵ Likewise, in *Ruckh*, the claims against the defendant involved charges of fraudulent overbilling for patients at each of its fifty-three medical facilities throughout the state of Florida.⁶⁶ Indeed, both *Martin* and *Ruckh* distinguished an earlier case that had prohibited the use of statistical sampling, *United States v. Friedman*, on the grounds that it involved a substantially smaller number of claims.⁶⁷ Unlike

⁶¹ *Martin*, 114 F. Supp. 3d at 571.

⁶² *Id.*

⁶³ *United States ex rel. Ruckh v. Genoa Healthcare, LLC*, No.8:11-cv-1303-T-23TBM, 2015 U.S. Dist. LEXIS 55384, at *10 (M.D. Fla. Apr. 28, 2015) (quoting *Martin*, 114 F. Supp. 3d at 565).

⁶⁴ *Martin*, 114 F. Supp. 3d at 565.

⁶⁵ *Id.* at 551, 556.

⁶⁶ *Ruckh*, 2015 U.S. Dist. LEXIS 55384, at *2.

⁶⁷ See *id.* at *8–10 (citing *United States ex rel. Martin* for the proposition that *Friedman* is distinguishable due to the smaller number of claims); *Martin*, 114 F. Supp. 3d at 565 (“*Friedman* is distinct from the instant case because there was a sufficiently limited universe

Martin and *Ruckh*, where thousands of claims were at issue, *Friedman* only contained 676 total claims.⁶⁸

But distinguishing *Friedman* only raises the question of how many claims are enough to warrant statistical sampling.⁶⁹ There is no guiding principle to establish the point at which claim-by-claim review becomes unfeasible, and drawing a line at a particular number seems an unsatisfactorily arbitrary alternative. To be sure, 676 total claims is not a small number, and the *Friedman* court gave no indication that its decision to not allow sampling was based in any way on the total number of claims.⁷⁰ Adding to the problem is the fact that the number of claims may not tell the whole story. Depending on the facts and difficulty of the case, it may be more or less feasible to perform a claim-by-claim review. Theoretically, two separate cases could have the same number of claims, but based on their facts, may be differently situated in regard to the feasibility of claim-by-claim review. Unfortunately, while both cases may in fact have been correctly decided, neither *Martin* nor *Ruckh* provides an answer to the question of how many claims are enough to warrant statistical sampling.

B. Statistical Sampling as a Viable and Accurate Scientific Methodology

Courts that have allowed statistical sampling also tend to focus on statistical sampling's reputation as an accurate and legitimate scientific method. In *United States ex rel. Loughren v. UnumProvident Corp.*, for instance, the court allowed for the use statistical sampling while noting its belief that "extrapolation is a reasonable method for determining the number of false claims so long as the statistical methodology is appropriate."⁷¹ The court in *Martin* adopted a similar confidence in statistical sampling, noting that "courts now consider 'mathematical and statistical methods [to be] well recognized as reliable and acceptable evidence in determining adjudicative facts.'"⁷² And while the *Martin* court recognized that "using extrapolation to establish damages when liability has been proven is different than using

of claims for the court to review each one individually rather than relying on extrapolation.").

⁶⁸ *United States v. Friedman*, No. 86-0610-MA, 1993 U.S. Dist. LEXIS 21496, *9 n.1 (D. Mass. July 23, 1993).

⁶⁹ The court in *United States ex rel. Martin* distinguished *Friedman* by its smaller number of claims, see 114 F. Supp. 3d at 565, but put forward no principle to determine at what point the number of claims becomes too large for claim-by-claim review.

⁷⁰ See *Friedman*, 1993 U.S. Dist. LEXIS 21496, *9 n.1. There is nothing in the *Friedman* opinion's analysis to suggest the court based its holding on a sufficiently limited number of claims.

⁷¹ *United States ex rel. Loughren v. UnumProvident Corp.*, 604 F. Supp. 2d 259, 261 (D. Mass 2009).

⁷² *Martin*, 114 F. Supp. 3d at 560 (quoting *Georgia v. Califano*, 446 F. Supp. 404, 409 (N.D. Ga. 1977)).

extrapolation to establish liability,” it nevertheless found no reason not to make the leap towards applying statistical sampling to a finding of liability.⁷³ Indeed, “the court’s opinion did not significantly engage with the damages/liability divide.”⁷⁴ It appears, at least in the view of courts adopting statistical sampling as a means of proving liability, that the same scientific legitimacy that allows for statistical sampling to be used in calculating damages is equally applicable for using it as a means of proving liability.⁷⁵

But whether this is actually true is a closer call than the court opinions in *Martin*, *Ruckh*, and *Loughren* lead on. Statistical sampling is, after all, an imperfect method, especially when used to prove a point.⁷⁶ Statistics are also prone to manipulation.⁷⁷ As statistician Richard Traflinger put it:

You can find statistics that show cigarettes are killers and that they have no effect on anyone’s health. You can find statistics that say you should cut down on the consumption of dairy products and that dairy products are good for you. You can find statistics that prove that soft drinks will give you cancer and that they have no effect on anything but your thirst (or even that they make you thirstier). Every one of these sets of statistics is absolutely true.⁷⁸

This is not to suggest that statistics are never trustworthy or reliable. On the contrary, as many courts have pointed out, statistical modeling enjoys a great deal of legitimacy and prestige as a reliable scientific tool in the realms of both academia and the law.⁷⁹ Traflinger’s point, however, is that statistics can be fairly arcane and surprisingly complex, and laypersons can be misled by what they believe is a fairly straightforward statistical model.⁸⁰ This is especially important with regard to FCA litigation, where expert witnesses hired by the parties will perform the statistical modeling. If statistics can be slanted in any variety of ways to prove the point that their proponent is attempting to establish, then their use in proving liability warrants caution and consideration.

⁷³ *Id.* at 563.

⁷⁴ *Recent Case: False Claims Act - Proof of Liability - Eastern District of Tennessee Rules that Statistical Extrapolation May Suffice to Prove Liability*, 128 HARV. L. REV. 2074, 2080 (2015).

⁷⁵ It is perhaps somewhat surprising that many of the courts addressing the statistical sampling question do not explicitly address the difference between using sampling for a damages calculation and using it to prove liability. For courts that have accepted statistical sampling for proving liability, it appears implicit in their reasoning that scientific legitimacy is a major part of the reason why they have accepted it.

⁷⁶ See Richard Traflinger, *The Problems with Statistics*, WASH. ST. UNIV. <http://public.wsu.edu/~taflinge/evistats.html> (last visited Jan. 24, 2016).

⁷⁷ *See id.*

⁷⁸ *Id.*

⁷⁹ See *United States ex rel. Martin v. Life Care Ctrs. Of Am., Inc.*, 114 F. Supp. 3d 549, 559–61 (E.D. Tenn. 2014).

⁸⁰ Traflinger, *supra* note 76.

Statistics may also be suspect because they “do not tell the whole story,” especially concerning the relevance and validity of statistical comparisons.⁸¹ These observations are especially relevant in the context of statistical sampling, which necessarily involves comparisons between different types of claims. Essentially, evidence of liability for one claim does not necessarily represent evidence of liability for another claim, especially where the two claims are factually distinct. Indeed, statistics are especially suspect where evidence of a certain outcome in one situation is taken to mean evidence of the same outcome in a different situation,⁸² which is the exact methodology that would be used to prove liability in FCA cases.

Furthermore, health care fraud cases pose their own unique problems with regard to the use of statistical sampling because it is very difficult for statisticians to create “truly representative” and homogenous samples in such cases.⁸³ For example, it may be difficult for the statistician to differentiate—at least in cases where the defendant health care provider controls multiple health care organizations—between “different state Medicaid programs that have different qualifying requirements [for purposes of Medicare and Medicaid billing],” as well as differences between “rural and suburban, as well as specialty, hospitals in [the] sample.”⁸⁴ Simply put, it is difficult to extrapolate claims from a small sample when that sample is tenuously related to the larger universe of claims, such as where differences between hospitals, state laws, and billing requirements necessarily create differences that are exceptionally difficult to quantify in a statistical methodology.⁸⁵ In this sense, complexity cuts both ways; claim-by-claim review may well be unfeasible in large and complex FCA health care fraud cases, but it is this same complexity that cautions against the free and uninhibited use of statistical sampling.

This is not to say that statistical sampling should never be permissible. No evidentiary method is perfect, and it may well be said that it is up to the adversarial process, rather than trial courts, to find flaws in the propagated statistical sampling method.⁸⁶ Still, the inherent problems with the use of statistics warrant, at the very least, a restrained approach. This is especially

⁸¹ *Id.*

⁸² *Id.*

⁸³ Kirby D. Behre & A. Jeff Ifrah, *Statisticians at DOJ may Overstate Case; Government's Use of Statistical Sampling to Prove False Claims Act Liability, Damages May be Unreliable, if Not Impermissible*, 21 NAT'L L.J. 22, 22 (1999).

⁸⁴ *See id.*

⁸⁵ *See id.*

⁸⁶ *See United States ex rel. Martin v. Life Care Ctrs. of Am., Inc.*, 114 F. Supp. 3d 549, 560 (E.D. Tenn. 2014) (“The opposing party can challenge the sample through cross-examination of the proponent’s expert, presentation of its own expert, as well as other competing witnesses and evidence.”).

true in smaller cases with a manageable number of claims, where the problems associated with statistical sampling may outweigh the benefits.

IV. REASONS FOR LIMITING THE USE OF STATISTICAL SAMPLING

Courts have given a number of justifications for denying the use of statistical sampling, including concerns that the plaintiff has not met its burden of proof, the fact-specific nature of many FCA cases, the fact that statistical sampling is not a form of concrete evidence, and the requirement that plaintiffs must prove each individual claim on its own merits.⁸⁷ The idea has also been put forward—by legal scholarship more than case law—that using statistical sampling to prove liability violates Rule 9(b) of the Federal Rules of Civil Procedure, which requires that fraud be pleaded with particularity.⁸⁸ Finally, at the fringes of the argument is the concept that using statistical sampling to prove liability violates the defendant's due process rights.⁸⁹

A. *How the Fact-Specific Nature of Health Care Fraud Cases Warrants Against Statistical Sampling*

Many of the arguments espoused for prohibiting the use of statistical sampling stem from a little-known, unpublished, and seemingly innocuous case out of the District of Massachusetts, *United States v. Friedman*, in which the court declined the government's request to extrapolate from a random sample of 350 out of a total of 676 claims prepared and analyzed by an expert witness.⁹⁰ The court based this decision on the "existence at trial of discrete claims which were analyzed and discussed and subjected to cross examination" and which thus necessitated a claim-by-claim review.⁹¹ The trial judge added that, "[w]hile [he was] mindful of the government's efforts to shorten the trial and present its evidence efficiently and clearly, [he was] reluctant to accept a statistical sampling as the basis for doubling the alleged overpayment without the same scrutiny and support [as that provided by

⁸⁷ For the most concise arguments against the use of statistical sampling, see, for example, *United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. 0:12-3466-JFA, 2015 U.S. Dist. LEXIS 82379 (D.S.C. June 25, 2015), *interlocutory appeal dismissed*, 848 F.3d 330 (4th Cir. 2017); *United States ex rel. El-Amin v. George Washington Univ.*, 533 F. Supp. 2d 12, 31 n.9 (D.D.C. 2008); *United States v. Friedman*, No. 86-0610-MA, 1993 U.S. Dist. LEXIS 21496 (D. Mass. July 23, 1993).

⁸⁸ See Behre & Ifrah, *supra* note 83, at 22.

⁸⁹ See *id.* ("[D]ue process arguments alone appear to be insufficient to preclude government use of random sampling."); *Martin*, 114 F. Supp. 3d at 570 (rejecting defendant's due process claim).

⁹⁰ *Friedman*, 1993 U.S. Dist. LEXIS 21496, at *9 n.1.

⁹¹ See *id.*

claim-by-claim review].”⁹² Sampling was not, however, one of the case’s main issues, and it was deemed by the trial judge as trivial enough to be relegated to a footnote.⁹³

This has not stopped courts from relying on *Friedman*’s reasoning. In *United States ex rel. Michaels v. Agape Senior Community, Inc.*,⁹⁴ the court “agree[d] with the analysis provided by the District Court in *Friedman*” and denied the plaintiffs’ request to use statistical sampling for proving liability.⁹⁵ In applying the principles of *Friedman* to the facts of its own case, the court in *Michaels* noted that “the patients’ medical charts are all intact and available for review by either party,” and thus a claim-by-claim examination of each patient’s medical charts was necessary for determining liability.⁹⁶ In a broader sense, the court’s holding seems to imply that extrapolation is not warranted in highly fact-sensitive cases where each claim is distinct, unique, and warrants individual examination.⁹⁷

Two other cases, *United States ex rel. El-Amin v. George Washington University* and *United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, also espouse these principles. In *El-Amin*, the defendant health care organization was accused of overbilling for anesthesia services.⁹⁸ The relators alleged that the defendants had defrauded Medicare by falsely representing that certain anesthesia procedures had been wholly performed by a licensed anesthesiologist, “when in fact portions of the procedure had been performed by residents or [nurse anesthetists].”⁹⁹ Each claim thus necessarily turned on what type of procedure was being performed and who had performed it.¹⁰⁰ In denying the use of statistical sampling, the court alluded to the fact-specific nature of the case, stating that “[f]or each claim, the Relators will be expected to provide, at a minimum, the date the claim was filed with Medicare, the name of the attending anesthesiologist, the type

⁹² See *id.*

⁹³ See *id.*

⁹⁴ *United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. 0:12-3466-JFA, 2015 U.S. Dist. LEXIS 82379 (D.S.C. June 25, 2015), *interlocutory appeal dismissed*, 848 F.3d 330 (4th Cir. 2017). On interlocutory appeal, the Fourth Circuit held that “the relators’ appeal [as to the question of statistical sampling] does not present a pure question of law that is subject to our interlocutory review” and thus dismissed the appeal as improvidently granted. *United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, 848 F.3d 330, 341 (4th Cir. 2017).

⁹⁵ *Michaels*, 2015 U.S. Dist. LEXIS 82379, at *20.

⁹⁶ See *id.* at *19–20.

⁹⁷ *Id.* at *5 (“Each and every claim at issue in this case is fact-dependent and wholly unrelated to each and every other claim.”).

⁹⁸ *United States ex rel. El-Amin v. George Washington Univ.*, 533 F. Supp. 2d 12, 18 (D.D.C. 2008).

⁹⁹ *Id.*

¹⁰⁰ See *id.* at 18–19, 26–27.

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of medical procedure involved, and the amount of the claim.”¹⁰¹ Similarly, the court in *Hockett*—a case concerning fraudulent activity related to the length of patient stays—declined to allow statistical sampling due in part to the highly fact-sensitive nature of the case.¹⁰² In particular, the court noted that in each particular claim, there could be “many other, completely innocuous alternative explanations for the increased length of patient stays – such as the patients just getting sicker.”¹⁰³ Thus, with the facts for each claim in doubt, the court opted for a traditional claim-by-claim review as opposed to statistical sampling.

As demonstrated in *Michaels*, *El-Amin*, and *Hockett*, statistical sampling is perhaps a poor tool in cases where there are large numbers of separate and distinct claims. The courts in these cases seemed to be in agreement that the presence of discrete and factually sensitive claims warranted a claim-by-claim analysis of the relevant evidence. To submit such fact-intensive inquiries to a broad and sweeping extrapolation test is simply counterintuitive, and the principle behind statistical extrapolation—that a small sample can be necessarily representative of a larger sample—loses much of its steam when applied to a situation where each item within the sample is distinctive from every other.¹⁰⁴

B. The Need for Concrete Evidence in FCA Cases

Closely related to the issue of fact-specificity is the necessity, at least in the belief of some courts, for the government and private relators to prove FCA claims with specific and concrete evidence.¹⁰⁵ In *Hockett*, for instance, the court held that “[w]elding different inferences together [through statistical sampling] cannot substitute for direct proof.”¹⁰⁶ Moreover, the court stated that it was “imperative for [the] relator to produce real evidence to support her contention that patients were actually held longer than necessary” as part of the defendant’s scheme to defraud the government.¹⁰⁷

¹⁰¹ *Id.* at 31 n.9.

¹⁰² See *United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25, 65–66 (D.D.C. 2007).

¹⁰³ *Id.* at 66.

¹⁰⁴ Statistical sampling works best where the sample is truly representative of the whole and where there is a great degree of homogeneity. Highly discrete and fact-sensitive claims necessarily obfuscate the certainty with which the statistical model can be said to be homogenous and representative of the whole. See *supra* notes 83–85 and accompanying text.

¹⁰⁵ The issues of fact-specificity and the need for concrete evidence converge, and at times conflate, at many points. This is due to the fact that highly fact-specific claims necessarily entail a great deal of evidence. As a result, many courts dealing with a highly fact-specific set of claims often raise the additional issue of the need for concrete evidence in proving each specific claim.

¹⁰⁶ *Hockett*, 498 F. Supp. 2d at 66.

¹⁰⁷ *Id.*

Though the court was cognizant of the fact that “where some degree of liability is conceded, slight deviations from traditional modes of proof are tolerable,”¹⁰⁸ it nevertheless held firm in its holding that statistical sampling could not by itself form a basis for liability in the absence of direct proof and concrete evidence.¹⁰⁹

United States ex rel. Crews v. NCS Healthcare of Illinois, Inc., a case out of the Seventh Circuit, further expounded on these principles. In *Crews*, the plaintiff-relators brought suit against a pharmaceutical company for the illegal recycling and repurposing of prescription drugs.¹¹⁰ The plaintiff’s statistical sampling methodology was based on the assertion that “[a]ll claims for recycled and redispensed [sic] medications . . . are false claims” as a matter of law.¹¹¹ Working off of this assumption, the plaintiffs then calculated the number of false claims based on the percentage of patients on Medicaid and the percentage of dispensed medications returned unused.¹¹² The plaintiffs next argued that the result of this calculation conclusively “prove[d] that [six percent] to [twelve percent] of recycled drugs would have been [re]distributed to Medicaid recipients” had it not been for the defendant’s fraudulent activity, and that the defendant was thus liable to this extent.¹¹³ In upholding the defendant’s summary judgment motion, the United States Court of Appeals for the Seventh Circuit held that the plaintiff could not simply rely on a bare calculation to prove liability, but rather had the burden of establishing liability with proof of actual false claims.¹¹⁴

C. *The Strange Case of Federal Rule of Civil Procedure 9(b)*

The need for concrete evidence to prove liability in FCA cases may also have a statutory basis in the form of Federal Rule of Civil Procedure 9(b), which states in pertinent part: “In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.”¹¹⁵ Thus, “[u]nder Rule 9(b), mere conclusory allegations of falsity are insufficient; rather, the plaintiff must set forth what is false or misleading about a statement, and why it is false.”¹¹⁶ The mandate of Rule 9(b) would apply to statistical sampling in the sense that each claim must be proven on

¹⁰⁸ *Id.* at 67.

¹⁰⁹ *See id.* at 65–67.

¹¹⁰ *United States ex rel. Crews v. NCS Healthcare of Ill., Inc.*, 460 F.3d 853, 854–55 (7th Cir. 2006).

¹¹¹ *Id.* at 856.

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.*; *see also* *United States ex rel. Trim v. McKean*, 31 F. Supp. 2d 1308, 1314 (W.D. Okla. 1998) (declining to allow a pure percentage calculation to prove liability).

¹¹⁵ FED. R. CIV. P. 9(b).

¹¹⁶ *Behre & Ifrah, supra* note 83, at 22.

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its own terms; liability cannot be proven for a particular claim simply through extrapolation based on a statistical model. The Department of Justice originally took the position that Rule 9(b) did not apply to cases brought under the FCA.¹¹⁷ A string of court rulings in the late 1990s, however, made clear that Rule 9(b) did, in fact, apply to FCA cases.¹¹⁸

At least one court has endorsed the view that Rule 9(b) prohibits the use of statistical sampling to prove liability. In *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, the plaintiff-relator alleged that the defendant physician had violated the FCA by submitting claims for unnecessary services.¹¹⁹ To support these allegations, the plaintiff put forward as evidence a statistical calculation showing that “in reasonable probability . . . approximately [forty] percent of claims submitted by defendants for services rendered . . . were for services that were not medically necessary.”¹²⁰ In affirming a judgment dismissing the plaintiff’s claims, the court held that the plaintiff had failed to satisfy the requirements of Federal Rule of Civil Procedure 9(b) because he “provided no factual basis for his belief that defendants submitted claims for medically unnecessary services other than his reference to statistical studies.”¹²¹ The plaintiff’s “allegations, therefore, amount[ed] to nothing more than speculation.”¹²²

But neither *Thompson* nor its approach to Federal Rule of Civil Procedure 9(b) has remained relevant in the debate over statistical sampling, despite it being a well-reasoned appellate decision and a seemingly perfect case for courts looking to add precedential support to a holding that statistical sampling cannot be used for purposes of proving liability.¹²³ Indeed, despite its seeming relevancy, Federal Rule of Civil Procedure 9(b) has faded entirely from both the case law and scholarship related to statistical sampling.¹²⁴ It is thus fair to say at this point in the debate that whether a court is willing to allow statistical sampling will depend almost entirely on its own judgment of the need for concrete evidence for proving specific claims.

¹¹⁷ *Id.*

¹¹⁸ *See id.*

¹¹⁹ *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 901 (5th Cir. 1997).

¹²⁰ *Id.* at 903.

¹²¹ *Id.*

¹²² *Id.*

¹²³ *Thompson*, despite being a relatively older case, is not cited, either positively or negatively, in any other case appearing in this Comment.

¹²⁴ *Thompson* is the only case appearing in this comment that interprets Federal Rule of Civil Procedure 9(b) as having any effect on the use of statistical sampling in FCA cases.

D. Possible Shortcomings in Cases that Have Disallowed Statistical Sampling

Much like the cases that have allowed statistical sampling, the cases that have disallowed the use of statistical sampling have not provided a clear and workable framework for when statistical sampling should be permitted and when it should not. Also, many, if not all, of the courts that have prohibited statistical sampling for proving liability have largely ignored or dismissed out-of-hand many of the strongest arguments espousing its permissibility, such as the fact that claim-by-claim review may be impossible where there is a large universe of claims.¹²⁵ Nor have these courts addressed the idea that statistical sampling may be warranted in a case where the claims are not highly fact-specific, and thus evidence of guilt in one claim necessarily implies evidence of guilt in the entire universe of claims.¹²⁶ These courts have thus warned of the dangers of statistical sampling—dangers which may well be relevant to the facts of the case at hand¹²⁷—without contemplating that there may be fact patterns where these dangers are extremely limited or totally non-existent. And simply because statistical sampling is not warranted—or is somehow dubious—as applied to a particular case, does not necessarily mean that it is never warranted in any case.

V. A UNIFIED FRAMEWORK FOR STATISTICAL SAMPLING

That courts have come out differently on the matter of statistical sampling does not necessarily mean that one side or the other is deciding the cases incorrectly. On the contrary, the different outcomes may be explained by fundamentally different sets of facts, where the problems of one approach are clearly evident and the problems of the other approach are minimal. The problem, it may be said, is not so much one of legal and interpretational conflict as much as it is the lack of a unifying principle for determining when statistical sampling can be used and when it cannot. This may be due to the fact that most of the courts that have decided issues related to statistical

¹²⁵ *But see* United States *ex rel.* Michaels v. Agape Senior Cmty., Inc., No. 0:12-3466-JFA, 2015 U.S. Dist. LEXIS 82379, at *18 (D.S.C. June 25, 2015) (inferring that statistical sampling may be permissible where evidence has been destroyed), *interlocutory appeal dismissed*, 848 F.3d 330 (4th Cir. 2017).

¹²⁶ This is perhaps due in part to the fact that the courts that have disallowed the use of statistical sampling have not confronted a case in which the universe of claims was sufficiently homogenous. *See, e.g.,* United States v. Friedman, No. 86-0610-MA, 1993 U.S. Dist. LEXIS 21496, *9 n.1 (D. Mass. July 23, 1993) (emphasis added) (noting the “existence at trial of *discrete* claims”).

¹²⁷ *See* United States *ex rel.* Hockett v. Columbia/HCA Healthcare Corp., 498 F. Supp. 2d 25, 66 (D.D.C. 2007) (noting a concern that statistical sampling allows a finding of liability through merely “[w]elding different inferences together”).

sampling are district courts, and there is thus less of an impetus in creating law—and thus a unified framework—than there is in simply deciding the case correctly on its facts.

The ensuing framework that forms the basis for this portion of the Comment will be an attempt to consolidate the various competing factors on both sides of the statistical sampling debate. Ultimately, it will call for a restrained approach to the use of statistical sampling, placing the burden on the plaintiff to show why the use of statistical sampling is warranted. In meeting this burden, the plaintiff will have to show some form of undue hardship that necessitates the use of statistical sampling. Finally, in determining whether the plaintiff has met this burden, the court should look to three categories: (1) the number of claims; (2) whether the level of fact-specificity and the discreteness of the individual claims is such that claim-by-claim review is necessary; and (3) other factors that may bear on the total outcome of the case, such as bad faith or consent of the parties. The effect of this framework, at least in a theoretical sense, will be to allow statistical sampling where it is necessary as the only viable way to ensure recovery, while denying the use of statistical sampling in cases where claim-by-claim review is feasible and necessary.

A. The Need for a Cautious Approach to Statistical Sampling

It would not be unfair to ask why the plaintiff should have the burden of demonstrating that statistical sampling should be used in a given case. Indeed, it has been argued that there is nothing wrong with using a “straightforward application of a long-standing and highly efficient [methodology] . . . to efficiently and accurately provide evidence as to liability.”¹²⁸ The answer lies in the fact that proving liability is a fundamentally different matter from proving damages. It is one thing to allow a statistical model for a damages calculation where liability has already been proven; it is quite another to allow a statistical model as the only means of proving liability, and without any claim-by-claim examination. Proving liability implicates concerns, problems, and procedural requirements that simply do not factor into a damages analysis.¹²⁹ This is especially true given the “quasi-criminal” nature of the FCA.¹³⁰ Indeed, the argument could be made “that such extrapolation would unfairly, or at least prematurely, shift the burden to the [defendant].”¹³¹ Simply put, the speed and efficiency of statistical sampling is not worth its procedural infirmities in cases where claim-by-claim review is otherwise available. It is therefore necessary for

¹²⁸ Markey & Sarola, *supra* note 15.

¹²⁹ See Behre & Ifrah, *supra* note 83, at 22.

¹³⁰ See *id.*

¹³¹ See *id.*

the plaintiff to show something more—some form of hardship—before statistical sampling is warranted.

Courts endorsing the use of statistical sampling have tried to argue around the issue of burden shifting. In *Martin* for instance, the court argued that no burden shifting had taken place because the defendant still had “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.”¹³² The court further solidified its approach to the subject by noting that the jury would provide a necessary check on the potential abuses of statistical sampling.¹³³ But this perhaps misses the point. If statistical sampling is not necessary, or even unwarranted in a particular case, there is simply no valid reason to complicate the matter and risk confusing the jury solely in the name of efficiency. This problem is exacerbated by the fact that statistical sampling methodology can be quite complicated.¹³⁴ It is not a stretch to say that a jury will be inclined to believe, perhaps without question, an expert’s declaration that a defendant is liable for a certain percentage of the total number of claims. If the defendant calls an expert witness to dispute the plaintiff expert’s methodology, then the case will devolve into a mathematical dispute even where there is readily available evidence to assess each claim on its own merits. This result is simply untenable where the plaintiff has not shown that statistical sampling is necessary.

It has also been argued that statistical sampling is necessary as a deterrent to stop the widespread perpetuation of fraud and to ensure that the government receives a full recovery of the money it has lost through fraud.¹³⁵ This is certainly true of cases where there are a large number of homogenous claims.¹³⁶ It is far less certain in cases with a smaller number of discrete claims. More importantly, this argument ignores the fact that the FCA contains both a treble damages provision as well as the potential for significant fines.¹³⁷ This means that for every claim where liability is found the government is receiving essentially three claims worth of recovery, even without consideration of potential fines. This greatly undermines any notion that statistical sampling is necessary as a deterrent or as a way of assuring

¹³² *United States ex rel. Martin v. Life Care Ctrs. Of Am., Inc.*, 114 F. Supp. 549, 570 (E.D. Tenn. 2014).

¹³³ *Id.* at 572.

¹³⁴ *See United States ex rel. Ruckh v. Genoa Healthcare, LLC*, No. 8:11-cv-1303-T-23TBM, 2015 U.S. Dist. LEXIS 55384, at *7 (M.D. Fla. Apr. 28, 2015) (explaining the complex methodology of statistical sampling through expert witness testimony).

¹³⁵ *See Markey & Sarola, supra* note 15.

¹³⁶ *See id.* (arguing that statistical sampling is especially warranted in cases where there are a large number of claims).

¹³⁷ *See supra* note 31 and accompanying text.

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full recovery. On the contrary, it may be argued that the use of statistical sampling in conjunction with fines and treble damages is quite plainly punitive.¹³⁸

B. Determining Whether the Plaintiff Has Met the Burden of Establishing that Statistical Sampling is Warranted

With the need for a restrained approach to statistical sampling—and thus a presumption against its use—now established, it is now necessary to provide an analysis of the factors courts must consider in determining whether the plaintiff has successfully met its burden of showing that statistical sampling is warranted by the facts of the case. The ensuing three-factor test is a synthesis of the various concerns and considerations framing the statistical sampling debate. It is designed to provide a flexible framework that can be applied to the facts of any given case. No factor in this test is solely determinative, and it is open to a significant amount of interpretation. This malleability is necessary, however, given the wide range of factual scenarios arising in health care fraud cases. It should be noted that, before this three-factor test can be applied, the plaintiffs must prove liability in at least one instance.¹³⁹ A bare statistical calculation applied to the entire universe of claims will not suffice without an underlying finding of liability based on some form of concrete evidence.¹⁴⁰

1. The Number of Claims

There is an unavoidable connection between the number of claims in a case and the fact-specificity of the claims at issue. On one hand, a high number of claims undoubtedly warrant the use of statistical sampling.¹⁴¹ On the other hand, a universe of highly discrete claims warrants claim-by-claim review.¹⁴² It seems clear, however, that where claim-by-claim review is completely untenable due to a large number of claims, statistical sampling is warranted.¹⁴³ This is especially true considering the fact that “large-scale perpetrators of fraud would reap the benefits” of a system that did not allow statistical sampling in cases with a large number of claims, “because the

¹³⁸ See Behre & Ifrah, *supra* note 83, at 22 (arguing that the government’s use of a “bloated damages provision which is the trebled” is primarily a way of strong-arming defendants into settlements).

¹³⁹ See *United States ex rel. Crews v. NCS Healthcare of Ill., Inc.*, 460 F.3d 853, 856 (7th Cir. 2006).

¹⁴⁰ See *supra* notes 110–114 and accompanying text.

¹⁴¹ See *supra* notes 61–63 and accompanying text.

¹⁴² See *supra* notes 91–97 and accompanying text.

¹⁴³ *United States ex rel. Martin v. Life Care Ctrs. of Am., Inc.*, 114 F. Supp. 3d 549, 565 (E.D. Tenn. 2014) (arguing that statistical sampling is warranted where there is not a sufficiently limited universe of claims).

government could not possibly pursue each individual false claim.”¹⁴⁴ Indeed, it may be said that *Martin*, in allowing extrapolation to the tens of thousands of total claims at issue, “ensured perpetrators of fraud would not be able to escape liability because of the broad scope of their fraud.”¹⁴⁵ At the same time, *Michaels*, in not allowing a statistical model to extrapolate for thousands of claims at issue, may well have been wrongly decided.¹⁴⁶

The point at which the number of total claims makes claim-by-claim review untenable will be a function of the claims’ overall discreteness. A high number of discrete, fact-specific claims will require a greater number of total claims before the court determines that claim-by-claim review is unfeasible. Conversely, the court can allow statistical sampling for a much lower number of claims where the claims at issue are largely homogenous.¹⁴⁷ In this way, the first factor of the framework serves the double purpose of allowing statistical sampling where it is absolutely necessary or where the risks are relatively small, while also protecting against its use where the claims’ discreteness warrants a greater deference to claim-by-claim review.

2. Whether the Level of Fact-Specificity and the Discreteness of the Individual Claims is Such that Claim-by-Claim Review is Necessary

The second part of the framework is designed to ensure that statistical sampling will rarely, if ever, be used where claim-by-claim review is feasible. The only exception would be where the claims are so homogenous in nature that proof of liability in one claim necessarily means a proof of liability in all, or at least a substantial number, of claims.¹⁴⁸ The principle behind this factor is simply that it runs counter to the basic and long-established principles of American jurisprudence to relieve the plaintiff from presenting specific evidence for each individual claim when such evidence is readily available.¹⁴⁹ Had statistical sampling been used in cases such as *Michaels* or *El-Amin*, the court would have essentially been allowing an

¹⁴⁴ *Id.* at 571.

¹⁴⁵ *Recent Case: False Claims Act*, *supra* note 74.

¹⁴⁶ See *United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. 0:12-3466-JFA, 2015 U.S. Dist. LEXIS 82379, at *3 (D.S.C. June 25, 2015) (“The total number of claims involved in the trial will be staggering.”), *interlocutory appeal dismissed*, 848 F.3d 330 (4th Cir. 2017).

¹⁴⁷ See *supra* notes 83–85 and accompanying text.

¹⁴⁸ See *United States v. Chen*, 402 F. App’x 185, 188–89 (9th Cir. 2010) (statistical sampling used at trial where defendant physician conceded that the services provided were the same for each claim at issue).

¹⁴⁹ See *Michaels*, 2015 U.S. Dist. LEXIS 82379, at *19–20 (disallowing the use of statistical sampling where specific evidence, including patient medical charts, were available for the parties’ review).

inference to take the place of readily available hard evidence.¹⁵⁰ While there is an understandable need for expediency in litigation, the price of ignoring especially relevant evidence in the place of an inference hardly seems worth the risk. In essence, the plaintiff will be unable to meet its burden of demonstrating that statistical sampling is warranted so long as the total number of claims is manageable in number and sufficiently discrete and heterogeneous in composition.

It should also be made clear exactly what is meant by terms such as “fact-specificity” and “discreteness.” For purposes of this framework, these terms apply to the level of homogeneity within a particular universe of claims. For example, a defendant in a particular case may provide only one type of health care service and the claims at issue may apply to only one type of treatment or billing procedure.¹⁵¹ In such a case, there would be a high level of homogeneity in the total universe of claims because every claim at issue relates to roughly the same type of fraudulent activity conducted in roughly the same way. The fact-specificity and discreteness of each individual claim would therefore be relatively small.

By contrast, a particular universe of claims may be highly discrete where the defendant operates multiple businesses in multiple states and in varying forms of health care practice and treatment.¹⁵² In such an instance, a statistical model based on data from a specific institution in a specific state would have little relation to other claims stemming from other institutions in other states. A trial court would thus be forced to determine whether statistical sampling is feasible given the defendant’s complex administrative scheme.

3. Other Mitigating Factors

This third category is designed as a catchall category for any number of extenuating circumstances that may warrant the use of statistical sampling. For instance, statistical sampling would be perfectly permissible where the defendant has consented to its use.¹⁵³ Likewise, statistical sampling would be permissible where a default judgment has been entered

¹⁵⁰ See *supra* notes 96–101 and accompanying text.

¹⁵¹ See *Chen*, 185 Fed. App’x at 188–89 (conveying how the jury found the physician liable under the FCA for submitting 3,544 false claims, but the parties only analyzed 37 claims at trial after the physician conceded that the referral request and services provided were the same for each of these claims).

¹⁵² See *United States ex rel. Trim v. McKean*, 31 F. Supp. 2d 1308, 1314 (W.D. Okla. 1998) (noting that the defendant’s interstate business model greatly complicated the use of statistical sampling).

¹⁵³ See *United States v. Krizek*, 859 F. Supp. 5, 7 (D.D.C. 1994) *supplemented*, 909 F. Supp. 32 (D.D.C. 1995), *aff’d in part and remanded*, 111 F.3d 934 (D.C. Cir. 1997) (defendant physician consented to sampling).

against the defendant.¹⁵⁴ It would also be warranted where there has been bad faith on the part of the defendants, or where the destruction of evidence has left the plaintiff, through no fault of its own, with no other feasible means of proving liability.¹⁵⁵ Courts should use caution and restraint, however, in deciding when novel circumstances call for the use of statistical sampling for proving liability.

VI. CONCLUSION

Statistical sampling has the potential to be an extremely powerful tool if permitted for use in proving liability in FCA cases.¹⁵⁶ As such, its application warrants a great degree of thoughtfulness, lest its uninhibited use become a vehicle for abuse. The fact that statistical sampling carries with it both numerous benefits and numerous drawbacks only creates further complexity. And with health care fraud cases increasing each year, the need for a resolution to the divided view on statistical sampling is not only necessary, but also pressing.

By creating a unified framework under which all statistical sampling cases can be analyzed, this Comment hopes to bridge the divide between the courts by expounding a set of principles that allows for statistical sampling when the benefits are large and the risks are small, and which prohibits statistical sampling where the benefits are slight and the risks are pervasive. Ultimately, this framework seeks to ensure the dual purposes of not allowing “widespread fraud to go unpunished,”¹⁵⁷ while also minimizing the risk that plaintiffs will be able to bypass traditional procedural safeguards where doing so would not be helpful or necessary.¹⁵⁸ The result is a standard for analyzing statistical sampling that ensures fundamental fairness for the parties, predictable results, and a stable set of enduring principles against which future claims can be analyzed.

¹⁵⁴ See *United States v. Cabrera-Diaz*, 106 F. Supp. 2d 234, 242 (D.P.R. 2000) (basing damages calculation off of estimated overpayments after entry of a default judgment).

¹⁵⁵ See *United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. 0:12-3466-JFA, 2015 U.S. Dist. LEXIS 82379, at *19–20 (D.S.C. June 25, 2015) (inferring that use of statistical sampling would be proper where evidence has been destroyed), *interlocutory appeal dismissed*, 848 F.3d 330 (4th Cir. 2017).

¹⁵⁶ Markey & Sarola, *supra* note 15.

¹⁵⁷ *Michaels*, 2015 U.S. Dist. LEXIS 82379, at *19.

¹⁵⁸ See *Behre & Ifrah*, *supra* note 83, at 22 (implying that statistical sampling affords defendants insufficient process).