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Peter T. Thomas[*]

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I. Introduction

The False Claims Act (FCA)[1] is a civil anti-fraud statute covering the intersection between the private sector and the government.[2] Originally designed to shield against contractor fraud during the Civil War,[3] the FCA is now one of the government's primary weapons for attacking potential fraud in industries that accept federal funds.[4] In the 2015 fiscal year, the government recovered over $3.5 billion in FCA settlements and judgments, compared to just over $1 billion in 2005 and $500 million in 1995.[5] As modern FCA litigation evolves in a climate where federal programs become more and more intertwined with the economy, the government and private plaintiffs have sought to use a mathematical process known as "statistical sampling" or "extrapolation" to facilitate the efficient resolution of large cases.[6]

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1. *See* 31 U.S.C. §§ 3729–33 (2012) (creating liability for fraudulent acts against the government).

2. *See* 1 JOHN T. BOESE, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS 1-5 (4th ed. 2011) (summarizing the FCA's history and purpose).

3. *See id.* (describing Congress's motivation in enacting the FCA).

4. *See* David Freeman Engstrom, *Public Regulation of Private Enforcement: Empirical Analysis of DOJ Oversight of Qui Tam Litigation Under the False Claims Act*, 107 NW. U. L. REV. 1689, 1707 (2013) (noting the trends in modern FCA litigation).

5. *See Fraud Statistics—Overview* 1–2, DEP'T OF JUST. (Nov. 23, 2015), https://www.justice.gov/opa/file/796866/download (last visited Oct. 27, 2017) (providing statistics on FCA recoveries since 1987) (on file with the Washington and Lee Law Review).

6. *See* United States v. Life Care Centers of Am., Inc., 114 F. Supp. 3d 549, 560 (E.D. Tenn. 2014) (listing previous cases where a party attempted to use statistical sampling).

Statistical sampling is a process where the parties try a small sample out of a larger body of claims in a bellwether trial.[7] An expert witness then extrapolates the rate of claims proved false in that sample to the larger body of claims.[8] In the FCA context, courts have generally recognized statistical sampling as an acceptable method for calculating damages where liability is uncontested or previously determined.[9]

The purpose of this Note is to examine the legal arguments underlying the question of whether statistical sampling can establish FCA liability as a matter of law. Relators[10] and the government consider sampling to be "indispensable" in their efforts to "combat increasingly widespread and systemic" fraud,[11] while defendants argue that statistical sampling is poorly suited

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7. *See* WILLIAM B. RUBENSTEIN, NEWBURG ON CLASS ACTIONS § 11:11 (5th ed. 2013) (describing bellwether trials as a potential solution for "situation[s] that ha[ve] engendered hundreds or thousands of individual . . . cases," and stating that plaintiffs use bellwether trials to approximate the strength of all the claims). A bellwether trial deals with only a portion of a larger case that can serve as a test for the potential success of the remaining portions of the case. *See id.* ("Because the few help lead to settlement of the whole, they are labeled 'bellwether,' in reference to the male sheep (wether) adorned with a bell to lead his flock.").

8. *See id.* § 11:21 (discussing the concept of statistical sampling).

9. *See, e.g.*, United States v. Vista Hospice Care, Inc., No. 3:07–CV–00604–M, 2016 WL 3449833, at *12 n.100 (N.D. Tex. June 20, 2016) (noting statistical sampling's use in FCA litigation for damages calculations); United States v. Cabrera-Diaz, 106 F. Supp. 2d 234, 240–41 (D.P.R. 2000) (applying statistical sampling in calculating damages only). When using statistical sampling to prove damages, the government attempts to prove the dollar amount of overpayment for a sample number of claims, then extrapolates that amount of average overpayment per claim to every claim in the full universe for a grand total amount of overpayment. *See* United States v. Fadul, No. DKC 11–0885, 2013 WL 781614, at *14 (D. Md. Feb. 28, 2013) (explaining a statistical sampling methodology for calculating damages).

10. *See* MCKENNA LONGA, ALDRIDGE LLP & RONALD A. KIENLEN, GOV'T CONTRACT DISPUTES § 23:8 (2016) (defining the term "relator"). Whenever this Note references the government as a litigation party, it intends to also incorporate relators because they litigate on behalf of the government. *See id.* (same).

11. Public Brief for the United States as Intervenor-Appellee at 39, United States *ex rel.* Michaels v. Agape Senior Cmty., Inc., No. 15–2145 (4th Cir. Oct. 26, 2016).

for proving the FCA's essential elements.[12] In 2014, a district court in Tennessee ruled for the first time[13] in *United States v. Life Care Centers of America, Inc.*[14] that statistical sampling could establish liability under the FCA.[15] More recently, a Texas district court ruled in *United States v. Vista Hospice Care, Inc.*[16] that statistical sampling could not establish FCA liability.[17] The question of whether statistical sampling can ever be used to establish FCA liability is an emerging issue that a federal appellate court has not yet decided.[18]

Courts could rule on statistical sampling's permissibility on two distinct grounds. The first is an evidentiary determination as to whether a particular methodology meets the scientific criteria set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*[19] The

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12. Brief of Defendants-Appellees Agape Senior Community Inc., et al. at 19, United States *ex rel.* Michaels v. Agape Senior Cmty., Inc., No. 15–2145 (4th Cir. Feb. 14, 2017).

13. *See* Case Comment, *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, 2081 (2015) (discussing *Life Care* and its impact).

14. 114 F. Supp. 3d 549 (E.D. Tenn. 2014).

15. *See id.* at 571 (allowing statistical sampling to establish liability).

16. No. 3:07–CV–00604–M, 2016 WL 3449833 (N.D. Tex. June 20, 2016).

17. *See id.* at *13 (ruling that "proof regarding one claim does not meet Relator's burden of proof regarding other claims" in addition to finding that the particular expert's methodology was flawed).

18. *See id.* at *12 (acknowledging a split amongst district courts in several circuits).

19. 509 U.S. 579 (1993); *see also* United States *ex rel.* Loughren v. UnumProvident Corp., 604 F. Supp. 2d 259, 269 (D. Mass. 2009) (excluding the relator's methodology of statistical sampling for establishing FCA liability due to insufficient reliability). *Daubert* requires trial judges to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable" under Federal Rules of Evidence Rule 702. 509 U.S. at 589; *see also* FED. R. EVID. 702 (permitting expert witness testimony where it is based on "(a) the expert's scientific . . . knowledge [that] will help the trier of fact . . . determine a fact in issue, (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts . . . ."). The Federal Rules of Evidence and *Daubert* govern the admissibility of statistical sampling testimony,

second is a legal determination as to whether FCA liability can ever be established using statistical sampling.[20] This Note focuses on sampling's legal sufficiency for proving FCA liability.

Part II will outline the promulgation and operation of the FCA, as well as statistical sampling as it relates to both the FCA and liability in other contexts.[21] Part III will discuss the recent split among the district courts regarding whether statistical sampling can establish FCA liability.[22] Part IV will analyze how

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which is a separate analysis from evaluating its legal sufficiency for proving each FCA element. *See* United States v. Life Care Centers of Am., Inc., 114 F. Supp. 3d 549, 572 (E.D. Tenn. 2014) (noting that the court's determination "does not decide the parties' pending motions regarding the admissibility of expert testimony"). Statistical sampling introduces a range of evidentiary concerns regarding the scientific reliability of any given sampling methodology, the problems with the accuracy of a sample's representation of the whole universe under examination, the so-called "blue bus" problem and the fairness concerns it raises, and the prohibition of propensity evidence under the Federal Rules of Evidence Rule 404(b). *See* Neil Issar, *More Data Mining for Medical Misrepresentation? Admissibility of Statistical Proof Derived from Predictive Methods of Detecting Medical Reimbursement Fraud*, 42 N. Ky. L. Rev. 341, 360–73 (2015) (discussing evidentiary issues with statistical sampling in healthcare fraud). Despite the evidentiary concerns with statistical sampling, one circuit court has found that statistical sampling can at least be used at the pleading stage. *See* United States *ex rel.* Customs Fraud Investigations, LLC v. Victaulic Co., 839 F.3d 242, 256–57 (3d Cir. 2016) (reviewing a motion to dismiss a complaint basing its allegations off a statistical sampling methodology). Although the samples were likely not "an accurate proxy" for the claims in question, the Third Circuit found that sampling could support a complaint's plausibility when judged without "any credibility determination[.]" *Id.* That court noted its skepticism of the methodology's validity, but ruled that such skepticism was not best placed at the pleading stage. *See id.* at 257 ("There is little evidence to show that [the relator's] unusual procedure of reviewing eBay listings is an accurate proxy for the universe of [the defendant's] products available for sale in the United States."). This pleading determination and the evidentiary admissibility of statistical sampling are closely related issues to the topic of this Note, but should not be confused with the question of statistical sampling's legal sufficiency for proving FCA liability.

20.   *See* United States v. Life Care Centers of Am., Inc., 114 F. Supp. 3d 549, 571 (E.D. Tenn. 2014) (ruling on whether statistical sampling is "a legally viable mechanism, which the Government may employ in attempting to prove . . . FCA claims").

21.   *Infra* Part II. The False Claims Act and Statistical Sampling

22.   *Infra* Part III. The Split on Statistical Sampling in the FCA Context

statistical sampling relates to the FCA's liability requirements and address the associated burden shifting and due process concerns.[23] Part V concludes that the FCA requires the government to identify each false claim individually to establish liability.[24]

II. The False Claims Act and Statistical Sampling

This Part provides a brief historical overview of the FCA and discusses the statute's current structure. It then examines previous uses of statistical sampling for damages calculations in the FCA context and explores cases from other areas of law that consider the use of statistical sampling for establishing liability.

A. History of the FCA

Congress enacted the FCA in 1863 as a tool for "prevent[ing] and punish[ing] frauds upon the government of the United States."[25] Concern with "frauds and corruptions practiced in obtaining pay from the government during the [Civil War]" motivated a forceful legislative response.[26] The Act created liability for a number of actions negatively affecting the government fisc,[27] set the damages and penalties that the government can recover,[28] and permitted private citizens to bring suit on behalf of the

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23.   *Infra* Part IV. The Legal Sufficiency of Statistical Sampling for Proving FCA Liability

24.   *Infra* Part V. Conclusion

25.   Act of Mar. 2, 1863, ch. 67, 12 Stat. 696.

26.   CONG. GLOBE, 37th Cong., 3d Sess. 952 (1863).

27.   *See* Act of Mar. 2, 1863, ch. 67, § 1, 12 Stat. 696, (defining violations of the Act).

28.   *See id.* § 3 (establishing double damages, civil penalties, and costs to be assessed against private citizens found in violation of the statute and for court marshals in cases involving military personnel).

government.[29] FCA suits brought by private citizen plaintiffs are known as *qui tam* actions.[30]

In 1986, Congress amended the FCA in order to better facilitate *qui tam* actions,[31] increase recoveries by raising the damages multiplier and civil penalties,[32] define the *scienter* requirement,[33] and clearly establish preponderance of the evidence as the burden of proof for each FCA element.[34] The Fraud Enforcement and Recovery Act of 2009 (FERA)[35] again amended the FCA[36] to remove a judicially created requirement that false claims be presented to a government employee.[37] This amendment also created a statutory definition for the materiality element.[38] There have also been two more recent amendments that are not relevant to statistical sampling.[39]

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29.   *See id.* § 4 (allowing a private person to bring suit under the Act on behalf of the government).

30.   *See* Vt. Agency of Nat. Resources v. United States *ex rel.* Stevens, 529 U.S. 765, 768–69 (2000) (examining the ability of relators to bring *qui tam* actions on behalf of the government).

31.   *See* S. REP. NO. 99-345, at 2 (1986) ("The proposed legislation seeks . . . to provide the Government's law enforcers with more effective tools . . . .").

32.   *See id.* at 17 (increasing the damages multiplier and penalties).

33.   *See id.* at 20 (clarifying the definition of knowledge under the FCA).

34.   *See id.* at 30–31 (stating the burden of proof under the FCA).

35.   Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1621 (2009) (amending the FCA).

36.   *See id.* (amending the FCA); *see also* S. REP. NO. 111-10, at 10–11 (2009) (altering language in the FCA relied upon by the Supreme Court in *Allison Engine Co., Inc. v. United States ex rel. Sanders*, 553 U.S. 662 (2008), when determining that the FCA required an intent "to get" the government to pay the amount falsely claimed).

37.   *See* Allison Engine Co., Inc. v. United States *ex rel.* Sanders, 553 U.S. 662, 668–69 (2008) (basing an additional intent requirement that a defendant have the "purpose of getting a false . . . claim paid or approved by the Government" on the language "to get").

38.   *See* S. REP. NO. 111-10 at 12 (2009) ("[T]he new term 'material' is defined later in this section to mean 'having a natural tendency to influence, or being capable of influencing, the payment or receipt of money or property.'").

39.   *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 10104(j)(2), 124 Stat. 119, 901 (2010) (modifying the public disclosure bar); Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, § 1079A(c), 124 Stat. 1376, 2079–80 (2010) (amending the FCA's

B. The FCA in Its Present Form

The FCA creates liability for seven types of conduct against the government: (1) direct submission of a false claim, (2) creation of false records material to a false claim, (3) conspiracy to violate the FCA, (4) incomplete delivery of government money or property, (5) delivery of a false receipt of government property use, (6) purchase of property from a government employee where the sale is unlawful, and (7) making a false claim to avoid or reduce obligations to pay the government.[40] The direct false claim, which is a claim that "cause[s] the United States to [wrongly] remit money directly to claimants,"[41] makes up the vast majority of FCA litigation.[42]

The federal circuit courts broadly agree that to establish FCA liability for a direct false claim, a relator or the government must establish at a minimum that (1) the defendant made a claim for payment to the government, (2) that claim was false, and (3) the defendant knew that claim to be false.[43] Some circuits go one step farther, at least in implied false certification cases,[44] by requiring proof that the false claim was material to the government's

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retaliation language).

40.   *See* 31 U.S.C. §§ 3729(a)(1)(A)–(G) (2012) (creating liability for the listed acts).

41.   United States *ex rel.* Landis v. Tailwind Sports Corp., 160 F. Supp. 3d 253, 255 (D.D.C. 2016).

42.   *See* 1 BOESE, *supra* note 2, § 2.01(A)(1) (predicting this post-1986 trend to continue after the FERA amendments).

43.   *See id.* (listing what "most courts have concluded are at least [the] three essential elements" of a direct false claim); United States *ex rel.* Wilkins v. United Health Grp., Inc., 659 F.3d 295, 304–05 (3d Cir. 2011) (describing the elements necessary to establish FCA liability); United States *ex rel.* Presser v. Acacia Mental Health Clinic, LLC, 836 F.3d 770, 777 (7th Cir. 2016) (same); Olson v. Fairview Health Servs. of Minn., 831 F.3d 1063, 1070 (8th Cir. 2016) (same); United States *ex rel.* Davis v. District of Columbia, 793 F.3d 120, 124 (D.C. Cir. 2015) (same).

44.   *See* Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 1999 (2016) (approving the implied false certification theory, which is where "a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements . . . .").

decision to pay.[45] Given that some cases involving sampling may be implied false certification cases, this Note will also consider the materiality element.

The Supreme Court's decision in *Tyson Foods, Inc. v. Bouaphakeo*[46] noted the importance of considering the elements of a particular cause of action when determining whether statistical evidence can be used for proving classwide liability.[47] Therefore, an examination of each FCA element is necessary to determine whether statistical sampling can be used to establish FCA liability.

1. The Claim Element

The FCA creates liability for the submission of "a false or fraudulent claim for payment or approval."[48] A claim is "any request or demand" made for "money or property" either owned or reimbursable by the government.[49] Government salaries and no-strings-attached income subsidies are excepted from this definition.[50] Courts interpret the term "claim" to incorporate "all fraudulent attempts to cause the Government to pay out sums of

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45. *See* United States *ex rel.* Rostholder v. Omnicare, Inc., 745 F.3d 694, 700 (4th Cir. 2014) (requiring the materiality element); United States v. Bollinger Shipyards, Inc., 775 F.3d 255, 259 (5th Cir. 2014) (same); United States *ex rel.* Sheldon v. Kettering Health Network, 816 F.3d 399, 408 (6th Cir. 2016) (same); United States v. United Healthcare Ins. Co., 688 F.3d 1037, 1047 (9th Cir. 2016) (same).

46. 136 S. Ct. 1039 (2016).

47. *See id.* at 1046 (stating the importance of a particular cause of action and its elements in determining the appropriateness of using statistical evidence).

48. 31 U.S.C. § 3729(a)(1)(A) (2012).

49. *Id.* § 3729(b)(2)(A).

50. *See id.* § 3729(b)(2)(B) (stating that a claim "does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual's use of the money or property").

money."[51] This includes claims that a defendant causes a third person to submit.[52] Thus, these claims can take a variety of forms.[53]

Proof of a "call upon the public fisc"[54] is "central" to an FCA cause of action because the statute "focuses on the submission of a claim."[55] The FCA creates liability for the claim itself, not for a fraudulent scheme or other related action.[56] Thus, the mere implication that a false claim exists in light of a fraudulent scheme will not substitute for proof of "a real false claim."[57] Accordingly, FCA actions cannot survive unless the government proves the existence of an "actual false claim[]."[58] The question that arises in

51.   United States v. Neifert–White Co*., 390 U.S. 228, 233 (1968).

52.   *See* United States *ex rel.* Rost v. Pfizer, Inc., 736 F. Supp. 2d 367, 376 (D. Mass. 2010) ("The Supreme Court has long held that a person may be liable under the FCA for causing an innocent third party to submit a false claim to the government without knowing it is false." (citing United States v. Bornstein, 423 U.S. 303, 313 (1976))).

53.   *See* 1 BOESE, *supra* note 2, § 2.02(B)(1) (listing different submissions characterized as claims by courts, including "progress report[s] and voucher[s] for government contractors").

54.   Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 785 (4th Cir. 1999).

55.   United States *ex rel.* Aflatooni v. Kitsap Physicians Service, 314 F.3d 995, 1002 (9th Cir. 2002) (citing *United States v. Rivera,* 55 F.3d 703, 709 (1st Cir.1995)).

56.   *See* United States *ex rel.* Longhi v. Lithium Power Techs., Inc., 575 F.3d 458, 467 (5th Cir. 2009) ("[T]he statute attaches liability, not to the underlying fraudulent activity or to the Government's wrongful payment, but to the claim for payment." (quoting *Harrison*, 176 F.3d at 785)).

57.   *Aflatooni*, 314 F.3d at 1002.

58.   *Id.* at 1002–03 (affirming summary judgment for the defendant where the relator's "evidence totally fail[ed] to describe in any detail any actual false claims"); *see also* United States *ex rel.* Quinn v. Omnicare Inc., 382 F.3d 432, 440 (3d Cir. 2004) (affirming summary judgment for the defendant where the relator "did not come forward with a single claim that [the defendant] actually submitted"); United States *ex rel.* Crews v. NCS Healthcare of Ill., Inc., 460 F.3d 853, 858 (7th Cir. 2006) (affirming summary judgment for the defendants because the FCA "specifically requires a claimant to point to a specific claim"). Though necessary at the summary judgment stage, the identification of specific claims prior to discovery is not always required. *See* United States *ex rel.* Heath v. AT&T, Inc., 791 F.3d 112, 126 (D.C. Cir. 2015) (joining six sister circuits in finding specific claims need not be identified in the complaint); *see also* United States *ex rel.* Wilkins v. United Health Group, Inc., 659 F.3d 295, 308 (3d Cir. 2011) (noting

the statistical sampling context is whether the attachment of liability to "*a* false or fraudulent claim" [59] requires identification of *which* false or fraudulent claim. This issue will be addressed *infra*.[60]

2. The Falsity Element

The FCA does not expressly define falsity, so the common law definition of fraud controls this element.[61] At common law, fraud includes "misrepresentation[s] of fact . . . for the purpose of inducing another to act."[62] The Restatement defines misrepresentation as words or conduct "that amount[] to an assertion not in accordance with the truth."[63]

FCA falsity encompasses demands for payment from the government where it should not pay anything, or wrongful statements that one owes less money to the government than is actually the case.[64] A false claim seeks payment for "money the

a distinction between the requirement that the government or relators be able to point to individual claims at the summary judgment stage from Rule 99B requirements at the motion to dismiss stage); *but see* Chesbrough v. VPA, P.C., 655 F.3d 461, 472 (6th Cir. 2011) (upholding a "strict requirement that relators identify actual false claims" in a complaint); Hopper v. Solvay Pharmaceuticals, Inc., 588 F.3d 1318, 1326 (11th Cir. 2009) (affirming the dismissal of a complaint that was unable to point to "the existence of a single actual false claim").

59.   31 U.S.C. § 3729(a)(1)(A) (2012) (emphasis added).

60.   *Infra* at IV.B. Statutory Analysis

61.   *See* Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 1999 (2016) (noting that under the FCA, "the term 'fraudulent' is a paradigmatic example of a statutory term that incorporates the common-law meaning of fraud").

62.   RESTATEMENT (SECOND) OF TORTS § 525 (AM. LAW INST. 1977).

63.   *Id.*

64.   *See* Costner v. URS Consultants, Inc., 153 F.3d 667, 677 (8th Cir. 1998) ("[O]nly those actions . . . which have the purpose and effect of causing the United States to pay out money it is not obligated to pay, or those actions which intentionally deprive the United States of money it is lawfully due, are properly considered "claims" within the meaning of the FCA."); United States *ex rel.* Shupe v. Cisco Sys., Inc., 759 F.3d 379, 385 (5th Cir. 2014) ("[C]ourts have limited the FCA's application to 'instances of fraud that might result in financial loss to the

government otherwise would not have paid" were the claim not false.[65] Recently, the Supreme Court ruled that the FCA also includes liability for misrepresentation by omission.[66] Under this implied false certification theory, a claim is false when it fails to acknowledge "violations of statutory, regulatory, or contractual requirements" if those violations are material to the government's payment decision.[67]

The FCA also requires objective falsity.[68] Mere "differences of interpretation" are not false under the FCA.[69] Thus, a disagreement in contractual or legal interpretation does not constitute falsity under the FCA.[70]

Falsity must be proven with respect to the actual claim—the mere implication of taint does not create a presumption of falsity when falsity cannot be connected to the claim.[71] Instead, falsity is

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Government.'" (quoting United States *ex rel.* Sanders v. American-Amicable Life Ins. Co. of Texas, 545 F.3d 256 (3d Cir. 2008))).

65.   Chesbrough v. VPA, P.C., 655 F.3d 461, 467 (6th Cir. 2011) (quoting Mikes v. Straus, 274 F.3d 687 (2d Cir. 2001)), *abrogated on other grounds by* Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989 (2016).

66.   *See Escobar*, 136 S. Ct. at 1995 (approving the implied "false certification" theory of FCA liability).

67.   *Id.* at 1999–2001.

68.   *See* United States *ex rel.* Yannacopoulos v. General Dynamics, 652 F.3d 818, 836 (7th Cir. 2011) ("A statement may be deemed false for purposes of the False Claims Act only if the statement represents an objective falsehood." (internal quotes omitted)); United States *ex rel.* Wilson v. Kellogg Brown & Root, Inc., 525 F.3d 370, 376–77 (4th Cir. 2008) ("[T]he statement or conduct alleged must represent an objective falsehood."); United States v. AseraCare, Inc., 153 F. Supp. 3d 1372 (N.D. Ala. 2015), *appeal docketed*, No. 16-13004 (11th Cir. May 27, 2016) (same).

69.   United States *ex rel.* Lamers v. Green Bay, 168 F.3d 1013, 1018 (7th Cir. 1999); *see also AseraCare*, 153 F. Supp. 3d at 1383 ("[E]xpressions of opinion or scientific judgments about which reasonable minds may differ cannot be false." (internal quotes omitted) (citing United States *ex rel.* Riley v. St. Luke's Episcopal Hosp., 355 F.3d 370, 376 (5th Cir. 2004))).

70.   *See Yannacopoulos*, 652 F.3d at 836–37 (discussing limitations on the definition of falsity under the FCA).

71.   *See* Kellogg Brown & Root Servs., Inc. v. United States, 728 F.3d 1348, 1367 (Fed. Cir. 2013) (rejecting the government's theory of a presumption of falsity in a kickback case where it did not show that individual invoices were

intrinsically tied to the claim itself.[72] The statute ties falsity to the claim by creating liability for "a false or fraudulent claim,"[73] not claims that are submitted "while fraud is afoot."[74] This is not to say that falsity must lie within the four corners of an actual form submitted to the government,[75] but the claim must ask for money which the government does not owe.[76] In a fraud-in-the-inducement case, for example, falsity for all claims derives from the original fraudulent inducement.[77] Fraudulent inducement creates FCA liability for payments made under a contract which was "procured by fraud."[78] But each claim is still false under the FCA because the claim demands a payment different from what the government actually owes.[79] Thus if the government does not

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false).

72.   *See id.* (rejecting the argument that claims for payment on a subcontract "were false or fraudulent because the subcontract itself was tainted by kickbacks" but distinguishing the case at hand from fraud-in-the-inducement cases).

73.   31 U.S.C. § 3729(a)(1)(A) (2012).

74.   United States *ex rel.* Hockett v. Columbia/HCA Healthcare Corp., 498 F. Supp. 2d 25, 67 (D.D.C. 2007).

75.   *See* Imperial Meat Co. v. United States, 316 F.2d 435, 439–40 (10th Cir. 1963) (finding that although the actual invoice requesting payments did not contain false information, reference to the whole body of contractual documents made clear that there was a "false claim for payment for what had not been delivered").

76.   *See supra* notes 64–65 and accompanying text (defining falsity).

77.   *See* Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 787–88 (4th Cir. 1999) (finding FCA liability under a fraud-in-the-inducement theory "because of the fraud surrounding the efforts to obtain the contract or benefit status, or the payments thereunder" rather than falsity found in any given invoice requesting for payment).

78.   United States *ex rel.* Longhi v. Lithium Power Techns., Inc., 575 F.3d 458, 467–68 (5th Cir. 2009).

79.   *Id.* One court reasoned that an "original misrepresentation taint[s] every subsequent claim made in relation to the contract." United States *ex rel.* Schwedt v. Planning Research Corp., 59 F.3d 196, 199 (D.D.C. 1995) (citing United States *ex rel.* Marcus v. Hess, 317 U.S. 537, 543 (1943)); *see also Harrison*, 176 F.3d at 787–88 (deciding that in *United States ex rel. Marcus v. Hess* and similar cases "liability attached . . . because of the fraud surrounding the efforts to obtain the contract or benefit status, or the payments thereunder"). These cases do not appear to rely on, or even analyze, the FCA's coverage of "false or fraudulent claim[s] for . . . *approval*" of the contract as a possible alternative

show that a particular claim asks for the wrong amount in payment, it has not established falsity for that claim.[80] The issue with this element then is whether statistical sampling can adequately connect falsity to a claim outside the statistical sample.

3. The Knowledge Element

Knowledge under the FCA includes actual knowledge, deliberate ignorance, or reckless disregard[81] that a submitted claim is false.[82] Specific intent is not required to establish FCA

theory of liability to a theory stretching "claim[s] for payment" to include invoices that are not falsely inaccurate in fraud-in-the-inducement scenarios. 31 U.S.C. § 3729(a)(1)(A) (2012) (emphasis added).

80.   *Cf.* Kellogg Brown & Root Servs., Inc. v. United States, 728 F.3d 1348, 1367 (Fed. Cir. 2013) (reasoning that the government did not show "that the invoices themselves were false or fraudulent" and agreeing with the district court that "[n]o presumption applies to the FCA that would relieve defendant of its burden to plead facts supporting the elements of an FCA claim"); United States *ex rel.* Hockett v. Columbia/HCA Healthcare Corp., 498 F. Supp. 2d 25, 57 (D.D.C. 2007) ("[R]elator 'bears the burden of establishing that the claim or statement submitted to the government was false.'"); 31 U.S.C. § 3729(a)(1)(A) (2012) (creating liability for anyone presenting "a false or fraudulent claim"); United States *ex rel.* Morton v. A Plus Benefits, Inc., 139 Fed. Appx. 980, 982 (10th Cir. 2005) ("[I]f the factual allegations do not support a conclusion that a 'false or fraudulent claim' was made, the case may not proceed under the FCA."); United States *ex rel.* Aflatooni v. Kitsap Physicians Service, 314 F.3d 995, 1002 (9th Cir. 2002) (listing the essential FCA elements as requiring "a claim against the United States . . . that was false or fraudulent"); *but see* United States v. Rogan, 517 F.3d 449, 453 (7th Cir. 2008) (stating that the trial judge need not examine each claim because "[s]tatistical analysis should suffice"). However, every single claim in this Seventh Circuit case had already been proven false. *See* United States *ex rel.* Absher v. Momence Meadows Nursing Center, Inc., 764 F.3d 699, 714 (7th Cir. 2014) ("[*E*]*ach and every* form filed by the defendant was false."). Although the *Absher* panel found that *Rogan* permitted statistical evidence to determine "how many of [the defendant's] documents contained false certifications," it also acknowledged that "the relators' difficulty in coming forward with evidence" cannot shift the relators' burden under the FCA. *Id.*

81.   *See* 31 U.S.C. § 3729(b)(1)(A) (2012) (defining "knowing" and "knowingly").

82.   *See* United States *ex rel.* Ubl v. IIF Data Solutions Eyeglasses, 650 F.3d 445, 452 (4th Cir. 2011) ("A defendant may be held liable under the FCA for 'knowingly' making or presenting a false claim."); United States *ex rel.* Kreindler

liability,[83] but mere negligence or honest mistakes fall outside the statute's scope.[84] The knowledge requirement applies at the time a claim is submitted.[85] It must be proven as to a particular individual,[86] but that "need not be the same individual who submits" the claim.[87] Furthermore, just as with the falsity element, objectively reasonable interpretations of ambiguous contractual and legal provisions will not constitute knowledge under the FCA.[88] The issue with statistical sampling and this element is whether sampling can prove that a defendant knew that a particular claim outside the sample was false where that claim is not identified at trial.

4. The Materiality Element

The FCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of

& Kreindler v. United Techs. Corp., 985 F.2d 1148, 1156 (2d Cir. 1993) (agreeing that "the statutory basis for an FCA claim is the defendant's knowledge of the falsity of its claim").

83. *See* 31 U.S.C. § 3729(b)(1)(B) (2012) (requiring "no proof of specific intent to defraud").

84. *See* Untied States *ex rel.* Miller v. Weston Educ., Inc., 840 F.3d 494 (8th Cir. 2016) (discussing the knowledge requirement).

85. *See* United States *ex rel.* Hefner v. Hackensack Univ. Med. Ctr., 495 F.3d 103, 109 (3d Cir. 2007) (affirming a grant of summary judgment, and reasoning that an "after-the-fact interpretation of the situation [by a supervisor] does not establish that the individuals submitting the claims knew that they were submitting false claims").

86. United States v. Fadul, No. DKC 11–0885, 2013 WL 781614, at *9 (D. Md. Feb. 28, 2013) (requiring proof that "a particular employee or officer acted knowingly" (citing United States v. Science Applications Inter. Corp., 626 F.3d 1257, 1274 (D.C. Cir. 2010))).

87. *Id.* (citing United States *ex rel.* Harrison v. Westinghouse Savannah River Co., 352 F.3d 908, 919 (4th Cir. 2003)).

88. *See* United States *ex rel.* Purcell v. MWI Corp., 807 F.3d 281, 290 (D.C. Cir. 2015) ("[T]he court's focus is on the objective reasonableness of the defendant's interpretation of an ambiguous term and whether there is any evidence that the agency warned the defendant away from that interpretation." (citing Safeco Ins. Co. of America v. Burr, 551 U.S. 47, 70 nn.19–20 (2007))).

money or property."[89] Materiality is a "demanding" standard that prevents the FCA from being used to litigate "garden-variety breaches of contract or regulatory violations."[90] Materiality turns on the "likely or actual behavior" of the government after discovering the false statements.[91] This element can be satisfied by proving a defendant's awareness of the government's tendency to not pay a claim which is "based on noncompliance with the particular statutory, regulatory, or contractual requirement."[92] Evidence that the government pays a claim despite knowing the claimant violated the governing provisions or regulations could be evidence that those provisions or regulations are not material.[93]

C. Previous Use of Statistical Sampling in FCA Cases

Courts have allowed statistical sampling for damages calculations in a number of FCA cases.[94] They "routinely endorse[]" this method where documentation is not available to prove damages, or where the government has already proven that every claim is false.[95] But the use of statistical sampling to prove damages does not require an examination of whether statistical sampling can establish the essential elements of FCA liability.[96]

Courts recognize at least three justifications for extrapolating damages. First, examining each claim may be impractical when

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89. 31 U.S.C. § 3729(b)(4) (2012).

90. Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 2003 (2016).

91. *Id.* at 2002 (quoting 26 RICHARD A. LORD, WILLISTON ON CONTRACTS § 69:12 (4th ed. 2003)).

92. *Id.* at 2003.

93. *See id.* at 2003–04 (explaining materiality).

94. *See, e.g.*, United States v. Life Care Ctrs. of Am., Inc., 114 F. Supp. 3d 549, 560 (E.D. Tenn. 2014) (noting past use of statistical sampling in FCA cases for damages calculations only).

95. United States v. Fadul, No. DKC 11–0385, 2013 WL 781614, at *14 (D. Md. Feb. 28, 2013) (permitting statistical sampling for damages calculations).

96. *See Life Care*, 114 F. Supp. 3d at 563 (explaining the difference between using statistical sampling in calculating damages and establishing liability).

there are thousands of claims in question.[97] For example, in one recent case, the trial court allowed statistical sampling to show both damages and liability where over 25,000 claims were at issue.[98] Second, the records and evidence needed to prove damages may be missing or non-existent for some claims.[99] In *United States v. Fadul*,[100] for example, the records for over 150 claims were unobtainable.[101] The court allowed statistical sampling to calculate damages.[102] Finally, statistical sampling appears in healthcare overpayment cases outside the FCA context.[103] The next subpart considers this area in more detail.

D. Use of Statistical Sampling for Establishing Liability in Non-FCA Contexts

Courts have allowed statistical sampling for proving liability in at least two other areas of law: administrative overpayment cases[104] and in class action cases.[105] This subpart addresses both before turning to Supreme Court precedent limiting the use of statistical evidence for proving liability.

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97.   *See Fadul*, 2013 WL 781614, at *14 (noting past endorsement of statistical sampling in other contexts where "claim-by-claim review is not practical").

98.   *See* United States v. Robinson, No. 13–cv–27–GFVT, 2015 WL 1479396, at *10 (E.D. Ky. March 31, 2015), *appeal docketed*, No. 16-6353 (6th Cir. Sept. 1, 2016).

99.   *See Fadul*, 2013 WL 781614, at *14 (permitting statistical sampling because the necessary evidence was unobtainable).

100.   No. DKC 11–0385, 2013 WL 781614 (D. Md. Feb. 28, 2013).

101.   *See id.* (permitting sampling for a damages calculation when the necessary evidence was missing).

102.   *See id.* (same).

103.   *See* United States v. Cabrera-Diaz, 106 F. Supp. 2d 234, 240–41 (D.P.R. 2000) (summarizing cases from several jurisdictions permitting statistical sampling as evidence for damages calculations in the Medicare and Medicaid contexts, then reasoning that such methods can carry over into FCA litigation).

104.   *Infra* II.D.1. Administrative Overpayment Recovery

105.   *Infra* II.D.2. Class Action

1. Administrative Overpayment Recovery

Courts have permitted statistical sampling in the administrative enforcement of healthcare regulations.[106] In *Chaves County Home Health Services, Inc. v. Sullivan*,[107] the Secretary of Health and Human Services (HHS) determined that statistical sampling was "the only feasible means" of recovering Medicare overpayments.[108] That methodology selected a random sample of claims, audited them to determine the rate of overpayment, and then extrapolated the audit to all claims within the suspect time period.[109] At the time, the relevant statute was silent on the Secretary's authority to employ statistical sampling, but the court found it to be a permissible method of proving overpayment after analysis under *Chevron U.S.A. Inc. v. NRDC*.[110] The court reasoned that because the statute gave the Secretary "general (and uncontested) authority to recoup overpayments" and statistical sampling was not "incompatible with either the statute or

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106.   *See, e.g.*, Chaves Cty. Home Health Serv., Inc. v. Sullivan, 931 F.2d 914, 923 (D.C. Cir. 1991), *cert. denied*, 502 U.S. 1091 (1992) (permitting statistical sampling for determining the number of overbilled Medicare claims); Ill. Physicians Union v. Miller, 675 F.2d 151, 157 (7th Cir. 1982) (finding statistical sampling in the administrative Medicaid context to be proper); State of Georgia v. Califano, 446 F. Supp. 404, 409–10 (N.D. Ga. 1977) (determining that statistical sampling was "not improper" for proving overpayments in an administrative enforcement action); United States' Memorandum in Opposition to Defendant Life Care Centers of America, Inc.'s Motion for Partial Summary Judgment at 16, United States v. Life Care Ctrs. of Am., Inc., No. 1:08-CV-251 (E.D. Tenn. Mar. 21, 2014), 2014 WL 5359287 (noting that "statistical extrapolation is routinely used in the medical necessity context").

107.   931 F.2d 914 (D.C. Cir. 1991).

108.   *Id.* at 922 ("[W]e cannot say that the Secretary's interpretation of his authority under the Act is unreasonable.").

109.   *See id.* (describing the methodology employed).

110.   467 U.S. 837 (1984) (stating that judicial review of an agency's interpretation of ambiguous or silent terms of the statute it administers focuses on whether the agency's interpretation is based on a permissible construction of the statute); *see also Chaves Cty.*, 931 F.2d at 915 (finding that the agency could interpret the statute it implemented to allow statistical sampling in the administrative recovery context).

Department regulations," the Secretary's interpretation was entitled to deference.[111]

The major distinction between administrative recovery and the FCA is that administrative recovery does not require analysis of the same statutory elements as the FCA.[112] Instead, the Secretary of Health and Human Services wields broad discretion to determine the amount of any overpayment.[113] One avenue of recovery is for States to recoup the overpayment by the method of their choosing, while the federal government reduces the amount it distributes to the State.[114] Another is for entities participating in the Medicare Integrity Program to repay the government directly, using extrapolation in some circumstances.[115] Furthermore, the Secretary's determination that there is a high rate of overpayments such that sampling is appropriate is unreviewable.[116] Notably, there is no requirement that the Secretary identify wrongful claims for payment when evaluating overpayments.[117] These statutory features create a major distinction between administrative recovery cases and FCA cases because the two recovery regimes set forth a "distinctly different standard" for liability.[118]

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111.   *Id.* at 917–22.

112.   *See* 42 U.S.C. § 1396b(d)(2)(A) (2012) (providing for the recovery of overpayments in the federal healthcare system by reducing future disbursements to States by the amount overpaid).

113.   *See id.* (directing the Secretary to modify payments to States administering federal medical programs for "any overpayment or underpayment which the Secretary determines was made under this section").

114.   *See id.* § 1396b(d)(2)(C) (granting the States "1 year in which to recover or attempt to recover such overpayment").

115.   *See id.* § 1395ddd(f)(3) (describing when the Secretary may permit extrapolation).

116.   *See id.* § 1395ddd(f)(3)(B) ("There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of determinations by the Secretary of sustained or high levels of payment errors under this paragraph.").

117.   *Id.* §§ 1395gg(b), 1396b(d)(2)–(3).

118.   *See* United States v. Life Care Ctrs. of Am., Inc., 114 F. Supp. 3d 549, 563 (E.D. Tenn. 2014) (looking to administrative applications of sampling only "as an example of how extrapolation *can* be used rather than a conclusive

2. Class Action

Courts have also considered statistical sampling for proving liability in the class action context. One notable instance where a court allowed statistical sampling to prove liability was in *Hilao v. Estate of Marcos*.[119] That case arose under the Alien Tort Statute and involved nearly 10,000 class members suing a foreign dictator for human-rights abuses.[120] The defendant's estate noted that the statistical sampling methodology that the plaintiffs advanced had never before been used in the class action context and argued that the methodology deprived the defendant of its due process rights.[121] The court, however, stated that "the time and judicial resources required to try the nearly 10,000 claims" would be "impossible."[122] Furthermore, it found no violation of procedural due process after balancing the plaintiffs' interest in recovery against the defendant's interest in avoiding an erroneous damages calculation.[123] The Fifth Circuit sought to distinguish *Hilao* two years later, or, in the alternative, to simply disregard it as incorrect.[124] Furthermore, the Supreme Court "flatly rejected" statistical sampling as employed in *Hilao* in a 2011 class action case.[125]

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determination of how statistical sampling *should* be used in FCA actions").

119.   *See* Hilao v. Estate of Marcos, 103 F.3d 767, 784–87 (9th Cir. 1996) (addressing a class action torts claim).

120.   *See id.* at 771–72 (describing the background and jurisdiction of the case).

121.   *See id.* at 784–85 (noting the estate's objection to statistical sampling).

122.   *Id.* at 785.

123.   *See id.* (finding no violation of procedural due process).

124.   *See* Cimino v. Raymark Indus., Inc., 151 F.3d 297, 319 (5th Cir. 1998) ("If *Hilao* is not thus distinguishable it is simply contrary to *Fibreboard,* which binds us and which in our opinion is in any event correct." (citing *In re* Fibreboard, 893 F.2d 706 (5th Cir. 1990))).

125.   John M. Husband & Bradford J. Williams, Wal-Mart v. Dukes *Redux: The Future of the Sprawling Class Action*, 40 COLO. LAW. 53, 59 (2011) (citing Wal-Mart Stores, Inc. v. Dukes, 564 U.S. 338 (2011)).

In *Wal-Mart Stores, Inc. v. Dukes*,[126] the plaintiffs sought to extrapolate back-pay eligibility from a sample of class members in place of Title VII's remedial procedures.[127] Under Title VII, employers have the opportunity to demonstrate that adverse employment decisions were taken against employees for non-discriminatory reasons, absolving them of liability for discrimination claims.[128] The plaintiffs proposed to determine the percentage of back-pay claims from a statistical sample, apply that percentage to the entire class, then multiply the extrapolated number of claims by the average back-pay award to arrive at damages.[129] The Supreme Court "disapprove[d of] that novel project."[130] It reasoned that Wal-Mart had the statutory right to litigate each individual claim in the Title VII action, and the Rules Enabling Act prohibited modifications of substantive rights.[131]

Five years later, the Court distinguished *Dukes* in *Tyson Foods*.[132] In that case, the class members sought to use statistical sampling to establish the amount of time for which the plaintiff-employees were not paid in violation of the Fair Labor Standards Act.[133] The Court concluded that "[w]hether a representative sample may be used to establish classwide liability will depend on the purpose for which the sample is being introduced and on the *underlying cause of action*."[134] The Court reasoned that statistical sampling was permissible in *Tyson Foods* because "each class member could have relied on that sample to establish liability if he

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126.   564 U.S. 338 (2011).

127.   *See id.* at 366–67 (discussing the plaintiffs' proposed "Trial by Formula").

128.   *See id.* (noting Title VII's remedial procedures).

129.   *See id.* (describing plaintiff's statistical sampling scheme).

130.   *Id.*

131.   *See id.* (rejecting the proposed "Trial by Formula").

132.   Tyson Foods, Inc. v. Bouaphakeo, 136 S. Ct. 1036, 1048 (2016).

133.   *See id.* at 1046 (describing the plaintiffs' argument that individual determinations for each class member's time spent donning and doffing protective equipment was "unnecessary because it can be assumed each employee donned and doffed for the same average time observed in [the statistical] sample").

134.   *Id.* at 1049 (emphasis added).

or she had brought an individual action."[135] Statistical sampling did not deprive Tyson Foods of its right to litigate individual claims because it would have litigated the same defenses to the exact same evidence in every individual case had the evidence not been applied classwide.[136] Thus the general acceptability of statistical evidence to prove the violation of a particular statute is dependent on the particular cause of action.

III. *The Split on Statistical Sampling in the FCA Context*

Divergent district court decisions have raised a question of law that had not seriously entered the realm of FCA litigation until 2014.[137] Some courts have allowed statistical sampling as a legally viable mechanism for proving FCA liability [138] and some courts have not.[139] The only appellate court to rule on the issue so far dispensed with the question on jurisdictional grounds.[140] Thus, the

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135.   *Id.* at 1046; *see also id.* at 1048 ("[I]f the employees had brought 1 ½ million individual suits, there would be little or no role for representative evidence.").

136.   *See id.* at 1047 ("[The defendant's] defense is itself common to the claims made by all class members.").

137.   *See* Robert T. Rhoad, Jason M. Crawford & Mary Kate Healy, *Extrapolation in FCA Litigation: A Statistical Anomaly or a Tactic Here To Stay?*, 58 GOV'T CONTRACTOR ¶ 9 (Jan. 13, 2016) (noting *Life Care*'s introduction of the statistical sampling and liability issue into FCA litigation).

138.   *See Life Care*, 114 F. Supp. 3d at 571 (permitting statistical sampling); United States v. Americus Mortgage Corp., No. 4:12–CV–2676, 2017 WL 4083589, at *4 (S.D. Tex. Sept. 14, 2017) (same); United States *ex rel.* Ruckh v. Genoa Healthcare, LLC, No. 8:11–cv–1303–T–23TBM, 2015 WL 1926417 (M.D. Fla. Apr. 28, 2015) (same); United States v. Robinson, No. 13–cv–27–GFVT, 2015 WL 1479396, at *10 (E.D. Ky. March 31, 2015), *appeal docketed*, No. 16-6353 (6th Cir. Sept. 1, 2016) (same); United States v. AseraCare, Inc., No. 2:12–CV–245–KOB, 2014 WL 6879254, at *10 (N.D. Ala. Dec. 4, 2014) (same), *vacated and substituted*, No: 2:12-CV-245-KOB, 2014 WL 12593996 (N.D. Ala. Dec. 19, 2014).

139.   *See* United States *ex rel.* Michaels v. Agape Senior Cmty., Inc., No. 0:12–3466–JFA, 2015 WL 3903675, at *8 (D.S.C. June 25, 2015) (declining to permit statistical sampling); United States v. Vista Hospice Care, Inc., No. 3:07-cv-00604-M, 2016 WL 3449833, at *13 (N.D. Tex. Jun. 20, 2016) (same).

140.   *See* United States *ex rel.* Michaels v. Agape Senior Cmty., Inc., 848 F.3d 330 (4th Cir. 2017) ("[W]e are constrained to dismiss that aspect of the relators'

legal sufficiency of statistical sampling will probably remain a live issue in FCA litigation for the foreseeable future.[141] This Part discusses the primary cases on either side of the split and examines the arguments for and against statistical sampling.

A. Cases Permitting Statistical Sampling

In *Life Care*, the government alleged that an elder care provider overbilled Medicare for skilled nursing services.[142] The government paid Life Care prospectively under a statutory per diem formula based on the number of hours of service and the classification of the services rendered.[143] The complaint alleged that Life Care billed for medically unnecessary services, and that the company pressured therapists to bill at the highest possible rate.[144] The relator specifically alleged that Life Care performed unnecessary treatments, treated patients who should not have been treated, improperly delivered group treatment to patients, and billed Medicare for skilled services that did not require a skilled specialist.[145] The case involved over 150,000 total submissions for payment.[146] The government sought to extrapolate the total number of false claims from a statistical sample of 400 patients.[147] Life Care moved for partial summary judgment, arguing that statistical sampling could not meet the government's burden of proof under the FCA.[148] The court addressed the use of

appeal as improvidently granted.").

141.   *See* James Swann & Eric Topor, *Outlook 2017: New Year May Bring Stark Reform, ACA Repeal, Heavy Dose of Uncertainty*, BNA'S HEALTH CARE FRAUD REP. at 8–9 (Jan. 4, 2017) (predicting that district courts will continue to rule differently on sampling).

142.   *See* United States v. Life Care Ctrs. of Am., Inc., 114 F. Supp. 3d 549, 553 (E.D. Tenn. 2014) (discussing the case's background).

143.   *See id.* at 552–53 (same).

144.   *See id.* at 553–54 (summarizing the complaint).

145.   *See id.* at 555 (same).

146.   *See id.* at 556 (noting the size of the case).

147.   *See id.* (explaining the government's statistical sampling scheme).

148.   *See id.* at 557 (discussing the parties' arguments).

statistical sampling in terms of each FCA liability element before briefly addressing Life Care's due process concerns.[149]

The *Life Care* court decided that the government did not have to "specify with detail all of the individual claims" involved in the lawsuit.[150] Although the court recognized that the government "*could*" litigate claim by claim and provide "individualized proof of specific claims," it reasoned that such an effort would take a long time and would be "impractical."[151] Furthermore, the court distinguished a case which Life Care relied upon,[152] *United States v. Friedman*.[153] In *Friedman*, the court declined to extrapolate from a statistical sample out of "reluctan[ce] to accept a statistical sampling as the basis for doubling the alleged overpayment without the same scrutiny and support" that the sample underwent at trial.[154] In declining to follow *Friedman*, the court noted that individual review for each individual claim was viable in *Friedman* due to the smaller number of claims.[155] By contrast, reviewing each of the 154,621 claims at issue in *Life Care* would take up an "unacceptable" amount of the court's time.[156]

Regarding the falsity element, the court rejected Life Care's argument that the individualized nature of medical diagnoses required a patient-by-patient look at the details of each case to determine whether any given patient's treatment was medically unnecessary.[157] Although it recognized that some of the many individual factors were determinative of the treatment chosen for

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149. *See id.* at 565 (analyzing the defendant's challenge to the proposed statistical sampling scheme).

150. *Id.* at 565 (internal quotes omitted).

151. *Id.*

152. *See id.* (stating that the court was not compelled by defendant's argument that the government would be unable to identify individual false claims upon request).

153. No. 86-0610-MA, 1993 U.S. Dist. LEXIS 21496 (D. Mass. July 23, 1993).

154. *Id.* at *9 n.1.

155. *See* United States v. Life Care Ctrs. of Am., Inc., 114 F. Supp. 3d 549, 565 (E.D. Tenn. 2014) (distinguishing *Friedman*).

156. *Id.*

157. *See id.* at 567 (declaring that the court was unpersuaded).

a given patient, the court reasoned that statistical sampling has been used "for decades," and the methodology was not "unique" to healthcare litigation.[158] The court then cited a case permitting statistical sampling to calculate damages in an administrative proceeding where "sampling was the only feasible method of audit available."[159] It further reasoned that Life Care could "employ cross examination and competing witnesses" if it wanted to show the differences between the claims.[160]

The court likewise rejected Life Care's knowledge element argument "that the Government will be completely unable to establish that [the defendant] had knowledge of the alleged false claims."[161] It reasoned that the argument attacked the evidence proffered by the government for claims in the sample, not that evidence's extrapolation to the full universe of claims.[162] Thus the arguments did not, in the court's eyes, adequately show why statistical sampling would be insufficient for proving knowledge of claims outside the sample.[163]

Finally, regarding the materiality element, the court again found Life Care's arguments unpersuasive.[164] Life Care argued that "the mathematical intricacies of the Medicare billing system" made it impossible for statistical sampling to show which claims "influence[d], or [were] capable of influencing" the government's payment decision.[165] The court disagreed for three reasons.[166]

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158. *Id.* at 566.

159. *Id.* (citing State of Georgia v. Califano, 446 F. Supp. 404, 409–10 (N.D. Ga. 1977)).

160. *Id.*

161. *Id.* at 568.

162. *See id.* (reasoning that the defendant's argument was "inapposite to the issue presently before the Court").

163. *See id.* (finding that "summary judgment in favor of [the defendant] would be unwarranted and without any support in the evidentiary record").

164. *See id.* at 569 (finding that statistical sampling could be used to establish the FCA's materiality element).

165. *Id.*

166. *See id.* at 569–70 (listing the court's reasons for ruling against the defendant on this element).

First, Sixth Circuit precedent focused on the "potential rather than . . . actual effect" of a false statement on the government's payment decision, whereas Life Care argued that statistical sampling could not prove actual effect.[167] Second, the court thought that the argument was speculative because "the Government's methodology will take into account overpayments that would not be reimbursable."[168] Finally, the court considered materiality to be a question of fact best left to the jury.[169]

After addressing each element that Life Care argued, the court turned to its due process argument.[170] Life Care argued that the government's failure to identify specific false claims would impair its ability to defend against the lawsuit and that statistical sampling amounts to a burden shift that forces the defense to put forward evidence rebutting presumptions made by the extrapolation methodology.[171] The court disagreed for two reasons.[172] First, it stated that the Due Process Clause[173] does not entitle defendants to defend each individual claim under the FCA.[174] The court also stated that Life Care "will be afforded due process by having the opportunity to depose the Government's

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167.   *Id.; but see* Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 2002 (2016) ("[M]ateriality look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." (internal quotes omitted)).

168.   *Id.* at 570.

169.   *See id.* (dismissing the defendant's arguments); *but see* Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 2003 n.6 (2016) ("We reject Universal Health's assertion that materiality is too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss or at summary judgment.").

170.   *See id.* (examining the due process concerns with statistical sampling).

171.   *See id.* (summarizing the defendant's argument).

172.   *See id.* (ruling against the defendant).

173.   U.S. CONST. amend. V.

174.   *See* United States v. Life Care Ctrs. of Am., Inc., 114 F. Supp. 3d 549, 570 (E.D. Tenn. 2014) (reasoning that the "low risk of error and the Government interest in minimizing administrative burdens" balanced in favor of allowing statistical sampling (quoting Yorktown Med. Lab., Inc. v. Perales*,* 948 F.2d 84, 90 (2d Cir. 1991))).

expert, challenge the qualifications of the Government's expert, retain its own expert, and to present all of this evidence at trial."[175]

Based on all of the above analysis, the *Life Care* court determined that statistical sampling was "a legally viable mechanism" for proving liability under the FCA.[176] The case settled in 2016 for $145 million.[177]

Since the *Life Care* decision, several district courts have approved the use of statistical sampling. Another district court in the Sixth Circuit reached the same result as *Life Care*, but without undertaking the same element-by-element analysis.[178] In *United States v. Robinson*,[179] the government alleged that the defendant submitted fraudulent claims to Medicare for medically unnecessary services and services that were not actually rendered.[180] The case involved over 25,000 potentially false claims, but the government sought to prove liability by using only thirty of them.[181] Without engaging in much substantive analysis, the court approved of this methodology and denied summary judgment.[182] A number of recent cases likewise have allowed for the use of statistical sampling without extensive analysis of the statute itself.[183]

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175. *Id.*

176. *Id.* at 571.

177. *See* Press Release, Department of Justice, Life Care Centers of America, Inc. Agrees to Pay $145 Million to Resolve False Claims Act Allegations Relating to the Provision of Medically Unnecessary Rehabilitation Therapy Services (Oct. 26, 2016) (announcing the settlement) (on file with Washington and Lee Law Review).

178. *See* United States v. Robinson, No. 13–cv–27–GFVT, 2015 WL 1479396, at *10 (E.D. Ky. Mar. 31, 2015), *appeal docketed*, No. 16-6353 (6th Cir. Sept. 1, 2016).

179. *Id.*

180. *See id.* at *3 (noting the government's allegations).

181. *See id.* at *10 (discussing the use of statistical sampling in the case)

182. *See id.* at *11 (relying primarily on Sixth Circuit precedent).

183. *See, e.g.*, United States v. Americus Mortgage Corp., No. 4:12–CV–2676, 2017 WL 4083589, at *4 (S.D. Tex. Sept. 14, 2017) (allowing statistical sampling); United States *ex rel.* Ruckh v. Genoa Healthcare, LLC, No. 8:11–cv–1303–T–23TBM, 2015 WL 1926417 (M.D. Fla. Apr. 28, 2015) (same); United States v. AseraCare, Inc., No. 2:12–CV–245–KOB, 2014 WL 6879254, at *10 (N.D. Ala.

B. Cases Not Permitting Statistical Sampling

Recent cases have denied the use of statistical sampling for establishing FCA liability. These opinions do not engage in the element-by-element analysis implemented in *Life Care*,[184] but instead look to broader precedent.[185]

1. United States ex rel. Michaels v. Agape Senior Community, Inc.[186]

Agape involved nursing home services reimbursed through federal Medicare, Medicaid, and Tricare programs.[187] The relator alleged that between 50,000 and 60,000 reimbursement claims were fraudulent.[188] The relator estimated that without statistical sampling, its hired experts would spend between four and nine hours reviewing each patient's files, costing somewhere between $16,200,000 and $36,500,000.[189] The relator sought to use statistical sampling, but the court ruled that the relator must "prove each and every claim based upon the evidence relating to that particular claim."[190]

Dec. 4, 2014) (same), *vacated and substituted*, No: 2:12-CV-245-KOB, 2014 WL 12593996 (N.D. Ala. Dec. 19, 2014) (same).

    184.   *See* United States v. Life Care Ctrs. of Am., Inc., 114 F. Supp. 3d 549, 565 (E.D. Tenn. 2014) (responding to Life Care's arguments that the government would be "unable to establish each element through statistical sampling").

    185.   *See* United States *ex rel.* Michaels v. Agape Senior Cmty., Inc., No. 0:12–3466–JFA, 2015 WL 3903675, at *8 (D.S.C. June 25, 2015) (relying primarily on broader cases when declining to permit statistical sampling); United States v. Vista Hospice Care, Inc., No. 3:07-cv-00604-M, 2016 WL 3449833, at *13 (N.D. Tex. Jun. 20, 2016) (same).

    186.   No. 0:12–3466–JFA, 2015 WL 3903675 (D.S.C. June 25, 2015).

    187.   *Id.* at *1 (discussing the case's background).

    188.   *See id* (same).

    189.   *See id.* (same).

    190.   *Id.* at *6.

The court's reasoning primarily rests on case precedent rather than, as in *Life Care*, an examination of the elements.[191] The court distinguished cases where statistical sampling was the only way to put on evidence because individualized evidence was missing or destroyed.[192] Every patient's chart here was "intact and available for review by either party."[193] The court then listed the "legion" of cases on both sides of the issue before determining that "the fairest course of action based upon the facts presented and the claims asserted in this case" was to reject the use of statistical sampling.[194] One of the cited cases, *United States ex rel. Hockett v. Columbia/HCA Healthcare Corporation*,[195] discusses D.C. Circuit precedent on statistical sampling in *United States v. Krizek*.[196] The *Columbia* court noted that previous cases permitted statistical sampling in FCA cases only where "some degree of liability is conceded" and the parties consent.[197] The *Columbia* court did not allow statistical sampling in the end because the defendant did not concede liability and did not consent to the use of statistical sampling.[198] Similarly, the defendant in *Agape* did not consent to statistical sampling and liability was contested.[199]

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191.   *See id.* (explaining the court's rationale).

192.   *See id.* (distinguishing cases where claim-by-claim evidence is impossible from where it is impractical).

193.   *Id.* at *7.

194.   *Id.* at *7–*8.

195.   498 F. Supp. 2d 25 (D.D.C. 2007).

196.   *See id.* at 66 ("Krizek thus permits that where some degree of liability is conceded, slight deviations from traditional modes of proof are tolerable . . . .") (citing 192 F.3d 1024 (D.C. Cir. 1999)).

197.   *Id.* at 67.

198.   *See id.* (distinguishing from precedent).

199.   *See* Memorandum in Opposition to Relators' Motion to Permit Statistical Sampling Evidence at 16, United States *ex rel.* Michaels v. Agape Senior Cmty., Inc., No. 0:12–3466–JFA, 2015 WL 3903675 (D.S.C. June 25, 2015) ("Agape does not consent to any statistical sampling method proposed by Relators—for the simple reason that sampling is not a legitimate means for proving the elements of a False Claims Act claim generally and it is particularly inappropriate given the specific facts of this case.").

The *Agape* court ultimately decided that the determination "of whether certain services furnished to nursing home patients were medically necessary" was a "highly fact-intensive inquiry" that did not lend itself to the use of statistical sampling.[200] The court did not reach the defendant's constitutional arguments and observed that the defendants would likely examine every claim in detail in their case-in-chief, meaning "that the statistical sampling would not significantly shorten the trial."[201]

The Fourth Circuit dismissed the statistical sampling appeal on jurisdictional grounds.[202] It reasoned that the district court ruled on the use of statistical sampling based on "the particular facts and evidence in this case."[203] Furthermore, the relator argued that the district court's ruling was an evidentiary determination, not one of pure law.[204] Thus the Fourth Circuit saw the question before it as one turning in part on questions of fact.[205] This ruling demonstrates how it is important for advocates before a district court to clearly denote whether they are arguing about the admissibility of an expert witness's statistical sampling methodology or about the legal sufficiency of statistical sampling for establishing the essential elements of a FCA cause of action.

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200. *See* United States *ex rel.* Michaels v. Agape Senior Cmty., Inc., No. 0:12–3466–JFA, 2015 WL 3903675, at *8 (D.S.C. June 25, 2015) (ruling against the use of statistical sampling).

201. *Id.* at *8 n.4.

202. *See* United States *ex rel.* Michaels v. Agape Senior Cmty., Inc., 848 F.3d 330, 340 (4th Cir. 2017) ("[W]e find it prudent to re-examine whether that aspect of the relator's appeal is appropriate for interlocutory review under 28 U.S.C. § 1292(b).").

203. *Id.* at 26.

204. *See id.* (citing to the relator's brief).

205. *See id.* at 25 ("[Section] 1292(b) review is not appropriate where, for example, the question presented 'turns on whether there is a genuine issue of fact or whether the district court properly applied settled law to the facts or evidence of a particular case.'" (citation omitted)).

2. United States v. Vista Hospice Care, Inc.[206]

Another district court in Texas recently declined to allow statistical sampling.[207] The defendant in this case was a hospice provider, and the relator was one of its employees.[208] The relator alleged, among other things, that the defendant improperly certified Medicare patients for hospice eligibility.[209] The relator sought to use a statistical sample of 291 patients to examine and extrapolate a percentage of false claims submitted for services rendered to roughly 12,000 patients.[210]

The *Vista* court ruled against statistical sampling both because the particular methodology proposed was unreliable[211] and because it found that statistical sampling could not establish the essential FCA elements for the claims outside the statistical sample.[212] It disagreed with "the proposition that sampling and extrapolation are *always* reliable, regardless of the nature of the data and the nature of the claim."[213] The *Vista* court recognized that Supreme Court precedent directed it to determine whether statistical sampling could "reliably prove the elements of the specific claim."[214] Considering the subjectivity in a doctor's decision to certify a patient as hospice eligible, the court determined that "proof regarding one claim does not meet [the r]elator's burden of proof regarding other claims involving different patients, different medical conditions, different caregivers, different facilities,

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206. No. 3:07-cv-00604-M, 2016 WL 3449833 (N.D. Tex. Jun. 20, 2016).

207. *Id.* at *13.

208. *See id.* at *1 (detailing the case's background).

209. *See id.* (same).

210. *See id.* at *10 (same).

211. *See id.* at *11 (noting that "the underlying determination of eligibility for hospice is inherently subjective, patient-specific, and dependent on the judgment of involved physicians").

212. *See id.* at *13 (recognizing that claims outside the sample were very factually diverse).

213. *Id.*

214. *Id.* (citing Wal-Mart Stores, Inc. v. Dukes, 564 U.S. 338, 367 (2011)).

different time periods, and different physicians."[215] The court additionally noted that the relator made the choice to pursue a large FCA action including many individual allegedly false claims "of which she did not have personal knowledge."[216] The relator's decision to pursue a massive lawsuit could not reduce her statutory burden of proof.[217]

IV. The Legal Sufficiency of Statistical Sampling for Proving FCA Liability

The cases discussed above introduce the ultimate question of this Note: Whether statistical sampling is appropriate for establishing liability under the FCA. First, this Part determines how to analyze the sampling question. It then proceeds with an analysis of the relationship between sampling and the FCA's liability requirements before addressing the burden shifting and due process implications of statistical sampling.

A. Precedent for Statistical Sampling

The FCA is silent on whether statistical sampling can establish the essential elements of a FCA claim.[218] As mentioned *supra*,[219] the Supreme Court disapproved of statistical sampling and extrapolation in *Dukes*.[220] Rather than prohibiting statistical

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215.   *Id.* at *13.

216.   *Id.*

217.   *See id.* ("These choices, made by Relator, do not reduce her burden to produce reliable evidence of liability.").

218.   *See* 31 U.S.C. § 3729–33 (2012) (stating nothing with regards to statistical sampling); *see also* United States v. Life Care Ctrs. of Am., Inc., 114 F. Supp. 3d 549, 571 (E.D. Tenn. 2014) (noting that there is no explicit prohibition concerning extrapolation in the text of the FCA).

219.   *See supra* notes 126–131 and accompanying text (discussing *Dukes*).

220.   *See* Wal-Mart Stores, Inc. v. Dukes, 564 U.S. 338, 367 (2011) (declining to allow a classwide injury to be proven with statistical sampling in a Title VII case). The Court's reasoning behind its disapproval was that the Rules Enabling Act forbade the modification of substantive rights via interpreting Rule 23(b). *See*

sampling outright, the Court clarified its stance on the issue in *Tyson Foods* by finding that sampling's permissibility depends "not on the form a proceeding takes . . . but on the degree to which the evidence is reliable in proving or disproving the *elements of the relevant cause of action*."[221] Thus examining the FCA itself is necessary to determine whether statistical sampling is appropriate in this context.[222]

B. Statutory Analysis

The ultimate question posed by statistical sampling is whether the government must identify *which specific claim* is the false claim resulting in liability, or whether it must only establish that a defendant submitted *a certain number of claims*. For the reasons below, the FCA requires identification of each false claim to establish liability for that claim.

Because the statute attaches liability to each individual claim, the FCA requires individual proof for each false claim. The FCA creates liability where a person knowingly submits "*a* false or fraudulent *claim*," and allows the recovery of damages for "the *act* of that person."[223] The use of singular words here shows that the source of FCA liability is the individual claim. This reading is consistent with the Dictionary Act, which states that singular terms can also apply to the plural of that term "unless the context indicates otherwise."[224] That context is the text of the rest of the

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id. (reversing the Ninth Circuit). The Court saw statistical sampling used to establish a classwide injury as depriving the defendant of its right to "litigate its statutory defenses to individual claims." *Id.*

221.   Tyson Foods, Inc. v. Bouaphakeo, 136 S. Ct. 1036, 1046 (2016) (emphasis added).

222.   *See id.* ("Whether a representative sample may be used to establish class-wide liability will depend on the purpose for which the sample is being introduced and on the elements of the underlying cause of action." (internal quotes omitted)).

223.   31 U.S.C. § 3729(a)(1)(A) (2012) (emphasis added).

224.   1 U.S.C. § 1 (2012).

FCA, as interpreted by the Supreme Court.[225] The Supreme Court has held that the penalty applies once for each act a defendant takes that fulfills all elements of FCA liability.[226] Its prior interpretation of Section 3729 as attaching a civil penalty to each individual false claim, instead of imposing one penalty for all of a defendant's conduct when submitting false claims, shows that the FCA attaches liability to each individual false claim.[227] Because each penalty attaches to an individual false claim, it would be inconsistent to read "a civil penalty" in Section 3729 as singular without also reading "a false or fraudulent claim" as also singular.[228] Under this reading, each false claim constitutes a separate, individual violation of the FCA for which the government must individually "prove all essential elements."[229]

Furthermore, the text requires the government to "prove all essential elements of *the cause of action*," rather than requiring proof of the essential elements for each false claim.[230] The dictionary definition of "cause of action" ties the term to "[t]he fact or facts which give a person a right to judicial relief" and the "legal effect of an occurrence in terms of redress."[231] The knowing submission of each false claim is the occurrence that creates the government's right to pursue relief under the FCA.[232] "Cause of action" as it is used in the FCA, then, refers the right of recovery stemming from the submission of the false claim, with each false

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225.   *See* Coleman v. Labor and Indus. Review Comm'n of Wis., 860 F.3d 461, 473 (7th Cir. 2017) (interpreting the Magistrate Judges Act).

226.   *See* United States v. Bornstein, 423 U.S. 303, 312–13 (1976) (assigning one civil penalty to a subcontractor for each individual action it knew would result in the submission of a false claim).

227.   *See* Vt. Agency of Nat. Res. v. United States *ex rel.* Stevens, 529 U.S. 765, 768 (2000) ("The defendant is liable for . . . a civil penalty of up to $10,000 *per claim*.") (emphasis added); S. REP. NO. 99-345, at 2 (1986) (stating that a penalty applies once for "each false claim submitted").

228.   31 U.S.C. § 3729(a)(1) (2012).

229.   *Id.* § 3731(d).

230.   *Id.* (emphasis added).

231.   *Cause of Action*, BLACK'S LAW DICTIONARY (5th ed. 1979).

232.   31 U.S.C. § 3729(a)(1)(A) (2012).

claim giving rise to its own right of recovery if examined individually.

For the same reason that there can be no FCA liability for one claim without establishing every element for that one claim, there can be no FCA liability for any other false claim without individually proving each element for that claim. Specific proof "in at least one instance"[233] establishes liability for at least one false claim,[234] not every possible false claim. Because the Act "requires a claimant to point to a specific claim," summary judgment for the defendant is proper where the government "can never point to a specific" false claim.[235] Thus when the court evaluates the legal sufficiency of the government's proof, the FCA requires individualized proof of at least one claim.[236] To apply the FCA consistently, the individual examination necessary to prove one claim should be required for each claim because each claim is an

233.   United States *ex rel.* Quinn v. Omnicare, Inc.*,* 382 F.3d 432, 440 (3d Cir. 2004) (agreeing with the defendant's argument).

234.   *See* 31 U.S.C. § 3729(a)(1)(A) (2012) (holding liable anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval").

235.   United States *ex rel.* Crews v. NCS Healthcare of Ill., Inc., 460 F.3d 853, 858 (7th Cir. 2006); *see also* United States *ex rel.* Wilkins v. United Health Group, Inc., 659 F.3d 295, 308 (3d Cir. 2011) ("[T]o recover under the FCA, we have recognized that *ultimately* a plaintiff must come forward with at least a 'single false [or fraudulent] claim . . . .'" (quoting United States *ex rel.* Quinn v. Omnicare Inc., 382 F.3d 432, 440 (3d Cir. 2004))). It is true that the government is not required "to identify every false claim submitted for payment" at the pleading stage. Chesbrough v. VPA, P.C., 655 F.3d 461, 470 (6th Cir. 2011). However, pleading requirements are quite different from liability requirements. *See Wilkins*, 659 F.3d at 308 ("It is axiomatic that the standards for dismissing claims under Fed. R. Civ. P. 12(b)(6) and granting judgment under . . . Fed. R. Civ. P. 56 are vastly different." (quoting Fowler v. UPMC Shadyside, 578 F.3d 203, 213 (3d Cir. 2009))).

236.   *See* United States *ex rel.* Crews v. NCS Healthcare of Ill., Inc., 460 F.3d 853, 856–57 (7th Cir. 2006) (finding that the relator "did not meet her burden" after failing to identify a second claim for payment when alleging a double billing scheme (citing United States *ex rel.* Quinn v. Omnicare, Inc.*,* 382 F.3d 432 (3d Cir. 2004); United States *ex rel.* Aflatooni v. Kitsap Physicians Serv.*,* 314 F.3d 995 (9th Cir. 2002); United States *ex rel.* Clausen v. Lab. Corp. of Am., Inc.*,* 290 F.3d 1301 (11th Cir. 2002))).

independent source of liability. Thus the FCA requires individualized proof for each individual false claim.

The purpose and actual effect of statistical sampling is to avoid an individual examination of each claim in a large universe of claims.[237] Without this individual examination, it is impossible to show which claim is allegedly false, or which claim an individual allegedly knows is false. Because the FCA requires an individualized examination of each false claim, the FCA's liability requirements "cannot be replaced [with a] 'Trial by Formula.'"[238] Therefore, statistical sampling cannot establish liability under the FCA.

C. Burden Shift

Statistical sampling may also amount to an improper burden shift under the FCA. As sampling does not differentiate the claim that it has proven false from the claim that it has not, it requires a defendant to examine every claim in its case in chief in order to identify and defend the specific claims that sampling predicts would be false. This effectively places the burden on the defendant, which would conflict with the FCA's plain text.[239]

One commentator has posited that allowing statistical sampling in *Life Care* was "the right doctrinal result"[240] in light of

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237. *See* William B. Rubenstein, Newburg on Class Actions § 11:21 (5th ed. 2013) (recognizing that of all the possible claims in a lawsuit, "only a subset can ever be actually tried" if sampling is employed); United States v. Life Care Ctrs. of Am., Inc., 114 F. Supp. 3d 549, 566 (E.D. Tenn. 2014) (stating that the purpose of sampling is "that a smaller portion of claims will be used to draw an inference about a larger, not entirely identical, population of claims").

238. United States v. Vista Hospice Care, Inc., No. 3:07-cv-00604-M, 2016 WL 3449833, at *12 (N.D. Tex. Jun. 20, 2016) (quoting Wal-Mart Stores, Inc. v. Dukes, 564 U.S. 338, 367 (2011)).

239. *See* 31 U.S.C. § 3731(d) (2012) ("In any action brought under section 3730, the *United States* shall be required to prove all essential elements of the cause of action . . . ." (emphasis added)).

240. Case Comment, *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-

the Supreme Court's ruling in *Bigelow v. RKO Radio Pictures, Inc.*[241] Where a defendant destroys evidence and makes it impossible to prove the existence of a false claim, perhaps imposing a burden shift is right for the calculation of damages.[242] But that is only because a "reasonable estimate of the cause of injury, and of its amount" may be the only way for the government to prove its allegations if a defendant's "misconduct has rendered [the necessary evidence] unavailable."[243] *Bigelow* calls for a presumption against wrongdoers who destroy or lose evidence,[244] which is not the same as situations, like in *Agape*, where the evidence is available for examination.[245] There is no precedent in the FCA context directing a burden shift to the defendant absent the destruction of evidence.[246] In fact, one circuit has found the exact opposite: "A defendant's wrongdoing does not shift the burden of proof to the defendant under the FCA."[247] *Bigelow* therefore does not permit a burden shift where proving the

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251, 1:12-CV-64, 2014 U.S. Dist. LEXIS 142660 (E.D. Tenn. Sept. 29, 2014), 128 HARV. L. REV. 2074, 2080 (2015)

241.   *See* Bigelow v. RKO Radio Pictures, Inc., 327 U.S. 251, 265 (1946) (recognizing that the "wrongdoer shall bear the risk of the uncertainty which his own wrong has created.").

242.   *See id.* at 265–66 ("The constant tendency of the courts is to find some way in which damages can be awarded where a wrong has been done. Difficulty of ascertainment is no longer confused with right of recovery for a proven invasion of the plaintiff's rights." (internal quotes omitted)).

243.   *Id.* at 265.

244.   *See id.* (discussing a presumption shift in cases where the "wrongdoer's misconduct has rendered unavailable" the necessary evidence).

245.   *See* United States *ex rel.* Michaels v. Agape Senior Cmty., Inc., No. 0:12–3466–JFA, 2015 WL 3903675, at *7 (D.S.C. June 25, 2015) (recalling a separate case that court previously handled "where statistical sampling represented the only way the plaintiff-relators could prove damages" because the evidence had "been destroyed or dissipated").

246.   *See* United States *ex rel.* Crews v. NCS Healthcare of Ill., Inc., 460 F.3d 853, 858 (7th Cir. 2006) ("At worst, [the defendant] was a criminal enterprise that kept poor records. There is simply no legal authority under the FCA for the proposition that [the relator]'s burden of proof must then be shifted to [the defendant] as a result.")

247.   United States *ex rel.* Absher v. Momence Meadows Nursing Ctr., Inc., 764 F.3d 699, 714 (7th Cir. 2014).

government's allegations is merely difficult, expensive, or inconvenient.[248] Though the cost of litigating each claim for which the government seeks to prove liability can seem burdensome, it is worth remembering that a losing defendant bears the costs of that litigation.[249]

D. Due Process

Finally, the use of statistical sampling for proving liability raises due process concerns. Due process challenges to statistical sampling appear frequently but unsuccessfully in medical overpayment cases.[250] As one commentator has recently addressed the due process concerns with sampling in FCA cases in more detail,[251] the issue will only be considered briefly here. The concern is that statistical sampling in effect prevents the defendant from presenting "a factual defense to any of the essential elements of FCA liability" for any claims outside the statistical sample.[252]

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248.   *See* United States *ex rel.* Michaels v. Agape Senior Cmty., Inc., No. 0:12–3466–JFA, 2015 WL 3903675, at *7 (D.S.C. June 25, 2015) (distinguishing precedent by observing that in the instant case, "nothing has been destroyed or dissipated").

249.   *See* 31 U.S.C. § 3729(a)(3) (2012) ("A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.").

250.   *See* United States' Memorandum in Opposition to Defendant Life Care Centers of America, Inc.'s Motion for Partial Summary Judgment at 23, United States v. Life Care Ctrs. of Am., Inc., No. 1:08-CV-251 (E.D. Tenn. Mar. 21, 2014), 2014 WL 5359287 ("Courts have consistently rejected the very same due process argument that Life Care makes here." (citing Yorktown Med. Lab., Inc. v. Perales, 948 F.2d 84, 90 (2d Cir. 1991); *In re* Chevron U.S.A., Inc., 109 F.3d 1016, 1021 (5th Cir. 1997); Ill. Physicians Union v. Miller, 675 F.2d 151, 157 (7th Cir. 1982); Ratanesen v. Cal., Dep't of Health Servs., 11 F.3d 1467, 1472 (9th Cir. 1993); Chaves County Home Health Serv. v. Sullivan, 931 F.2d 914, 919 (D.C. Cir. 1991))).

251.   *See generally* Christina Vlahos, *When the Ends Do Not Justify the Means: The Application of Statistical Sampling to Determine Liability in False Claims Act Cases*, 90 St. John's L. Rev. 813 (2016) (examining the due process concerns with employing statistical sampling in FCA litigation).

252.   Life Care's Memorandum in Support of Its Motion for Partial Summary Judgment As to the Government's "Unidentified Claims" at 22, United States v.

Forcing defendants to litigate all claims outside the sample without any indication as to which specific claims are supposedly false may deprive defendants of the opportunity to effectively defend against the government's allegations.[253]

The Fifth Amendment prohibits the deprivation "of life, liberty, or property, without due process of law."[254] *Mathews v. Eldridge*[255] governs the procedural due process concerns raised here.[256] This test balances "(1) the private interest affected; (2) the risk of erroneous deprivation of that interest; and (3) the government interest."[257]

The defendant's private interest here is the "due process right to raise individual challenges and defenses to claims,"[258] analogous to the class action context. In *Carrera v. Bayer Corp.*,[259] the court noted that defendant's due process right to provide defenses for each of the elements of a particular plaintiff's claim and analogized this to a due process right to defend against class membership.[260] The particular interest at stake in an FCA case would be the right to provide a defense to each time that the defendant allegedly "knowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval."[261]

Life Care Ctrs. of Am., Inc., No. 1:08-CV-251 (E.D. Tenn. Feb. 18, 2014), 2014 WL 12628637.

253. *See id.* at 23 ("[Statistical sampling] leaves Life Care to defend against unknown claims, relating to unknown patients, for unknown therapy services, on unknown dates – and to face quasi-criminal, treble damages and civil penalties for each such unknown claim.").

254. U.S. CONST. amend. V.

255. 424 U.S. 319, 335 (1976).

256. *See* Yorktown Med. Lab., Inc. v. Perales, 948 F.2d 84, 90 n.7 (2d Cir. 1991) (applying *Mathews* to an administrative overpayment case involving statistical sampling).

257. *Id.*

258. Carrera v. Bayer Corp., 727 F.3d 300, 307 (3d. Cir. 2013).

259. *Id.*

260. *See id.* at 307 ("A defendant has a similar, if not the same, due process right to challenge the proof used to demonstrate class membership as it does to challenge the elements of a plaintiff's claim.").

261. 31 U.S.C. § 3729(a)(1)(A) (2012).

Courts have grounded their analysis of the risk of erroneously impinging upon a defendant's private interests on the understanding that statistical sampling carries "low risk of error."[262] This factor therefore depends on the scientific reliability of the particular statistical methodology employed in that case.[263] To the degree that the due process clause is concerned with depriving defendants of a right using problematic proof,[264] the weight of this factor may vary case-to-case.

Courts have also weighed "the government interest in minimizing administrative burdens" heavily in this context.[265] The consideration here is whether sampling may be "the only feasible method" by which the government can combat large-scale fraud.[266] But where "an explicit provision in the statute . . . requires individualized claims adjudications," the government's interest in easing the burdens of proving its case may not so easily outweigh the due process rights at stake.[267] Along these lines, the FCA's individual liability requirements[268] distinguishes FCA cases from the administrative enforcement cases that have considered the due process question in the past.[269]

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262.   *Yorktown*, 948 F.2d at 90; *see also* Chaves Cty. Home Health Serv., Inc. v. Sullivan, 931 F.2d 914, 922 (D.C. Cir. 1991) ("[I]n light of the fairly low risk of error so long as the extrapolation is made from a representative sample and is statistically significant, the government interest predominates.").

263.   *See, e.g.*, United States *ex rel.* Loughren v. UnumProvident Corp., 604 F. Supp. 2d 259, 269 (D. Mass. 2009) (excluding a statistical sampling methodology that had not been shown to be generally accepted by the scientific community and that was "susceptible to manipulation and significant error").

264.   *See* Neil Issar, *More Data Mining for Medical Misrepresentation? Admissibility of Statistical Proof Derived from Predictive Methods of Detecting Medical Reimbursement Fraud*, 42 N. KY. L. REV. 341, 360–73 (2015) (discussing the evidentiary issues associated with statistical sampling).

265.   *Chaves*, 931 F.2d at 922; *see also* Ill. Physicians Union v. Miller, 675 F.2d 151, 157 (7th Cir. 1982) (noting that "balance is heavily weighed in favor of" the government in an administrative enforcement case).

266.   State of Georgia v. Califano, 446 F. Supp. 404, 410 (N.D. Ga. 1977).

267.   *Chaves Cty.*, 931 F.2d at 922.

268.   *See supra* IV.B. Statutory Analysis (discussing the FCA's requirement that the government individually prove each claim).

269.   *See supra* notes 112–118 and accompanying text (distinguishing

On balance, statistical sampling may violate a FCA defendant's due process rights. The right to defend against each individual alleged violation of a statute merits more weight than the right to possess money when balanced against sampling's reliability in a due process analysis.[270] It becomes burdensome for a defendant to put on the best possible defense for the individual claims alleged to be false when it does not know for which claims it would be held liable.[271] Thus, even where a statistical sampling methodology is scientifically reliable, a defendant may have no choice but to put on evidence regarding each claim outside the statistical sample to address all the claims for which it could be liable.[272] Although the effort necessary for the government to put on individualized evidence for each claim is great, the size of a particular suit should not affect how a court evaluates a constitutional right.[273] Effectively necessitating that a defendant

administrative enforcement cases from FCA cases based on the statutory elements implicated in each). Thus the *Life Care* court's reliance on an administrative enforcement case in its procedural due process analysis should be revisited. *See* United States v. Life Care Ctrs. of Am., Inc., 114 F. Supp. 3d 549, 570 (E.D. Tenn. 2014) ("Specifically, courts that have considered the issue of statistical extrapolation to calculate overpayment have found that it is an acceptable practice which does not violate a defendant's due process rights." (citing Yorktown Med. Lab., Inc. v. Perales, 948 F.2d 84, 90 (2d Cir.1991))).

270. *See* Chaves Cty. Home Health Serv., Inc. v. Sullivan, 931 F.2d 914, 922 (D.C. Cir. 1991) (noting that statutory language requiring an individualized analysis may lead to a different due process analysis than in the administrative recovery context).

271. *See* Life Care's Memorandum in Support of Its Motion for Partial Summary Judgment as to the Government's "Unidentified Claims" at 22, United States v. Life Care Ctrs. of Am., Inc., No. 1:08-CV-251 (E.D. Tenn. Feb. 18, 2014), 2014 WL 12628637 (noting that statistical sampling "fails to apprise [defendants] of the specific claims and statements the Government contends constitute violations of the FCA, and thus precludes [defendants] from investigating, developing and presenting factual and expert evidence related defenses to each of the essential FCA elements").

272. *See, e.g.*, United States *ex rel.* Michaels v. Agape Senior Cmty., Inc., No. 0:12–3466–JFA, 2015 WL 3903675, at *8 n.4 (D.S.C. June 25, 2015) ("[I]n their case-in-chief, the Defendants would delve into the medical issues involved in each and every claim for which the Plaintiff–Relators seek recovery, thereby insuring that the statistical sampling would not significantly shorten the trial.").

273. *Cf.* United States v. Vista Hospice Care, Inc., No. 3:07-cv-00604-M, 2016

put on evidence to defend against a number of claims that the government has not identified as false amounts to a burden shift, which itself may constitute a violation of due process.[274] The Due Process Clause's "constraints" on "governmental decisions which deprive individuals of 'liberty' or 'property'" should fully apply here.[275]

V. Conclusion

The emerging use of statistical sampling for establishing liability in FCA litigation raises a number of issues addressed in this Note. The Supreme Court's previous rulings on statistical sampling call for an examination of the FCA's liability requirements to determine if statistical sampling can satisfy the Act's elements.[276] Under this analysis, statistical sampling cannot properly prove violations of the FCA.[277]

Ultimately, the government attempts to employs statistical sampling to ease the inconveniences associated with massive FCA actions.[278] Whatever convenience statistical sampling offers, the fundamental requirements of the FCA preclude its use in this context.[279] This is not to say that the government is without

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WL 3449833, at *13 (N.D. Tex. Jun. 20, 2016) (deciding the case without reaching the due process issue, but noting that there was no requirement that the relator pursue such a large case).

274.   *See* Montana v. Egelhoff, 518 U.S. 37, 54 (1996) (recognizing that in a criminal case, a jury instruction that amounts to a burden shift violates due process).

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

276.   *See supra* note 134 and accompanying text (calling for an examination of the statute's elements when determining the suitability of statistical sampling in this context).

277.   *See supra* IV.B. Statutory Analysis (discussing statistical sampling as it relates to the FCA's essential elements).

278.   *See* United States v. Life Care Ctrs. of Am., Inc., 114 F. Supp. 3d 549, 565 (E.D. Tenn. 2014) ("[I]t would be impractical for the Court to review each claim individually.").

279.   As one court recently wrote:

   If individual review of each chart were impractical, [the relator] was

recourse when it overpays for services on a massive scale. For example, the government may use statistical sampling to recover overpayments in an administrative recovery proceeding, where the FCA's statutory requirements are not in play.[280] As courts consider whether statistical sampling can ever establish FCA liability moving forwards, the arguments and analysis should center on whether sampling can establish the FCA's essential elements. Because the FCA requires individualized proof for each false claim, courts addressing this issue in the future should find that statistical sampling cannot establish liability under the FCA.

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not required to pursue all potential false claims submitted in fourteen states over nearly a decade, of which she did not have personal knowledge. These choices, made by [the relator], do not reduce her burden to produce reliable evidence of liability.

United States v. Vista Hospice Care, Inc., No. 3:07-cv-00604-M, 2016 WL 3449833, at *13 (N.D. Tex. Jun. 20, 2016).

280. *See supra* II.D.1. Administrative Overpayment Recovery (discussing sampling in the administrative recovery context).