When the Ends Do Not Justify the Means: The Application of Statistical Sampling to Determine Liability in False Claims Act Cases

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WHEN THE ENDS DO NOT JUSTIFY THE MEANS: THE APPLICATION OF STATISTICAL SAMPLING TO DETERMINE LIABILITY IN FALSE CLAIMS ACT CASES

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INTRODUCTION

The False Claims Act serves as the primary tool for the federal government's recovery of funds that were fraudulently disbursed under national security and defense contracts, entitlement programs, federally insured loans and mortgages, transportation and research grants, and agricultural supports.[1] In 2013, the Department of Justice recovered $3.8 billion under the False Claims Act,[2] and in 2014, that number soared to almost $6 billion.[3]

For the last five years, the federal government has recovered $2 billion a year under health care fraud claims alone.[4] These cases originate when health care companies submit false claims to the federal government for reimbursement under such programs as Medicare, Medicaid, and TRICARE.[5] Defendants include major corporations like Johnson & Johnson, Omnicare,

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[1] Press Release, Dep't of Justice, Office of Pub. Affairs, Justice Department Recovers Nearly $6 Billion from False Claims Act Cases in Fiscal Year 2014 (Nov. 20, 2014), https://www.justice.gov/opa/pr/justice-department-recovers-nearly-6-billion-false-claims-act-cases-fiscal-year-2014.

[2] Press Release, Dep't of Justice, Office of Pub. Affairs, Justice Department Recovers $3.8 Billion from False Claims Act Cases in Fiscal Year 2013 (Dec. 20, 2013), https://www.justice.gov/opa/pr/justice-department-recovers-38-billion-false-claims-act-cases-fiscal-year-2013.

[3] Department of Justice, Office of Pub. Affairs, *supra* note 1.

[4] *Id.*

[5] *Id.*

and Community Health Systems, Inc.[6]   For example, in September of 2015, KMART Corp. was compelled to pay $1.4 million to the federal government when it unlawfully incentivized Medicare and Medicaid beneficiaries to fill their prescriptions at KMART pharmacies.[7]

Along with enabling the federal government to recover billions of dollars from major corporations and government contractors, the False Claims Act has enabled the federal government to prosecute individuals like Farid Fata, a hematologist-oncologist who administered chemotherapy and cancer treatments to hundreds of healthy patients whom he intentionally misdiagnosed.[8] Not only did he administer those treatments to perfectly healthy individuals, but he also had those patients undergo many more sessions of treatment than even a cancer-afflicted patient would need.[9] His intention was to submit claims for those treatments for reimbursement from government programs.[10]

The False Claims Act is clearly a useful and important tool for the federal government to recover funds that were, essentially, wrongfully disbursed to meritless claimants. The Justice Department should enforce the False Claims Act even more extensively against companies and individuals like Dr. Fata

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[6] *Id.* Johnson & Johnson paid $1.1 billion in a settlement over False Claims Act allegations regarding several of its prescription drugs. *Id.* Omnicare also settled for $116 million, as a result of its violations of the Anti-Kickback Statute, which falls under the broader umbrella of the False Claims Act. *Id.* Community Health Systems is "the nation's largest operator of acute care hospitals," and the company was required to pay $98.15 million for claims submitted for unnecessary inpatient treatments that should have been provided at lower cost elsewhere. *Id.*

[7] *KMART Corp. Pays $1.4 Million To Resolve False Claims Act Allegations in Connection with Drug Manufacturer Coupons, Gas Discounts*, BUFF. REFLEX (Sept. 3, 2015, 10:30 AM), http://buffaloreflex.com/news/kmart-corp-pays-million-to-resolve-false-claims-act-allegations/article_710d9f34-511b-11e5-812b-df823731a52f.html.

[8] Press Release, Dep't of Justice, Office of Pub. Affairs, Detroit Area Doctor Sentenced to 45 Years in Prison for Providing Medically Unnecessary Chemotherapy to Patients (July 10, 2015), https://www.justice.gov/opa/pr/detroit-area-doctor-sentenced-45-years-prison-providing-medically-unnecessary-chemotherapy.

[9] *Id.*

[10] *Id.* Following Fata's sentencing, Assistant Attorney General Leslie R. Caldwell explained, "Time and again, Dr. Fata callously violated his patients' trust as he used false cancer diagnoses and unwarranted and dangerous treatments as tools to steal millions of dollars from Medicare, even stooping to profit from the last days of some patients' lives." *Id.* Fata engaged in such practices "to increase his billings to Medicare . . . . [He] then submitted fraudulent claims to Medicare . . . for these unnecessary treatments." *Id.*

who engage in unlawful practices in the interest of accumulating more wealth at the expense of the federal government and American taxpayers. Citizens would be better protected from further exploitation, both monetary—as their tax dollars are first spent on false claims, then further expended by the government through its attempts to recover those stolen tax dollars, thereby multiplying the adverse effect by diverting those funds from other uses—and personal, like Dr. Fata's patients, whose collective health was exploited for his gain.

Several courts have recently made it easier to successfully bring claims under the False Claims Act. In cases where defendants have allegedly submitted thousands of false claims to the federal government for reimbursement, rather than presenting proof of each claim's falsity, as is typically required,[11] a court in the Eastern District of Tennessee recently permitted, instead, the submission of a sampling of claims.[12] Based on the analysis of liability in that sample, that court extrapolated liability to the remainder of the alleged false claims.[13]

While the federal government has a compelling interest in recovering as much of those fraudulently disbursed funds as possible, especially in cases where the defendants are acting with such ignoble intent as Dr. Fata, the federal government's recovery should not come at the price of the defendants' Due Process rights under the Fifth Amendment. By permitting statistical sampling to determine liability, the courts lower the burden of proof for liability in False Claims Act cases, essentially bypassing pleading requirements and finding fraud without granting the defendants an opportunity to defend themselves.

Thus, this Note argues that the use of statistical sampling to determine liability in False Claims Act cases constitutes a violation of a defendant's constitutional right to Due Process under the Fifth Amendment. Part I of this Note provides some historical context for the False Claims Act and discusses its contemporary application as a tool for the federal government to recover funds that were disbursed to fraudulent claimants. Part

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[11] Roger S. Goldman et al., *Fourth Circuit May Address Use of Statistical Sampling in False Claims Act Actions*, LATHAM & WATKINS: CLIENT ALERT 1 (July 21, 2015), https://www.lw.com/thoughtLeadership/lw-statistical-sampling-false-claims-act.

[12] United States *ex rel.* Martin v. Life Care Ctrs. of Am., Inc., Nos. 1:08-cv-251, 1:12-cv-64, 2014 WL 4816006, at *19 (E.D. Tenn. Sept. 29, 2014).

[13] *Id.*

II examines earlier False Claims Act cases in which statistical sampling was assessed as a tool for evidentiary analysis. It also examines a recent False Claims Act trial in which the presiding judge held that extrapolation for a statistical sample was sufficient to prove liability, notwithstanding many years of precedent holding otherwise. Part III argues that, on balance, even though the federal government has a strong interest in enforcing the False Claims Act and recovering government funds, statistical sampling fails to provide adequate procedural due process to defendants. This methodology deprives defendants of their Seventh Amendment rights, fails to adhere to civil litigation pleading requirements, and defies accepted standards of proof for liability.

I.   FALSE CLAIMS ACT IN CONTEXT

A.   *History of the False Claims Act*

Since its initial passage in 1863 in the wake of the Civil War, the False Claims Act continues to be among the most effective enforcement tools employed by the federal government to combat the fraudulent taking of public funds.[14] The Unions spent vast amounts of money to sustain its army's efforts against the Confederacy, and a substantial portion of the population enlisted in the armed forces.[15] But, as Representative Fortney Stark explained during his remarks on the Congressional Record in 1985 regarding amendments to the False Claims Act, opportunists "appeared who sold shoddy, dangerous, or worthless merchandise. There were military men who extorted contractors or took kickbacks and gratuities from contractors, and politicians who participated in . . . uncontrolled spending."[16]

In consequence of such exploitation—which included, among many other fraudulently and poorly executed contracts, the sale of blind and diseased mules that were "unfit for the service, and almost worthless" to the federal government, rather than artillery horses and cavalry horses—the False Claims Act was

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

[15] 131 CONG. REC. 1,636-01 (1985) (statement of Rep. Stark).

[16] *Id.*

conceived.[17] The 37th Congress appointed a special committee to "inquire into all the facts and circumstances connected with contracts and agreements by or with the [g]overnment growing out of its operations in suppressing the rebellion."[18] The statute, which provided that "any person who knowingly submitted false claims to the government was liable for double the government's damages plus a penalty of $2,000 for each false claim,"[19] saved the federal government millions of dollars after its enactment.[20]

B.   *Initiating False Claims Act Litigation*

A False Claims Act case may be initiated in several different ways: the Attorney General may file suit in district court; attorneys working on behalf of the country's nearly one hundred U.S. Attorney's Offices may file suit; alternatively, as stated above, a "private person[]" may file his own suit on behalf of the federal government, in what is called a *qui tam* action.[21] This private person, who is called a "relator," may act on any incentive, even just for personal gain.[22] Still, the result is that fraud is brought to the federal government's attention, and

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[17] *Id.*

[18] *Id.*

[19] DEP'T OF JUSTICE, THE FALSE CLAIMS ACT: A PRIMER (2011), www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf.

[20] 131 CONG. REC. 1,636-01 (1985) (statement of Rep. Stark). The False Claims Act has continued to serve as a useful tool for the federal government:

[The False Claims Act] is intended to protect the treasury against the hungry and unscrupulous host that encompasses it on every side, and should be construed accordingly. It was passed upon the theory . . . that one of the least expensive and most effective means of preventing frauds on the treasury is to make the perpetrators of them liable to actions by private persons acting . . . under the strong stimulus of personal ill will or the hope of gain. Prosecutions conducted by such means compare with the ordinary methods as the enterprising privateer does to the slow-going public vessel.

James B. Helmer, Jr., *False Claims Act: Incentivizing Integrity for 150 Years for Rogues, Privateers, Parasites and Patriots*, 81 U. CIN. L. REV. 1261, 1267 (2013) (alteration in original).

[21] DEP'T OF JUSTICE, *supra* note 19; Helmer, *supra* note 20, at 1267 (citing United States v. Griswold, 24 F. 361, 366 (D. Or. 1885)).

[22] The *qui tam* relator may receive up to twenty-five percent of the damages awarded at the end of a False Claims Act suit. 31 U.S.C. § 3730(d)(1) (2012). *Qui tam* actions are initiated when nongovernment agents bring claims on behalf of the government. By initiating this action, the *qui tam* "relator" is generally able to share in the Government's recovery. *Qui tam* comes from *qui tam pro domino rege quam pro si ipso in hac parte sequitur*, meaning "[w]ho sues on behalf of the king as well as for himself." Helmer, *supra* note 20, at 1262 (citing BLACK'S LAW DICTIONARY 1251 (6th ed. 1990)).

funds, which would not otherwise have been recovered, are recovered. This has allowed perpetrators of fraud against the government to be found and brought to trial in ways that are otherwise impossible considering the Justice Department's limited capital and human resources.

C.   *Contemporary Amendments to the False Claims Act*

Since its initial passage, the False Claims Act has been amended a number of times.[23] The federal government now collects treble damages at trial, rather than just double damages.[24]

Additionally, certain steps have been taken to expedite plaintiffs' efforts in bringing False Claims Act cases. For instance, one amendment that was made to the False Claims Act was the modification of the defendant's requisite state of mind—it was reduced from a "knowing" to a "recklessness" standard.[25] Another amendment that has facilitated recovery through the False Claims Act is the reduction of the standard for the burden of proof. In 1986, Congress adopted the preponderance of evidence standard, replacing the clear and convincing evidence standard.[26] Consequently, plaintiffs are more likely to achieve success in bringing a False Claims Act case now than they were previously.[27]

The features of this law, from the *qui tam* provisions allowing nongovernment actors to bring cases on behalf of the government, to the modification of the proof standard, are indicative of a commitment on behalf of Congress to enable the federal government to recover as much money as it can when the government has been wrongfully deceived into paying fraudulent claims.

D.   *Elements of a False Claims Act Cause of Action*

Though the False Claims Act is applied to a wide variety of fraudulently submitted claims to the federal government, whether it is a health care fraud claim or fraudulent

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[23] DEP'T OF JUSTICE, *supra* note 19.

[24] *Id.*

[25] 31 U.S.C. § 3729 (2012).

[26] LaSalle, *supra* note 14, at 500–01.

[27] *Id.* at 501.

disbursements under a military contract, the following are the "requisite elements" that plaintiffs must prove when any False Claims Act case proceeds to trial:

> (1) a [defendant] presents, or causes to be presented, a claim for payment or approval; (2) the claim is false or fraudulent; and (3) the [defendant's] acts are undertaken "knowingly," i.e., with actual knowledge of the information, or with deliberate ignorance or reckless disregard for the truth or falsity of the claim.[28]

To prove the falsity of the information, the plaintiff must establish that the claim "involves an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided."[29] However, False Claims Act cases rarely go to trial.[30]

Moving forward towards litigation, given the publicity and potential damages that may accompany a trial, is unfavorable for defendants,[31] but the pleading and proof standards imposed at trial are also fairly difficult for plaintiffs to satisfy. To determine whether claims submitted to the federal government by defendants are fraudulent, either the government or plaintiff-relators must prove liability for each individual false claim asserted. For instance, in *United States ex rel. Bunk v. Gosselin World Wide Moving, N.V.*, the United States Court of Appeals for the Fourth Circuit, deciding a False Claims Act case, "[treated] each of the 9,136 claims as a discrete basis for liability."[32] One can imagine the time and resources that would be required to

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[28] United States v. Robinson, No. 13-cv-27-GFVT, 2015 WL 1479396, at *4 (E.D. Ky. Mar. 31, 2015) (quoting United States *ex rel.* Bledsoe v. Cmty. Health Sys., Inc., 501 F.3d 493, 503 (6th Cir. 2007)); *see also* United States v. Villaspring Health Care Ctr., Inc., No. 3:11-43-DCR, 2011 WL 6337455, at *4–5 (E.D. Ky. Dec. 19, 2011).

[29] United States v. Fadul, No. DKC 11-0385, 2013 WL 781614, at *7 (D. Md. Feb. 28, 2013) (quoting *Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001)).

[30] It is worth noting that when False Claims Act cases actually proceed to trial, the federal government is able to recover more money than it would at settlement, as treble damages are accounted for in the final judgment, whereas they are not accounted for generally at settlements. *See 2014 Year–End False Claims Act Update*, GIBSON DUNN 5, 11 (Jan. 7, 2015), http://www.gibsondunn.com/publications/documents/2014-Year-End-False-Claims-Act-Update.pdf. Moreover, an unfavorable verdict for defendants in a False Claims Act case can result in such punitive measures as the cancellation of government contracts with those companies, institutions, or individuals who failed to comply with the statute. *Id.* at 11.

[31] *See id.* (regarding repercussions of False Claims Act verdicts for defendants).

[32] *See* United States *ex rel*. Bunk v. Gosselin World Wide Moving, N.V., 741 F.3d 390, 401 (4th Cir. 2013).

effectively review each of the 9,136 claims to determine whether each element of a False Claims Act cause of action is satisfied. It would require so much time, and so many resources, in fact, that some courts have begun to reconsider the evidentiary mandate imposed on plaintiffs in such False Claims Act cases. An alternative means of determining liability, which purports to save both time and resources, is statistical sampling.

II. SAMPLING IN FALSE CLAIMS ACT CASES

"Sampling is a technique which selects a representative portion . . . of the relevant universe of items and, using the results obtained in this sample, makes inferences about unknown quantities of interest in the relevant universe."[33] Statistical sampling has already proven to be a useful tool in class action cases, mass tort cases, and other areas of mass litigation.[34] Sampling allows parties to a trial to avoid the "fishing expeditions" and exorbitant costs of discovery in cases where there are thousands of claims.[35] Still, the use of statistical sampling as a means of determining liability in False Claims Act cases would dramatically "change . . . the landscape of litigating and defending False Claims Act cases."[36] The use of statistical sampling would, controversially, permit plaintiffs in False Claims Act cases to circumvent standard procedure, and instead of presenting the "claim-by-claim proof typically required in highly fact-dependent civil cases,"[37] plaintiffs could simply present either an arbitrarily selected or, worse still, intentionally selected, nonrepresentative cross section of claims and, based on the information extracted from a sample, find that the defendant is liable for the aggregated claims.

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[33] Expert Report on Data Processing, Sample Selection and Proposed Estimation Methodology of Constantin T. Yiannoutsos, Ph.D. at 2, United States v. Life Care Ctrs. of Am., Inc., No. 112CV00064, 2014 WL 7778494 (E.D. Tenn. Mar. 21, 2014).

[34] Charles Yablon & Nick Landsman-Roos, *Discovery About Discovery: Sampling Practice and the Resolution of Discovery Disputes in an Age of Ever-Increasing Information*, 34 CARDOZO L. REV. 719, 722–23 (2012). Sampling was even "expressly" approved as a discovery procedure for e-discovery disputes in the 2006 revisions to the Federal Rule of Civil Procedure 26(b)(2)(B). *Id.*

[35] *Id.* at 725–26.

[36] Chris Haney, *Extrapolating False Claims: The Debate in* U.S. v. Life Care, LAW360 (Oct. 7, 2014), http://www.law360.com/articles/579373/extrapolating-false-claims-the-debate-in-us-v-life-care.

[37] Goldman, *supra* note 11.

A. *False Claims Act Cases in Which Statistical Sampling Was Rejected*

It appears that courts resolving False Claims Act cases have generally been unreceptive to parties who proffer statistics rather than hard, concrete evidence.[38] Rendering a judgment of liability on the basis of probabilities and projections, rather than undergoing a claim-by-claim examination at trial, is still an uncommon practice in most courthouses and one with which judges seem to be uncomfortable.[39]

Traditionally, even in cases where there are thousands of false claims, courts have rejected statistical sampling if it is possible to examine each claim individually to determine its falsity.[40] For instance, in *United States v. Friedman*, where the defendant had his patients unnecessarily hospitalized in order to file reimbursable claims with Medicare, the United States District Court for the District of Massachusetts rejected the government's attempt to employ random sampling of more than fifty percent of the defendant's alleged 676 violations of the False Claims Act.[41] The sample had been subjected to review, and was found to support medical documentation produced by the defendant and the relevant hospitals.[42] However, the presiding judge declined to consider that statistical evidence.[43] The final judgment rested on the findings that forty-two separate claims were indeed violations of the False Claims Act, and the court

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[38] *See, e.g.*, United States *ex rel.* Crews v. NCS Healthcare of Ill., Inc., 460 F.3d 853, 856 (7th Cir. 2006); *see also* United States *ex rel.* El-Amin v. George Wash. Univ., 533 F. Supp. 2d 12, 31 n.9 (D.D.C. 2008).

[39] Judge Mazzone explained his rationale for rejecting the opportunity to extrapolate liability based on a sample:

While I recognize the validity of the mathematical and statistical projections based on a review of a smaller number of claims I have declined to extrapolate in the manner urged by the government. My declination is based on the existence at trial of discrete claims which were analyzed and discussed and subjected to cross examination. I was able therefore to review each claim in reaching my conclusions. While I am mindful of the government's efforts to shorten the trial and present its evidence efficiently and clearly, I am reluctant to accept a statistical sampling as the basis for doubling the alleged overpayment without the same scrutiny and support.

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

[40] *Id.*

[41] *Id.* at *2, *9 n.1, *16–17.

[42] *Id.* at *6–8.

[43] *Id.* at *5–9 n.1.

arrived at this finding because each claim was "analyzed and discussed and subjected to cross examination" at trial.[44] However, the court declined the opportunity to extrapolate that finding of liability to the remaining claims; so long as the individual analysis of each claim was not impossible or utterly impracticable, the judge was reluctant to extrapolate a certain amount of liability based on the results of that statistical analysis.[45]

The reticence on the part of judges to render judgments on the basis of sampling is clearly perceptible in the United States Court of Appeals for the Seventh Circuit case, *United States* ex rel. *Crews*.[46] In *Crews*, the relator brought a *qui tam* complaint against a pharmacy where she was previously employed, subsequent to the employees of that pharmacy pleading guilty to offenses under the Food, Drug and Cosmetic Act.[47] The relator alleged that the pharmacy, which resold medications after patients returned their unfinished prescriptions, submitted false claims by reselling medication, which had already been paid for once, to people who were covered by Medicaid.[48] However, instead of presenting evidence of individual instances where medications that were paid for once by Medicaid were returned and resold, and paid for again by Medicaid, the relator presented "basic math."[49] Her claim was that:

> [The pharmacy] provided prescription medication to nursing home residents, 60% of whom were on Medicaid. Furthermore, 10% to 20% of the dispensed medications were returned unused by the patients. Therefore . . . "basic math prove[d] that 6% to 12% of recycled drugs would have been [re]distributed to Medicaid recipients [and thus rebilled . . .]."[50]

The relator's failure to provide actual proof of false claims—that is, her failure to identify individual claims that were definitively falsely filed, and instead speculating, and presenting calculated probabilities—resulted in summary judgment for the defendant.[51]

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[44] *Id.* at *9 n.1.
[45] *Id.*
[46] 460 F.3d 853 (7th Cir. 2006).
[47] *Id.* at 855.
[48] *Id.* at 856.
[49] *Id.*
[50] *Id.*
[51] *Id.* at 858.

Similarly, in *United States* ex rel. *El-Amin v. George Washington University*,[52] the United States District Court for the District of Columbia responded to a motion in limine by rejecting the submission of claims of which relators did not have "personal knowledge."[53] The relators claimed that the George Washington University hospital received "thousands, if not millions, of [federal] dollars" as reimbursement for anesthesia treatments, which the hospital claimed were conducted by anesthesiologists, though they were actually conducted by CRNAs or residents, which would have been considerably less expensive for patients covered by Medicare.[54] Demonstrating their disinclination to determine liability on the basis of percentages and extrapolations, rather than firsthand information and concrete, reviewable evidence, the court instead required the claimants to plead each claim individually,[55] or at least, to "identify the exact Medicare claims that were allegedly false."[56] Moreover, for each claim, the relators were instructed to provide "the date the claim was filed with Medicare, the name of the attending anesthesiologist, the type of the medical procedure involved and the amount of the claim."[57] The court demanded this specificity of fact because the plaintiffs asserted that the defendants engaged in a regular practice of submitting false claims for reimbursement of procedures that were only conducted by CRNAs. However, there was doubt as to the uniformity of this practice and as to the circumstances surrounding the submission of each of those claims for reimbursement.[58] Principally, the claims were insufficiently similar and so could not be analyzed in the aggregate and, instead, required individualized inquiries.[59] The relators' failure to provide the requested information hardly strengthened their assertion that there were thousands of falsely submitted Medicare claims.[60]

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[52] 533 F. Supp. 2d 12 (D.D.C. 2008).

[53] *Id.* at 31.

[54] *Id.* at 18.

[55] *Id.* at 31 n.9.

[56] *Id.*

[57] *Id.*

[58] *Id.* at 31.

[59] *Id.* at 30.

[60] *Id.* at 31 n.9.

Judges have also felt that the potential for error in statistical analysis is another consideration that precludes them from allowing statistical data to be submitted as proof of fraudulent activity by the defendants. This was the case in *United States* ex rel. *Trim v. McKean*.[61] There, the United States District Court for the Western District of Oklahoma did not allow the use of a statistical sample as evidence of false claims; in particular, the court did not accept extrapolation from that data sample as evidence of false claims.[62] The sample was deemed too small in size, and the claims were not sufficiently uniform.[63] The claims included in the sample were neither "consistent" nor "predictable," and therefore were "not a reliable or accurate representation of *all* [the] claims."[64] When the sample is not comprised of relatively uniform claims, showing uniform patterns and uniform claim amounts, the claims are necessarily not subject to the fact-specific analysis they ought to be undergoing. Furthermore, the likelihood that the outcome of the statistical analysis will be accurate is quite low.[65]

Finally, in the District of Columbia District Court case, *United States* ex rel. *Hockett v. Columbia/HCA Healthcare Corp.*,[66] the relators had ample opportunity to examine each individual claim. Consequently, their presentation of statistical sampling as an alternative to examining each claim individually was rejected.[67] Thus, the court would not accept inferences by the relators that there were certain patterns of behavior that the defendant engaged in, thereby violating the False Claims Act.[68] Instead, the court mandated the production of "real evidence to support [each] contention."[69] The relators had access to the relevant records for each false claim that they alleged.[70] It was

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[61] 31 F. Supp. 2d 1308 (W.D. Okla. 1998).

[62] *Id.* at 1314.

[63] *Id.*

[64] *Id.*

[65] *Id.*

[66] 498 F. Supp. 2d 25 (D.D.C. 2007).

[67] *Id.* at 65–66.

[68] *Id.* at 66.

[69] *Id.*

[70] *Id.* at 65 ("Relator has had access to the records of the 66 patients at issue. No attempt has been made to review each of those records to determine if impropriety can be gleaned from them. Likewise, there has been no concerted effort, through discovery aimed at records keepers or caregivers, to pin down the who, what, and when of the alleged false claims.").

certainly feasible for the relators to review these records, and the discovery of the "who, what, and when of the alleged false claims," was no insurmountable feat.[71]   The relators' failure to specifically plead each false claim, when that evidence was readily available to them, resulted in the court's rejection of statistical sampling in that case.[72]

These cases demonstrate that judges are typically guided by the public's interest in both ensuring accurate outcomes and protecting defendants' procedural due process rights.   Courts have been unwilling to permit statistical sampling so long as the claims are concrete and information is sufficiently accessible, such that individual review of each claim is feasible. Additionally, where there has been reason to believe that the results of the statistical sampling would not be representative of the population of claims sampled, or they would otherwise be inaccurate, courts have rejected the use of statistical sampling.

B.   Defining the Parameters of Statistical Sampling's Limited Application Prior to 2014

Despite courts' wariness of statistical sampling, there are indeed limited circumstances in which courts have allowed the use of statistical sampling during False Claims Act litigations. One line of precedent demonstrates courts' willingness to permit sampling for the determination of damages.[73]   Another line of cases demonstrates that, in very limited circumstances and within a closed universe of specific facts, there may be mitigating factors that enable a court to permit statistical sampling, while avoiding the possibility of depriving defendants of their due process rights.   Subsequent courts have chosen not to broaden the scope of such usage of statistical sampling, or have otherwise found that those rulings were very fact specific and circumstantial, and therefore not more broadly applicable.

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[71] *Id.* at 65.

[72] *Id.* at 66, 70. The relator failed to "point to a single specific false claim or a sufficiently detailed description of one." *Id.* at 71 (quoting United States *ex rel.* Aflatooni v. Kitsap Physicians Serv., 314 F.3d 995, 997 (9th Cir. 2002)) (internal quotation mark omitted).

[73] *See False Claims Act—Proof of Liability—Eastern District of Tennessee Rules that Statistical Extrapolation May Suffice to Prove Liability*, 128 HARV. L. REV. 2074, 2078 (2015) [hereinafter *False Claims Act—Proof of Liability*].

1. Statistical Sampling for the Determination of Damages

The use of statistical sampling to measure damages in False Claims Act cases is a "long-standing" practice, and "relatively uncontroversial"—it is not challenged on due process grounds.[74] In *United States v. Cabrera-Diaz*,[75] the United States District Court for the District of Puerto Rico allowed a sample, which had been selected by the government for an audit of the defendant's claims for reimbursement for anesthesia services he provided, to be used to determine just how many of the submitted claims were false.[76] The results of this audit, which examined the operating reports, anesthesia records, and nurse notes relating to the claims included in the sample,[77] were then extrapolated to the entire quantity of claims submitted by the defendant to determine an estimate of the amount overpaid to the defendant by Medicare.[78] These findings were used to determine the measure of damages to be awarded to the government.[79] The court, in line with earlier holdings, held that statistical sampling was acceptable when its function was limited to the determination of damages.[80]

Similarly, in *United States v. Rogan*,[81] the Seventh Circuit concluded that statistical sampling was acceptable to determine the measure of damages where the manager of a healthcare company was engaged in a kickback scheme—patients were referred to a particular medical center and kickbacks were disbursed.[82] There were 1,812 claims in question; the defendant argued that "the district judge had to address each of the 1,812 claim forms," to prove that there were patients who did indeed receive treatment at the medical center that qualified for

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[74] Jeanne A. Markey & Raymond M. Sarola, *4th Circ. FCA Statistical Sampling Case Is One To Watch*, LAW360 (Oct. 8, 2015), http://www.law360.com/articles/712001/4th-circ-fca-statistical-sampling-case-is-one-to-watch.

[75] 106 F. Supp. 2d 234 (D.P.R. 2000).

[76] *Id.* at 237, 242.

[77] *Id.* at 240.

[78] *Id.* at 237.

[79] *Id.* at 242.

[80] *Id.* at 240 ("Numerous cases involving Medicaid and Medicare overpayments have endorsed proof of damages through the use of statistics and statistical sampling . . . . [T]he Ninth and Second Circuits rejected plaintiffs' due process challenges to the use of statistical extrapolation from a sample to calculate the amount of Medicaid overpayments.").

[81] 517 F.3d 449 (7th Cir. 2008).

[82] *Id.* at 451–52.

reimbursement.[83] But this argument was rejected as "a formula for paralysis," by the Seventh Circuit, which held instead that "[s]tatistical analysis should suffice."[84] Statistical analysis was sufficient for the determination of damages because it was nearly impossible to find information regarding each individual claim to clearly prove that each one was fraudulently submitted.[85]

The use of statistical sampling and extrapolation was again approved to determine damages in a 2013 District of Maryland case, *United States v. Fadul*.[86] There, the defendant was a doctor who had allegedly submitted false claims for reimbursement by Medicare, essentially "double dipping"[87] and receiving payments for more procedures than were rendered. The government supplied an analysis of statistically valid random samples and found that the procedure in question for which reimbursement was sought, retroperitoneal ultrasounds, were not medically necessary, if they were even performed at all.[88] Ultimately, the court found that the use of sampling was allowable because the relevant medical records for all 551 claims alleged were difficult to obtain,[89] and because the extrapolation method was "the soundest measure of damages."[90]

Courts have long distinguished the evidentiary standards for liability from the evidentiary standards for damages. In fact, the United States Supreme Court reinforced this principle in *Story*

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[83] *Id.* at 453 ("Nor does Rogan get any mileage from the argument that Edgewater's records do not 'rule out' the possibility that the four physicians provided some medical services.").

[84] *Id.* at 453. At trial, in the Northern District of Illinois, the court had treated each claim as an individual basis for determining the monetary penalty:

Each knowing submission of a false or fraudulent claim is a separate violation of the False Claims Act. Thus, the number of violations of the False Claims Act depends on the number of false or fraudulent claims or other requests for payments that defendant caused to be submitted. A penalty is assessed per false claim.

United States v. Rogan, 459 F. Supp. 2d 692, 720 (N.D. Ill. 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008) (citation omitted). Nevertheless, the Court of Appeals for the Seventh Circuit determined that it was unimportant that the patients may have received medical care meriting reimbursement, and instead accepted a statistical analysis—"the entire amount that [the defendant] received on these 1,812 claims must be paid back." *Rogan*, 517 F.3d at 453.

[85] *Id.*

[86] No. DKC 11-0385, 2013 WL 781614 (D. Md. Feb. 28, 2013).

[87] *Id.* at *2.

[88] *Id.* at *3.

[89] *Id.* at *14.

[90] *Id.*

Parchment Co. v. Paterson Parchment Paper Co.,[91] holding: "[T]here is a clear distinction between the measure of proof necessary to establish the fact that petitioner had sustained some damage, and the measure of proof necessary to enable the jury to fix the amount."[92] When parties have reached the stage in the trial where they are debating damages, the defendant has already been deemed culpable, following the court's stringent review of the alleged claims. Because the defendant has already been found culpable, the defendant must accept the consequences of its actions, including the consequence that the court will determine the damages based on statistical analyses and approximations.[93] It is acceptable for the defendant to suffer the negative consequences of the application of statistical sampling to the determination of damages because the defendant has been found liable.[94] This same reasoning clearly cannot be applied to a defendant at any earlier stage in the proceeding; the court should not modify or weaken the procedures that are in place during any stage at trial where the defendant has not yet been found liable.

2. Statistical Sampling's Application upon Waiver of
    Defendant's Procedural Due Process Rights

Though statistical sampling is generally proposed by the plaintiffs—at the objection of defendants—who hope to complete their evidentiary analysis more efficiently, there are occasions when sampling has been accepted by the defendants. In such instances, the defendant's express consent to sampling preempts any concerns regarding procedural due process, as they waive their right to more stringent review.

For instance, in 2010, the United States Court of Appeals for the Ninth Circuit conceded in *United States v. Chen* that the use of statistical sampling to determine liability in a False Claims Act case involving a healthcare provider was allowable when the defendant submitted that the sampling was representative of all claims.[95] The jury found the defendant liable for submitting 3,544 false claims to Medicare for reimbursement, although only 37 claims had been reviewed in depth as part of the federal

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[91] 282 U.S. 555 (1931).

[92] *Id.* at 562.

[93] *False Claims Act—Proof of Liability*, *supra* note 73, at 2078.

[94] *Id.* at 2079.

[95] 402 F. App'x 185, 188 (9th Cir. 2010).

government's investigation.[96]   The Ninth Circuit held that the review of only 37 claims in a case involving over 3,000 claims was allowable because the defendant himself conceded that each of the 3,544 claims were filed under similar circumstances and conformed to a certain pattern.[97]   By effectively granting permission to complete a statistical analysis rather than individual analyses, the defendant waives the procedural requirement of determining liability on an individual basis for each claim.

Another instance in which sampling was permitted with the permission of both parties is *United States v. Krizek*,[98] in the District Court for the District of Columbia. There, the defendant billed more than twenty-four hours in a day and submitted those billings for reimbursement by the federal government.[99]   Upon the agreement of both parties, the court reviewed a sampling of only 200 claims, rather than examining all 8,002 reimbursement claims alleged.[100]   "The fact that there was some liability was a foregone conclusion, and the nature of the case meant that '[a] determination of liability on the issue of improper coding would be equally applicable to all other claims.' "[101]   The parties' mutual decision to forego analysis of each individual claim led to the use of a sampling technique.

In most cases, where the court harbored concern that the individual claims were too fact specific for sampling, sampling was rejected altogether. However, the United States District Court for the Eastern District of Louisiana was able to find an acceptable compromise in In re *Vioxx Products Liability Litigation*.[102]   A "Special Master" completed a report in which he evaluated all 30,000 claims, and completed an individual valuation for each unique claim. For the claims that bore overwhelmingly similar characteristics, the court allowed the

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[96] *Id.* at 188–89.

[97] *Id.*

[98] 192 F.3d 1024 (D.C. Cir. 1999).

[99] *Id.* at 1025.

[100] United States v. Krizek, 111 F.3d 934, 940–41 (D.C. Cir. 1997).

[101] United States *ex rel.* Hockett v. Columbia/HCA Healthcare Corp., 498 F. Supp. 2d 25, 66 (D.D.C. 2007) (alteration in original) (emphasis omitted) (quoting United States v. Krizek, 859 F. Supp. 5, at *7 (D.D.C. 1994)).

[102] *See generally* 239 F.R.D. 450 (E.D. La. 2006 Nov. 21, 2006); *see also* Paul Trapani, In re Vioxx Products Liability Litigation*: Circumventing Due Process Concerns by Allowing Individualization in Sampling Procedures*, 82 TUL. L. REV. 2517, 2518 (2008).

claimant to present an analysis of a statistical sample as evidence, rather than examining each of the claims separately.[103] For the remaining claims, the "Special Master" performed individualized fact-specific analyses.[104] In so doing, the court was able to "lessen[] the burden of discovery upon the parties," without "circumventing a party's burden of proof."[105]

When defendants effectively waive their rights to individual trials of law and fact on each of the claims alleged against them, the court is justified in skipping procedural steps that may otherwise be required for the sake of due process.[106] Consent to particular methods of sampling further allows the plaintiffs and the court to utilize procedures and tools that would otherwise be unavailable to them.[107]

3. The Use of Statistical Sampling to Overcome a Motion for Summary Judgment

The use of statistical sampling has also been accepted at earlier stages of trial, before the time arises for a final determination of liability on the part of the defendants. Sampling has been judged an adequate source of evidence to overcome the hurdle of defeating a motion for summary judgment.

For example, in the recent Eastern District of Kentucky case, *United States v. Robinson*,[108] the court determined that the information extracted from a statistical sample was sufficient to overcome the defendant's motion for summary judgment.[109] The defendant in that case argued that the plaintiff's use of an expert, who examined a sample of thirty claims out of 25,000 alleged claims, was "an insufficient method to prove the 'falsity' of any individual claim in this case,"[110] but the court ignored this argument, holding that the statistical analysis performed by the

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[103] Trapani, *supra* note 102, at 2523.

[104] *Id.* at 2527.

[105] *Id.* at 2529.

[106] Robert G. Bone, *Statistical Adjudication: Rights, Justice, and Utility in a World of Process Scarcity*, 46 VAND. L. REV. 561, 622 (1993).

[107] *Id.* at 623.

[108] No. 13-cv-27-GFVT, 2015 WL 1479396 (E.D. Ky. Mar. 31, 2015).

[109] *Id.* at *11. "For purposes of summary judgment, however, the United States as the non-moving party only needs to 'set forth specific facts showing there is a genuine issue for trial.'" *Id*. at *6 (quoting FED. R. CIV. P. 56(e)).

[110] *Id.*

plaintiff's expert was sufficient to present a "genuine issue of a material fact," for the purpose of defeating a motion for summary judgment.[111]   The court wrote that even though the plaintiff's expert "may not have proved definitively that each of the over 25,000 claims at issue were unreasonable or unnecessary, such proof is unnecessary at this stage of litigation."[112]   Therefore, statistical sampling appears to have been deemed acceptable at the summary judgment stage of a proceeding, because it establishes a genuine issue of material fact that merits consideration at trial.   Nonetheless, this opinion provides no indication as to whether statistical sampling would be accepted as evidence for the trial stage of a case.   The court did not respond to the defendant's argument regarding the burden of proving each individual claim's falsity.

The use of statistical sampling has thus been permitted, albeit in very limited circumstances, with great caution.   Courts have demonstrated neither a readiness to allow plaintiffs to effectively skip several steps in the proof-gathering process at trial, nor a willingness to sacrifice diligence and fact-specific analysis for the sake of efficiency.

4.   Breaking Ranks with Precedent—*U.S.* ex rel. *Martin v. Life Care Centers of America, Inc.*[113]

The United States District Court for the Eastern District of Tennessee recently departed from the strong precedent rejecting the use of statistical sampling to determine liability in False Claims Act cases.[114]   In that case, *United States ex rel. Martin v. Life Care Centers of America, Inc.*, the court considered the admissibility of expert testimony promoting the use of statistical sampling to determine liability in a False Claims Act case involving Life Care Centers' submission of false claims for reimbursement by Medicare and TRICARE.[115]

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[111]   *Id.* at *6.

[112]   *Id.*

[113]   Nos. 1:08-cv-251, 1:12-cv-64, 2014 WL 4816006 (E.D. Tenn. Sept. 29, 2014).

[114]   See *supra* text accompanying notes 38–39, for discussion of False Claims Act cases in which statistical sampling was rejected.

[115]   *Life Care Ctrs. of Am., Inc.*, 2014 WL 4816006, at *3 (E.D. Tenn. Sept. 29, 2014).

In *United States ex rel Martin v. Life Care,* the court was presented with 154,621 claims under the False Claims Act.[116] The government hired an expert witness, Dr. Constantin Yiannoutsos, a professor of Biostatistics at the Indiana University Department of Medicine.[117] Dr. Yiannoutsos was contracted to provide his expert statistical analysis; using a three-step process, he arrived at an estimation of the number of alleged claims, which were, in fact, for noncovered services—that is, falsely filed claims which were reimbursed by the federal government—and an estimation of the loss the government incurred as a result of those claims.[118]

First, at the government's prompting, Dr. Yiannoutsos selected a sample of claims—400 out of the alleged 154,621.[119] Next, he conducted "a medical review of the records related to the claims contained in the sample admissions."[120] Finally, he scrutinized the results of his analysis and arrived at an estimate of the total number of claims that were actually falsely filed.[121] The results of this statistical analysis were offered by the plaintiffs as evidence in support of their charge that the defendants violated the False Claims Act.

The defendants, Life Care Centers of America, Inc., challenged the admissibility of Dr. Yiannoutsos's report for a number of reasons. Stefan Boedeker, the expert for the defendants, asserted that Dr. Yiannoutsos's methodology would "ultimately yield an arbitrary, non-representative, and invalid selection of facilities that will be part of the sampling universe while the rest of the facilities will be ignored."[122] Despite Boedeker's claims that Dr. Yiannoutsos's methodology was "flawed," primarily with regards to the selection of his sample,[123] though also with regards to the particular form of statistical

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[116] *Id.* at *5.

[117] *Id.* at *4.

[118] *Id.* at *6.

[119] *Id.* at *5–6.

[120] *Id.* at *6.

[121] *Id.*

[122] *Id.* at *8 (citing Expert Report by Stefan Boedeker of Stefan Boedeker, United States *ex rel.* Martin v. Life Care Centers of America, Inc., No. 1:08-CV-00251, 2014 WL 4816006 (E.D. Tenn. Nov. 14, 2013) (2013 WL 12066076) [hereinafter Expert Report of Boedeker].

[123] *Id.* at *9.

analysis Dr. Yiannoutsos applied,[124] the Eastern District of Tennessee still held that Dr. Yiannoutsos's testimony was admissible.[125]

To arrive at this finding, the court applied the *Daubert* test.[126] In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[127] the United States Supreme Court held that under the Federal Rules of Evidence, a trial judge is charged with the responsibility of "ensuring that" expert testimony "both rests on a reliable foundation" and "is relevant to the task at hand."[128] Further, the Court stated that "[p]ertinent evidence based on scientifically valid principles will satisfy those demands."[129]   The following factors must be satisfied before expert testimony may be deemed worthy of admission:

> [(]1) whether the expert's scientific technique or theory can be, or has been, tested; [(]2) whether the technique or theory has been subject to peer review and publication; [(]3) the known or potential rate of error of the technique or theory when applied; [(]4) the existence and maintenance of standards and controls; and [(]5) whether the technique or theory has been generally accepted in the scientific community.[130]

While these factors are essential to the court's determination of the acceptability of the proffered scientific evidence, the Supreme

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[124] *Id.* at *12. Boedeker claimed that a "probe sample" would have been a preferable alternative to Dr. Yiannoutsos's stratification technique and use of simulations. *Id.* Boedeker explained in his Expert Report:

> In statistical sampling applications involving very complex populations in which there is insufficient knowledge about the variation in the underlying data, it is absolutely necessary to perform a pilot or probe sample. A pilot or probe sample is a statistically valid random sample on a smaller scale which is then used to assess the variation in the population and to calculate the sample size necessary to achieve a desired (or required) level of confidence and precision such that the extrapolations to the entire universe will be accurate and reliable.

Expert Report of Boedeker, *supra* note 122.

[125] *Life Care Ctrs. of Am., Inc.*, 2014 WL 4816006, at *19.

[126] *Id.* at *10. In *Daubert*, the Supreme Court adjudicated a case in which two minors brought suit against Merrell Dow, claiming they suffered limb reduction birth defects because their mothers had taken Bendectin, a drug prescribed for morning sickness to about 17.5 million pregnant women in the US between 1957–1982. Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 579 (1993).

[127] 509 U.S. 579.

[128] *Id.* at 597.

[129] *Id.*

[130] *Life Care Ctrs. of Am., Inc.*, 2014 WL 4816006, at *2 (citing United States v. Beverly, 369 F.3d 516, 528 (6th Cir. 2004)).

Court also iterated in the *Daubert* opinion that the procedure and methodology must be the focus of such determination, not "the conclusions that they generate."[131] Moreover, the party who introduces this expert testimony in support of their position bears the burden of proving that these criteria have been met.[132] Applying this test, the Eastern District of Tennessee concluded that Dr. Yiannoutsos's testimony sufficiently satisfied the pertinent standards.[133] Consequently, the court held that the Government's proffered expert testimony—in particular, Dr. Yiannoutsos's statistical sampling, analysis, and extrapolation was an acceptable basis for determining liability in a False Claims Act case.

As such, the Eastern District of Tennessee rejected the defendants' arguments that statistical sampling was inappropriate in the context of False Claims Act cases, including their assertions that: (1) the False Claims Act requires "proof of a false claim for payment," and "individualized proof as to every claim"; (2) that the United States must demonstrate that the defendant had the "knowledge with respect to the details of each individual claim"; (3) extrapolation is an inappropriate methodology to measure the falsity of claims allegedly submitted to the government; and (4) sampling and extrapolation "violate" the defendant's "due process rights under the Fifth Amendment."[134]

The Eastern District of Tennessee in supporting its holding stated: "Courts have approved of the use of statistical sampling and extrapolation where an individualized claim-by-claim-review of the elements in a case would be unfeasible or extremely costly

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[131] *Daubert*, 509 U.S. at 595.

[132] *Life Care Ctrs. of Am., Inc.*, 2014 WL 4816006, at *2.

[133] *Id.* at *1. The federal government presented the following arguments in support of Dr. Yiannoutsos's testimony, as applied to the *Daubert* standards:

> [T]he Government's use of sampling is limited to the number of claims for non-covered services and the loss associated with those claims; (2) Defendant's arguments about representativeness are unsupported by statistics, law or logic; (3) a probe sample is not necessary to develop a statistically valid sample; (4) any arguments about issues with the medical review should be directed at the medical review rather than the sample design; and (5) Dr. Yiannoutsos'[s] testimony is supported by well-accepted statistical methods.

Id. at *13.

[134] Brief for United States at 1, United States *ex rel.* Martin v. Life Care Centers of America, Inc., No. 1:08-CV-00251, 2014 WL 4816006 2014 WL 5359287 (E.D. Tenn. Mar. 21, 2014).

and where the challenging party is afforded an opportunity to rebut the results."[135] The court held that the defendants' due process rights were satisfied because they had the opportunity to cross examine the plaintiff's expert statistician, and offer competing evidence.[136]

In making this ultimate conclusion, the Eastern District of Tennessee has opened doors for False Claims Act plaintiffs which were otherwise closed—it has expanded the scope of acceptable usage of statistical sampling, without much consideration of the extensive precedent holding otherwise, in such a way that could dramatically affect the future of False Claims Act litigation.[137]

5. *United States* ex rel. *Michaels v. Agape Senior Community, Inc.*[138]—Undoing What *Life Care* Undid

A year after the decision in *Life Care*, the District of South Carolina, in *United States ex rel. Michaels v. Agape Senior Community Inc.*, also considered, but rejected, the use of statistical sampling to determine liability in False Claims Act cases. In this case, which was a *qui tam*, and where the claims alleged were "fact-dependent and wholly unrelated to each and every other claim,"[139] the parties on both sides agreed to a bellwether analysis.[140] This is a specific form of statistical sampling whereby a sample of cases "large enough to yield reliable results is tried to a jury."[141] The federal government ultimately rejected this methodology, despite the parties' mutual agreement to use statistical sampling, claiming that the results were inaccurate, with an "error rate" of 20–60%.[142]

The court acknowledged the obvious difficulty of demonstrating liability for each individual claim, considering the sheer volume of claims; and it recognized that quite often, as in *United States ex rel. Michaels*, the plaintiffs must hire experts

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[135] *Id.* at 6. The defendants took the opportunity to rebut this evidence at trial by contesting the method and accuracy of the statistical analysis. They were not able to contest the apparent falseness of each individual alleged false claim.

[136] Markey & Sarola, *supra* note 74.

[137] *False Claims Act—Proof of Liability*, *supra* note 73.

[138] No. 0:12-3466-JFA, 2015 WL 3903675 (D. S.C. June 25, 2015).

[139] *Id.* at *2.

[140] *Id.*

[141] *Id.*

[142] *Id.*

who review each individual claim.[143]   In *United States ex rel. Michaels*, it was necessary for the plaintiff-relators to pay $400 an hour for file review to experts who spent 4 to 9 hours reviewing each individual claim, in a case where over fifty thousand false claims were alleged.[144]   The expense of such an exercise is likely a disincentive for plaintiffs who would otherwise pursue their cases all the way through to trial.   However, the District of South Carolina's ultimate ruling, even after considering and citing the decision in *Life Care*, was that these claims are intrinsically fact specific, and as a result, these cases are simply not "suited for statistical sampling."[145]   The court also highlighted the fact that the evidence necessary to prove liability for each individual claim, the patients' medical charts, was "intact and available for review by either party."[146]   The government's interest in ensuring an accurate and fair outcome was so strong in this case that it superseded any interest in expediting the procedural process whereby liability was determined—so much so that the government decided to intervene in a *qui tam* case to rectify the bad outcome brought about by statistical sampling.

The conflicting outcomes of these cases underscore the struggle of balancing the interests of the federal government in facilitating recovery of fraudulently disbursed funds under the False Claims Act and the public's interest in preserving defendants' due process rights.

III. PROCEDURAL DUE PROCESS ANALYSIS APPLIED TO STATISTICAL SAMPLING

Most scholarship regarding the acceptability of sampling as a tool for adjudication of mass litigations diverges based upon two analytical theories. Some argue that sampling allows for the efficient adjudication of these large cases, where courts are faced with the enormous task of adjudicating claims numbering in the thousands, if not hundreds of thousands. Others argue that

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[143] *Id.* at *1.

[144] *Id.*

[145] *Id.* at *8.

[146] *Id.* at *7.

sampling, though it may "maximize utility," obstructs justice by bypassing the procedural safeguards necessary for the protection of defendants' right to Due Process.[147]

Representing the former school of thought, in his article regarding the use of sampling in class action litigation, Hillel Bavli argues that sampling is an acceptable method to determine liability so long as the outcome of the sampling is accurate.[148] So long as the ends are just, Bavli argues, the means by which those ends are achieved—that is, statistical sampling—will be acceptable, despite the misgivings expressed by judges, in a number of cases, who rejected statistical sampling in the interest of protecting defendants' due process rights.[149]

Defending the latter school of thought, and employing a rights-based, rather than utility-based, understanding of mass litigation, Robert Bone argues in *Statistical Adjudication* that a "rights-based theory assumes that the purpose of adjudication is," also, "to determine each party's legal rights accurately."[150] The proponents of this theory assert that sampling is a flawed methodology, which does not guarantee accurate results, and so it should not be accepted as an appropriate alternative for evidentiary analysis in mass litigations.[151]

While each of these theories justifies or refutes statistical sampling based on the perceived accuracy or inaccuracy of the outcomes derived from statistical analysis,[152] the apparent accuracy or inaccuracy of the outcome should not overshadow or discount the importance of the means by which those outcomes are achieved. The methodology that allows the court to arrive at a particular result must conform to constitutional requirements, and should it fail to meet those requirements, then that methodology should be retooled or replaced.

Courts risk arbitrarily depriving defendants of their property when they use statistical sampling to determine liability in False Claims Act cases, and so statistical sampling affords defendants insufficient process under the *Mathews v. Eldridge* test and

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[147] Bone, *supra* note 106, at 594.

[148] Hillel J. Bavli, *Aggregating for Accuracy: A Closer Look at Sampling and Accuracy in Class Action Litigation*, 14 L. PROBABILITY & RISK 1, 3 (2015).

[149] *Id.* at 2–3.

[150] Bone, *supra* note 106, at 598.

[151] *Id.*

[152] *See* Vern R. Walker, *Restoring the Individual Plaintiff to Tort Law by Rejecting "Junk Logic" About Specific Causation*, 56 ALA. L. REV. 381, 390 (2004).

should not be used to determine liability.[153]   There are several factors that must be considered to determine whether the modification of procedures in a trial—for instance, the adoption of statistical sampling rather than proving individual liability for each claim[154]—deprives defendants of their right to due process. In *Mathews v. Eldridge*, the United States Supreme Court listed several criteria for making this determination.[155] First, the Court considers "the private interest that will be affected" by the procedure; second, it examines "the risk of an erroneous deprivation" through the procedures under attack and the "probable value" of additional or alternative safeguards; and third, principal attention is given to the interest of the party seeking the procedure, with, nonetheless, due regard for any ancillary interest the government may have in providing the procedure or forgoing the added burden of providing greater protection.[156]

A.   *Defendants Have Substantial Property Interests That Are at Stake in False Claims Act Litigations*

First, the private interest that is affected by the use of statistical sampling is easily discernible in False Claims Act cases. There is an obvious property interest at stake: The money that may be recovered from the defendants, which may number in the hundreds of millions of dollars,[157] and the False Claims Act also permits the government to collect treble damages.[158] There may even be a liberty interest at stake[159]—a ruling against the defendant may result in not only reputational harm to the

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[153] *See generally* Mathews v. Eldridge, 424 U.S. 319 (1976).

[154] Christopher J. Roche, Note, *A Litigation Association Model To Aggregate Mass Tort Claims for Adjudication*, 91 VA. L. REV. 1463, 1507 (2005).

[155] *Mathews*, 424 U.S. at 335.

[156] *Id.*

[157] *Record Year for False Claims Act Recoveries*, TAXPAYERS AGAINST FRAUD EDUC. FUND, http://www.taf.org/press-releases/record-year-false-claims-act-recoveries (last visited Jan. 12, 2017).

[158] LaSalle, *supra* note 14, at 522.

[159] Paul v. Davis, 424 U.S. 693, 701 (1976). The "stigma" plus test is derived from *Paul v. Davis*. Reputation alone is not a constitutionally protected liberty interest. *Id.* Instead, there needs to be some right or status, which was previously recognized by state law, that was altered or extinguished—for example, loss of employment opportunities. *Id.* In the context of False Claims Act cases, the impact to the company's reputation following a finding of fraud, together with the rescission of government contracts, or the future inability to contract with the government, may be sufficient to establish a liberty interest.

company, but the defendants may also lose the "ability to contract with the government."[160] These are substantial interests and merit substantial procedural safeguards so that defendants may not be arbitrarily deprived of these interests.

B. *Statistical Sampling Increases the Risk of Erroneous Deprivation of Defendant's Property*

Second, with statistical sampling, the risk of erroneous deprivation of property is great. Statistical sampling is not necessarily a reliable or accurate means of determining whether each of the alleged claims satisfies the requisite elements of the False Claims Act cause of action. The factors that courts generally consider when measuring the risk of erroneous deprivation include the accuracy, fairness, and reliability of the outcomes of the procedure.[161] By allowing plaintiffs to present a statistical analysis of a sample, rather than undergoing evidentiary analysis of each alleged claim, the courts essentially lower the standard of proof for False Claims Act cases, and, consequently, heighten the risk of erroneous deprivation.[162]

1. Methodological Flaws of Statistical Sampling

Statistical sampling has been enthusiastically approved as a prospective alternative to individualized assessments of each claim asserted in other types of mass litigation.[163] However, so

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[160] LaSalle, *supra* note 14, at 521, 523–24 ("There is a significant possibility that a contractor or health care provider will lose its ability to contract with the government if a False Claims Suit is successfully brought. Particularly in the health care field, the most substantial threat of any investigation is the possibility of exclusion—'the death penalty for health care providers.' ").

[161] *Mathews*, 424 U.S. at 343.

[162] *See* Kirby D. Behre & A. Jeff Ifrah, *Statisticians at DOJ May Overstate Case*, 21 NAT'L L. 22, 22 (1999).

[163] Mass litigation involves "numerous similar claims," which "[number] in the tens of thousands." Some common examples of mass litigations include mass torts, product defects, antitrust conspiracy, securities fraud, and more. David Rosenberg, *New Approaches for a Safer and Healthier Society: A Sampling-Based System of Civil Liability*, 15 THEORETICAL INQUIRIES L. 635, 638 (2014). The use of statistical sampling has long been promulgated within the context of mass tort litigations because the encumbrance of litigating each claim individually, and offering adequate evidence for each claim, is so great that plaintiffs are often "preclude[ed]" from "trying cases." Roche, *supra* note 154, at 1502. Indeed, in the context of such mass litigations, courts are now far more accepting of statistical sampling than perhaps ever before: Statistical sampling is "a well-accepted alternative for the trial judge facing crippling discovery and evidentiary costs." *Id.* (citing *In re* Simon II Litig., 211

long as there is doubt as to the reliability and validity of its results, in the context of the False Claims Act, it is not a just alternative. This methodology is inherently flawed in a number of ways. There is little uniformity in the application of statistical sampling; experts disagree about which methodology to use, the means by which a sample is selected, the size of the sample, and whether it is even appropriate to use sampling as a means to "cut-off discovery or merely [to] shift costs."[164]

First, there are various techniques for statistical sampling, and statisticians disagree as to which techniques are most effective, as well as the problems each technique presents.[165] Moreover, statisticians recognize that their own analyses may bring about inaccurate results. For instance, in the United States District Court for the District of Massachusetts case *United States ex rel. Loughren v. UnumProvident Corp.*,[166] the court rejected sampling for the determination of liability.[167] The plaintiffs presented the testimony of their expert witness, who elected to use cohort sampling, as opposed to random sampling or stratified sampling, which are more familiar to most lawyers and judges.[168] Upon presenting the results of his initial analysis, the plaintiff's expert was heavily criticized by the defendant's expert, so much so that the plaintiff actually accounted for the

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F.R.D. 86, 149 (E.D.N.Y. 2002), *vacated, remanded on other grounds*, 407 F.3d 125 (2d Cir. 2005)).

[164] Yablon & Landsman-Roos, *supra* note 34, at 724. "The Federal Rules provide no guidance on any of these matters and the discussion of these issues in the cases themselves is limited." *Id.* at 723.

[165] Random sampling is most commonly used, but its results are unreliable unless the population from which the sample is drawn is homogeneous. On the other hand, while stratified sampling accounts for the differences in characteristics possessed by individual claims in the entire population, the stratifications are not guaranteed to create uniform bodies of claims. Moreover, the "confidence interval" for stratified sampling is lower. JOSEPH L. GASTWIRTH, STATISTICAL SCIENCE IN THE COURTROOM 410 (2000).

[166] 604 F. Supp. 2d 259 (D. Mass. 2009).

[167] *Id.* at 269.

[168] *Id.* at 261; *see also* Yale Department of Statistics, *Sampling*, http://www.stat.yale.edu/Courses/1997-98/101/sample.htm ("Simple random sampling is the basic sampling technique where we select a group of subjects (a sample) for study from a larger group (a population). Each individual is chosen entirely by chance and each member of the population has an equal chance of being included in the sample. Every possible sample of a given size has the same chance of selection.").

Id. Stratified random sampling, on the other hand, is "generally used when the population is heterogeneous, or dissimilar, where certain homogeneous, or similar, sub-populations can be isolated (strata)." *Id.*

defendant's expert's criticism and incorporated his suggestions into his analysis.[169] Ultimately, the court held that the results of the plaintiff's expert were flawed, as a result of his flawed method of statistical analysis.[170] Because the plaintiff was unable to demonstrate, by a preponderance of the evidence, that its expert's testimony was reliable, the court determined that extrapolating liability from its expert's sample was inappropriate.[171]

Second, if any elements of a claim are unaccounted for in the sample, the outcome of a statistical analysis is not likely to be accurate.[172] Ultimately, a finding of liability in a False Claims Act case requires the plaintiff to prove that the claims were both fraudulent and that the defendant has the requisite intent—facts proving these elements are not captured in a statistical sample.[173]

In his article regarding individualized determinations of liability in mass tort cases, Vern Walker argues that the classification of claims for the purpose of defining a sample is a major source of error in statistical analysis. The extrapolation of data from a statistical analysis of a sample, or group, that is incorrectly classified, and the eventual drawing of inferences from an initial faulty premise, "may result in erroneous conclusions about groups of individuals."[174]

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[169] *Loughren*, 604 F. Supp. 2d at 263.

[170] *Id.* at 269.

[171] *Id.*

[172] Peter Simon, *Pros and Cons of Statistical Sampling*, LAW360 (Mar. 22, 2011), http://www.law360.com/articles/232125/pros-and-cons-of-statistical-sampling ("In a construction case involving defective windows installed in a new housing development, the plaintiff hired an expert who identified all the windows that readily showed signs of defect, and examined a random sample of these windows. The expert then extrapolated his results to all windows, not just those with signs of defect. This was inappropriate, because the sample included only the windows that were known to (very likely) be defective. Extrapolation to the entire population overstated the true rate of defect among windows.").

[173] GASTWIRTH, *supra* note 165.

[174] Walker, *supra* note 152; *see also* Michael J. Saks & Peter David Blanck, *Justice Improved: The Unrecognized Benefits of Aggregation and Sampling in the Trial of Mass Torts*, 44 STAN. L. REV. 815, 837 (1992) ("The more heterogeneous the subgroups, the greater the error involved. Either the subgroups need to be composed of sufficiently similar cases to insure reduction rather than magnification of error, or the plaintiffs would have to waive their right to more accurate determinations."). In their article defending statistical sampling's application in mass tort cases, Saks and Blanck argued that statistical sampling produces both reliable and valid results when the following criteria are satisfied: (1) the cases in the population are identical,

Third, as Judge Richard Posner explained in *An Economic Approach to the Law of Evidence*, the use of statistical sampling to determine liability at trial may be problematic because jurors could misunderstand the math and its application to the facts.[175] Judge Posner cited the work of Ronald Allen, who argued that:

> [T]he standard burden of proof instruction to a jury in a civil case . . . will often imply that the jury should find in favor of the plaintiff even if the probability that his claim is valid is much less than .5. The jury will be instructed to render a verdict for the plaintiff if it is satisfied that he has proved each of the elements of his claim by a preponderance of the evidence even if the elements are independent that is, their probabilities are uncorrelated. It is as if the court were telling the jury, that as soon as it finds one element proved by a preponderance of the evidence, it should assume that that element has been proved to a certainty. In other words, the jurors are being told to be bad mathematicians![176]

The results of an analysis of a nonrepresentative sample may be mistakenly interpreted by the jury as proof of all elements of the claim. This failure to sufficiently review evidence supporting each element of the claim—that is, falsity and intent and the actual submission of false claims for reimbursement—could very well result in a ruling against the defendants, and the erroneous deprivation of their property.

Finally, in cases where parties have challenged the sample size that is selected for analysis, it is generally required that the parties "retain an expert statistician to explain, both at the investigative stage and at an administrative hearing or a trial,

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and "perfectly homogeneous with respect to damage-related variables"; (2) the cases are, in fact, so similar, that repeating an analysis of a single case 100 times would have substantially the same result if 100 different cases were analyzed; (3) the average of sample verdicts "more closely" [approximates] the correct damages figure for any case in the population than the verdict from an individual trial of that case; and (4) even if the population is not comprised of identical claims, if "the variation is not *too* great and the sample size is large enough," the outcome is still likely to be accurate. *Id.* at 833–37; Bone, *supra* note 106, at 578. The likelihood that parties to a False Claims Act litigation will be able to determine, with any certitude, that each of the claims presented is essentially "identical" is very low; consequently, this methodology's usefulness is correspondingly unlikely.

[175] Richard Posner, *An Economic Approach to the Law of Evidence*, 51 STAN. L. REV. 1477, 1512 (1999).

[176] *Id.*

why the sample size is statistically inadequate."[177] For instance, in *Michigan Department of Education v. United States Department of Education*, the United States Court of Appeals for the Sixth Circuit held that a sample size of .4% of the total population was acceptable, in contravention of an earlier holding in the Middle District of Florida, *Daytona Beach General Hospital v. Weinberger*, where a 10% sample was deemed too small to achieve an accurate result.[178]

Statistical sampling is therefore an unpredictable and unreliable methodology, and so the risk of erroneous deprivation is correspondingly high. This methodology is not a valid means to determine the merits of a False Claims Act case.

2. Statistical Sampling and the *De Facto* Reduction of the Burden of Proof

Under this second prong of the *Mathews v. Eldridge* test, it is necessary to examine the "sufficiency of the current procedures, and the availability of alternative or substitute procedures."[179] When the burden of proof for False Claims Act cases was reduced from the "clear and convincing" evidence standard to the "preponderance of the evidence" standard, Frank LaSalle argued in *The Civil False Claims Act: The Need for a Heightened Burden of Proof as a Prerequisite for Forfeiture*, that the penalty imposed on those who are judged to have violated the False Claims Act is "quasi-criminal," and so defendants are entitled to a more strenuous review of the plaintiffs' allegations than the new standard of proof affords them.[180] The use of statistical sampling reduces the standard of proof even further.[181]

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[177] Jack R. Bierig, Note, *Methodological Challenges to Government Sampling Techniques in Civil Fraud and Abuse Cases*, 32 J. HEALTH L. 339 (1999).

[178] *Id.* The difference in holdings was rationalized by the fact that the defendant in the former was "given every opportunity to challenge" the sample size and the "technique" by which the sample was evaluated.

[179] LaSalle, *supra* note 14, at 526.

[180] *Id.* at 527, 529.

[181] Statistical sampling was deemed permissible for the calculation of damages by the United States Supreme Court in 1927 in *Eastman Kodak Co. of N.Y. v, S. Photo Materials Co.*, where liability had already been established. 273 U.S. 359, 379 (1927). In *Story Parchment Co. v. Patterson Parchment Paper Co.*, the Supreme Court judged that the proof requirement for liability exceeds the proof requirement for damages. 282 U.S. 555, 562 (1931). Even in mass tort cases, in order to determine liability, the burden of proof is the preponderance of the evidence—a different standard than that used to determine damages. Walker, *supra* note 152, at 460.

Statistical sampling, as a means of evidentiary analysis for the purpose of proving liability, is simply insufficient to protect defendants' property interests. The "more severe the sanction, the more procedure must protect against sanctioning of the innocent, and . . . the more it must protect the accused's dignity and privacy."[182] In cases where statistical analysis would be used to determine defendants' liability, defendants are vulnerable— the methodology whereby liability is determined may be, as discussed in the previous section, flawed—and defendants are denied the opportunity to defend themselves against each individual claim of fraud.[183] Consequently, the defendants:

> [S]tand to lose a tremendous amount of money, disproportionate to the actual harm they caused and potentially their ability to participate in government programs. . . . Also, both parties involved are not private, but rather the Government is prosecuting the case. When the Government is a party to an action, there is an increased risk of error due to the disparity in resources and options available to the Government *vis a vis* the defendant.[184]

Statistical sampling enables the plaintiffs to bypass individual examinations of each claim, and effectively denies defendants the opportunity to challenge those claims. While the plaintiffs benefit from doing less work and achieving more favorable outcomes, the risk of erroneous deprivation of the defendants' property increases.

3. Sampling's Implications for Defendants' Seventh Amendment Rights

Other process-related concerns regarding statistical sampling include what some have described as "[stripping] adjudication of . . . its most essential attribute—a trial of factual and legal issues in the context of an individual dispute."[185] A common argument in opposition to the adoption of statistical sampling to determine liability is that statistical sampling deprives defendants of their Seventh Amendment right to a trial

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[182] LaSalle, *supra* note 14, at 530.

[183] Saks & Blanck, *supra* note 174, at 838 ("[A]lthough all defendants would have an opportunity to present their evidence and arguments, they would not get to do so in response to every plaintiff, but only to a sample of them.").

[184] LaSalle, *supra* note 14, at 531.

[185] Bone, *supra* note 106, at 617–18 (quoting *In re Fibreboard Corp.*, 893 F.2d 706, 712 (5th Cir. 1990)).

by jury.[186] Defendants' rights are abrogated under the Seventh Amendment when courts fail to consider individual evidence from each claim before the jury.[187] In *Bigelow v. RKO Radio Pictures, Inc.*, the court held that "the jury may not render a verdict based on speculation or guesswork."[188] Instead, as in *In re Vioxx*, a products liability litigation, courts insist that the defendants' Seventh Amendment rights supersede plaintiffs' interest in efficiency. Courts have declined to apply statistical sampling in other litigation contexts, including products liability litigation, where judges were unconvinced that the use of sampling did not deprive defendants of their Seventh Amendment rights.[189]

4.   Statistical Sampling and Specificity of Pleading Requirements

The use of statistical sampling also circumvents another crucial step of the False Claims Act adjudicatory process—or of any litigation, for that matter. To present a cognizable claim, under Rule 8 of the Federal Rules of Civil Procedure, the plaintiff must present an issue that is supported by enough facts to defeat a motion for summary judgment—the facts must be specific enough to demonstrate that there is a justiciable issue.[190]

Various circuit courts differ as to what degree of specificity must be alleged in plaintiffs' complaints to successfully initiate litigation on a False Claims Act claim. The Federal Rules of Civil Procedure provide, in Rule 8, that a party which submits its pleading to the court must include "a short and plain statement of the claim showing that the pleader is entitled to relief."[191] Additionally, each allegation should be expressed in a manner which is "simple, concise, and direct."[192] Of particular interest is the requirement under Rule 9(b)—if fraud or mistake is alleged in the pleading, "the circumstances constituting such fraud or

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[186] Roche, *supra* note 154, at 1508–09.

[187] *Id.*

[188] Bigelow v. RKO Radio Pictures, Inc., 327 U.S. 251, 264 (1946).

[189] Trapani, *supra* note 102, at 2522.

[190] FED. R. CIV. P. 8.

[191] FED. R. CIV. P. 8(a)(2).

[192] FED. R. CIV. P. 8(d).

mistake must be stated with 'particularity.' "[193] On the one hand, the First Circuit and the Seventh Circuit have held that the plaintiffs need not enumerate specific false claims to meet the 9(b) pleading standard—and so, perhaps, statistical sampling would be deemed sufficient at this stage.[194] On the other hand, the Fifth, Eleventh, Sixth, Eighth, and Tenth Circuits have concluded that plaintiffs do need to allege specific false claims.[195] These conflicting holdings challenge those who would offer up statistical sampling as an alternative to individually proven and argued claims as evidence at trial.

Still, the requirement of specificity is a mandate that was imposed for the purpose of protecting the due process rights of the defendants.[196] This requirement also protects defendants from prosecutors conducting witch-hunts, claiming fraud without any factual basis and then fishing around for evidence to support that conclusion, after the defendants have already suffered the risks that accompany a finding of liability.[197] Since courts are unable to conclude that statistical sampling presents sufficient

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[193] Barney J. Finberg, *Construction and Application of Provision of Rule 9(b), Federal Rules of Civil Procedure, That Circumstances Constituting Fraud or Mistake be Stated with Particularity*, 27 AM. L. REP. FED. 407, § 2a (1976).

[194] *See, e.g.*, United States *ex rel.* Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13, 29 (1st Cir. 2009) (holding that a relator could satisfy Rule 9(b) by providing factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details as to each claim); United States *ex rel.* Lusby v. Rolls-Royce Corp. 570 F.3d 849, 854 (7th Cir. 2009).

[195] *See, e.g.*, Hopper v. Solvay Pharms., Inc., 588 F.3d 1318, 1325 (11th Cir. 2009) (holding that an allegation of fraud under the False Claims Act must meet the heightened pleading standard of 9(b), which should be applied and enforced predictably and reliably: if "Rule 9(b) is to carry any water, it must mean that an essential allegation and circumstance of fraudulent conduct cannot be alleged in such conclusory fashion" (quoting United States *ex rel.* Clausen v. Lab. Corp. of Am., 290 F.3d 1301, 1313 (11th Cir. 2002))); Sanderson v. HCA-The Healthcare Co., 447 F.3d 873, 877 (6th Cir. 2006); United States *ex rel.* Sikkenga v. Regence Bluecross Blueshield of Utah, 472 F.3d 702, 728 (10th Cir. 2006) (holding that complaints alleging false claims must be based on facts, and not "speculation and conclusory allegations"); United States *ex rel.* Spicer v. Westbrook, 751 F.3d 354, 365 (5th Cir. 2014); United States *ex rel.* Vigil v. Nelnet, Inc., 639 F.3d 791, 796 (8th Cir. 2010).

[196] "To satisfy the particularity requirement in pleading fraud, the pleader must set out the time, place, and content of the alleged misrepresentation with specificity." Finberg, *supra* note 193, ¶ 2a. Furthermore, the defendant requires notice so that he: (1) may be able "to prepare meaningful responses"; (2) "to preclude the use of a groundless fraud claim as a pretext to discovering a wrong"; and (3) "to safeguard defendants from frivolous charges which might damage their reputations." *Id.*

[197] *Id.*

evidence at the pleadings stage, they surely cannot conclude that statistical sampling provides enough factual evidence to justify a determination of liability, and the grave consequences a finding of liability entails.

C. *Balancing of Interests—Efficiency Versus Due Process Rights*

Under the third prong of the *Mathews v. Eldridge* test, the federal government clearly has a compelling interest in enforcing the False Claims Act more vigorously, because it will then be able to recover even more wrongfully disbursed federal funds. But these ends do not justify using statistical sampling as the means. The requirement of individually pleading each claim is a burden the government would be grateful to bypass in the interest of efficiency. Still, the loss risked by defendants if of substantial value, such that the defendant ought to be entitled to all of the protections of a civil trial's procedural requirements before it is deprived of that value.

Admittedly, in other contexts, the government's interests in efficiency and expedience have won out over adjudications over individual clams.[198] In mass tort cases, for example, arriving at a settlement occurs through a process akin to sampling—"[b]oth procedures extrapolate from a subset of cases to generate outcomes for all cases in the larger population."[199] The use of statistical sampling has long been promulgated within the context of mass tort litigations, because the encumbrance of litigating each claim individually, and offering adequate evidence for each claim, is so great that plaintiffs are often "preclude[d]" from "trying cases."[200] So, too, in class action litigations—in *Hilao v. Estate of Marcos*,[201] the Ninth Circuit allowed compensatory damages for 9,541 class members to be calculated using a random sample of 137 claims, and the court extrapolated the validity and value of the sample set to the remaining

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[198] Laurens Walker & John Monahan, *Sampling Liability*, 85 VA. L. REV. 329, 343 (1999) ("Individualized information should be used where it is practical—i.e., cost effective—to obtain. If individual information is not practical to obtain, however, sampling should be used so that a judgment can be reached efficiently and expeditiously.").

[199] Bone, *supra* note 106, at 574.

[200] Roche, *supra* note 154, at 1502.

[201] 103 F.3d 767 (9th Cir. 1996).

claims.[202] The court in that case also considered the difficulty of adjudicating nearly 10,000 claims individually to determine the defendant's liability and determined that some degree of accuracy in the outcome was justifiably sacrificed in the interest of efficiently determining the claims' outcome.[203]

Indeed, in the context of such mass litigations, courts are now far more accepting of statistical sampling than perhaps ever before—statistical sampling is "a well-accepted alternative for the trial judge facing crippling discovery and evidentiary costs."[204] However, as discussed in the foregoing sections, when the competing interests at stake are administrative efficiency on the one hand, and protecting defendants' due process rights on the other, as is the case in False Claims Act matters, the latter must always prevail.

CONCLUSION

Statistical sampling is not an appropriate tool for litigating liability in False Claims Act cases. It deprives defendants of their Due Process rights under the Fifth Amendment, by depriving them of property without providing them with the opportunity to defend themselves against a finding of liability for each individual claim alleged. Statistical sampling enables plaintiffs, including *qui tam* relators and the federal government, to circumvent their burden of proof, including the burden of providing evidence of each element of a False Claims Act claim.

Though statistical sampling certainly presents a means of saving time and resources for plaintiffs bringing False Claims Act cases, and its use would facilitate False Claims Act enforcement, and, consequently, the recovery of more assets for

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[202] *Id.* at 782–87. The use of sampling in this case was ultimately approved because of the caution the plaintiffs exercised in completing their statistical analysis—the thousands of claims were divided into smaller groups based on shared characteristics, and the analysis was completed across those groups, accounting for those differences. *Id.* at 785.

[203] *Id.* at 786.

[204] Roche, *supra* note 154, at 1502. This alternative was adopted for the litigation of asbestos-related injuries in *Cimino v. Raymark Industries, Inc.*, where the District Court judge allowed a sample of 160 claims to be analyzed to determine the damages to be awarded to each member of a full class of 2,298 claims. 751 F. Supp. 649, 653 (E.D. Tex. 1990), *rev'd*, 151 F.3d 297 (5th Cir. 1998). This technique was eventually rejected by the Fifth Circuit, which held that the defendant was entitled to a jury trial on each individual claim to determine damages. *Id.* at 319 (5th Cir. 1998).

the federal government, these benefits should not be provided at the expense of defendants' due process rights under the Constitution.