Can Statistical Sampling Be Used to Prove Liability Under the FCA or Does Each Provision of the Statute Require Individual Proofs?

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Introduction

The False Claims Act (FCA) is the federal government's primary anti-fraud tool for recovering payments made for false claims submitted to government agencies or programs.[1] Under the FCA, a defendant must pay triple actual damages plus civil penalties.[2] FCA recoveries have exceeded $56 billion, due largely to the help of whistleblowers.[3] With

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[1] Avco Corp. v. U.S. Dep't of Justice, 884 F.2d 621, 622 (D.C. Cir. 1989).

[2] False Claims Act (FCA), 31 U.S.C. § 3729(a)(1)(G) (2012).

[3] U.S. DEP'T OF JUSTICE, CIVIL DIVISION, FRAUD STATISTICS—OVERVIEW, OCTOBER 1, 1986 - SEPTEMBER 30, 2017 (2018) (citing statistics that the Department of Justice has recovered $56,259,857,892 from 1986 through fiscal year 2017, over $40 billion ($40,645,761,148) of which was from FCA whistleblower cases brought under the qui tam provisions).

such large sums at stake, the fight over the use of statistical sampling is one of the most important and hotly litigated topics in FCA litigation today. Because there are no circuit court of appeals cases that squarely address the use of statistical sampling for establishing liability, the lower courts are in disarray and in need of a proper framework. When correctly approached, there are two questions that need to be answered—one of which is a legal issue, and the other, a factual issue. The legal question asks if statistical sampling is proper in FCA cases and, in particular, whether it can be used for proving liability under any of the FCA provisions. The factual question asks if the plaintiff picked the right sample. When addressed separately, the answers become clear, and a proper framework can be established.

Part I of this Article is confined to a pure question of law: What is the legal standard for proving liability under the FCA, and how does that standard apply to statistical sampling? The legal question, in other words, is whether each of the FCA liability provisions actually requires individual proofs to prove liability or, alternatively, permits the use of extrapolation. Because the FCA has two different types of liability provisions—one requiring either the presentation or use of a false claim and the other merely requiring that a defendant knew that it was improperly avoiding an obligation to return overpayments[4]—Part I separately addresses each type of provision.

With respect to whether statistical sampling can be used for liability provisions containing a requirement of a presentation or use of a false claim, the lower courts have typically answered this question in one of two ways: (1) sampling can never prove liability because the statute *requires* proof of specific claims; or, more commonly, (2) sampling can *sometimes* be used to prove liability, but *only* in larger-than-life cases where there is either: (a) no "direct evidence," or (b) there is direct evidence, but the cost of individual proofs outweighs the possible recovery.[5] This Article argues that neither approach is correct. Notwithstanding the fact that the first type of FCA liability is predicated on either

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[4] 31 U.S.C. § 3729(a)(1)(G).

[5] *See* United States *ex rel.* Michaels v. Agape Senior Cmty., No. 0:12-3466-JFA, 2015 WL 3903675, at *7-8 (D.S.C. June 25, 2015) (citing cases which employ the different approaches to assessing damages).

the presentation or use of a false claim for payment, that approach still misrepresents the statutory standard that there is no true "specific claim" requirement in the FCA.[6] The latter approach erroneously conflates factual disputes (which change from case to case) with legal rules (which remain fixed and constant, regardless of cost). This Article alleviates the confusion by correctly separating the legal question from the factual question and focusing instead on the actual legal standard at play. First, this Article demonstrates that sampling is already recognized as a legally permissible method of proving liability in cases of widespread fraud. Second, it discusses the propriety of said methodology as wholly independent of any practicality (such as cost) or direct evidence concerns.

As for the second type of FCA liability, known as a reverse false claim for knowingly retaining overpayments, Congress amended the provision in 2009 to remove the requirement that the defendant present a false claim or use a false statement to conceal retention of overpayments.[7] This Article argues that, because there is no longer a requirement of the use of a false statement or claim for recovering overpayments under the new reverse false claim provision, all of the arguments based upon the need for individual proofs evaporate. In short, for reverse false claims liability, statistical sampling is functionally reduced to establishing damages, which the lower courts have consistently upheld in both FCA and Medicare overpayment cases. In addition, in 2010, Congress enacted a separate federal statute that created an obligation to detect and repay Medicare overpayments.[8] The new statute also specifically states that failure to repay Medicare overpayments constitutes an obligation under the 2009 FCA reverse false claim provision.[9] Because Congress and the courts have long permitted statistical sampling when calculating Medicare overpayments, these two statutes working in tandem clearly permit plaintiffs in Medicare FCA cases to use statistical sampling for the

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[6] *See, e.g.*, United States v. Life Care Ctrs. of Am., 114 F. Supp. 3d 549, 565 (E.D. Tenn. 2014) (recognizing that the government could litigate claim by claim and provide "individualized proof of specific claims," but that such an effort would take a long time and would be "impractical").

[7] 31 U.S.C. § 3729(a)(1)(G).

[8] 42 U.S.C. § 1320a-7k(d)(1)-(3) (2012).

[9] *Id*.

recovery of Medicare overpayments, at least in the reverse false claims setting.

Part II of this Article outlines a framework for the role of the parties and the courts in selecting and approving a sampling plan to be used at trial. It seems there are a large number of court decisions that have been wrongly decided, which may be due to parties or courts improperly lumping the legal and factual issues together. To fix this problem, courts must apply a two-step approach. The first step, as addressed in Part I, is to determine the pure legal issue of whether statistical sampling can be relied upon under one or more FCA liability provisions. Once it is determined that statistical sampling is legally permitted, the second step is to ensure that a proper sampling plan is used.

Part II proposes a framework for the courts to follow for ruling upon the reliability of a proposed sampling plan.[10] First, the trial court should require statistical sampling plans to be included in the scheduling conference and mandate that the parties cooperatively approach such sampling plans. Specifically, the parties must meet and seek to reach an agreement upon the manner of statistical sampling. If the parties cannot agree, they should submit briefs addressing the proposed plan. However, the courts should not allow a defendant to merely pick apart a plaintiff's plan, but must instead require the parties to work cooperatively to establish a sampling plan that may involve making recommendations for an alternative sampling plan. This will spare judicial resources and save the court and parties time and money. Next, prior to the close of discovery, the trial court should rule upon the validity of the proposed sampling plan in order to allow time to correct any deficiencies prior to trial. In fact, the court should rule upon the propriety of a sampling plan before it is carried out, and it should do so in sufficient time to permit the plaintiff to conclude the sampling plan during discovery. Finally, if the court-approved sampling plan is reversed on appeal, the appellate court should remand for a new trial with a new sampling plan that corrects any deficiencies, rather than simply throwing out the sampling plan that includes the plaintiff's damage calculations.

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[10] This Article does not address the particulars of what must be included in the sample but focuses on the role of the parties and the court in determining if the sample is reliable.

I. The Legal Question: Can Statistical Sampling Be Used to Prove Liability in FCA Cases?

In large Medicare fraud cases, it is not uncommon for a defendant to have overcharged Medicare for many thousands of patients, thus rendering a claim-by-claim analysis practically impossible. For instance, assume that a hospital administrator held a meeting and told all doctors to upcode[11] the Medicare billing code from treating for a cold to treating for pneumonia for all Medicare patients.[12] Assume further that the year before this directive, the hospital had treated and billed 1,000 cases of pneumonia for Medicare patients, but this year, the same hospital is now billing 10,000 Medicare patients for pneumonia per year. The issue here for the government is to determine whether the sharp increase in cases (from 1,000 cases in Year A to 10,000 cases in Year B) was caused by a fraudulent scheme and, if so, to what extent. This is where statistical sampling comes in. The government is able to establish the fraudulent

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[11] *See* United States *ex rel.* Bledsoe v. Cmty. Health Sys., 342 F.3d 634, 638 (6th Cir. 2003) ("Upcoding" is a common form of Medicare fraud in which a healthcare provider bills Medicare for medical services or equipment that is more expensive than what a patient actually needed or for more or better services than the patient was actually provided.).

[12] Medicare and Medicaid typically reimburse hospitals, doctors and healthcare providers using a Prospective Payment System (PPS). Every illness or medical procedure is assigned a diagnostic code, which is referred to as a Current Procedural Terminology (CPT) code. Centers for Medicare and Medicaid Services (CMS) have issued a guideline to use the CPT codes that are to be considered for the PPS payment of Federally Qualified Health Centers (FQHC) services. *See, e.g.,* Rio Grande Cmty. Health Ctr. v. Rodriguez Mercado, No. 03-1640 (GAG), 2017 WL 4225455, at *1-2 n.1, *7 (D.P.R. Apr. 12, 2017) (deciding the report and recommendation is adopted as a modified sub norm); Rio Grande Cmty. Health Ctr. v. Puerto Rico, No. CV 03-1640 (GAG), 2017 WL 4217332, at *1 (D.P.R. May 10, 2017) (adopting the report and recommendation with modifications). The CPT code represents the amount of money hospitals, doctors and healthcare providers will be reimbursed for the medical services they provide to Medicare or Medicaid recipients. For instance, if a Medicare provider uses the CPT diagnosis code for a cold, they get paid a set amount of money regardless of how much the treatment cost. However, if they use the CPT diagnosis code for pneumonia, they get paid a much higher PPS amount because it generally costs more to treat that condition. *2.07: Intro to CPT Coding,* MEDICAL BILLING & CODING CERTIFICATION, https://www.medicalbillingandcoding.org/intro-to-cpt (last visited Feb. 21, 2018).

scheme through testimony of witnesses that were instructed to upcode. The calculation of the amount of the overpayment could be conducted two ways: by reviewing all 10,000 Medicare patient charts, or through statistical sampling, which requires reviewing a subset based upon a sampling plan.[13] When using sampling, the exact same analysis of a patient's file would be conducted.[14] For instance, a medical expert would review each of the selected samples and determine if the notes had sufficient evidence to prove that each patient was actually being treated for pneumonia, such as if X-rays were done or certain pills prescribed.[15] Once a rate of erroneous billing is set for the sample, that ratio is applied to all 10,000 files. For example, if the sampling reveals that 80% of the billings were improper for pneumonia, that figure would correlate to 80% of the 10,000 billings being fraudulent.[16]

The problem with requiring a claim-by-claim analysis of all 10,000 medical files is that it could take years to accomplish and at such an exorbitant cost as to render it practically impossible.[17] Indeed, courts have recognized that an "[a]udit on an individual claim-by-claim basis of the many thousands of claims submitted each month by each state would be a practical impossibility as well as unnecessary."[18] It is not

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[13] Chaves County Home Health Serv. v. Sullivan, 931 F.2d 914, 917 (U.S. App. D.C. 1991), *aff'd sub nom.*, 931 F.2d 914 (D.C. Cir. 1991) (holding that statistical sampling is not precluded by the statute).

[14] WILLIAM B. RUBENSTEIN, NEWBURG ON CLASS ACTIONS § 11:21 (5th ed. 2013) (discussing the concept of statistical sampling).

[15] Peter T. Thomas, *Trial by Formula: The Use of Statistical Sampling and Extrapolation in Establishing Liability Under the False Claims Act*, 74 WASH. & LEE L. REV. ONLINE 103, 105 (Nov. 2, 2017), https://scholarlycommons.law.wlu.edu/cgi/viewcontent.cgi?article=1089&context=wlulr-online ("An expert witness then extrapolates the rate of claims proved false in that sample to the larger body of claims. In the FCA context, courts have generally recognized statistical sampling as an acceptable method for calculating damages where liability is uncontested or previously determined.").

[16] *See, e.g.*, United States v. Fadul, No. DKC 11–0885, 2013 WL 781614, at *14 (D. Md. Feb. 28, 2013) (detailing the statistical sampling methodology for calculating damages).

[17] *See* Hilao v. Estate of Marcos, 103 F.3d 767, 786 (9th Cir. 1996) ("[T]he time and judicial resources required to try the nearly 10,000 claims in this case would [be] impossible.").

[18] Ga. *ex rel.* Dep't of Human Res. v. Califano, 446 F. Supp. 404, 410 (N.D. Ga. 1977); *accord* Mich. Dep't of Educ. v. U.S. Dep't of Educ., 875 F.2d 1196, 1205 (6th

surprising, therefore, in 2016, the Supreme Court acknowledged that, "[i]n many cases, a representative sample is the only practicable means to collect and present relevant data establishing a defendant's liability."[19]

Because of the wide acceptance of sampling and the impossibility of conducting claim-by-claim analysis in large Medicare overpayment cases, courts have routinely endorsed relying upon statistical sampling to recover Medicare overpayments, as well as in calculating damages under the FCA.[20] The only requirement is that the sample must be fairly representative and statistically valid, which is a factual issue determined in each case. [21]

Recently, however, defendants in large Medicare FCA cases have creatively argued that the use of statistical sampling is impermissible under the FCA, at least for proving liability.[22] The argument goes that the FCA generally requires either a submission or use of a false claim for payment and therefore a claim-by-claim approach is required in all instances—even if it would be practically impossible to prove and thus provide the largest violators a free pass under the FCA.[23] Although there has not yet been a circuit court case ruling on this precise issue, the district courts are split as to whether it is truly a liability issue and, even so, if individual proof is required by the FCA.[24] The question, therefore,

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Cir. 1989) (recognizing random sampling as a reliable and acceptable means of evidence when an individual "audit of . . . thousands of cases comprising the universe of cases would be impossible").

[19] Tyson Foods v. Bouaphakeo, 136 S. Ct. 1036, 1046 (2016) (internal quotation marks omitted) (concluding, however, that the permissibility of statistical sampling turns on "the degree to which the evidence is reliable in proving or disproving the elements of the relevant cause of action," supporting this Article's premise that there is a two-step process).

[20] *See infra* Part I(B).

[21] MANUAL OF COMPLEX LITIGATION § 11.493 (4th ed. 2004) (outlining criteria for determining the admissibility of sampling including a proper population, a representative sample, accurately reported data and proper statistical analysis of the data).

[22] United States v. Robinson, No. 13-CV-27-GFVT, 2015 WL 1479396, at *10 (E.D. Ky. Mar. 31, 2015).

[23] *Id.* at *11 (E.D. Ky. Mar. 31, 2015) (disallowing sampling in large Medicare cases "would frustrate the purposes of the FCA because it would likely encourage anyone who fraudulently submitted claims to Medicare to do so in extremely large quantities so as to prevent the government from logistically being able to bring suit").

[24] United States v. Vista Hospice Care, No. 3:07–CV–00604–M, 2016 WL 3449833, at *12 (N.D. Tex. June 20, 2016) (At this time, no circuit has resolved

is whether there is something within the FCA itself that requires a claim-by-claim approach when the use of statistical sampling might be characterized as implicating liability, as well as damages.

The permissibility of a plaintiff's use of sampling to prove liability in a FCA case is a pure question of law, not a factual determination. Simply put: facts have nothing to do with the initial inquiry regarding the acceptability of sampling under the FCA. Despite significant confusion in the court system—largely attributable to defendants convoluting the issue by suggesting that sampling depends upon whether it is used for proving liability or damages and the relator's[25] misplaced reliance on off-point *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[26] analyses—the legal question regarding liability is clear: do all of the FCA liability provisions require individual proofs to show liability?

If a particular liability provision of the FCA *does* require individual proofs (or "direct evidence," "direct proof," or "proof of specific claims"), then sampling can *never* be allowed under *any* circumstances for such provision, *even if* all the direct evidence would either be practically unattainable or has dissipated. On the other hand, if a particular liability provision does not require individual proofs, then statistical sampling—assuming it was done properly—is always permissible to show liability. Why? Because liability lies in the fraudulent *scheme*, not the individual proofs.

Note the framing of the question. We are not asking, "Did Particular Plaintiff A conduct Particular Test B in Particular Way C to arrive at a random sample?" The particulars are irrelevant in answering the initial question of whether sampling can be used. The *legal* question here—like

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whether statistical sampling and extrapolation can be used to establish liability in an FCA case, however, there have been various state district courts that have decided on the issue); *see, e.g.*, United States v. Fadul, No. DKC 11–0885, 2013 WL 781614, at *14 (D. Md. Feb. 28, 2013) (allowing extrapolation to be used to establish damages in FCA cases); United States *ex. rel.* Loughren v. UnumProvident Corp., 604 F. Supp. 2d 259 (D. Mass. 2009); United States v. Cabrera-Diaz, 106 F. Supp. 2d 234, 234 (D.P.R. 2000) (allowing extrapolation to be used at the default judgment stage); United States v. Krizek, 859 F. Supp. 5, 7 (D.D.C. 1994) (providing an example of this process being allowed in cases where upcoding was alleged).

[25] *Relator*, BLACK'S LAW DICTIONARY (10th ed. 2014) ("A 'relator' is '[a] party in interest who is permitted to institute a proceeding in the name of the People or the Attorney General when the right to sue resides solely in that official.'").

[26] 509 U.S. 579 (1993).

all other abstract legal questions—already *assumes* the particulars. And not just any particulars, but precisely those *particular* particulars. In other words, when asking whether sampling can be used to prove liability, the court is already operating under the factual assumption that the sampling will be (or has been) properly conducted (that is, in an objective, unbiased manner using a random sample). That is an entirely different inquiry (and constitutes a factual inquiry) that takes place only after a court permits sampling. Simply put, to question the objectivity or "randomness" of the sampling method used by the plaintiff is a factual fight, and thus an entirely different question altogether from the legal issue at hand. The factual fight—how the testing was done and which samples were used—varies from case to case, whereas the legal standard—the burden for proving liability—is fixed and constant in all cases. The importance of this distinction between factual disputes and legal standards and, relatedly, the importance of the framing of the question, comes to light in a recent decision from the Fourth Circuit.

The Fourth Circuit recently declined to (explicitly) rule on the permissibility of the use of statistical sampling to prove FCA liability.[27] In *United States ex rel. Michaels v. Agape Senior Community, Inc.*,[28] the court held that the use of sampling or, more accurately, the *framing* of the relators' question on the use of sampling, was not a "pure question of law" subject to interlocutory appeal[29] but was, instead, an evidentiary issue subject to the lower court's discretion.[30] Unlike the issue of the Attorney General's veto power over settlement agreements, the use of sampling to prove liability was not, in the Court's view, subject to appellate review.[31] In finding so, the Court reasoned that, "the relators' appeal does not present a pure question of law" because the relators focused their question on whether the particular sampling method was

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[27] United States *ex rel.* Michaels v. Agape Senior Cmty., 848 F.3d 330, 340 (4th Cir. 2017).

[28] 848 F.3d 330 (4th Cir. 2017).

[29] *Michaels*, 848 F.3d at 341; *see* 28 U.S.C. § 1292(b) (2012) (stating that interlocutory appeal may be appropriate only if there is a "controlling question of law").

[30] *Michaels*, 848 F.3d at 341; *see also* 28 U.S.C. § 1292(b) (interlocutory appeal).

[31] *Michaels*, 848 F.3d at 341.

conducted in a scientifically proven manner, per *Daubert* standards.[32] Quoting from the relators' brief, the Fourth Circuit stated:

> [I]n their opening appellate brief, the relators clarify that "[t]he true question for the District Court is *not* whether statistical sampling and extrapolation, in and of itself, is appropriate." Rather, the relators insist that the issue is whether their proposed "statistical sampling is conducted in a scientifically proven and accepted manner pursuant to the Supreme Court's ruling in [*Daubert*]." Thus, the relators' appeal raises the question of whether the district court may, in its discretion, allow the relators to use statistical sampling to prove their case.[33]

The problem here was not the court's reasoning but the relators' framing of the question. Instead of presenting the court with an abstract legal question—that is, one that factually assumes the sampling was properly conducted, the relators brought the court an evidentiary issue clearly beyond its scope of review.[34] Asking the court to decide whether a particular sample meets *Daubert* is tantamount to asking them to decide a factual fight. Appellate courts do not, in general, determine such things. The *Daubert* inquiry addresses whether evidence is reliable and relevant,[35] which is a purely factual determination; it has nothing to do with the legal issue. The legal issue—indeed, the *only* issue the appellate court could have addressed, had it been presented—asks whether the FCA permits the use of sampling to prove liability. *Daubert*, on the other hand, asks whether a particular sample in a particular case was done properly—that is, if the evidence "both rests on a reliable foundation and is relevant to the task at hand" and if the expert is qualified.[36] The latter is a black and white evidentiary issue obviously subject to the district court's discretion.[37] The former is an abstract legal question squarely within appellate review. Therefore, it follows, that the Fourth Circuit

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[32] *Id.*

[33] *Id.* (citing Opening Brief of Appellants at 11, United States ex. *rel.* Michaels v. Agape Senior Cmty., 848 F.3d 330 (4th Cir. 2017), Nos. 15-2145(L), 15-2147 (citing *Daubert*, 509 U.S. at 597)).

[34] *Michaels*, 848 F.3d at 333.

[35] *Daubert*, 509 U.S. at 590-91.

[36] *Id.* at 590, 597.

[37] *Id.* at 592.

appropriately declined to issue an opinion on the legality of sampling, not because there is no legal question at all but, rather, because the relators did not present it.[38]

Instead of narrowing the question to a *Daubert* determination (and thus metaphorically "shooting themselves in the foot" so to speak, at least about their sampling appeal), the relators should have framed the question as a pure question of law and asked the court to decide whether the statute "requires" direct proof for each claim, or, alternatively, permits sampling. By explicitly telling the court that the question was "*not* whether statistical sampling and extrapolation, in and of itself, is appropriate,"[39] the relators unwittingly removed from the court's grasp the only legal issue subject to appellate review. Whether sampling is, in and of itself, appropriate as a legal method of proving FCA liability is the very question the Fourth Circuit ought to have addressed. By contrast, the particulars of *when* and *how* the sampling was conducted (that is, whether the expert testimony in *Michaels* met the admissibility standards of *Daubert*) are all factual fights decided by the lower court.[40]

The crux of the matter is this: when the relators lose the factual fight at the district court level (because their sampling was not random or because their experts volunteered personal opinions instead of merely reporting scientific results), they will not find relief on appeal absent an abuse of discretion.[41] If, however, the relators *did not* lose the factual fight because the statistical sampling *was* random and properly conducted, they may find relief on appeal. However, they will only find that relief if they present the court with the correct question, that is, if they ask the court to recognize that statistical sampling is a permissible method of proving FCA liability, *even if* "direct proof" still exists.[42] Thus, the Fourth Circuit in *Michaels* was proper in declining to address the relators' question on sampling.[43] This is so, not because there was no legal

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[38] *Michaels*, 848 F.3d at 336.

[39] *Id.* at 341.

[40] *Id*.

[41] *See, e.g.*, *id.* (quoting Bryte v. Am. Household, 429 F.3d 469, 475 (4th Cir. 2005)).

[42] *Id.*

[43] *Id.*

question worth addressing, but because the question, *as packaged by these particular relators*, was a factual determination not within its scope of review for interlocutory appeal.[44]

Note, however, that *Michaels* never declared sampling to be legally *impermissible*. Rather, the opposite: by holding that sampling "can sometimes be permissible,"[45] the Fourth Circuit answered the legal question posed in this Article (but unfortunately not posed by the relators): whether the FCA requires individual proofs.[46] No, clearly not. How do we know? The proof is in the recipe, or, in this instance, the statute.

A. The Legal Standard for Liability Under the FCA Provisions Does Not Require Individual or Direct Proofs

There are two types of FCA liability provisions: one requiring either the presentation of a false claim or use of a false statement and one dismissing such requirements.[47] Whether each type of FCA liability mandates direct proofs requires separate analyses.[48] The three most common FCA liability provisions read:

> (a) Liability for certain acts.—
> (1) In general.—Subject to paragraph (2), any person who—
> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
> . . . .

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[44] *Michaels*, 848 F.3d at 341.

[45] *Id.*

[46] *Id.* If the Fourth Circuit Court of Appeals viewed statistical sampling as impermissible, it could have stopped there instead of saying that the question presented was not ripe for interlocutory appeal. The Court never indicated that statistically sampling cannot be used as a matter of law but noted that the question presented was a factual fight over the sample selected.

[47] 31 U.S.C. § 3729 (2012).

[48] *Id*.

> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, plus 3 times the amount of damages which the Government sustains because of the act of that person.[49]

The first provision, § 3729 (a)(1)(A), requires a defendant to present a false claim to the government.[50] The second provision, § 3729 (a)(1)(B), although not requiring presentment, still requires the use of a false statement material to a false claim.[51] At least until 2009, these two provisions had been the staple of the government or relator's FCA claims, and therefore, have been center-stage in the recent dispute as to whether statistical sampling is appropriate.[52] The argument against sampling for liability purposes for these two provisions is that there can be no actual FCA violation absent evidence in the record of a particular claim being either presented or a false statement used by the defendant. Thus, the legal question is whether individual proof of a claim is required or if statistical sampling can be used to prove liability under (a)(1)(A) or (B). The next section specifically addresses that point.

As to the reverse false claim provision, (a)(1)(G), the status quo changed in 2009 when Congress amended this subpart.[53] In particular, Congress added an alternative way of establishing FCA liability for reverse false claims that does not require either a presentation of a claim or the use of a false statement.[54] In short, Congress entered the mix by eliminating the individual claim requirement.[55] Now, a defendant is liable

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[49] *Id*. § 3729(a)(1)(A)-(B), (G) (citations omitted).

[50] *Id.* § 3729(a)(1)(A).

[51] *Id.* § 3729(a)(1)(B).

[52] The Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21 § 4, 123 Stat. 1617, 1621 (2009). The Fraud Enforcement and Recovery Act of 2009 amended the False Claims Act, removing the requirement that claims be presented to government employees, as well as creating a statutory definition for the materiality element.

[53] *Id*.

[54] *Id*.

[55] *Id*.

under subpart (a)(1)(G) simply by knowingly avoiding repayment of an existing obligation to return overpayments.[56] Because this liability provision does not include the presentment or use of a false claim, the legal question regarding statistical sampling for liability does not encounter the same concerns or arguments advanced under (a)(1)(A) or (B). In fact, as discussed in Section I(A)(2), there no longer are any serious arguments prohibiting statistical sampling in the reverse false claims setting post 2010.[57] Indeed, Congress further closed that door in 2010 by passing another statute that created an obligation to return Medicare overpayments and specifically declaring that failure to do so was a violation of the FCA's reverse false claim provision.[58] In short, post-2009, there is no need for individual proof of specific false claims. The government may seek repayment of the cumulative total of over-payments in a single count and, therefore, use statistical sampling as a means of determining damages, which is always legally proper. Thus, the sole question is the factual issue, as discussed in Part II, as to whether the sample plan is factually sound.

1. The Legal Standard for Liability Under FCA Subsections (a)(1)(A)-(B)

This subpart addresses whether statistical sampling can be used to establish liability under subsections (a)(1)(A) and (B) of the FCA. It is well established, though admittedly not yet well articulated, that subsections (a)(1)(A) and (B) of the FCA do not require direct evidence of each allegedly false claim to prove liability. Why? Because liability lies in the fraudulent scheme, not the individual claim. There are two methods of proving this legal assertion. The first, and primary method,

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[56] United States *ex rel.* Barrick v. Parker-Migliorini Int'l, 878 F.3d 1224, 1226 (10th Cir. 2017).

[57] *See infra* Section I(A)(2).

[58] *See, e.g.*, Karen Nelson, *CMS Finalizes 60-Day Overpayment Rule: Key Take-aways for Healthcare Providers and Suppliers*, DLA PIPER (Feb. 12, 2006), https://www.dlapiper.com/en/us/insights/publications/2016/02/cms-finalizes-60-day-overpayment-rule/; Shelley R. Slade, *Liability Under the False Claims Act for Retained Overpayments: New Horizons,* VOGEL SLADE & GOLDSTEIN, L.L.P., https://www.vsg-law.com/blog/liability-under-the-false-claims-act-for-retained-overpayments-new-horizons (last visited Feb. 21, 2018).

is the statute (or the recipe), which clearly outlines the legal standard for liability and, notably, does not include a requirement of individual proofs. The second is the courts' existing recognition and use of sampling to prove liability in certain instances of fraud (or the pudding).

The phrase, "the proof is in the pudding," is the short form of an ancient proverb, "the proof of the pudding is in the eating," which, in plain English, means that the "real value [or proof] of something can be judged only from practical experience or results and not from appearance or theory."[59] For example, a marketing agency desiring to know how successful its advertising campaign was for Product X would look to the sales figures before and after the ads were launched. Similarly, a bakery wanting to assess the success or failure of its new blueberry muffin recipe would calculate how many muffins were sold before and after the new recipe was implemented. In both instances, *the proof is in the pudding* because both the marketing agency and the bakery are looking at the results, that is, the "practical" effects of the ad campaign or the new muffin recipe to measure success. The bakery, in other words, cannot assess the quality of its muffins by merely studying the ingredients in its new recipe. It must, instead, look to the practical consequences of the matter and see if customers actually purchased the new pastry.

Here, by contrast, the government or relator need not look to the practical consequences of statistical sampling (the results or the cost) to assess whether the *legal standard* actually requires direct proofs. The standard or burden for proving FCA liability does not require an assessment of the practical concerns; it requires only an analysis of the statutory requirements.[60] Simply put: the recipe, in and of itself, answers the legal question. The recipe is the FCA statute. The FCA lays out the legal standard, which does not require individual proof of each and every allegedly false claim to prove liability.[61] The pudding (that is, the practical considerations such as the cost of obtaining direct proofs for each claim) certainly helps whistleblowers argue in favor of sampling, but the

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[59] Oxford Living Dictionaries, *The Proof of the Pudding Is in the Eating*, https://en.oxforddictionaries.com/definition/the_proof_of_the_pudding_is_in_the_eating (last visited Feb. 21, 2018).

[60] John T. Boese, *Recent Developments Under the Federal False Claims Act*, HEALTHCARE COMPLIANCE ASS'N, Apr. 2016, at 20.

[61] *Id.* at 13.

pudding is merely a secondary proof. The recipe, the statute itself, is the primary proof. That is why the proof for statistical sampling (or, more accurately, the primary proof) in this particular instance, is *not* in the pudding.[62] If the statute actually required direct evidence for each claim, then the practical cost of obtaining that evidence—even if such cost is astronomical and outweighs the recovery—would be irrelevant. The court, in other words, would not care about the cost to the relator of providing individual proofs if such proofs were actually *required* by statute. The burden of proof for FCA liability is, therefore, a purely legal question, distinct from all practical considerations of cost and inconvenience to the relator.

2. Liability Lies in the Scheme: The Standard (the Recipe) Does Not Require Specific Proofs

The legal elements for proving liability for fraud under any of the False Claims Act provisions do not require proof of specific claims.[63] Such notions are judicial additives, not statutory requirements. The FCA requires only proof of four elements, none of which requires particularized, specific, or direct evidence.[64] To establish liability, the plaintiff must prove only: "falsity, causation, knowledge, and materiality."[65] There is no language in the statute requiring "specific knowledge" or

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[62] *Id.* at 23.

[63] *See generally* 31 U.S.C. § 3729 (2012) (outlining the necessary requirements for proving liability).

[64] *E.g.*, United States *ex rel.* Petratos v. Genentech Inc., 855 F.3d 481, 487 (3d Cir. 2017) ("A False Claims Act violation includes four elements: falsity, causation, knowledge, and materiality.").

[65] *Id.* (citing Universal Health Servs. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 1996 (2016) (discussing an FCA violation where liability was established without reference to specific proof)); *accord* United States *ex rel*. King v. Solvay Pharm., 871 F.3d 318, 324 (5th Cir. 2017) (addressing "(1) whether there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due (i.e., that involved a claim)"); United States v. United Healthcare Ins. Co., 848 F.3d 1161, 1173 (9th Cir. 2016) ("The essential elements of a false certification claim are: '(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due.'").

"specific proof."[66] For instance, the statute does not say, "The relator must provide individual proofs for each and every alleged claim," nor does it say, "Proof of knowledge requires proof of specific knowledge of specific claims."[67] In fact, it is already well-established law that neither specific intent, nor specific knowledge is required under the FCA.[68]

The plaintiff does not need to prove that the defendant actually knew that he or she was committing fraud.[69] The standard for proving knowledge does not, in other words, require proof of "actual knowledge" to prove liability.[70] Because "deliberate ignorance" or "reckless disregard" are enough, a defendant can be found liable for fraud even if all they did was recklessly ignore the entire situation or bury their head in the sand.[71] Applying this standard to the issue of statistical sampling, we can see that the plaintiff need not prove the defendant specifically intended to defraud the government in *each and every* alleged instance of presenting or using a false claim for payment. The absence of a specific intent requirement, in other words, also means the absence of a specific proof requirement. Consider, for example, the reverse: had the statute actually required proof of specific intent to defraud (which, as previously stated, it does not) the plaintiff would have no option but to produce evidence to prove specific intent for each and every allegation.

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[66] *See generally* 31 U.S.C. § 3729 (outlining the necessary requirements for proving liability).

[67] *Id*.

[68] United States *ex rel.* Spay v. CVS Caremark Corp., 875 F.3d 746, 758 (3d Cir. 2017) (holding that "no proof of specific intent" is required under the FCA); United States *ex rel.* Harman v. Trinity Indus. Inc., 872 F.3d 645, 657 (5th Cir. 2017) (noting that the scienter requirement of an FCA claim is met when a defendant has acted in reckless disregard to the truth or falsity information); United States *ex rel.* Phalp v. Lincare Holdings, Inc., 857 F.3d 1148, 1155 (11th Cir. 2017) (quoting 31 U.S.C. § 3729(b) (2012)) ("[A] relator must show that the defendant acted 'knowingly,' which the FCA defines as either 'actual knowledge,' 'deliberate ignorance,' or 'reckless disregard.'"); United States *ex rel.* Marshall v. Woodward, Inc., 812 F.3d 556, 561 (7th Cir. 2015) (citing 31 U.S.C. § 3729(b)(1) (2012)) ("[K]nowledge does not require specific intent to defraud.").

[69] *Marshall*, 812 F.3d at 561.

[70] *E.g.*, *Universal Health Servs*., 136 S. Ct. at 1999 n.2 (2016) (quoting 31 U.S.C. § 3729(b)(1)(B) (2009)) (finding that "the [FCA]'s scienter requirement 'require[s] no proof of specific intent to defraud'").

[71] *See* 31 U.S.C. § 3729.

Sampling, in that scenario, would logically be impermissible to prove liability because it could not prove specific intent for each allegation.

Because there is no "specific intent" requirement, however, statistical sampling clearly satisfies the burden of proof because the plaintiff need not show intent for each and every alleged claim, but intent for the *entire scheme*. Extrapolation, when done properly, satisfies the burden because it demonstrates the defendant's general intent to defraud the government. Once the fraud scheme is set in motion, some, but not necessarily all of the invoices become tainted by the fraud. Indeed, the goal of the fraudulent scheme is to conceal the overpayments. The role of statistical sampling is to determine the efficiency of the fraudulent scheme and serve as the vehicle for measuring the extent of overpayments due to the fraudulent scheme. In short, the invoices themselves are not the fraud, but simply a byproduct of containing the overpayment due to the scheme. Thus, the proof of the FCA's level of intent to create a false claim does not come from the invoices or even the statistical sampling itself; rather, the proof of the fraudulent scheme is established through testimony of individuals together with memos, emails, or other documents implementing the scheme. Once the scheme is established, the role of sampling is to measure how far the scheme extended and to approximate the harm and thus the amount to be repaid. There is neither a requirement in the FCA nor, more importantly, a need for the government to analyze each particular invoice or submitted claim. So long as the allegedly fraudulent claims arise from the same scheme, the government need only prove liability for the overall scheme, not the individual claim, in order to meet its burden. We proffer that statistical sampling is the tool enabling it to do so.

The centrality of the scheme—and thus the importance of statistical sampling as a tool for unveiling said scheme—was articulated by the Fourth Circuit in *United States v. Conner*.[72] In that case, the court relied upon the scheme to justify the use of sampling for both liability and loss, stating: "The pervasive nature of the fraudulent *scheme*, as well as the methods used by Conner, justified the district court's attribution of fraud to all of the sample claims."[73]

Although the *Conner* court did not further elaborate on the issue of sampling, its focus on the "scheme" affirms the notion that FCA liability

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[72] 262 F. App'x 515 (4th Cir. 2008).

[73] *Conner*, 262 F. App'x at 519 (emphasis added).

lies in the fraudulent scheme, not necessarily the individualized assessment of each claim.[74] The appellate court in *Conner* ultimately affirmed the government's reliance on extrapolation because it recognized that all four elements in the FCA— presentment of a claim, falsity of the claim, knowledge of falsity, and materiality—can be proven using random sampling.[75]

In sum, whether statistical sampling can be used in a FCA case, to prove liability or damages, is a pure question of law.[76] As demonstrated herein, the legal answer is that statistical sampling can and should be used under (a)(1)(A) and (B) in FCA cases because neither specific intent nor specific knowledge is required under the FCA and the proof of the fraudulent scheme is established through testimony of individuals together with memos, emails, or other documents implementing the scheme itself.[77]

B. The Reverse False Claim Provision, (a)(1)(G), Does Not Require Individual Proofs

Another reason why proving liability under subsection (a)(1)(G) through statistical sampling is entirely appropriate is that several circuit courts have ruled that the 2009 reverse false claim provision added to subsection (a)(1)(G) of the FCA does not contain any requirement that a false claim be presented to the government or any false statement be used in assessing liability for retaining overpayments.[78] Therefore, the arguments opposing statistical sampling relating to the need for individual proofs of false claims from the prior section do not exist. Rather, plaintiffs simply need to allege that the defendant has knowingly retained overpayments, which can be assessed cumulatively and such overpayments are properly calculated using statistical sampling.[79]

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[74] *Id.*

[75] *Id.*

[76] *Id.*

[77] *Id*.

[78] *See, e.g.,* United States *ex rel.* Boise v. Cephalon, No. 08-287, 2015 WL 4461793, at *6 (E.D. Pa. July 21, 2015).

[79] Graves v. Plaza Med. Ctr., 276 F. Supp. 3d 1335, 1348 (S.D. Fla. 2017).

Congress amended the reverse false claims provision in 2009 by adding a new, alternative way of establishing liability that does away with using a false statement material to a false claim.[80] The 2009 amendment reads in part that a person is liable under (a)(1)(G) if the person "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government."[81] In 2016, the Sixth Circuit described this amendment to subpart (a)(1)(G) as follows:

> In 2009, Congress passed the Fraud Enforcement and Recovery Act ("FERA"), Pub. L. No. 111-21, 123 Stat. 1617 (2009), which omitted the requirement that a defendant "mak[e], us[e], or caus[e] to be made or used, a false record or statement" from the relevant part of the reverse-false-claim provision. Under the current version of the FCA, anyone who "knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government" is civilly liable.[82]

In December 2017, the Tenth Circuit agreed and stated that the standard for the new version of the reverse false claims provision is as follows:

> The reverse-false-claims provision now imposes liability on any person who: [1] knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or [2] knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.' 31 U.S.C. § 3729(a)(1)(G) (bracketed numbers added for clarity). This second route to liability expands on the first by not requiring a "false record or statement." Simply "knowingly and improperly avoid[ing] . . . an obligation to pay or transmit money or property to the Government" is enough.[83]

The Fifth Circuit has also ruled that all that is required under the new reverse false claims provision is that the person "knowingly and improp-

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[80] 31 U.S.C. § 3729 (2012).

[81] 31 U.S.C. § 3729(a)(1)(G).

[82] U.S. *ex rel.* Harper v. Muskingum Watershed Conservancy Dist., 842 F.3d 430, 436 (6th Cir. 2016), *cert. denied sub nom.* U.S. *ex rel.* Harper v. Muskingum Watershed Conservancy Dist., 138 S. Ct. 69 (2017) (quoting 31 U.S.C. § 3729(a)(1)(G) (2009)).

[83] United States *ex rel.* Barrick v. Parker-Migliorini Int'l, L.L.C., 878 F.3d 1224, 1230 (10th Cir. 2017) (quoting 31 U.S.C. § 3729(a)(1)(G)).

erly avoids an obligation to pay the United States,"[84] and the Third Circuit has stated: "The plain text of the [2009] FCA's reverse claims provision is clear: any individual who 'knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government' may be subject to liability."[85] Thus, it is clear from both a plain reading of the statute and circuit decisions that there is no requirement that a plaintiff establish FCA liability under subpart (a)(1)(G) by introducing proof of individual false statements or claims. All that is required is evidence that there is a duty to repay overpayments and the defendant had requisite scienter.[86]

Because there is no need under subpart (a)(1)(G) to establish that any false claims were either presented or used, the arguments from the prior section evaporate because those objections were predicated upon the need for proving individual false claims as a part of liability.[87] Rather, under subpart (a)(1)(G), statistical sampling is being used merely as a calculation of the amount of the overpayments, which is really a damages issue as opposed to a liability issue. In addition, sampling has been widely recognized as legally permissible for calculating damages under all provisions of the FCA.[88] The cases that have disallowed sampling for

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[84] United States *ex rel.* Simoneaux v. E.I. duPont de Nemours & Co., 843 F.3d 1033, 1035-36 (5th Cir. 2016) ("[A] person is liable under the reverse-FCA provision if he knowingly and improperly avoids an obligation to pay the United States.").

[85] United States *ex rel.* Customs Fraud Investigations v. Victaulic Co., 839 F.3d 242, 254 (3d Cir. 2016), *cert. denied sub nom.*, 138 S. Ct. 107 (2017).

[86] Jonathan G. Cedarbaum et al., *An* Escobar *Roundup: Falsity, Materiality, and Scienter,* WILMERHALE, L.L.P. (Mar. 9, 2018), http://www.mondaq.com/unitedstates/x/681034/trials+appeals+compensation/An+Escobar+Roundup+Falsity+Materiality+And+Scienter.

[87] *See* 31 U.S.C. § 3729(a)(1)(G).

[88] *E.g.*, United States *ex rel.* Michaels v. Agape Senior Cmty., No. 0:12-3466-JFA, 2015 WL 3903675, at *7-8 (D.S.C. June 25, 2015) (gathering and discussing cases that permit or reject sampling in FCA cases, and rejecting sampling based upon the factual difficulties in this particular case); United States *ex rel.* Doe v. DeGregorio, 510 F. Supp. 2d 877, 890 (M.D. Fla. 2007) ("[T]he computation of damages does not have to be done with mathematical precision, but, rather, may be based on a reasonable estimate of the loss."); United States *ex rel.* Harris v. Bernad, 275 F. Supp. 2d 1, 7-8 (D.D.C. 2003) (allowing use of statistical sampling to determine damages caused by the overpayment of Medicare reimbursements in FCA case); United States v. Cabrera-Diaz, 106 F. Supp. 2d 234, 240 (D.P.R. 2000) (establishing that statistical sampling is

FCA damages did not disallow sampling altogether, but instead disallowed sampling that occurred in situations where the plaintiff did not use a reliable sampling plan.[89] Thus, as a matter of law, sampling is legally permissive under the revised reverse false claim provision.

The legal issue under subpart (a)(1)(G) is therefore confined solely to whether there existed an obligation to repay funds.[90] Congress settled this issue in the context of Medicare overpayments.[91] Just one year after Congress amended the FCA's reverse false claim provision to do away with requiring the use of any false statements or claims, Congress passed the Affordable Care Act (ACA) requiring a person who has received an overpayment of Medicare or Medicaid to report and return the overpayment within sixty days.[92]

> (1) In general
> If a person has received an overpayment, the person shall—
> (A) report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and
> (B) notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.
> (2) Deadline for reporting and returning overpayments
> An overpayment must be reported and returned under paragraph (1) by the later of—
> (A) the date which is 60 days after the date on which the overpayment was identified; or
> (B) the date any corresponding cost report is due, if applicable.
> (3) Enforcement
> Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as

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generally permitted for establishing damages and providing an overview of cases that have permitted it).

[89] *See* John LeBlanc & Shoshana S. Speiser, *Using Statistical Sampling in False Claims Act Cases*, MANNAT PHELPS & PHILLIPS, L.L.P. (Aug. 23, 2017), https://www.lexology.com/library/detail.aspx?g=4733d10b-7b36-4e86-9f11-2c1d783f874d ("[S]ampling evidence would hinge, like other evidence, on its reliability.").

[90] *See Barrick*, 878 F.3d at 1230 ("[U]nder either clause of this provision [reverse false claim], there must exist an "obligation to pay . . . money . . . to the government.").

[91] 42 U.S.C. § 1320a-7k(d)(2) (2012).

[92] *Id*.

> defined in section 3729 (b)(3) of title 31) for purposes of section 3729 of such title.[93]

Thus, the person billing Medicare has an affirmative obligation to return any overpayments when it is or should have been aware that it was not entitled to retain the payments.[94] Like the FCA, there is no individual claim requirement under the ACA; the only requirement is that there were overpayments.[95] Thus, if a person has been cheating for five years, he has a continual knowledge that he received overpayments and, therefore, has a continuing duty to repay all overpayments.[96] The government need not present each particular claim in which it had received an overpayment in seeking a recovery of the overpayments, but merely needs to show that the person is currently in possession of overpayments.[97] Thus, the government may rely upon statistical sampling to determine the amount of overpayments.[98] Indeed, it is well settled that when the government seeks the return of overpayments, such as under the ACA, it is allowed to use statistical sampling to calculate the overpayments.[99] In fact, not only is statistical sampling permitted in Medicare overpayment cases, but there is also a presumption of validity.[100] In addition, courts have rejected due process arguments in upholding sampling in Medicare overpayment cases.[101]

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[93] *Id*. § 1320a-7k(d)(1)-(3).

[94] *Id*. § 1320a-7k(d)(3).

[95] *Id*. § 1320a-7k(d)(1).

[96] *Id*.

[97] *Id.*

[98] Ill. Physicians Union v. Miller, 675 F.2d 151, 155 (7th Cir. 1982).

[99] *See id.* (stating "the use of statistical samples has been recognized as a valid basis for findings of fact in the context of Medicaid reimbursement"); Chaves Cty. Home Health Serv. v. Sullivan, 732 F. Supp. 188, 190 (D.C. 1990) ("Several district courts have accepted statistical sampling as an appropriate auditing technique for settling accounts between the government and a private sector care provider under both Medicaid and other social welfare programs.").

[100] Maxmed Healthcare, Inc. v. Price, 860 F.3d 335, 339 (5th Cir. 2017).

[101] Michael Sant'Ambrogio & Adam S. Zimmerman, *Inside the Agency Class Action*, 126 YALE L.J. 1634, 1656 (2017) (citing Chaves County Home Health Serv., Inc. v. Sullivan, 931 F.2d 914, 919-22 (U.S. App. D.C. 1991), *aff'd sub nom.*, 931 F.2d 914 (D.C. Cir. 1991)) ("[C]ourts have consistently rejected claims that statistical sampling in the Medicare and Medicaid programs violates due process, explaining that if a sample is representative and statistically significant, the risk of error to a provider

The ACA did not stop at creating an obligation to return overpayments, but went one step further.[102] The ACA also specifically stated that retaining the overpayments also constitutes an obligation under the FCA.[103] Thus, Congress settled another issue with the reverse false claim provision: namely that the "obligation" element of (a)(1)(G) is met through the ACA, which established a duty to repay overpayments and therefore an obligation under the FCA.[104] Thus, the ACA has the dual effect of not only allowing statistical sampling to calculate the amount of overpayments, but rendering any knowing failure to return the overpayments a violation of the FCA's reverse false claim provision found in (a)(1)(G). In short, as of at least 2010, retaining Medicare overpayments is a violation of (a)(1)(G), provided FCA scienter is established, and it does not require individual proof of the submission of individual false claims.[105] Thus, the amount of overpayments under the reverse false claim provision of (a)(1)(G) is calculated in the same manner as overpayments under the ACA, including the use of statistical sampling. The only difference between the ACA and the FCA's reverse false claim provision is whether the defendant "knowingly" failed to return the overpayments.[106] If not, the ACA is the sole mechanism for recovering overpayments; but, if so, it is also a FCA violation.

In short, statistical sampling is clearly allowed under subpart (a)(1)(G) because there is no requirement that a false statement be used.[107] Rather,

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is fairly low and the private interest 'at stake is easily outweighed by the government interest in minimizing administrative burdens.'"); Ratanasen v. Cal. Dep't of Health Servs., 11 F.3d 1467, 1471 (9th Cir. 1993) (approving the use of random sampling in audits regarding Medicare); *Miller*, 675 F.2d at 157 ("[I]n view of the enormous logistical problems of Medicaid enforcement, statistical sampling is the only feasible method available."); Bend v. Sebelius, No. 09-3250, 2010 WL 4852230, at *6 (C.D. Cal. Nov. 19, 2010) ("The sample taken by the Carrier met the requirements of the Medicare program and when combined with the inherently low risk of error and the substantial government interest in statistical sampling, [the plaintiff] has not suffered a procedural due process violation in this case.").

[102] *See* 42 U.S.C. § 1320a-7k(d)(3) (2012).

[103] *Id.*

[104] 31 U.S.C. § 3729(b)(3).

[105] *Id.*; Kane *ex rel*. U.S. v. Healthfirst, Inc., 120 F. Supp. 3d 370, 380-81 (S.D. N.Y. 2015).

[106] *See* 31 U.S.C. § 3729(b)(1) (defining "knowingly").

[107] Cindi Woolery & Matt Sparks, *Recent Developments Governing Reverse False Claims Under the False Claims Act*, 64 U.S. ATT'YS BULL. 29, 32 (2016).

all that is required is that a defendant knowingly and improperly avoids an obligation to pay money to the government.[108] The determination of the amount of overpayments is considered a damages issue, for which calculation the FCA permits the use of statistical sampling. Thus, the plaintiff may use statistical sampling under (a)(1)(G).

The only real issue is whether the plaintiff uses a *reliable* sampling plan, which is a separate factual question addressed in Part II below.

II. The Factual Question: The Manner of Conducting a Statistical Sampling

As established in Part I, the issue of whether statistical sampling is permitted to establish liability under one or more FCA provisions is a pure question of law. Courts must guard against conflating this legal issue with the factual issue of whether the parties have selected and followed a reliable sampling plan.

Thus, there is a two-step process which, we contend, courts should follow. The first step is to determine if, as a matter of law, statistical sampling can be used to prove liability under one of the FCA provisions: (a)(1)(A)—presentation of a false claim; (a)(1)(B)—use of a false statement material to a false claim; or (a)(1)(G)—knowingly avoiding an obligation to pay money to the government. At this stage, facts and the particular sampling plan are not relevant. Part I provides a framework for answering the legal issue and demonstrates why the legal answer is that statistical sampling may be used under each of the three provisions.

Assuming a court determines that statistical sampling is proper under one or more of the FCA provisions, the next step involves the factual determination of whether the sampling plan is reliable.[109] This section outlines a framework for the role of the parties and the courts in selecting and approving a sampling plan to ensure reliability. Specifically, it proposes a framework for the courts to follow for the timing and process of ruling upon the admissibility of the results of a particular statistical sample.

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[108] 31 U.S.C. § 3729(a)(1)(G).

[109] Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 590-91 (1993).

First, the trial court should require that the parties identify any proposed use of statistical sampling plans to be included in the initial scheduling conference. Once identified, the court should promptly rule upon the legal issue of whether sampling is legally permitted under a particular provision of the FCA.[110]

Second, assuming that sampling is legally permissible, the court should issue a scheduling order for the timing of the submission of a proposed sampling plan by the plaintiff. However, the order should include provisions requiring the parties to meet and seek to reach an agreement upon a proposed sampling plan. If the parties cannot agree, they should submit briefs addressing proposed plans. However, the court should not allow a defendant to merely pick apart a plaintiff's plan, but must require said defendant to work cooperatively to establish a joint plan or submit its own alternative sampling plan.

Third, prior to the close of discovery, the court should rule upon the validity of the proposed sampling plan in order to allow time to correct any deficiencies prior to trial. The court can and should hire outside experts to aid in making a determination of the validity of the plan or recommending an alternative sampling plan if the parties cannot agree.

Fourth, the court should issue an order finding that one of the submitted sampling plans is determined reliable, whether a joint plan or one suggested by one of the parties or a court-appointed expert. The court should issue a ruling accepting a plan in sufficient time to allow the plaintiff or parties to carry out the plan during discovery.

Fifth, if the defendant refuses to either submit its own plan or agree to the plaintiff's plan and assuming that a court does not approve the plaintiff's plan over the defendant's objection, the defendant should be required to pay for the costs incurred by the plaintiff in conducting a claim-by-claim analysis and grant the plaintiff time to complete the claim-by-claim analysis. This prospect should incentivize the defendant to work towards agreeing to a sampling plan or to devise its own. Shifting the cost is also consistent with Rule 1 of the Federal Rules of Civil Procedure requiring that the parties act to "secure the just, speedy, and inexpensive determination of every action and proceeding."[111] It is

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[110] *See infra* Part I.

[111] *See* FED. R. CIV. P. 1.

also within the court's authority to shift discovery costs,[112] and doing so would be consistent with the recently amended discovery rules designed to reduce the cost of discovery by imposing a proportionality framework.[113] In other words, the defendant should be the one to bear the risk and expenses because it rendered calculation of damages more difficult and has not agreed to a sampling plan to determine damages. Indeed, the Supreme Court has long-held that "[t]he most elementary conceptions of justice and public policy require that the wrongdoer shall bear the risk of the uncertainty which his own wrong has created."[114] Accordingly, the court should use its authority to shift the cost of conducting a claim-by-claim analysis upon the one causing the damages and refusing to agree to a sampling plan.

Sixth, the court should rule on any further motions pertaining to the plan as carried out and make a reliability determination in time to correct any deficiencies prior to trial.

Finally, if the court-approved sampling plan is reversed on appeal, the appellate court should remand for a new trial with a new sampling plan that corrects any deficiencies noted by the appellate court rather than simply throwing out the sampling plan and with it, the plaintiff's damage calculations.

Conclusion

Statistical sampling for establishing liability is one of the most hotly contested issues under the False Claims Act.[115] While there is still

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[112] *E.g.*, Spears v. City of Indianapolis, 74 F.3d 153, 158 (7th Cir. 1996) (finding that the Federal Rules of Civil Procedure grant "trial courts considerable discretion in . . . expense-shifting in discovery production").

[113] *See* FED. R. CIV. P. 26(b)(1) ("Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit.").

[114] Bigelow v. RKO Radio Pictures, 327 U.S. 251, 265 (1946).

[115] Bryan Cave, *Statistical Sampling in FCA Cases Remain Uncertain, But the Government's Absolute Veto Power Regarding Settlements Gets Affirmed* (Feb. 16, 2017), https://www.bryancave.com/en/thought-leadership/statistical-sampling-in-false-claims-act-cases-remains-uncertain.html.

division among the courts due to a misapplication of the various legal and factual questions at hand, this Article established a two-step approach for addressing these often-convoluted issues. Part I addressed the pure legal question of whether sampling is permitted to establish FCA liability. It separately addressed the two main types of FCA liability: one requiring either the presentation of a false claim or use of a false statement or claim, and the other simply requiring that a person knew that they avoided repaying an overpayment. Part II of this Article addressed the factual aspect of sampling, namely, the process of determining whether a particular sampling plan is reliable and therefore admissible.

The question of whether statistical sampling is permitted to prove liability is a pure legal question that must be addressed separately from whether the proposed sampling plan is reliable. Prior to 2009, all FCA liability provisions required either the presentation of a false claim or use of a false statement or claim.[116] Against this backdrop, opponents of statistical sampling argued that sampling can never be used for liability because unless specific proof of each false claim was introduced at trial, there could be no liability.[117] This Article argued that this is an incorrect reading of the statute and that particular proofs of the fraud scheme are not required for each false statement. The FCA expressly states that specific intent is not required to prove liability.[118] To establish liability, the plaintiff must prove only: "falsity, causation, knowledge, and materiality."[119] There is no requirement of "specific knowledge" or "specific proof."[120] Rather, scienter under the FCA is met by evidence other than the sampling, such as testimony of witnesses and other

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[116] *See* 31 U.S.C. 3729 (2012).

[117] Christina Vlahos, *When the Ends Do not Justify the Means: The Application of Statistical Sampling to Determine Liability in False Claims Act Cases*, 90 ST. JOHN'S L. REV. 813, 815 (2016).

[118] *E.g.*, United States *ex rel.* Spay v. CVS Caremark Corp., 875 F.3d 746, 758 (3d Cir. 2017) ("However, 'no proof of specific intent to defraud is required.'"); *Marshall*, 812 F.3d at 561 ("The FCA defines knowledge to include actual knowledge, deliberate ignorance, or reckless disregard for the truth; knowledge does not require specific intent to defraud.").

[119] *E.g.*, United States *ex rel.* Petratos v. Genentech, 855 F.3d 481, 487 (3d Cir. 2017).

[120] *See* 31 U.S.C. § 3729.

documentation of the fraud scheme.[121] Thus, sampling may be used with respect to the liability provisions still requiring the presentation or use of a false statement or claim.

With respect to the other type of FCA liability, known as liability under the reverse false claim provision, prior to 2009, the provision rendered liability when a person knowingly used a false record or statement material to an obligation to pay money to the government.[122] Thus, at that time, it contained a similar requirement that a person use a false record or statement and therefore was subject to the same individual proofs argument.[123] However, in 2009, Congress entered the fray by adding an alternative way of establishing liability under the reverse false claim provision. Now, a person is liable under the FCA simply if the person "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government."[124] This subpart did away with requiring the use of a false statement and, with it, any argument that individual proof is required. Under the 2009 version, all that is required is to show that there existed a duty or obligation to repay funds.[125] In 2010, Congress answered this question too, in the context of Medicare overpayments, by creating a duty within the ACA.[126] The ACA includes a duty for those receiving an overpayment of Medicare or Medicaid to report and return the overpayment within sixty days.[127] Moreover, the ACA added that this duty also constitutes an obligation under the reverse false claim provision of the FCA.[128] Thus, as of at least 2010, the ACA and FCA, working in tandem, created a duty to repay Medicare overpayments and establish FCA liability without needing to introduce specific proofs of individual false statements or claims. Because courts having previously held that

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[121] James Adams, *Proof of Violation Under the False Claims Act § 8*, 78 AM. JUR. PROOF OF FACTS 3D 357 (2018).

[122] 31 U.S.C. § 3729(a)(1)(G).

[123] *Id.*

[124] *Id.*

[125] *Id.*

[126] 42 U.S.C. § 1320a-7k(d).

[127] *Id.*

[128] *Id.*

the government may rely upon statistical sampling either for establishing FCA damages or Medicare overpayments, the individual proofs argument against sampling is nonexistent under the 2009 reverse false claim provision and statistical sampling is therefore permitted for recovering overpayments.[129]

Part II of this Article assumed that sampling is legally permitted under at least one FCA provision and addressed the factual question of whether a particular sampling plan is reliable and therefore admissible. It proposed the roles and functions of the parties and the courts, including the timing of the submission and ruling upon a particular sampling plan. Specifically, the parties must work together to agree upon a sampling plan and the court should approve a plan it determines to be reliable prior to the close of discovery to allow the parties the time to conduct the plan. In addition, if the defendant refuses to consent to a sampling plan, the court should shift the discovery costs and require the defendant to pay all of the costs of conducting a claim-by-claim analysis. Finally, if a sampling plan is reversed on appeal, the court should remand for a new trial using an acceptable sample.

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[129] *See* United States v. Fadul, No. DKC 11–0885, 2013 WL 781614, at *14 (D. Md. Feb. 28, 2013) (allowing sampling to determine damages); United States v. Cabrera-Diaz, 106 F. Supp. 2d 234, 240 (D.P.R. 2000) (allowing sampling to determine Medicare overpayment).