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Statistical Sampling And The False Claims Act: *Updates and Trends*

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#FBA

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- Mr. Benedetto is a partner in the Los Angeles Office of WilmerHale. His practice focuses on complex civil litigation and government investigations. He has extensive experience representing pharmaceutical companies, healthcare companies, and financial institutions in both federal and state False Claims Act actions. In the healthcare space, he has unique experience litigating California's Insurance Frauds Prevention Act, a qui tam statute in the Insurance Code, including argument before the California Court of Appeal. He also has experience representing qui tam whistleblowers, and before joining WilmerHale was a member of a trial team in a four-week federal jury trial involving FCA allegations against a major insurance company.

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Today's Agenda

- I. False Claims Act Overview
- II. The Basics of Statistical Sampling
- III. Statistical Sampling in Other Civil Contexts
- IV. Statistical Sampling in the FCA Context
- V. Cases Before *Life Care*
- VI. The Turning Point: *Life Care*
- VII. Cases Since *Life Care*
- VIII. Expert Issues

The Basics of Statistical Sampling

What Is Statistical Sampling?

- “Statistical Sampling” refers to a set of quantitative methods that draw conclusions about a large data set from the characteristics of a sample of that data set.
- “The general purpose of statistical sampling is to ‘provide a means of determining the likelihood that a large sample shares characteristics of a smaller sample.’” *U.S. ex rel. Martin v. Life Care*, 114 F. Supp. 3d 549 (E.D. Tenn. 2014).

How Sampling Works

- Objective is to create a model of the population to scale
 - The population is “the whole” that we are interested in
 - We draw a representative sample from the population
 - We gather needed information from the sample
 - We project/extrapolate information from the sample back to the population

Requirements of Valid Sampling

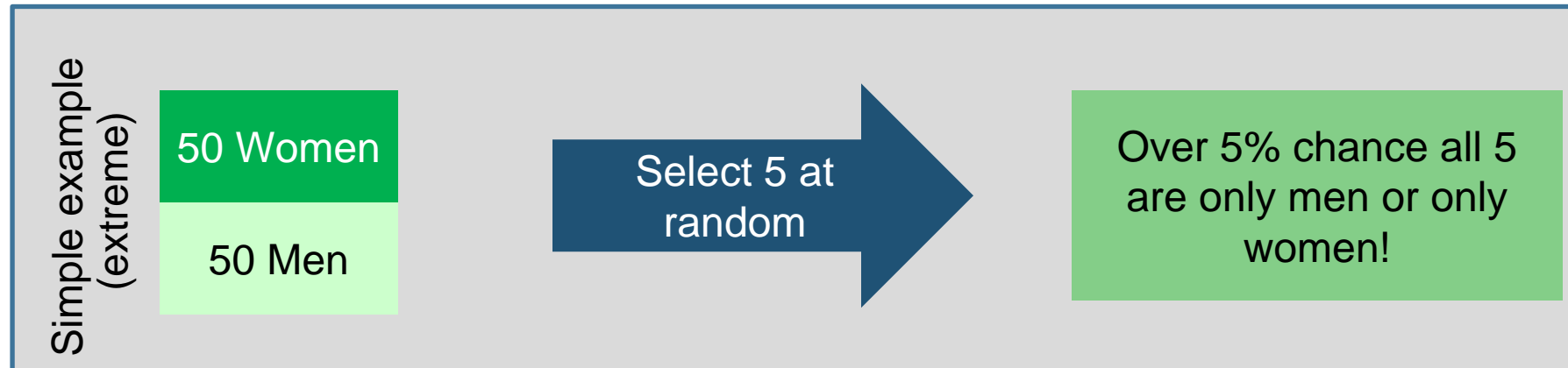
- “[A] valid statistical survey essentially has three steps:
 - i. identify a population of interest,
 - ii. take a random sample from that population, and
 - iii. use the observations in the sample to draw inferences about the population as a whole.”
- *United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, 839 F.3d 242, 261 (3d Cir. 2016).
- The Third Circuit noted two “critical features” of a valid sample:
 - “First, it is important for the sample to be drawn from the **correct population** If there are differences between the population being studied and the population actually sampled, the survey's results will necessarily be unreliable.” *Id.*
 - “Second, a valid statistical sample must be drawn **randomly**. . . . In a nonrandom sample, by contrast, the selection rule ‘may inadvertently . . . introduce bias.’” *Id.*

Sampling Variability

- Random samples are random
 - Each time we draw a different sample from the same population we will (generally) obtain a different result
 - The term “sampling variation” refers specifically to the *effect* of this randomization on *sample averages*
- Sampling variability can generally be predicted and controlled by reference to two “key ingredients”:
 - 1) variability of the data itself
 - 2) sample size

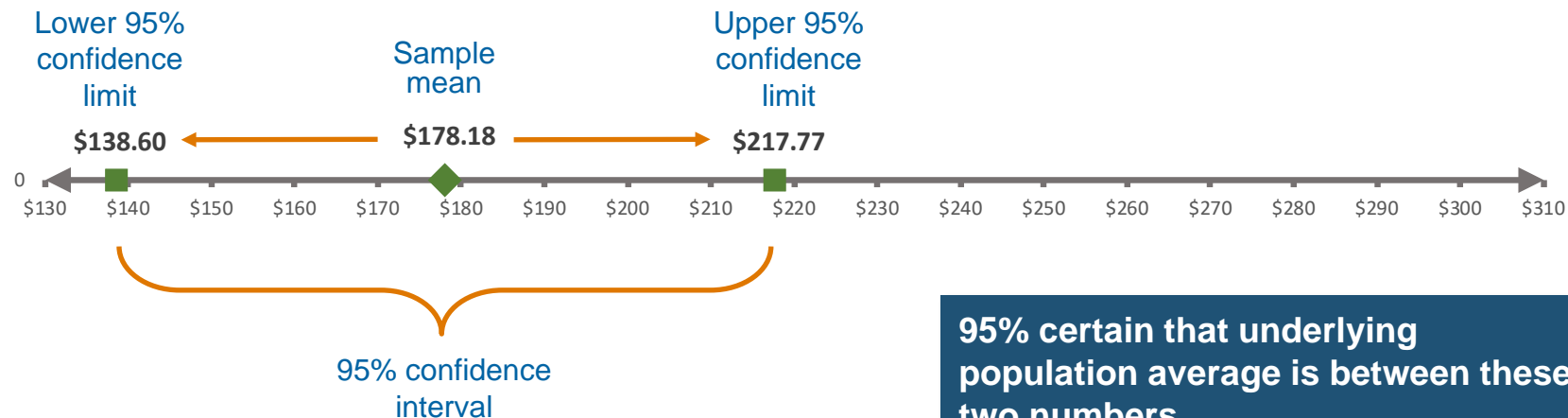
Random Samples Are Only Representative *on Average*

- There is no mathematical guarantee that a given set of randomly picked observations will be representative
- Particularly with small samples, observations might actually misrepresent the larger population
- Larger sample size and careful technique can address this issue



Measures of Sampling Variability

- A **confidence interval** is a range that we are reasonably confident contains the population mean
- Increasing the level of confidence requires a wider range
- A wide confidence interval can indicate low reliability



95% certain that underlying population average is between these two numbers...

...5% chance it is not

Building a Reliable Model with Probability Sampling

- Random selection is a standard method for building a representative sample
 - Random is not arbitrary; it has **precise meaning**
 - Each member of the population must have a **known chance of selection**
 - Most common form is a **simple random sample** where every member has an equal chance of selection
 - This form of selection ensures that characteristics of the sample will typically “look like” the population
- How do we test the “looks like” property?
 - Statisticians talk about checking **covariate balance**
 - Covariates are measurable characteristics of the population
 - In the sample, these covariates should look like (be in balance with) the population

Why Sampling Is Important

- Plaintiffs, for one, argue that statistical sampling helps avoid expensive and prolonged litigation
- Using a small sample to extrapolate to a larger population is cost effective, as the larger population will, in theory, no longer require discovery
- Without sampling, many large-scale cases brought by plaintiffs would likely not be feasible given the vast amount of individual claims to evaluate

Statistical Sampling As Used in Other Contexts

- **Civil audits**

- Use by HHS or a contractor when there is a determination of one of the following:
 - “sustained or high level of payment error, or
 - “documentation that educational intervention has failed to correct the payment error.”
- Determination is not reviewable
 - “There shall be no administrative or judicial review ... of determinations by the Secretary of sustained or high levels of payment errors.”
 - *Gentiva Healthcare Corp. v. Sebelius*, 723 F.3d 292, 297 (D.C. Cir. 2013) (federal court lacks jurisdiction to review the merits of the “sustained or high level of payment error” determination)
 - *Palm Valley Healthcare, Inc. v. Azar*, 947 F.3d 321, 329 (5th Cir. 2020) (“The threshold determination that there are ‘sustained or high levels of payment errors’ is not reviewable”)

Statistical Sampling As Used in Other Contexts

- **Civil audits**

- "Sustained or high level of payment error" as defined in the Medicare Program Integrity Manual
 - high error rate determinations by the contractor or by other medical reviews (i.e., greater than or equal to 50 percent from a previous pre- or post-payment review);
 - provider/supplier history (i.e., prior history of non-compliance for the same or similar billing issues, or historical pattern of non-compliant billing practices);
 - CMS approval provided in connection to a payment suspension
 - information from law enforcement investigations;
 - allegations of wrongdoing by current or former employees of a provider/supplier; and/or audits or evaluations conducted by the OIG.

Statistical Sampling As Used in Other Contexts

- **Health care fraud criminal cases**

- Statistical sampling is not commonly used
- The government does not need to prove any loss amount at trial, let alone beyond a reasonable doubt
- Judge needs to make a "reasonable estimate" of loss
- Judge is allowed to make findings without conducting an evidentiary hearing if the judge finds that it would be too burdensome to determine a precise loss amount
- Providers may be able to use sampling to rebut government arguments and the problem of WYSIATI (what you see is all there is)

Statistical Sampling in False Claims Act Cases

Element	Allowed
Damages	Commonly used
Liability	New method that is the subject of multiple judicial opinions

Statistical Sampling Historically Used for Damages Calculations in FCA Cases

- “Courts have routinely endorsed sampling and extrapolation as a viable method of proving damages in cases involving Medicare and Medicaid overpayments where a claim-by-claim review is not practical.” *U.S. v. Fadul* (D. Md. 2013).
- The Department of Justice has recently expressed the view that: “[A]llowing the use of statistical sampling evidence is not only routine but essential in False Claims Act cases where the defendants’ conduct caused the submission of more false claims and records than could reasonably be tried before a court on a claim-by-claim basis.” (U.S. Statement of Interest in *Ruckh* (2015)).

Statistical Sampling in False Claims Act Cases

- **The Issue:** In large-scale FCA cases, the government and relators are increasingly seeking to prove not only damages, but also **liability**, by means of statistical sampling.
- Courts have taken different approaches to the relevance and admissibility of statistical sampling evidence.

Should Statistical Sampling Be Accepted and Used to Prove Other Elements of FCA Causes of Action?

- **General test for admissibility:**
 - Relevant – “if it has any tendency to make a fact more or less probable than it would be without the evidence” (F.R.E. 401);
 - Not otherwise inadmissible (F.R.E. 402);
 - And probative value is not substantially outweighed by dangers such as unfair prejudice, wasting time, etc. (F.R.E. 403).
- **General test for expert opinions:**
 - Qualified opinions that will help the trier of fact understand evidence or determine a fact in issue, that are based on sufficient data, and are the product of reliable methods reliably applied (F.R.E. 702).

Should Statistical Sampling Be Accepted and Used to Prove Other Elements of FCA Causes of Action?

- **Context**
- Typical: healthcare fraud
- Medical necessity of treatment, “upcoding,” etc.
- Plaintiffs may allege thousands to millions of potential false claims
- Defendants say that data is not dispositive, claim-by-claim review required

- **Plaintiff:** Claim-by-claim analysis infeasible, would incentivize mass fraud that could not be prosecuted

- **Defendant:** Right to defend each and every claim / due process

Statistical Sampling in False Claims Act Cases

Case	Liability use
U.S. v. Friedman (D. Mass 1993)	used to establish liability
U.S. ex rel. Trim v. McKean (W.D. Okla. 1998)	rejected by court
U.S. ex rel. Loughren v. UnumProvident Corp. (D. Mass. 2009)	rejected by court
U.S. ex rel Martin v. Life Care Centers of America, Inc. (E.D. Tenn. 2014)	allowed by court
U.S. v. AseraCare (N.D. Ala. 2014)	used at trial
U.S. v. Robinson (E.D. Ky. 2015)	used at trial
U.S. ex rel Ruckh v. Genoa Healthcare (M.D. 2015)	used at trial
U.S. ex rel. Michaels v. Agape Senior Community, Inc. (D. S.C. 2015)	rejected by court
U.S. ex rel. Wall v. Vista Hospice Care (N.D. Tex. 2016)	rejected by court
U.S. ex rel. Lisitza v. Par Pharm Cos. (N.D. Ill. 2017)	rejected by court
U.S. v. Rite Aid Corporation (E.D. Cal. 2020)	allowed by court
U.S. ex rel. Scott v. Arizona Center for Hematology and Oncology, PLC (D. Ariz. 2020)	allowed by court
U.S. ex rel. Integra Med Analytics, LLC v. Baylor Scott & White Health (W.D. Tex., 2019)	rejected by court
U.S. ex rel. Conroy v. Select Medical Corp. (S.D. Ind. 2018)	rejected by court

State of the Law Today Is in Flux

- Although the Fourth Circuit in *Michaels*, the Fifth Circuit in *Hodge*, the Sixth Circuit in *Robinson*, and the Eleventh Circuit in *Ruckh* had the opportunity to take a position on sampling, none did.
- Accordingly, no appellate court has explicitly affirmed the use of statistical sampling to prove liability under the FCA.
- As reflected in the discussion today, district courts remain split over whether to allow statistical sampling.

Statistical Sampling in Other Civil Contexts

- “Sampling has long been considered an acceptable method of determining the characteristics of a large universe.”



Rosado v. Wyman, 322 F. Supp. 1173, 1180 (E.D.N.Y. 1970).

Statistical Sampling in Other Civil Contexts

- **Complex Wage Litigation**

- *Reich v. Southern New England Telecommunications Corp.*, 121 F.3d 58, 66-67 (2d Cir. 1997) (holding that testimony of representative sample of 2.5% of workers was adequate to award back wages to entire group of employees)

- **Trademark and Copyright Infringement**

- *Exxon Corp. v. Texas Motor Exchange of Houston, Inc.*, 628 F.2d 500, 507 (5th Cir. 1980) (using statistical sampling to establish likelihood of confusion between Texon and EXXON in trademark infringement suit)
- *Harolds Stores, Inc. v. Dillard Dept. Stores, Inc.*, 82 F.3d 1533, 1546 (10th Cir. 1996) (using statistical sampling to determine copyright infringement damages)

Statistical Sampling in Other Civil Contexts

- **Human Rights**

- *Hilao v. Estate of Marcos*, 103 F.3d 767, 782-86 (9th Cir. 1996) (frequently cited endorsement of representative sampling to determine damages for victims of Philippine dictator)
- *Presbyterian Church of Sudan v. Talisman Energy, Inc.*, 226 F.R.D. 456, 483 (S.D.N.Y. 2005) (Hilao “would be unlikely to survive today,” denying certification to victims of violence in Sudan)
- *Augustin v. Jablonsky*, 819 F. Supp. 2d 153, 174 (E.D.N.Y. 2011) (holding “inherently individualized” emotional distress damages for strip searches could not be determined from sampling)

Statistical Sampling in Other Civil Contexts

- **Consumer Protection and Antitrust**

- *In re Cathode Ray Tube (CRT) Antitrust Litig.*, No. C-07-5944-SC, 2013 WL 5391159, at *8-9 (N.D. Cal. Sept. 24, 2013) (upholding sampling in class certification of consumers who purchased price-fixed television components)
- *Dow Chem. Co. v. Seegott Holdings, Inc.* (In re Urethane Antitrust Litig.), 768 F.3d 1245, 1257 (10th Cir. 2014) (upholding sampling in class certification and damages determination for industrial purchasers of price-fixed chemicals)
- *Gutierrez v. Wells Fargo & Co.*, No. C-07-05923 WHA, 2009 WL 1247040 at *3 (N.D. Cal. May 5, 2009) (holding sampling of damages improper in consumer class action for overcharging practices because plaintiffs could calculate damages from bank records)

Statistical Sampling in Other Civil Contexts

- **Government Reimbursement**

- *Scottsdale Mem'l. Health Sys., Inc. v. Maricopa Cty.*, 224 Ariz. 125, 141–42 (Ct. App. 2010) (holding hospitals could use sampling to determine reimbursement county owed them for providing emergency services if sampling was “fair and accurate”)

- **Employment Discrimination**

- *Moore v. Napolitano*, 926 F. Supp. 2d 8, 18–27 (D.D.C. 2013) (certifying class of 120 African-American Secret Service employees upon extrapolation of commonality from roughly 10 members’ claims of racial discrimination)

Statistical Sampling in Other Civil Contexts

- **Mass Tort**
- *In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1020 (5th Cir. 1997) (vacating bellwether trial plan because cases selected did not represent larger group of cases at issue)
- *Cimino v. Raymark Industries, Inc.*, 151 F.3d 297, 329 (5th Cir. 1998) (in class action involving 3,031 cases of asbestos-related injuries, refusing to extrapolate damages from a statistical sample, holding that Seventh Amendment required individualized proof)
- *Arch v. American Tobacco Co., Inc.*, 175 F.R.D. 469, 493 (E.D. Pa. 1997) (in class action suit against tobacco companies, statistical sampling unfit to address individual issues of addiction, causation, and damages on class-wide basis)

Tyson Foods v. Bouaphakeo (S. Ct. 2016)

- In suit under the Fair Labor Standards Act (FLSA), employees filed a class action complaint alleging that Tyson failed to pay them overtime for time spent “donning and doffing” protective gear.
- Tyson did not record the time it took for employees to don and doff equipment, so the plaintiffs could not perform a claim-by-claim analysis.
- An expert examined a sample of 744 videotaped observations and found that donning and doffing activities took on average 18 or 21.25 minutes per day depending on the department
- A second expert used this data to conclude 3,132 of the total 3,344 class members were potentially uncompensated about \$6.7 million in unpaid wages.
- The plaintiffs won jury verdict of \$2.9 million in unpaid wages, and the 8th Circuit affirmed.
- Tyson challenged the class certification based on statistical sampling, arguing each claim required a fact-specific inquiry into an individual’s work time

Tyson Foods v. Bouaphakeo (S. Ct. 2016)

- The Supreme Court affirmed judgment for Plaintiffs and held that statistical sampling was an acceptable form of evidence.
- Justice Kennedy:
 - “A categorical exclusion [of statistical sampling evidence], however, would make little sense. A representative or statistical sample, like all evidence, is a means to establish or defend against liability. Its permissibility turns not on the form a proceeding takes – be it class or individual action – but on the degree to which the evidence is reliable in proving or disproving the elements of the relevant cause of action.” (citing Federal Rules of Evidence 401, 403, and 702).

Tyson Foods v. Bouaphakeo (S. Ct. 2016)

- **First**, whether a sample may be used depends on its relevance to the governing law's application. The form of proceeding is *not* relevant
- **Second**, “[i]n many cases, a representative sample is the only practicable means to collect and present relevant data establishing a defendant’s liability.”
- **Third**, relying on the sampling did not deprive Tyson of its ability to litigate individual defenses—it could bring a *Daubert* motion challenging the sample’s reliability
- Does caution that “[t]he fairness and utility of statistical methods in contexts other than those presented here will depend on facts and circumstances particular to those cases.”

Statistical Sampling in the FCA Context

Statistical Sampling in False Claims Act Cases

- **The Issue:** In large-scale FCA cases, the government and relators are increasingly seeking to prove not only damages, but also **liability**, by means of statistical sampling.
- Courts have taken different approaches to the relevance and admissibility of statistical sampling evidence.

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Cases Before *Life Care*

U.S. v Friedman (D. Mass. 1993)

- The Government alleged that psychiatrist submitted false claims to Medicare for reimbursement for (1) unnecessary medical services (*e.g.*, unwarranted in-patient care), (2) services never rendered, and (3) psychiatric services in lieu of general medical care actually given.
- Between January 1, 1982 and June 30, 1984, **676 total claims** submitted to Medicare.
 - Gov't experts reviewed sample of **350 claims**
 - Experts deemed **297 claims** to contain at least one false representation
 - **42** of those claims presented at trial

U.S. v Friedman (D. Mass. 1993)

- The Court ruled that the 42 claims presented at trial violated FCA.
- It then extrapolated damages from the 42 claims to the sample of 350 claims
- The Government urged the Court to extrapolate liability from the random sample of 350 claims to all claims submitted, even those not presented at trial or reviewed by the Government experts
- This method would have doubled the alleged overpayment.
- Interestingly, the Court rejected this additional extrapolation: Court was “reluctant to accept [] statistical sampling as the basis for doubling the alleged overpayment without the same scrutiny and support” it gave to the 42 “discreet” claims at trial, 1993 U.S. Dist. LEXIS 21496, *9 n.1 (D. Mass. July 23, 1993).

U.S. ex rel. Trim v. McKean (W.D. Okla. 1998)

- Relator alleged that EPBS, a provider of coding and billing services for emergency physician groups, violated the FCA by submitting to Medicaid and Medicare higher billing codes than were justified by physicians' charts.
- The coders used "presumptive coding" and would "code based on [] 'services rendered' without regard to what was documented [in the chart]." 31 F. Supp. 2d 1308, 1312 (W.D. Okla. 1998). For example, if a patient's chart indicated that she was admitted to the hospital, the coder would classify it as a level 5 without further analysis. *Id.*
- After suit was filed, audits were performed on EPBS's billing practices for payors in Pennsylvania, Oregon, and Arizona, among others.

U.S. ex rel. Trim v. McKean (W.D. Okla. 1998)

- Court rejected sampling
 - Audits were insufficient “to find a percentage of false claims from *all* [of the] claims.” *Id.* at 1314. Given the “subjective nature of coding, the relatively small sample size, and the variation in years covered . . . [the Court found] the audits [were] not a reliable or accurate representation of all EPBS claims.” *Id.*
 - In particular, found the Oregon audit was not without bias
- Court did determine the audits contained evidence of false claims.
- The Court left the question of the exact number of false claims to the damages phase.

U.S. ex rel. Loughren v. UnumProvident Corp.
(D. Mass. 2009)

- Relator alleged that Unum, a group health insurer, submitted false claims to the Social Security Administration (“SSA”) for Social Security Disability Insurance (“SSDI”) benefits.
- Between January 1997 and July 2007, **468,641 claims** filed by Unum insureds for SSDI
- Relator’s expert conducted a statistical sampling to extrapolate the total number of false claims submitted.
- Court held **bellwether trial on 7 claims** before deciding *Daubert* issues (jury found 2 claims false, no liability on others)
 - Factual finding that Unum had an SSDI policy and practice affecting all insureds/claims

U.S. ex rel. Loughren v. UnumProvident Corp. (D. Mass. 2009)

- The expert used **cohort sampling**. “In cohort sampling, groups that share a specific trait thought to make them more likely to possess the sought after characteristic are more heavily sampled, and each group's results are then reweighted to account for the group's relative size in the overall population. The cohorts . . . are not necessarily exclusive and [] do not necessarily represent every element in the population.” 604 F. Supp. 2d 259, 261–62 (D. Mass. 2009).
- The expert created **21 cohorts** based on “the claimant's disease classification, age, disability date, and whether a claimant's SSDI claim was denied.” *Id.* at 262.
- Out of a random sample of **1,591 claims**, Relator’s experts found **58 claims** were false.

U.S. ex rel. Loughren v. UnumProvident Corp. (D. Mass. 2009)

- To calculate the total percentage of false claims, the expert first calculated the percentage of false claims in each cohort. “He multiplied that percentage . . . by the total population size of the cohort to derive the ‘weighed percent.’ [He] then added up the ‘weighted percents’ for all the cohorts.” *Id.* at 262.
- Since several cohorts had overlapping claims, the expert divided “the sum of ‘weighted percents’ by the sum [] of claims in all [] cohorts, counting overlapping claims in multiple cohorts multiple times. [He then] multiplied th[at] result by the total number of unique claims in the entire population.” *Id.* at 262-63.
- Using this method, the expert concluded that **8,027** of the **468,641 total claims** submitted were false.

U.S. ex rel. Loughren v. UnumProvident Corp. (D. Mass. 2009)

- The Court excluded the Relator's expert's testimony under *Daubert* as unreliable.
- Not only did the expert fail to cite any peer-reviewed literature or other supporting text, but Unum's expert provided a clear example where his methodology to account for overlapping cohorts could produce highly inaccurate results due to double counting.
- Court found "extremely wide confidence level" troubling. *Id.* at 269.

U.S. ex rel. Fry v. Guidant Corp. (M.D. Tenn. 2009)

- Relator alleged that Guidant, a manufacturer of cardiac devices, intentionally failed to inform hospitals and clinics that certain warranty and replacement credits were available for implantable cardiac devices, thereby violating the FCA.
- In discovery, Guidant asked Government to identify and produce all documents constituting a false claim.
- Government resisted production, citing undue burden of producing roughly **8,213 to 16,323 cost reports**.
- Government moved to use statistical sampling to establish both **liability** and damages.
- The Court ordered production of ***all*** alleged false claims.
 - Cost reports formed “the basis of a False Claims Act case and [were] clearly relevant to a determination of liability and damages.”
 - Government failed to cite any cases that directly addressed a motion to compel. Instead, the cases were either class action lawsuits or “discussed[ed] the sufficiency of statistical evidence presented *at trial*.”

Bayer Corp. v. United States (W.D. Pa. 2012)

- Government routinely supports statistical sampling and extrapolation to prove liability when individualized proof of multiple claims would be too burdensome and impractical.
- Here, Government cited *Fry* to take the contrary position
- Bayer sought a federal income tax refund after the IRS denied it qualified research expense (“QRE”) credits. Given the millions of expenditures at issue, Bayer moved to use statistical sampling to prove its entitlement to the tax credits.
- **8 of 49 research sites** generating QREs would be selected, and then **2 credit years** (1990–2006) would be randomly selected for each of the 8 sites. **100 costs centers** would then be randomly selected for analysis during that period, and the expert would extrapolate liability to all other centers at all 49 research sites.
- The Government strongly opposed Bayer’s motion. Citing *Fry*, the Government argued that no matter how accurate statistical sampling could be, it would eliminate Bayer’s burden of proof as to the non-sampled credits
- The Court agreed and denied Bayer’s motion. As in *Fry*, identification of the individual claims was critical for establishing liability. 850 F. Supp. 2d 522, 545 (W.D. Pa. 2012). “[A] sampling plan that would not identify all of the business components underlying the claimed QRE credits [was] not acceptable” *Id.*

U.S. ex rel. Martin v. Life Care Centers of America, Inc.

Turning point

U.S. ex rel. Martin v. Life Care Centers of America, Inc. (E.D. Tenn. 2014)

- Skilled nursing facilities are paid based on patient's classification, so such facilities make more money treating patients in the highest rehabilitative levels
- The Government alleged that Life Care, an owner and operator of such a facility, submitted false claims to Medicare for unnecessary medical services
- Using stratified random sampling, Government expert evaluated a random sample of **400 patient admissions** to nursing homes out of a total of **54,396 patient admissions** and **154,621 claims**
- Rather than prove liability for each claim, the Government sought to introduce expert testimony at trial.

U.S. ex rel. Martin v. Life Care Centers of America, Inc. (E.D. Tenn. 2014)

- Life Care made two motions to exclude this expert testimony.
- **First**, Life Care moved to exclude it as unreliable under *Daubert*. The methodology was flawed “because [expert] did not perform a probe sample, calculate a sample size, account for any variables, set precision requirements up front, and address issues with the medical review.” 2014 WL 4816006, *13 (E.D. Tenn. Sept. 29, 2014).
- **Second**, Life Care moved for partial summary judgment: (1) Proving liability for all claims through statistical sampling and extrapolation violated Due Process by impermissibly “shift[ing] the burden of proof onto [Life Care].” 2014 U.S. Dist. LEXIS 142660, at *59 (E.D. Tenn. Sept. 29, 2014); (2) The Government must prove the falsity of each claim, especially given the subjective factors that dictate an individual patient’s treatment.

U.S. ex rel. Martin v. Life Care Centers of America, Inc. (E.D. Tenn. 2014)

- The Court denied both motions and held the Government could use statistical sampling and extrapolation to show liability for all claims.
 - **First**, the Court noted that “statistical sampling has been used for decades,” quickly dismissing Life Care’s argument that each claim’s uniqueness calls for a claim-by-claim analysis. *Id.* at *49. All sampling requires the fact finder to draw an inference about a larger and not identical population of claims. If Life Care were right, sampling would never be allowed.
 - **Second**, the expert testimony met each *Daubert* factor. The Court emphasized that stratified random sampling is well-established and it makes no difference that statistical sampling has not been used to prove FCA liability until this point.

U.S. ex rel. Martin v. Life Care Centers of America, Inc. (E.D. Tenn. 2014)

- **Third**, there was no Due Process violation because Life Care could challenge and rebut the Government's expert testimony at trial through cross-examination and competing witnesses
- **Fourth**, it would be impractical to require individualized proof of each claim, given the breadth of claims at issue.
- **Fifth**, requiring the Government to show liability claim by claim would frustrate the FCA's purpose: "to combat fraud against the government." *Id.* at *62-63. An alternative result would encourage perpetrators to submit larger quantities of false claims to preclude the Government from being able to bring an action.
- The case settled in October of 2016, with Defendants agreeing to pay the Government \$145 million.
- *Interestingly, the Court heavily cited cases where sampling was permitted in the damages context without much regard to the case law critical of its use in the liability context.*

Cases Since *Life Care*

State of Uncertainty

U.S. v. AseraCare (N.D. Ala. 2014)

- The government intervened in this qui tam lawsuit and alleged that AseraCare, a hospice provider, defrauded Medicare by submitting hospice claims for patients that did not meet coverage requirements.
- The government sought to use statistical evidence “to show that AseraCare had a widespread problem with falsely certified claims, entitling the government to a large recovery.”
- Specifically, the government’s expert reviewed **233 out of 2,181 patients at issue** and concluded that “the medical records do not support that over half of the patients (**124 of the 233**) in the samples were terminally ill for at least some portion of their hospice stay at AseraCare.”

U.S. v. AseraCare (N.D. Ala. 2014)

- The Court denied AseraCare’s motion for summary judgment as to claims outside those sampled by the government expert.
 - “AseraCare mis-characterizes the Government’s case when it argues that the Government has produced no evidence regarding these four sets of claims. The Government has statistical evidence regarding all of the Government’s universe of 2,181 claims. Statistical evidence is evidence.”
 - “Questions of credibility and fact exist for the jury regarding the relative weight to be accorded AseraCare’s direct evidence (*e.g.* medical director attestations, evidence that Palmetto GBA approved claims) and the Government’s statistical evidence.”

U.S. v. AseraCare (N.D. Ala. 2014)

- The Court found that “the Government met its burden of establishing that the testimony of [this expert] meets the basic requirements of qualification, reliability, and helpfulness and is admissible pursuant to Federal Rule of Evidence 702.”
- This case went to a jury, which found in the first phase that **104 out of 121** claims in the sample were false.
- The Court subsequently ordered a new trial, holding that the evidence presented suggested only a “difference of opinion” on falsity, then granted summary judgment to defendants.
- The government appealed to the 11th Circuit.

U.S. v. AseraCare (11th Cir. 2019)

- On September 9, 2019, the 11th Circuit issued a decision in favor of AseraCare.
- **First**, the court held that a “properly formed and sincerely held clinical judgment” is not false under the FCA “even if a different physician later contends that judgment is wrong.” Rather, to state an FCA claim in the context of hospice reimbursement, a plaintiff must show that the underlying clinical judgment reflects “an objective falsity.”
- **Second**, the court held that the DOJ must be able to “link this evidence of improper certification to the specific [] claims at issue in its case . . . to demonstrate falsity and knowledge.” Although the court did not expressly say so, the import of this requirement would seem to be that statistical sampling would not suffice to prove falsity.



- The case ultimately settled for \$1 million after being remanded to the

U.S. v. Robinson (E.D. Ky. Mar. 31, 2015)

- The Government alleged that the defendant optometrist billed Medicare for more time than he spent with patients and for more expensive services
- Between January 1, 2007 and January 31, 2012, the defendant submitted **25,799 claims** to Medicare.
- Government expert reviewed a random sample of **30 claims** and found **25** to be false
- Robinson moved for summary judgment, arguing that statistical sampling insufficiently captured the subjective nature of each patient's treatment.

U.S. v. Robinson (E.D. Ky. Mar. 31, 2015)

- The Court disagreed and cited the difficulty of proof as to each of the 25,799 claims. Requiring individualized proof would also encourage people to violate the FCA “in extremely large quantities so as to prevent the government from logistically being able to bring suit.” 2015 WL 14793696, at *11 (E.D. Ky. Mar. 31, 2015).
- Importance of summary judgment posture: “[T]he exact number, if any, of claims that may be fraudulent, and the exact amount of damages, if any, may not have been definitively proven and are debatable questions” for a jury. Id.
- Defendant did not offer any feasible alternative to sampling

U.S. v. Robinson (E.D. Ky. July 8, 2016)

- Jury found for Government, and Court denied defendant's motion for a new trial
- At trial, government used an expert to present sampling and extrapolation techniques to calculate damages. Expert gave a range of damages at the **90 percent confidence interval**.
- Court rejected defendant's challenge to this method, and stated that the jury could have returned a verdict for a lesser amount if it so chose.

U.S. v. Robinson (6th Cir. 2017)

- In December 2017, the Sixth Circuit affirmed the jury verdict in the government's favor.
- On appeal, the defendant had argued that using statistical sampling to calculate *damages* was improper under the FCA
- The Court did not consider this argument, finding it was raised for the first time on appeal. The defendant did challenge the use of sampling in a summary judgment motion, but only as to *liability*, not damages.
- In February 2018, the mandate for the case was issued, and there has been no further action to date.

U.S. ex rel. Ruckh v. Genoa Healthcare (M.D. Fla. Apr. 28, 2015)

- Court denied defendant nursing home operator’s motion to exclude statistical sampling evidence offered to prove its liability.
 - “[N]o universal ban on expert testimony based on statistical sampling applies in a qui tam action (or elsewhere), and no expert testimony is excludable in this action for that sole reason (although defects in method, among other evidentiary defects, might result in exclusion).”
- Court held that a *Daubert* hearing, after the statistical analysis was performed, was the proper way to address admissibility.

U.S. ex rel. Ruckh v. Genoa Healthcare (M.D. Fla. Dec. 29, 2016)

- Plaintiff did offer a statistical sampling expert to opine on damages.
- Genoa offered its own expert to challenge Plaintiff's methodology – for example, that sampling was not subdivided (did not stratify) by nursing home facility.
- Court allowed Genoa's expert to testify as to sampling methodologies, since the testimony would assist the jury in evaluating the evidence presented.
- In January 2018, the Court vacated the nearly \$350 million jury award, holding the plaintiff failed to meet the materiality and scienter requirements of the FCA.

Ruckh v. Salus Rehab., LLC (11th Cir. 2020)

- On June 25, 2020, the 11th Circuit affirmed the district court's ruling and vacated the Medicaid claims, but it reversed as to the Medicare claims.
- The court reinstated the jury verdict in the amount of \$85 million and ordered the district court to enter judgment on those claims after applying trebling and statutory penalties.
- The 11th Circuit expressly declined to address the issue of statistical sampling, however, because "the defendants have abandoned any argument regarding the admission of the expert testimony on appeal ...

Accordingly, we do not address whether the sampling method and extrapolation employed by the relator's

U.S. ex rel. Michaels v. Agape Senior Community, Inc. (D.S.C. 2015)

- Plaintiffs sought to use statistical sampling to prove liability and damages in a suit alleging Medicare fraud at nursing homes.
- The Court described the total number of claims at issue in the case as “staggering.” Between **10,166–19,820 patients were admitted** during the applicable time period for whom approximately **53,280–61,643 claims** were submitted (the parties did not agree on the correct numbers)
- Using a conservative estimate of the number of claims, the Court noted that it would cost the Plaintiffs between \$16 and \$36 million in expert fees to review each and every claim.
- The likely damages in the case were estimated by the Government at \$25 million.

U.S. ex rel. Michaels v. Agape Senior Community, Inc. (D.S.C. 2015)

- Nonetheless, the Court held that Plaintiffs could not use statistical sampling for either liability or damages purposes. It based this holding on its findings that:
 - The evidence needed for a claim-by-claim review was available to the parties, and
 - Determining falsity for each claim was a “highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patient.”
- However, acknowledging the importance of this issue, the Court certified it for interlocutory appeal to the Fourth Circuit.

U.S. ex rel. Michaels v. Agape Senior Community, Inc. (4th Cir. 2017)

- The Fourth Circuit, however, ultimately avoided ruling on this issue
- Instead, the court dismissed the interlocutory appeal as improvidently granted because it did not present a pure question of law.
- How the Fourth Circuit would rule on the issue of statistical sampling to prove FCA liability thus remains unclear
- The DOJ ultimately accepted a settlement of \$275,000. The case was subsequently dismissed in August 2017.

U.S. ex rel. Wall v. Vista Hospice Care (N.D. Tex. June 20, 2016)

- Case alleging fraudulent billing of hospice services provided to Medicare beneficiaries.
- Plaintiff offered an expert to show liability and damages using a sample of **291 patients** out of a relevant population of **12,000 patients**
- Court rejected Plaintiff's expert evidence as unreliable: "the underlying determination of eligibility for hospice is inherently subjective, patient-specific, and dependent on the judgment of involved physicians."
- Notes other courts have accepted sampling evidence, but that only *Michaels* dealt with hospice treatment and denied such evidence.
- Distinguished *Tyson* because "statistical evidence was not the only practicable means to present data establishing Defendants' liability," but offered only the alternative of evaluating all 12,000 patients at issue or simply not pursue that universe of claims.
- In November 2017, the Court denied the plaintiff's motion for reconsideration
- In January 2018, the appeal was dismissed pursuant to the appellant's motion

U.S. ex rel. Lisitza v. Par Pharm. Cos. (N.D. Ill. May 10, 2017)

- Relators alleged Par Pharm. induced pharmacies to fill prescriptions not with the prescribed generic drugs but with more expensive forms of those drugs that it manufactured
- The Court rejected Relators' attempt to use statistical sampling and granted Par's summary judgment motion
- The Court reasoned in footnote 14 that "to do statistical sampling, there must be statistically reliable proof . . . that some portion of a statistically relevant sample of claims are actually false. . . . [T]he plaintiffs here cannot get to statistical sampling because **they haven't proved that even one claim is actually false, much less that there is a representative rate of falsity** from which the number of false claims could be extrapolated."
- The parties ultimately signed a dismissal agreement, and the case was dismissed in October 2017

United States v. Americus Mortg. Corp. (S.D. Tex. Sept. 14, 2017)

- The Government alleged the defendant loan provider made fraudulent representations to HUD and the FHA.
- The Government's experts drew random stratified samples from the over **17,000 loans** submitted between 2001 and 2011.
 - The experts re-underwrote the loans from these samples to determine the number of properly underwritten loans in the sample
 - These findings were extrapolated to determine the total number of falsely underwritten loans.
- The jury found against the defendant, awarding nearly \$300 million in damages. The Court denied defendant's renewed motion for judgment as a matter of law: "The jury heard exhaustive testimony from the [] experts discussing the methodology of extrapolation. . . . [T]he experts' testimony provided a substantial basis for jury's verdict." 2017 U.S. Dist. LEXIS 149482 , at *11-12 (S.D. Tex. Sept. 14, 2017).

United States v. Hodge (5th Cir. 2019)

- *United States v. Americus Mortg. Corp* was appealed to the 5th Circuit as *United States v. Hodge*.
- The Fifth Circuit declined to address the statistical sampling question, holding that “[a]ny challenge to the sampling other than the number of files selected was waived.”
- The Fifth Circuit suggested, however, that it was not necessarily opposed to the use of statistical sampling, reasoning that “[w]e expect that connecting false statements and defaults with specific loans is not feasible in a case that relies on sampling and extrapolation, as does this one. The government fairly reasons that HUD linked unregistered branches to higher risks of default, and that the expert evidence showed those loans, as predicted, defaulted at higher rates.”
- The case was appealed to the Supreme Court, which denied certiorari in 2020.

U.S. v. Long Grove Manor, Inc. (N.D. Ill. July 2, 2019)

- The relator alleged false claims based on statistical analysis of Medicare beneficiary data maintained by defendants, alleging that defendants provided medically unnecessary treatment.
- Defendants moved for summary judgment, arguing that the relator failed to show that defendants provided medically unnecessary treatment to any specific patient.
- The court granted summary judgment for defendants, holding that “it is not enough ... to point to the statistical probability that defendants provided unnecessary medical care ... [the relator] must present **individualized evidence of at least one claim** involving the provision of medically unnecessary care.”

U.S. v. Rite Aid Corporation (E.D. Cal. July 14, 2020)

- The relator alleged that Rite Aid was liable under the FCA for falsely certifying compliance with certain Medi-Cal claim submission requirements. The State of California subsequently intervened.
- Plaintiffs sought to use statistical sampling to prove the element of falsity, employing a stratified random sample of 1,904 claims pulled from a sample frame size of 505,645 claims.
- Rite Aid moved to dismiss the sampling evidence, citing *Michaels* and *Vistacare* to argue that the use of sampling to establish falsity required a claim-specific evaluation.
- The court rejected Rite Aid’s argument and held that “**plaintiffs’ proposed statistical sampling plan is a permissible approach in attempting to prove falsity**” under the FCA. The court reasoned that whereas *Agape* and *Vistacare* implicated “subjective factors,” here the claims process was “relatively simple.” The court went on to allow the sampling into evidence under *Daubert*.
- The case remains before the district court.

U.S. ex rel. Scott v. Arizona Center for Hematology and Oncology, PLC (D. Ariz. April 29, 2020)

- The relator alleged that defendant submitted at least 4,000 false claims for reimbursement to Medicare, Medicaid, and Tricare in violation of the FCA by, among other things, improperly billing for procedures that were not performed or were medically unnecessary. The relator used a statistical sampling expert to estimate alleged overpayments.
- Defendant moved for summary judgment, arguing that statistical sampling cannot be used to establish liability under the FCA.
- The court rejected defendant’s argument, holding that “reliable, statistical evidence may be admitted at trial and the jury must then decide whether it satisfies the plaintiff’s burden of proof.”
- The court further explained, citing *Life Care*, that “[n]o reasonable trial could include individualized proof of 4,000 separate occurrences of fraud.”
- The case settled shortly after the court’s ruling.

U.S. ex rel. Integra Med Analytics, L.L.C. v. Baylor Scott & White Health (W.D. Tex. Aug. 5, 2019)

- The relator alleged that Defendants violated the FCA by engaging in a scheme to fraudulently upcode Medicare diagnosis codes.
- The relator applied “various proprietary methods of statistical analysis” on a data set of inpatient claims data and determined that Defendants coded for the alleged upcoded diagnosis codes at rates significantly higher than the average of other hospitals. The relator alleged this was sufficient to allege a false claim.
- The court granted the defendants’ motion to dismiss, finding that the relator’s statistical analysis alone was insufficient to support a claim. The court reasoned that the relator’s conclusion “appears to be based entirely on the mere fact that Defendants provided this service at rates higher than average” and failed to account for the possibility that the defendants were simply better than their peers in their efforts to ensure coding maximized legitimate reimbursement.
- The relator appealed the case to the 5th Circuit.

U.S. ex rel. Integra Med Analytics, L.L.C. v. Baylor Scott & White Health (5th Cir. May 28, 2020)

- On appeal, the Fifth Circuit sided with the district court in favor of the defendants.
- The Fifth Circuit reasoned that the statistical analysis was “consistent with both Baylor having submitted fraudulent Medicare reimbursement claims to the government and with Baylor being ahead of most healthcare providers in following new guidelines from CMS.”
- The court concluded that statistical data alone therefore could not meet FCA pleading requirements if, “among other possible issues, it is also consistent with a legal and obvious alternative explanation.”

U.S. Ex Rel. Conroy v. Select Medical Corp. (S.D. Ind. Apr. 2, 2018)

- The relator brought an FCA action against an acute care hospital operated by the defendant. The relator claimed that the defendant extended or shortened patient stays at its hospitals to maximize Medicare reimbursement, regardless of the medical necessity for the length of the stay.
- The relator sought to use nationwide statistical sampling across more than 100 hospitals in order to establish FCA liability.
- Though the court noted that sampling may be appropriate to determine damages, it rejected the use of sampling to prove FCA liability on a medical necessity theory.
- The court held that “[t]he plaintiffs cite no authority for the proposition that proving that a particular Medicare reimbursement claim was fraudulent based on a theory of lack of medical necessity can be done by a random-sampling method that does not evaluate whether each particular claim for which the plaintiffs seek relief was actually knowingly false within the meaning of the FCA.”

State of the Law Today Is in Flux

- Although the Fourth Circuit in *Michaels*, the Fifth Circuit in *Hodge*, the Sixth Circuit in *Robinson*, and the Eleventh Circuit in *Ruckh* had the opportunity to take a position on sampling, none did.
- Accordingly, no appellate court has explicitly affirmed the use of statistical sampling to prove liability under the FCA.
- As reflected in the discussion today, district courts remain split over whether to allow statistical sampling.

Expert Issues & Best Practices

Future Implications

General Test for Expert Witness Testimony

- Under **F.R.E. 702**, a witness who is qualified as an expert may testify in the form of an opinion or otherwise if:
 - a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
 - b) the testimony is based on sufficient facts or data;
 - c) the testimony is the product of reliable principles and methods; and
 - d) the expert has reliably applied the principles and methods to the facts of the case.

Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993)

- Judges have a “gatekeeping” role in deciding whether to admit or exclude expert testimony
- “This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue. . . . Many factors will bear on the inquiry, and we do not presume to set out a definitive checklist . . .” *Id.* at 592.
- However, “[n]othing in the text of [F.R.E. 702] establishes ‘general acceptance’ as an absolute prerequisite to admissibility.” *Id.* at 588.

Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999)

- After *Daubert*, the question was whether the gatekeeping role of judges and the factor test applied to all expert testimony or only to “scientific” testimony
- The court held that “[w]e, like the parties, believe that it applies to all expert testimony.” *Id.* at 147.
- In so holding, it reiterated the *Daubert* factors judges may consider: (1) whether a theory/technique is testable, (2) whether it has been subject to peer review and publication, (3) whether there is a high known or potential rate of error, and (4) whether the theory/technique enjoys “general acceptance” within a “relevant scientific community” *Id.* at 145

Expert Issues

- No matter the size of the sample, the fundamental requirement is that it must adequately represent the entire universe of claims at issue
- Realistically, sampling will probably first emerge through a discovery dispute, as in *Fry*
- Once the sample is admitted into evidence, “its persuasiveness is, in general, a matter for the jury.” (*Tyson*)
- Therefore, when the sample is based on implausible assumptions or is statistically inadequate, defendants should bring a *Daubert* motion challenging the sample’s reliability to exclude expert testimony

Future Implications

- Company counsel might consider how best, and when best, to tee up the sampling issue: is it through a discovery request, and accompanying motion practice, such as we saw in *Fry*? Is it by early summary judgment briefing that resembles in *limine* practice?
- Company counsel might also begin early discussions (with the client) about what alternatives would be acceptable: bellwether trial as in *Unum*? What about preclusive effect? Agree on scope?
- Parties may stipulate to parameters of sampling in discovery
- Settlement leverage
- Given the substantial growth in both complexity and dollars of major government programs like healthcare and defense, there will be increasing efforts by the DOJ/relators to use sampling to prove liability in these sectors.