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# Everything You Wanted to Know About the Use of Statistical Sampling to Establish FCA Liability (But Were Afraid to Ask)

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150 YEARS

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# Agenda

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- Setting the Stage
- Overview of Key Statistical Principles
- Caselaw Trends
- Q&A

## Background

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- Statistical sampling has long been used in False Claims Act (“FCA”) litigation (and elsewhere) to estimate damages.
- Statistical sampling to establish overpayment liability is authorized in the administrative repayment context. See 42 U.S.C. § 1395ddd.
- Plaintiffs argue
  - In some cases, claim-by-claim review is impossible
  - Refusing to accept statistical sampling immunizes widespread fraud
- Defendants argue
  - Inferences of fraud are generally ill-suited to proof by statistical sampling
  - Sampling improperly ratchets up liability settlement pressure
- The new class certification?

## The Supreme Court On Sampling

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- In 2016, the Supreme Court rejected a “categorical exclusion” of statistical sampling to establish Fair Labor Standards Act liability
  - *Tyson Foods v. Bouphakeo*, No. 14–1146 (U.S. 2016).
- Whether sampling should be admitted depends on a variety of factors

<b><i>Tyson Foods</i> Factors</b>
The extent to which the sample is meaningfully representative of the universe of claims
The extent to which the statistical sampling methodology is otherwise reliable
The elements of the underlying cause of action
The purpose for which the evidence is introduced
The harm to a defendant’s ability to assert individual defenses
The availability of substitute evidence, including direct proof

# The Potential Consequences

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UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF FLORIDA, TAMPA DIVISION

UNITED STATES OF AMERICA ex rel. ANGELA RUCKH, Plaintiff, v. GENOA HEALTHCARE, LLC, et al., Defendants.

CASE NO. 8:11-cv-1303-T-23TBM

- Allegation: Chain of nursing and rehabilitation centers upcoded claims.
- Relator's experts identified \$43,000 in damages associated with a sample of 600 "resident days," representing .01% of total resident days at issue.
- Extrapolation resulted in damage claim of \$350 million.
- District court rejected *Daubert* challenges and permitted sampling testimony at trial

## The Potential Consequences: United States ex rel. Ruckh v. CMC II, LLC

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### Consulate Health Care Could Face \$345M Hit From Fraud Verdict

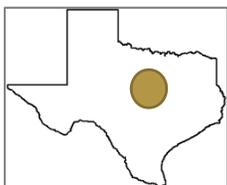
BNA Health Law Reporter (Feb. 22, 2017)

“A jury has found that skilled nursing facility chain Consulate Health Care submitted fraudulent Medicare and Medicaid claims, **causing over \$115 million in damages to the programs**... two days of deliberations, the jury found Feb. 15 that Consulate and several affiliated facilities named as co-defendants were liable for **over 400 instances of causing false claim submissions and retaining fraudulent overpayments**, though many of those violations could overlap. FCA violations carry heavy penalties, including triple damages for losses suffered by the government and a penalty of between \$5,500 and \$11,000 for each false claim submission, though Judge Steven D. Merryday hasn't issued a damages award yet. The potential damages that Consulate could be forced to pay from the jury's finding may reach over \$345 million from the Medicare and Medicaid program loss findings alone, in addition to penalties assessed for each false claim submission.”

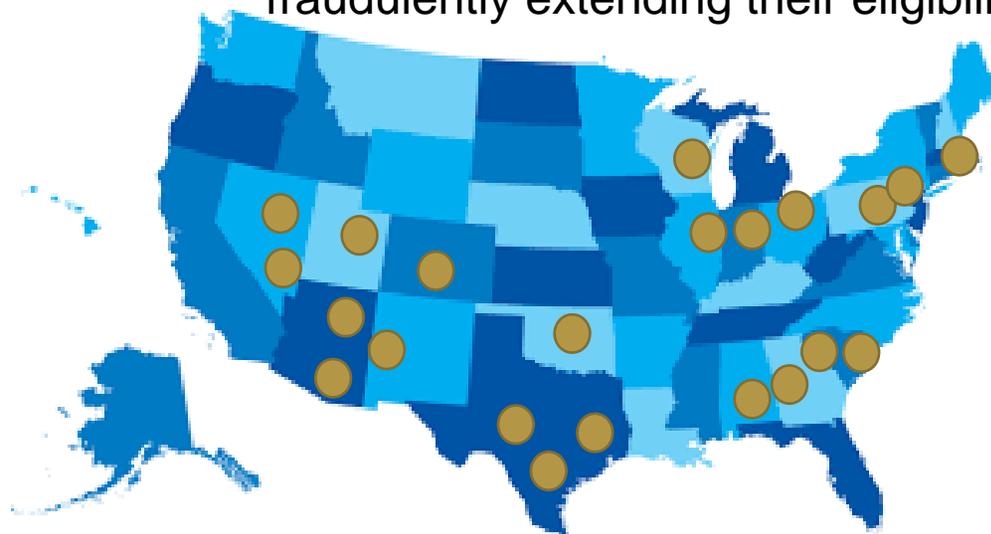
# Overview of Key Statistical Principles

## United States ex rel. Wall v. Vista Hospice Care

- Defendants VistaCare operate a chain of hospice facilities. Federal healthcare programs cover hospice care, but only for patients meeting certain criteria, including a certification by a physician that in his or her clinical judgment, an individual is terminally ill.
- The relator was employed as a social worker at one of VistaCare's facilities in Texas for two years.
- She alleged that across multiple facilities in multiple states for a period of time extending well past the pendency of her employment, VistaCare engaged in a corporate-directed pattern of enrolling ineligible patients for hospice care and fraudulently extending their eligibility.



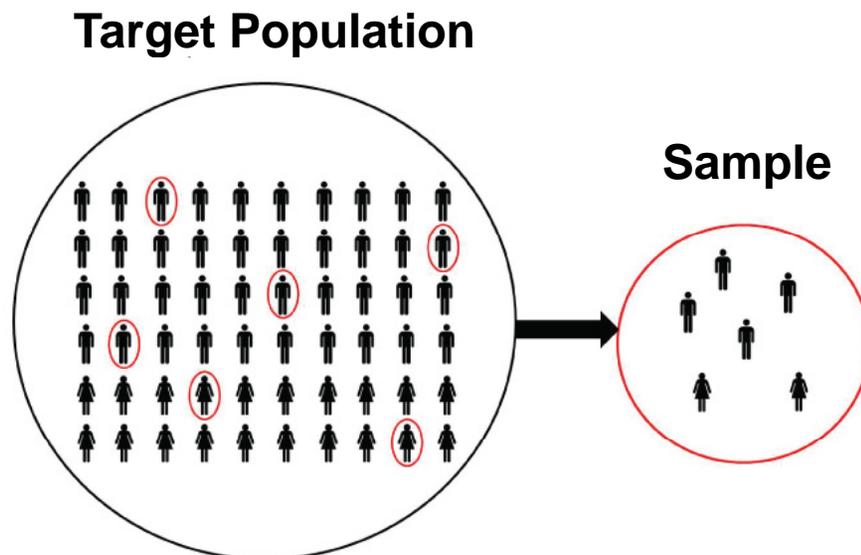
2003-2005



2003-2012

## What is Statistical Sampling?

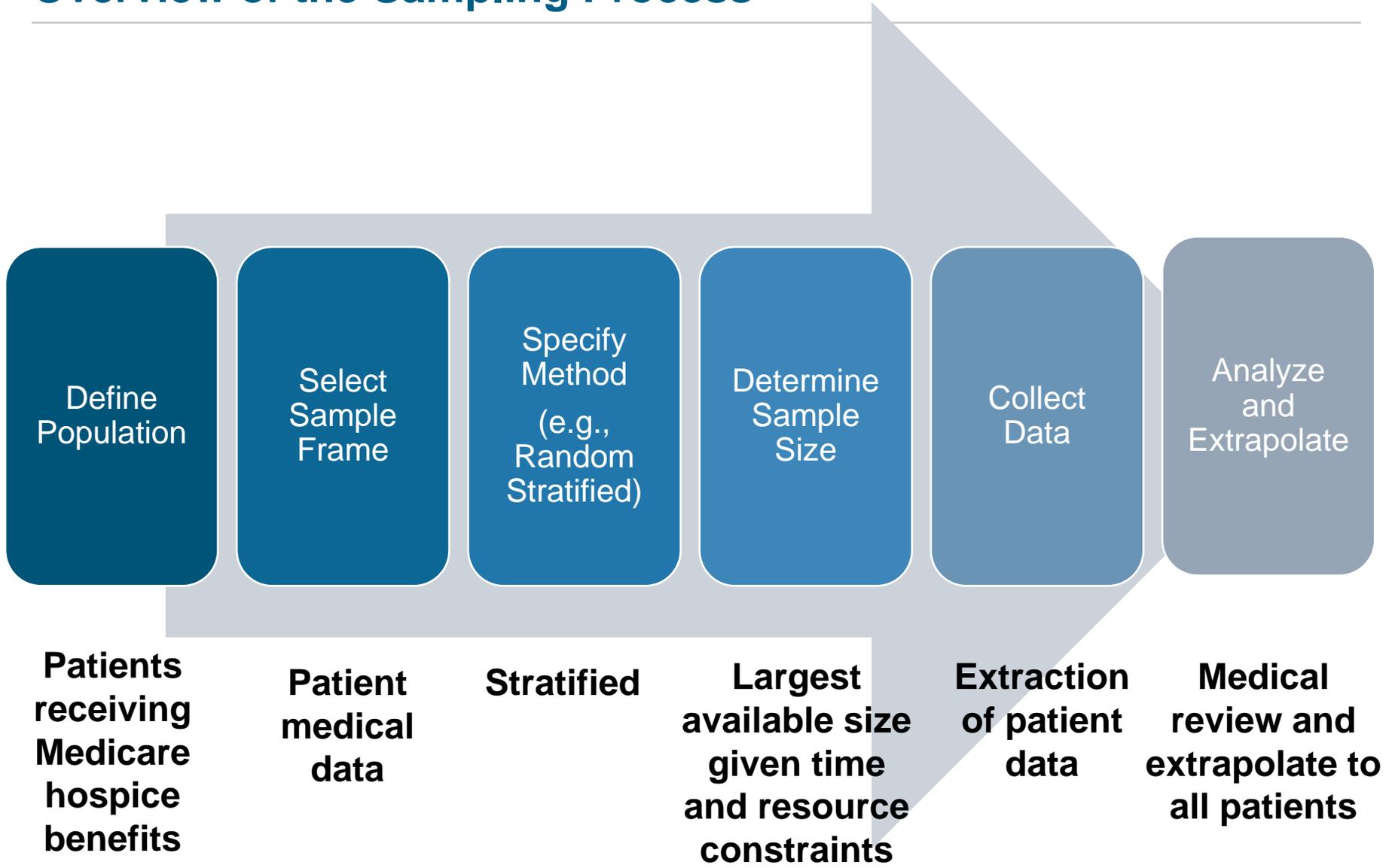
- Statistical sampling is the process of identifying a representative subset of a population (e.g., people, claims) and using that subset to estimate characteristics of the whole population.



- In *VistaCare*, the expert pulled a sample of 300 medical records from the over 12,000 hospice patients.

A key question in many cases is whether statistical sampling is needed or whether other reasonable options to establish liability exist.

# Overview of the Sampling Process



## Sampling Errors

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The goal of sampling is to ensure that the sample mirrors the larger population the sample purports to represent. This goal can be undermined by two types of errors: sampling and non-sampling.

Common sampling errors include:

- Sampling bias: when some members of the population are less likely than others to be included in the sample. For example, in the *VistaCare* sample selection:
  - Duplicate records for patients were included in the universe, causing these patients to be more likely than others to be selected within the sample.
  - Some distinct patients were erroneously identified as duplicates and removed from the population universe.
  
- Random sampling error: when there are differences between the selected sample and the population that occur by chance.

## Non-sampling Errors

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- Non-sampling errors can be introduced through data collection and data processing. Some examples of non-sampling errors include:
  - Over-coverage error: when a sample includes data from outside of the target population.
  - Processing error: when there are mistakes introduced during data extraction.
- Relator's expert in *VistaCare* did not appropriately narrow down the patient and claim population to the alleged at-issue period resulting in about 20% of the patients in the sample having claims outside of the at-issue period.

## Interpreting Results

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- No method of sampling is perfect. A common way to evaluate results for random sampling is through reviewing the *margin of error*.
- For purposes of assessing liability, it is important to compare the results from the sample, including the estimated margin of error, to a benchmark.

### Illustrative Example

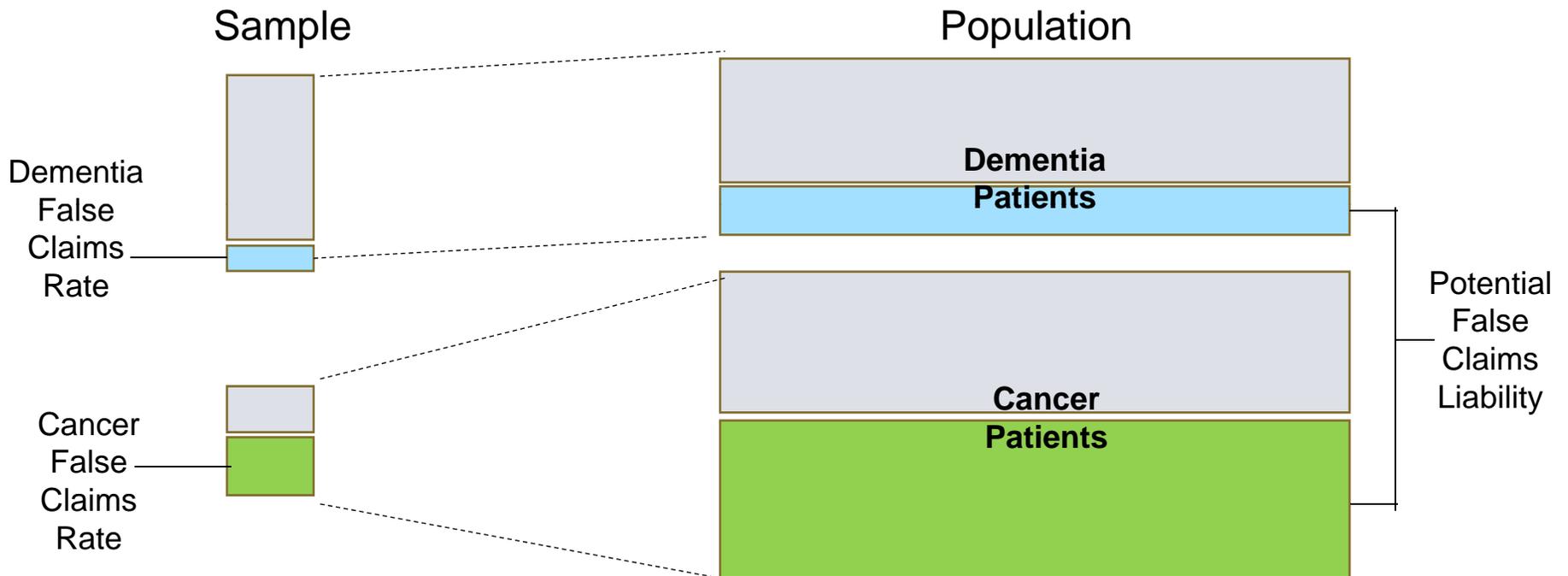
False Claims Rate from Sample	95% Confidence Interval of Sample	Benchmark Error Rate
5% ( $\pm 3\%$ )	2%-8%	4%

**The margin of error of the sample is within the benchmark error rate.**

- Because the *VistaCare* sample was not drawn in a random fashion, the margin of error rates are not valid.

## Extrapolation

- In order to appropriately extrapolate results, the sample must be representative of the population.



- In *VistaCare*, Relator's expert did not confirm that the sample was representative of the disease trajectory. Hypothetically, a false claims rate consisting only of data for dementia patients would have been used to extrapolate to a patient population with many different diseases.

## Some Considerations for Working with a Sample

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- What is the question to be answered?
- What is the population of interest?
- What level of accuracy is required?
- What size sample is required to achieve the desired accuracy level?
- Is there a benefit to selecting a stratified sample?
- Is the sample representative? Is it biased?
- Were the sampling plan and data collection properly implemented?
- Is the selected sample large enough to answer the question of interest?

## Appropriateness of Sampling in FCA Cases: Some Issues to Consider

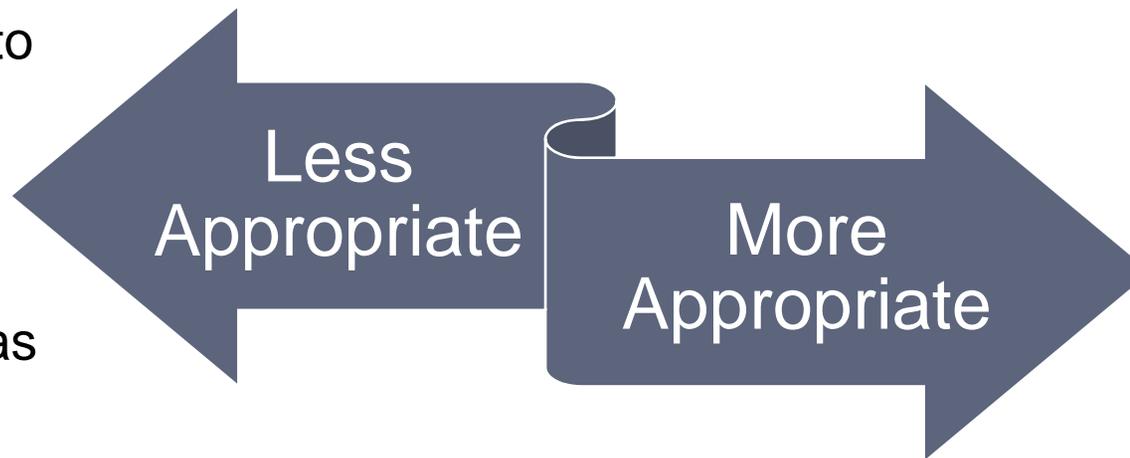
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Alleged fraud  
is isolated

Possible/  
reasonable to  
review all  
claims

Risk of  
sampling bias  
is high

Direct proof of  
evidence is  
possible



Alleged fraud  
is  
widespread

Impossible/  
unreasonable  
to review all  
claims

Rigorous  
scientific method  
used to generate  
samples

Similarity in  
nature of  
alleged  
false claims

# Caselaw Trends

## Caselaw Trends

Case	Allegations	Posture	Outcome
<i>U.S. ex rel. Martin v. Life Care Centers (E.D. Tenn.)</i>	Upcoding patient needs for rehabilitation services		Sampling admissible; settlement
<i>U.S. ex rel. Paradies v. AseraCare (N.D. Ala.)</i>	Certifying ineligible patients for hospice care		Sampling admissible; sua sponte SJ for defendants
<i>U.S. ex rel. Guardiola v. Renown Health (D. Nev.)</i>	Inappropriate billing for inpatient admissions		Settlement before ruling on admissibility
<i>U.S. ex rel. Ruckh v. CMC II, LLC (M.D. Fla.)</i>	Upcoding patient needs for rehabilitation services		Sampling admissible; jury found damages
<i>U.S. ex rel. Michaels v. Agape Senior Cmty. (D.S.C.)</i>	Inappropriate billing for hospice, therapy, and nursing services		Litigation ongoing
<i>U.S. ex rel. Wall v. Vista Hospice Care (N.D. Tex.)</i>	Certifying ineligible patients for hospice care		Summary judgment for defendants
<i>U.S. ex rel. Berntsen v. Prime Healthcare (C.D. Cal.)</i>	Inappropriate billing for inpatient admissions		Litigation ongoing

Sampling not admissible in FCA cases where the evidence is available and falsity turns on individual fact-specific claims.

Sampling is admissible but subject to standard *Daubert* assessments as to admissibility of plaintiff's particular sampling protocol.

Premature to decide.

## Tension Behind the Debate: When Should We Infer Fraud?

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- So far, courts have not focused on the encouragement in *Tyson Foods* to look to “the underlying cause of action” when assessing the appropriateness of statistical sampling.
- If they do, the result could benefit defendants: Arguably, the nature of the FCA makes such cases ill-suited to proof of liability with statistical sampling.
  - Plaintiffs must prove each element of the FCA by a preponderance of the evidence.
  - Defendants have argued that the elements must be established for every claim at issue. Accordingly, plaintiffs must prove a set claims that were false and for which the defendant also acted with the requisite scienter.
  - Defendants have argued that using statistical sampling to establish both falsity and scienter is often inappropriate, particularly where plaintiffs lob sweeping complaints against a broad spectrum of a company. In these circumstances, the overlap between falsity and scienter may vary significantly across the population of claims.
  - Some courts seem hesitant to infer fraud based on statistics.

## Tension Behind the Debate: What About Costs?

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- Although the *Agape* court refused to allow statistical sampling to establish liability, the court acknowledged the fiscal drain on the parties were a claim-by-claim review to go forward:

“These experts estimate they spend between four and nine hours reviewing each patient’s chart. Thus, the review of a single patient’s services would cost between \$1,600 and \$3,600 dollars. Using the conservative figure submitted by Plaintiff-Relators (10,166 patients), this means that the total outlay for expert file review (not including depositions, trial testimony, and the like) is between \$16.2 million and \$36.5 million.”

- Plaintiffs pushing to use statistical sampling often point to the conservation of judicial resources. Denying plaintiff requests to use sampling may propel the parties to settle quickly or, at the opposite extreme for courts, lead to far lengthier trials.

## The New Class Certification?

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- Large claims require large data (claims or class members)
- Does data require sampling (or, does a common method of proof exist)
- Increasingly complex expert analysis (ability and taste for techniques)
- Earlier and earlier, and the path-dependence of sampling

## Takeaways for FCA Investigations and Litigation

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- Courts are poised in the future to more frequently allow statistical sampling to support FCA liability. The increasing digitization of data enhances the risk.
- Does your compliance program address sampling issues?
  - When is sampling appropriate (root cause)
  - Timing / overpayment liability
- Determine early whether the government is pursuing a sampling approach, including during resolution negotiations.
- Get an expert involved early to try and direct the course of litigation:
  - *Tyson Foods* offers courts a principled basis for rejecting the use of sampling.
  - Even if courts give plaintiffs a chance to prove their methodology under *Daubert*, statistical sampling is a complex process with great risk for error, and these pitfalls can be used defensively.
- Even if the government is not pursuing sampling, companies should consider sampling themselves to ensure a fair methodology.

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# Questions?