Strafford

Presenting a live 90-minute webinar with interactive Q&A

FCA Litigation: Leveraging Statistical Sampling and Extrapolation to Prove or Disprove Liability

WEDNESDAY, FEBRUARY 1, 2017

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

Matthew D. Benedetto, Counsel, **Wilmer Cutler Pickering Hale and Dorr**, Los Angeles

Jeanne A. Markey, Partner, **Cohen Milstein Sellers & Toll**, Philadelphia

Raymond M. Sarola, Esq., **Cohen Milstein Sellers & Toll**, Philadelphia

The audio portion of the conference may be accessed via the telephone or by using your computer's speakers. Please refer to the instructions emailed to registrants for additional information. If you have any questions, please contact **Customer Service at 1-800-926-7926 ext. 10**.

Tips for Optimal Quality

FOR LIVE EVENT ONLY

Sound Quality

If you are listening via your computer speakers, please note that the quality of your sound will vary depending on the speed and quality of your internet connection.

If the sound quality is not satisfactory, you may listen via the phone: dial **1-866-927-5568** and enter your PIN when prompted. Otherwise, please **send us a chat** or e-mail **sound@straffordpub.com** immediately so we can address the problem.

If you dialed in and have any difficulties during the call, press *0 for assistance.

Viewing Quality

To maximize your screen, press the F11 key on your keyboard. To exit full screen, press the F11 key again.

Continuing Education Credits

FOR LIVE EVENT ONLY

In order for us to process your continuing education credit, you must confirm your participation in this webinar by completing and submitting the Attendance Affirmation/Evaluation after the webinar.

A link to the Attendance Affirmation/Evaluation will be in the thank you email that you will receive immediately following the program.

For additional information about continuing education, call us at 1-800-926-7926 ext. 35.

Program Materials

FOR LIVE EVENT ONLY

If you have not printed the conference materials for this program, please complete the following steps:

- Click on the ^ symbol next to “Conference Materials” in the middle of the left-hand column on your screen.
- Click on the tab labeled “Handouts” that appears, and there you will see a PDF of the slides for today's program.
- Double click on the PDF and a separate page will open.
- Print the slides by clicking on the printer icon.

WILMERHALE

COHEN MILSTEIN

FALSE CLAIMS ACT LITIGATION

LEVERAGING STATISTICAL SAMPLING AND EXTRAPOLATION TO PROVE OR DISPROVE LIABILITY

February 1, 2017

SPEAKER INTRODUCTIONS

- **Jeanne A. Markey, Cohen Milstein Sellers & Toll**
  - Co-head of Qui Tam/False Claims Act Practice Group
  - Represents whistleblowers in all manner of FCA cases
- **Matthew Benedetto, WilmerHale (Los Angeles)**
  - Member of False Claims Act Working Group
  - Represents companies in FCA investigations and suits
- **Raymond Sarola, Cohen Milstein Sellers & Toll**
  - Qui Tam/False Claims Act Practice Group

STATISTICAL SAMPLING AS A MEANS OF PROVING OR DISPROVING LIABILITY 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.
- The Fourth Circuit has heard oral argument on an appeal that may decide whether and for which purposes statistical sampling evidence may be used in FCA cases in that circuit.

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 (E.D. Tenn. 2014)

THE USES OF STATISTICAL SAMPLING

- "Sampling is nothing new or unusual. For thousands of years, people have been basing judgments about a large group of objects on their observations of a few of them." GAO Report, "Using Statistical Sampling" (1992).
- Commonly used in:
  - Auditing
  - Quality Assurance
  - Epidemiology

STATISTICAL SAMPLING HAS HISTORICALLY BEEN 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)).

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 more probative than prejudicial (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).

CASES BEFORE LIFE CARE

THE ROAD TO LIABILITY

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 42 claims presented at trial violated FCA.
- The Government urged the Court to extrapolate liability from the random sample to all claims submitted, which would have doubled the alleged overpayment.
- Court rejected 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 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* [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.
- Court found the audits to contain evidence of false claims.
- The Court left the question of the exact number of false claims to the damages phase.

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*."

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, **468,641claims** 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 Relator's expert's testimony under Daubert as unreliable. Not only did 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.
- Court found "extremely wide confidence level" troubling. Id. at 269.

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.
- 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)

- The Government alleged that Life Care, an owner and operator of nursing homes, 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 and extrapolated that **154,621 claims** were false.
- 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. 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.
- Fourth, it would be impractical to require individualized proof of each claim, given the breadth of claims at issue.
- Finally, 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.

- 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. Robinson
(E.D. Ky. Mar. 31, 2015)

- The Government alleged that 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, **25,799 claims** submitted to Medicare.
- Government expert reviewed a random sample of **30 claims** and found **25** to be false
- Defendant moved for summary judgment, arguing that statistical sampling insufficiently captures 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 in 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, *11 (E.D. Ky. Mar. 31, 2015).
- Importance of SJ 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 the jury. Id.
- Defendant did not offer any feasible alternative

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 chose.

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

- The government intervened in this qui tam lawsuit and alleged that the defendant 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."

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

- Court denied defendant hospice operator's motion for summary judgment as to claims outside those sampled by 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)

- 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."
- 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 sample were false. The Court subsequently ordered a new trial, holding that the evidence presented only suggested a "difference of opinion" on falsity, then granted summary judgment to defendants. The government has appealed to the 11th Circuit.

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

- Court rejected defendant nursing home operator's opposition to statistical sampling evidence offered to prove damages.
  - "[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.
- Defendant offered its own expert to challenge Plaintiff's methodology – for example, that sampling did not stratify by nursing home facility.
- Court allowed Defendant's expert to testify as to sampling methodologies, since it would assist the jury in evaluating the evidence presented.

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 an FCA case alleging Medicare fraud at nursing homes.
- The Court described the total number of claims at issue in the case as "staggering."
- 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.

Tyson Foods v. Bouaphakeo (S. Ct. Mar. 22, 2016)

- Fair Labor Standards Act (FLSA) case regarding payment of time workers spent "donning and doffing" gear.
- Plaintiff won jury verdict and Eight Circuit affirmed.
- Defendant challenged class certification based on statistical sampling evidence.
- The Supreme Court affirmed judgment for Plaintiffs and held that statistical sampling was an acceptable form of evidence.

Tyson Foods v. Bouaphakeo (S. Ct. Mar. 22, 2016)

- 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. Mar. 22, 2016)

- Discusses statistical sampling evidence as establishing or defending against liability (not just damages).
- Notes that "[i]n many cases, a representative sample is the only practicable means to collect and present relevant data establishing a defendant's liability."
- 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."

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

- False Claims Act case regarding provision of hospice services to Medicare beneficiaries.
- Plaintiff offered an expert to show damages and liability using statistical sampling.
- Court rejected Plaintiff's expert evidence as not reliable, since "the underlying determination of eligibility for hospice is inherently subjective, patient-specific, and dependent on the judgment of involved physicians."
- Notes that 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.

FUTURE IMPLICATIONS

- 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.
- Also, given the discovery authorized in Guardiola, plaintiffs may be requesting data on which to perform statistical analysis early in litigation/investigation timeline.
- Parties may stipulate to parameters of sampling in discovery
- 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 client) about what alternatives would be acceptable: bellwether trial as in Unum? What about preclusive effect? Agree on scope?
- Settlement leverage

CONTACT INFO

- **Jeanne A. Markey**
- **Raymond Sarola**
  - jmarkey@cohenmilstein.com
  - rsarola@cohenmilstein.com
  - (267) 479-5700

COHEN MILSTEIN

- **Matthew Benedetto**
  - Los Angeles Office of WilmerHale
  - Matthew.Benedetto@wilmerhale.com
  - (213) 443-5323

WILMERHALE