

INSIGHTS | Healthcare Fraud & the False Claims Act

Extrapolating Damages in Healthcare Fraud: A Case Study

United States v. Solomon Melgen

The reasonableness of an extrapolated loss calculation was a significant sentencing issue in *United States v. Melgen* earlier this year.

The court found flaws in both the government's and defendant's statistical sampling analysis, and then calculated its own loss figures

SUCCESSFUL DAUBERT MOTIONS

Top challenges to financial experts offer an instructive look at inadequate analysis.

FCA LITIGATION - CONTRACTOR FRAUD

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With Daubert challenges more frequently seen in the courts, it is more important than ever to choose your expert wisely.

These Daubert challenges to financial experts offer an instructive look at the hazards posed by inadequate experts.



TOP-TEN DAUBERT CHALLENGES TO FINANCIAL EXPERTS

Failure to Perform Due Diligence

The plaintiff's expert in this breach of contract case was excluded for failure to perform due diligence on the business records used in his damage calculations. The plaintiff never identified witnesses to lay a proper foundation for the documents, thus the information in the documents could not be properly vetted. The court found the expert was unable to provide an opinion based on sufficient facts and data. *Auto Industries Supplier Employee Stock Ownership Plan v. Ford Motor Co.*, 09-2126, 2011.

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EXPERT WITNESSES ON BEHALF OF **BOTH**
PLAINTIFFS AND DEFENDANTS.

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Blind Application of a Rule of Thumb

The plaintiff's financial expert blindly applied a 25% royalty rate as he believed it was generally accepted. However, the court concluded the 25% rule is not one size fits all, and it requires evidence to prove the

relevance of the 25% rate. The court excluded his testimony for failure to support his use of the rate. *Uniloc v. Microsoft*, 2010-1035, 2010-1055, 03-CV-0440, 2011.

Testimony Not Considered Relevant

The plaintiff's damages expert provided testimony that was "disconnected from this case's facts." The expert assumed the defendant was liable for all counts alleged by the Plaintiff, ignored other factors that may have contributed to lost profits, and "indiscriminately assessed all losses to the Appellee." The court excluded the expert's testimony because the "evidence was simply 'not sufficiently tied to the facts of the case.'" *PharmaNetics, Inc. v. Aventis Pharmaceuticals, Inc.*, 182 Fed. Appx. 267, 272-73 (4th Cir. 2006).

Failure to Apply Accepted Methodologies

The defendant's intellectual property expert was challenged for improperly calculating the reasonable royalty rate. The expert disregarded the facts of the case and failed to determine the necessary features to perform the calculation. His methodology was not considered generally accepted and his testimony was therefore not considered admissible. *Dynetix Designs Solutions, Inc., v. Synopsys, Inc.*, C 11-05973 PSG, 2013.

Reliance on Too Little Facts

The defendant's damages expert calculation was based on only two figures: pre-damage value at replacement cost and depreciation. The expert failed to substantiate these numbers with facts. His value was based on merely, a "feeling," which does not fit the reliability factors required for expert admission under Daubert. *James River Ins. Co. v. Rapid Funding, LLC*, 07-cv-01146C, 2009

Failure to Review Discovery

Forensic economists in this wrongful death case were challenged for their dependence on national databases and studies, without consideration of discovery materials available to them. The court found the expert's projections to be "speculative and conjectural, based on unrealistic assumptions," and therefore it was excluded. *Lee v. City of Richmond*, 3:12-cv-471, 2014.

Lack of Qualifications or Knowledge

The expert in this bankruptcy matter, who was a CPA and CFE, was challenged for lack of industry knowledge "about the content and methodology" of a study used in his report. The expert was given time to cure his lack of knowledge on the study prior to his testimony. *Texans CUSO ins. Group, LLC*, 09-35981-BJH-11, 2010.

Testimony/Report Not Submitted Timely

The plaintiff in this damages case, proffered a fact witness as an expert at trial without proper designation filed by the expert witness disclosure deadline. The court held the witness' testimony fell within the scope of Rule 702. The witness was excluded, however, because the plaintiff did not disclose the witness before trial, denying the defendant the ability to challenge the opinion, obtain rebuttal experts, or take additional depositions. *BRC Rubber & Plastics v. Continental Carbon Co.*, 1:11-cv-190, 201

Insufficient Input on the Expert Report

The expert report in this patent infringement case was determined to be authored by counsel rather than the expert. It was asserted the expert met with counsel for eight hours to review the report, and made "fairly minor" changes. The court excluded the testimony of the expert, stating "an expert witness who is merely a party's lawyer's avatar contributes nothing useful to the decisional process." *Numatics, Inc v. Balluff, Inc.*, No. 2-13-cv-11049, 2014 WL 7211167.

Venturing Into Legal Territory

The defendant's expert was excluded for incorporating aspects of legal premises in his calculation of damages. He offered opinions on the legal reasoning behind seeking damages, as well as opinions to the nature of the governing contract. These legal assumptions were not only outside his expertise, but also applied incorrectly. *Level 3 Communications, LLC v. Floyd*, 1:09-0082, 2011.

FEDERAL RULES OF EVIDENCE; RULE 702

A WITNESS WHO IS QUALIFIED AS
AN EXPERT BY KNOWLEDGE,
SKILL, EXPERIENCE, TRAINING, OR
EDUCATION MAY TESTIFY IN THE
FORM OF AN OPINION OR
OTHERWISE IF:

- 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;

AND

-THE TESTIMONY IS BASED ON
SUFFICIENT FACTS OR DATA;

AND

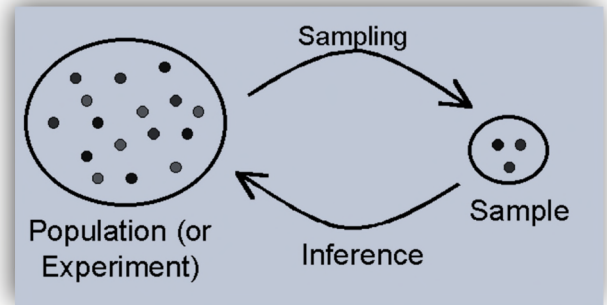
-THE TESTIMONY IS THE
PRODUCT OF RELIABLE
PRINCIPLES AND METHODS;

AND

-THE EXPERT HAS RELIABLY
APPLIED THE PRINCIPLES AND
METHODS TO THE FACTS OF THE
CASE.

KEY STATISTICAL ISSUES IN EYE DOC FRAUD SENTENCING

Statistical sampling and extrapolation are routinely accepted as evidence to estimate damages, and established methodologies to design and implement valid sampling studies are well-known. Yet the role and propriety of a given analysis in litigation continues to be hotly contested.



By Jennifer Dowdell Armstrong and Christopher Haney

Introduction

The reasonableness of an extrapolated loss calculation was a significant sentencing issue in *United States v. Solomon Melgen*, in the United States District Court for the Southern District of Florida. Relying on an extrapolated loss calculation, the government argued that the loss amount for sentencing purposes was as high as \$160 million. Conversely, defense counsel maintained that the government had “cherry-picked” its nonrandom sample, and that it improperly included over 700 additional patients that served to increase the affected population — and subsequently the government’s loss estimates. Defense counsel argued that the total amount of losses proven by the government were no more than \$125,000.

The court found flaws in both the government’s and defendant’s analyses and, as a result, calculated its own loss figures in determining a reasonable loss amount for sentencing. Based on this calculation, the court found an intended loss of over \$73 million. This article provides an overview of that case, along with a technical summary of the key statistical issues and the court’s ultimate findings.

Case Overview

In April 2017, Dr. Solomon Melgen was convicted by a jury on charges that he engaged in a scheme to defraud Medicare and other health care benefit programs through his clinic, Vitreo-Retinal Consultants. Melgen was found guilty of routinely diagnosing patients with wet or dry age-related macular degeneration and then submitting false claims to Medicare and billing for medically unnecessary procedures such as laser surgeries and eye injections.

As part of its initial investigation, the government randomly selected a sample of 310 patients from the total population treated by Melgen between January 2010 and December 2012. That sample was subsequently examined by government investigators and medical experts. The investigation led to the 2015 indictment against Melgen and a subsequent trial and jury verdict concluding in April 2017. Upon conviction of all charges by the jury, the government sought to extrapolate its findings from the sample to estimate losses for the purposes of sentencing. Multiple sentencing hearings were conducted in December 2017 and January 2018, and the court ultimately sentenced Melgen to a term of imprisonment of 204 months on Feb. 22, 2018. On March 8, 2018, Melgen filed a motion for new trial in the district court. That same day, Melgen filed a notice of appeal in the Eleventh Circuit. *[continued on next page]*

The Government's Extrapolation

Sample Selection

Between January 2010 and December 2012, Melgen treated a total of 1,606 unique Medicare patients (the "original population"). The government sought "to have a statistically significant sample drawn, so that any findings with respect to this sample group could be extrapolated to the whole group of 1,606." Subsequently, three samples of 310 patients each, labeled A, B and C, were randomly selected. Following a preliminary analysis, the government ultimately chose sample C for further investigation.

Review of the Sample

The government's medical experts reviewed Melgen's medical and billing records for each patient in sample C. Experts evaluated, among other things, whether the patient records supported or refuted specific diagnoses reflected in Melgen's billings for each respective patient. Ultimately, the government determined the proportion of unsupported billings associated with each diagnostic code. For instance, it alleged that 84 percent of the sample's billings submitted under diagnostic code 362.52 were unsupported.

Extrapolation

Despite its initial goal of extrapolating findings across the original population of 1,606 patients, the government ultimately sought to extrapolate across a broader population. "the findings of [its medical expert] can be applied to the larger patient population comprising of 2,294 patients to arrive at a reasonable estimate of loss." The expanded population of 2,294 unique Medicare patients (the "revised population"), represented all patients treated by Melgen in the period covered by the indictment from January 2008 to December 2013. The government argued that "limiting the loss calculation to the time period of 2010-2012 would significantly underrepresent the amount of intended loss and actual loss caused by the defendant's conduct between 2008-2013." Rather than articulating a precise loss amount in its filings, the government offered a variety of potential loss calculation methodologies depending on the legal interpretation of "loss" as determined in the sentencing guidelines (i.e., actual loss, intended loss, etc.). The largest loss figures based on its statistical analysis was over \$160 million.

Defense Objections

In addition to various legal objections to the government's loss calculation methodology, Melgen's counsel also objected to the statistical validity of its extrapolation on several grounds.

Nonrandom Selection of Patients

Counsel argued that the government's sample of 310 patients was not selected randomly, therefore findings based on that sample could not be validly extrapolated. In particular, the defense took exception with the government's methodology of selecting multiple samples at random then conducting preliminary analysis on each sample in efforts to select the "best" sample for their purposes. The defense argued that the government effectively "cherry-picked" its sample, which rendered the chosen sample to be effectively nonrandom.

The statistical argument presented here is significant. When discussing randomness in statistics, it is worthwhile to first understand the concept of representativeness. Specifically, "a representative sample contains all of the attributes of the population in the same proportion that they exist in the population. This allows one to generalize from the sample to the population." If the sample chosen is not reasonably representative of the population, inferences about the population may be irreparably biased and invalid. Further, random sample selection is the method anticipated to lead to a representative sample. Such selection is independent of the sampler, and the resulting sample's characteristics are anticipated to be predictable based upon the laws of probability theory. The random selection of a sample removes recognized and unrecognized sources of human bias, such as conscious or unconscious tendencies to select units with larger (or smaller) than average values of the variables of interest (i.e. patients with systematically higher or lower overpayments). Without using proper randomization to select a sample, the presence of selection bias may prevent a sample from being reasonably representative. Notably, randomness also justifies the use of statistical equations to estimate confidence intervals. *[continued on next page]*

Extrapolating Losses in Sentencing (continued)

While it is prudent to review a randomly selected sample in order to ensure it is reasonably representative of the population, that is not what occurred here. Instead, the government chose multiple random samples simultaneously and compared them to one another, as opposed to selecting one sample and comparing it to the population. In fact, the government admitted that its decision to select sample “C” ultimately was based on the number of patients diagnosed with macular degeneration in each particular sample, as compared to the other samples. The presence of such decision-making effectively side-steps the utility of random selection. Said another way, cherry-picking which sample to use, even if all samples were randomly selected, negates its true randomness and injects sources of human bias when determining which patients are ultimately examined.

Sample Not Drawn from the Extrapolated Population

Counsel also objected to the government’s extrapolation of the sample findings across the Revised Population of patients treated by Dr. Melgen from 2008 to 2013, even though the sample was selected from only the Original Population of patients treated from 2010 to 2012. The difference of almost 700 additional patients increased the government’s affected population – and subsequently its loss estimates – by almost 50%. The defense argued that, even if the government’s sample had been drawn randomly, it would only be permissible to extrapolate the findings made about the sample to the population from which it was drawn (i.e. only to the Original Population).

Again, the statistical objection here is substantial. No matter how a population is defined, the results obtained from random sampling can only be objectively extrapolated to the population from which the sample was drawn. For instance, healthcare claims sampled from a particular date range, should not be used to yield statistical conclusions about other periods, even at the same facility or treated by the same provider. Such conclusions may be instructive – but they are not statistically objective.

District Court’s Ruling

The Court ultimately found flaws in both the government and defense’s statistical analysis and calculated its own loss figures in determining a reasonable loss amount for sentencing. With regard to defense objections over the randomness of the selected sample, the Court found the government’s sampling analysis sufficiently reliable for the purposes of estimating loss in this instance. While it found that the government’s selection and comparison of multiple samples and its subsequent selection of a preferred sample did not follow proper sampling protocols, the Court concluded that the government’s actions did not materially misrepresent its analysis. Specifically, the Court seemed to conclude that even though the selected sample was not technically random due to the government’s cherry-picking efforts, those actions were not sufficiently malicious or material as to render the sample unrepresentative or invalid. This point was effectively conceded by the defense’s statistical expert, who was cited by the Court in its reasoning for allowing the government’s sampling.

However, the Court agreed with defense objections regarding the government’s extrapolation across the Revised Population. The Court stated “Because there was no sampling of patients during the years 2008, 2009 and 2013, the Court will base its findings on the data and statistical analysis relative to the 2010-2012 time period.” Ultimately, the Court calculated its own estimated loss amount by relying on the rates of unsupported billings found in the government’s sample, then extrapolating those rates across total billings for respective procedures from 2010 to 2012. That calculation resulted in an estimated loss amount of \$73,417,620. Although the defense was successful in significantly reducing the government’s loss calculation (i.e. by as much as 50%), the Court overruled Defendant’s objection to the additional 24-level enhancement for loss of more than \$65 million but less than \$150 million. For purposes of the Guideline calculation, the Court found that Dr. Melgen had an Offense Level of 38, Criminal History Category I (235-293 months). *[continued on next page]*

Statistical Implications

The presence of cherry-picking can cause an analysis to lose objectivity and become fatally flawed. However, the Court in this case found that the degree of bias injected by the government's actions did not rise to the level of a fatal flaw. For analysts developing and executing sampling analysis, be mindful of methodologically valid procedures for randomization and sample selection and avoid deviating from these protocols to mitigate potential claims of cherry-picking and non-randomness. For those scrutinizing opposing analysis, consider objections to both randomness and representativeness. Presenting empirical evidence along with technical arguments may also provide useful evidence when disputing sampling analysis. For instance, in *Pruchniewski v. Leavitt*, the Court found that the plaintiff failed to present any empirical support for his suggestion that a different stratification would have made a material difference in the overpayment calculation or that the method chosen resulted in an unreliable overpayment estimate. Presenting such empirical evidence may have resulted in a more persuasive argument.

As the Court found here, there is no basis to objectively extrapolate findings from a sample beyond the population from which the sample was drawn. Analysts should diligently define and document the population for which it seeks to infer findings before selecting the sample. Preliminary evaluation of the population can also help to identify relevant characteristics which can impact the sample design, such as the need for stratification or cluster sampling. When presented with opposing analysis, ensure the sample was validly selected from the population subjected to extrapolation. The nuance and attention-to-detail necessary for this task can often yield errors and inconsistencies, which may ultimately invalidate extrapolated conclusions.

Conclusion

The use of statistical sampling and extrapolation is a growing trend in legal matters and it has become a leading tool in the struggle for efficiency when collecting evidence. This case illustrates how technical flaws in sampling analysis might be insufficient to invalidate the underlying conclusions. On the other hand, it also highlights the significant benefits of diligent scrutiny by opposing parties. Whether scrutinizing opposing analysis or developing your own, a thorough understanding of statistical sampling continues to be an asset in government enforcement.

Jennifer Dowdell Armstrong, Esq. is a Member in the Litigation Department at McDonald Hopkins, LLC. Jennifer focuses her practice on governmental investigations and white collar criminal defense, as well as complex commercial litigation. She is the Ohio Chapter Co-Chair of the Women's White Collar Criminal Defense Association.

Chris Haney, CPA, CFE, CHC is a statistician and a forensic accountant specializing in regulatory and compliance matters. Chris is a Managing Director of the Forensus Group and he has been admitted and testified as an expert witness in federal court on the topics of statistical sampling and financial damages.

FOCUS ON SMALL BUSINESS FALSE CLAIMS LIABILITY

PRESUMPTION OF LOSS RULE

We continue to see significant and steady FCA enforcement on the small business front, ensnaring large and small businesses alike. The Department of Justice, in tandem with the Small Business Administration's OIG, are aided by the *Small Business Act's presumption-of-loss rule*. The rule provides that if a concern willfully seeks and receives an award by misrepresenting its small business size or status, there is a ***presumption of loss to the United States equal to entire value of the contract***. Significantly, the new rule shifted the burden of producing evidence with respect to damages to the contractor.

2017 saw the first application of the presumption-of-loss rule in a civil FCA case in *United States ex rel. Savage v. Washington Closure Hanford LLC*. In *Savage*, the DOJ intervened in a qui tam suit where the defendant held a multi-billion-dollar contract for environmental cleanup. The contract included a 65 percent small business subcontracting goal and incorporated FAR clause 52.219-16, under which the government is entitled to liquidated damages if a contractor fails to meet its subcontracting goals.

Notably, The *Savage* court rejected the defendant's arguments that any damages must be offset by the value received and retained by the government. The court reasoned that the harm was not related to whether or not the government received the services it bargained for under the contract, but rather the loss of business and experience going to eligible small businesses: "[a]ccordingly the value received by the government through the contractor's performance is irrelevant to calculating damages."

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Contact:

Christopher Haney, CPA, CFE, CHC
MANAGING DIRECTOR
FORENSUS GROUP, LLC
+1 804 464-3610
CHRISTOPHER.HANEY@FORENSUS.COM