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United States District Court, E.D. Tennessee.

UNITED STATES of America ex rel. Glenda MARTIN and State of Tennessee ex rel. Glenda Martin, Plaintiffs / Relator,
v.
LIFE CARE CENTERS OF AMERICA, INC., Defendant.
United States of America ex rel. Tammie Johnson Taylor, Plaintiff / Relator,
v.
Life Care Centers of America, Inc., Defendant.

Nos. 1:08–cv–251, 1:12–cv–64. | Signed Sept. 29, 2014.

Attorneys and Law Firms

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ORDER

HARRY S. MATTICE, JR., District Judge.

***1** Before the Court is the Government's Motion to Partially Exclude Testimony of Stefan Boedeker (Doc. 135), and Defendant's Motion to Exclude Expert Testimony of Constantin T. Yiannoutsos (Doc. 137). For the reasons stated hereafter, the Court will **RESERVE RULING** on the Government's Motion to Partially Exclude Testimony of Stefan Boedeker (Doc. 135), and will **DENY** Defendant's Motion to Exclude Expert Testimony of Constantin T. Yiannoutsos (Doc. 137).

I. STANDARD OF LAW

Federal Rule of Evidence 702 provides that 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." Fed.R.Evid. 702. The expert's testimony may be admissible under Rule 702 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.

Fed.R.Evid. 702.

The Supreme Court analyzed the language and scope of Rule 702 in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993) ("The adjective 'scientific' implies a grounding in the methods and procedures of science. Similarly, the word 'knowledge' connotes more than subjective belief or unsupported speculation."). In *Daubert*, the Court found that in addition to being relevant, scientific testimony or evidence must also be "reliable." *Id.* at 590. Thus, the Court has two roles under *Daubert:* determining whether the evidence is reliable and analyzing whether the evidence is relevant.

The Court in *Daubert* instructed that, in considering the admissibility of expert testimony, courts must focus "solely on principles and methodology, not on the conclusions that they generate." *Id.* at 595; *see also Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 675 (6th Cir.2010) ("The important thing is not that experts reach the right conclusion, but that they reach it via a sound methodology"). Additionally, the Court explained that a court's role in considering expert testimony is a gatekeeping role, seeking to "to strike a balance between a liberal admissibility standard for relevant evidence on the one hand and the need to exclude misleading 'junk science' on the other." *Best v. Lowe's Home Centers, Inc.*, 563 F.3d 171, 176–77 (6th Cir.2009) (citing *Daubert*, 509 U.S. at 593); *see also Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997) ("while the Federal Rules of Evidence allow district courts to admit a somewhat broader range of scientific testimony than would have been admissible under *Frye*, they leave in place the 'gatekeeper' role of the trial judge in screening such evidence"). As a gatekeeper, the

court only has the authority to determine the admissibility of the evidence; the weight of the evidence is a determination left to the jury. *United States v. Stafford,* 721 F.3d 380, 394 (6th Cir.2013) *cert. denied,* —— U.S. ——, 134 S.Ct. 463, 187 L.Ed.2d 310 (2013).

***2** Based on the Court's ruling in *Daubert,* to determine reliability of the evidence as well as compliance with Rule 702, the Court must first make a threshold determination that the expert is testifying as to scientific knowledge and that such knowledge will assist the trier of fact. Following this determination, the Court must assess the additional factors set forth in *Daubert* to determine whether the expert testimony or evidence should be admitted. These factors include:

> 1) whether the expert's scientific technique or theory can be, or has been, tested; 2) whether the technique or theory has been subject to peer review and publication; 3) the known or potential rate of error of the technique or theory when applied; 4) the existence and maintenance of standards and controls; and 5) whether the technique or theory has been generally accepted in the scientific community.

United States v. Beverly, 369 F.3d 516, 528 (6th Cir.2004). Additionally, the United States Court of Appeals for the Sixth Circuit "has recognized for some time that expert testimony prepared solely for purposes of litigation, as opposed to testimony flowing naturally from an expert's line of scientific research or technical work, should be viewed with some caution." *Johnson v. Manitowoc Boom Trucks, Inc.,* 484 F.3d 426, 434 (6th Cir.2007). When considering these factors, the Supreme Court has been clear that the test of reliability set forth in *Daubert* "is 'flexible,' and *Daubert'* s list of specific factors neither necessarily nor exclusively applies to all experts or in every case." *Kumho Tire Co., Ltd. v. Carmichael,* 526 U.S. 137, 141, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999).

The proponent of the expert evidence has the burden of establishing that the evidence is admissible. *See* Fed.R.Evid. 104(a); *Donathan v. Orthopaedic & Sports Med. Clinic, PLLC,* 2009 WL 3584263, at *20 (E.D.Tenn. Oct.26, 2009). An expert is different from a lay witness and "is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation." *Daubert,* 509 U.S. at 593. The proposed expert must "employ [ ] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co., Ltd.,* 526 U.S. at 152.

In determining whether to admit or exclude expert testimony, it is "broadly accepted that the district court has considerable leeway in making these sorts of determinations." *Baker v. Chevron U.S.A. Inc.,* 533 F. App'x 509, 520 (6th Cir.2013). District courts have broad discretion over the admissibility of expert testimony because "where one person sees speculation ... another may see knowledge." *Tamraz,* 620 F.3d at 672. An expert "need not base his opinion on the best possible evidence, but upon 'good grounds, based on what is known.' " *Deutsch v. Novartis Pharm. Corp.,* 768 F.Supp.2d 420, 453 (E.D.N.Y.2011) (quoting *Daubert,* 509 U.S. at 590); *see also In re Countrywide Fin. Corp. Mortgage–Backed Sec. Litig.,* 984 F.Supp.2d 1021, 1036 (C.D.Cal.2013) ("The *Daubert* standard does not exist to ensure that only the most ideal scientific evidence is admissible in court proceedings, but instead to ensure that expert testimony is derived by the scientific method.") (internal quotation omitted). As a general matter, "rejection of expert testimony is the exception, rather than the rule." *In re Scrap Metal Antitrust Litig.,* 527 F.3d 517, 530 (6th Cir.2008).

***3** There are many tools a party seeking to discredit evidence can use if the evidence is not excluded, such as "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof." *Daubert,* 509 U.S. at 596. Additionally, if the evidence is deemed admissible by a court, but it is ultimately found "insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court remains free to direct a judgment." *Id.; see* Fed.R.Civ.P. 50.

II. THE GOVERNMENT'S MOTION TO PARTIALLY EXCLUDE TESTIMONY OF STEFAN BOEDEKER

In its Motion, the Government argues that Stefan Boedeker's testimony does not contain "purely statistical considerations" but rather expresses legal conclusions.[1] (Doc. 136 at 2). Thus, the Government seeks exclusion of the portions of Mr. Boedeker's testimony regarding the application of statistics to the False Claims Act ("FCA"). In response, Defendant argues that Mr. Boedeker's testimony only discusses the limitations of statistical sampling and "relate[s] to False Claims Act elements that Mr. Boedeker states the *Government's* statistical expert should *not* offer testimony about (i.e., Life Care's

state of mind, falsity of claims) because these elements cannot be reliably measured through the use of statistical sampling." (Doc. 150 at 2) (emphasis in original).

The Federal Rules of Evidence address the specific issue raised in the Government's Motion. Federal Rule of Evidence 704(a) provides that an "opinion is not objectionable just because it embraces an ultimate issue." Fed.R.Evid. 704(a). The United States Court of Appeals for the Sixth Circuit has interpreted Rule 704(a) as encompassing opinions "that suggest the answer to the ultimate issue or that give the jury all the information from which it can draw inferences as to the ultimate issue." *Berry v. City of Detroit*, 25 F.3d 1342, 1353 (6th Cir.1994). As an example, the court in *Berry* explained that it "would not allow a fingerprint expert in a criminal case to opine that a defendant was guilty (a legal conclusion), even though [it] would allow him to opine that the defendant's fingerprint was the only one on the murder weapon (a fact). The distinction, although subtle, is nonetheless important." *Id.*

Thus, although an expert may testify as to an ultimate issue, his testimony cannot amount to a "legal conclusion." *Shahid v. City of Detroit*, 889 F.2d 1543, 1547 (6th Cir.1989). Expert's testimony cannot contain legal conclusions because their testimony may convey "unexpressed, and perhaps erroneous, legal standards to the jury. This invades the province of the court to determine the applicable law and to instruct the jury as to that law." *Torres v. Cnty. of Oakland*, 758 F.2d 147, 150 (6th Cir.1985). Accordingly, if an expert's testimony opines on terms which "have a separate, distinct and specialized meaning in the law different from that present in the vernacular, ... exclusion is appropriate." *Id.* at 151.

***4** The particular language that the Government argues is inadmissible is the portion of Mr. Boedeker's expert report which indicates that he plans to offer testimony regarding whether elements of a FCA claim may be proven through statistics. (Doc. 88 at 4). From the representations of the parties both in their briefs and at the *Daubert* hearing, it is clear that the parties agree that an expert cannot testify as to legal conclusions. *See* Doc. 170 at 9. Thus, the contested portion of the expert report by Mr. Boedeker in which he makes the legal conclusion that a FCA claim may not be proven through statistics would not be admissible testimony. Further, this consideration was always a matter of law left for the Court to decide, not the jury. As the Court has already decided this issue in its ruling upon Defendant's Motion for Partial Summary Judgment, in certain aspects, this issue has become moot. *See* Doc. 184.

Despite these considerations, given the scope of Mr. Boedeker's testimony and its reliance on the testimony of the Government's expert witness, the Court finds that the Government's Motion is one that is best left to be resolved at trial. As discussed previously, the Court also agrees that legal conclusions are not admissible, and Mr. Boedeker will not be permitted to testify as to legal conclusions at trial. However, the Court recognizes the fine line between embracing an ultimate issue and stating a legal conclusion and finds it appropriate and prudent to address this issue at trial, rather than prospectively limiting Mr. Boedeker's testimony. Accordingly, the Court will **RESERVE RULING** on the Government's Motion to Partially Exclude the Testimony of Stefan Boedeker.

III. DEFENDANT'S MOTION TO EXCLUDE EXPERT TESTIMONY OF CONSTANTIN T. YIANNOUTSOS

In its Motion to Exclude Expert Testimony of Constantin T. Yiannoutsos, Defendant asserts that the Court should exclude the testimony of Dr. Yiannoutsos because he did not use a reliable methodology in creating his sampling and extrapolation plan. (Doc. 138 at 7). Specifically, Defendant argues that Dr. Yiannoutsos' methodology is unreliable because (1) he did not use a probe sample to account for variables in the sample universe; (2) he worked with a sample predetermined by the Government; and (3) the sample size is not large enough to be representative of the universe of possible claims. (*Id.* at 7–9). In its Response, the Government asserts that Dr. Yiannoutsos' methodology is sufficiently reliable to meet the standard set forth in *Daubert.* (Doc. 151 at 10). The Court will outline the evidence presented in Dr. Yiannoutsos' Statistical Report, Mr. Boedeker's Statistical Report, and their testimony at the *Daubert* Hearing, and then address the parties arguments in turn.

A. Expert Statistical Reports

1. Expert Report of Dr. Constantin T. Yiannoutsos

Dr. Constantin T. Yiannoutsos was retained by the Government to provide expert statistical services in the instant matter. (Doc. 151–1 at 2). Dr. Yiannoutsos is currently employed as a Professor of Biostatistics at the Indiana University Department of Medicine in Indianapolis, Indiana. (*Id.* at 22). Prior to his employment with Indiana University,

Dr. Yiannoutsos was employed as a Senior Research Scientist at the Center for Biostatistics in AIDS Research at the Harvard School of Public Health in Boston, Massachusetts. (*Id.*). Dr. Yiannoutsos graduated from Central Connecticut State University in 1986 with a Bachelor of Arts Degree in Mathematics and a concentration in Actuarial Science; he graduated from the University of Connecticut with a Master's Degree in Statistics in 1989 and a PhD in Statistics in 1991. (*Id.*). Dr. Yiannoutsos has authored approximately 120 publications related to statistical sampling.

***5** Dr. Yiannoutsos submitted an expert report summarizing steps that were taken or will be taken to "estimate the number of claims submitted for non-covered services to Medicare or TRICARE that were provided during the Relevant Period by skilled nursing facilities ("SNF") owned or operated by Life Care and to estimate the total overpayment by Medicare and TRICARE[.]" (*Id.* at 3). The Court will summarize Dr. Yiannoutsos' process and proposed methodology based on the facts submitted in that report.

The relevant Medicare universe was limited to include admissions of Medicare beneficiaries during the relevant time period at the 82 Life Care facilities who stayed at least 30 days and who were assigned to the Ultra High RUG level during their 30, 60, or 90 day assessment period. (*Id.* at 8). Dr. Yiannoutsos defined an "admission" as "the period of time from a beneficiary being admitted to a Life Care facility until the beneficiary was discharged from the facility." (*Id.*). During the relevant time period, 54,396 admissions (encompassing 154,621 total claims) met these criteria.[2] (*Id.*). Of the 154,621 claims, 5,442 claims were for dual-eligible TRICARE beneficiaries.

On March 18, 2013, the Department of Justice ("DOJ") provided Dr. Yiannoutsos with 6 datasets, containing Medicare data for the 82 Life Care facilities in the sample universe. (*Id.* at 4). The Medicare data included claims for services from January 1, 2006 through February 1, 2013, and provided information regarding the beneficiary, the facility and SNF stay-level information, data from the qualifying inpatient stay, and 5–day assessment information from the minimum data sets ("MDS"). On March 29, 2013, DOJ provided Dr. Yiannoutsos with an Excel spreadsheet containing TRICARE claims data for the 82 Life Care facilities in the sample universe. The TRICARE data included claims from January 1, 2006 through January 1, 2013, and provided information regarding the beneficiary, the facility and SNF admission information.

The Medicare data relates to 127,641 unique beneficiaries and 392,562 claims. (*Id.* at 5). All of the claims have a "positive claim paid amount" with values ranging from $0.05 to $44,617.87. To gain familiarity with the Medicare data, Dr. Yiannoutsos performed certain tasks, including "generating and reviewing frequencies and distributions of certain variables as well as generating and reviewing descriptive statistics such as mean, standard deviation, maximum, minimum, median, and interquartile range for continuous variables." (*Id.*).

The TRICARE data relates to 4,074 beneficiaries and 10,960 unique claims. All of the claims have a "positive claim paid amount" with values ranging from $1.72 to $109,433.77. Dr. Yiannoutsos cross-referenced the Medicare data and the TRICARE data and "10,152 [claims] (97.4%), corresponding to 3,841 TRICARE beneficiaries (99.6%), were successfully linked with Medicare claims." (*Id.* at 7).

***6** Dr. Yiannoutsos proposed a three-step process to estimate the total number of claims for non-covered services: (1) select a sample of admissions from the relevant universe; (2) conduct a medical review of the records related to the claims contained in the sample admissions; and (3) analyze the results of the review and estimate the total number of claims for non-covered services. He used the average daily amount paid per admission "as a surrogate of the total amount paid in each admission" to identify strata based on the amounts paid in each admission. (*Id.* at 9). The two strata that Dr. Yiannoutsos selected were the four Life Care divisions with the lowest average daily amount paid (Stratum 1–Eastern, Garden Terrace, Heartland, and Southeast Divisions) and the four Life Care divisions with the highest average daily amount paid (Stratum 2–Mountain States, Northeast, Northwest, and Southwest Divisions). *See* Doc. 151–1 at 10–11. In addition to stratifying the sample, Dr. Yiannoutsos determined that "a sample size of 400 was appropriate." *Id.* at 11. Thus, each stratum consisted of 200 patient admissions from the four divisions in the stratum.

Dr. Yiannoutsos stated in his report that the "precision that will be obtained from a sample size of 400 is impossible to know until the medical review is completed." (*Id.*). Dr. Yiannoutsos conducted simulations of the 400 admissions and estimated the amount of overpayment based on certain assumptions: (1) the overall proportion of admissions in the universe "containing non-covered services was allowed to vary between 5% and 35% by 10% increments"; and

(2) the proportion of the amount paid within an admission was associated with "claims which contained non-covered services was allowed to vary between 25% and 100% in increments of 25%." (*Id.* at 12). He performed 100 repeated simulated samples for each of the 16 possible combinations resulting from these assumptions. *See* Doc. 151–1 at 12, Table 4.

Dr. Yiannoutsos also explained how he selected the sample. (*Id* . at 14). He used a statistical and data management system called SAS version 9.3, which randomly selected sample admissions within each stratum. In his expert report, Dr. Yiannoutsos asserted that the "distribution of the random numbers is Uniform, meaning that all admissions within each stratum had the same stratum-specific probability (40195/54396 and 14201/54396 respectively) of being selected (Table 3)." (*Id.*). He also emphasized the importance of selecting a random sample by explaining that "a random sample is necessary to ensure representativeness." (*Id.* at 15). He elaborated on the concept of "representativeness" by stating that, while it is "impossible" to review the entire universe of claims, "surrogate measures ... can be considered and compared between sampled and non-sampled admissions to ensure representativeness." (*Id.*). Dr. Yiannoutsos ultimately concluded that there was "strong evidence for the representativeness of the sample" because the sample was selected randomly and there was a "universal lack of differences" between sampled admissions and non-sampled admissions. (*Id.* at 17).

***7** After the sample was selected, Dr. Yiannoutsos stated that the patient records associated with the 400 sampled admissions will be "obtained and reviewed by medical expert(s) to ascertain whether claims within sampled admissions were submitted for non-covered services and to determine whether any overpayment resulted by submitting such claims to Medicare." (*Id.*). The medical experts will provide Dr. Yiannoutsos with (1) a yes/no statement regarding whether each claim includes non-covered services; and (2) a dollar amount of the overpayment at the claim level. If a claim is not considered to have been overpaid, it will receive a $0.00 amount of overpayment. (*Id.*).

The individual claim amounts calculated by the medical experts will be aggregated to calculate a total overpayment amount at the admission level for the sampled admissions. Using the total overpayment amount at the admission level, Dr. Yiannoutsos will then calculate an average per-admission overpayment amount in the sample, multiply this amount by the total admissions in the relevant universe, and estimate the total amount of overpayment made by Medicare. (*Id.* at 18). This calculation would be considered the point estimate of the total overpayment amount, and he would identify confidence intervals based on a normal distribution around the point estimate to "quantify the uncertainty." (*Id.*). Dr. Yiannoutsos has attached the details of his statistical considerations for his estimation of the total overpayment to his report, and he refers to his design as a stratified sampling design. *See* Doc. 151–1 at 49 (explaining the formulas used to statistically calculate the total overpayment).

Dr. Yiannoutsos has also detailed his methodology for calculating the total number of claims within the relevant universe for non-covered services. (*Id.* at 19). For this calculation, Dr. Yiannoutsos plans to use a combined stratified cluster design where the admission will be "the primary sampling unit but it is thought of as a *cluster* of the individual claims that it contains." (*Id.*) (emphasis original). Dr. Yiannoutsos will first estimate the proportion of claims within each admission, and then multiply that estimate by the 154,621 claims in the relevant universe of Medicare claims. (*Id.*). Dr. Yiannoutsos has attached the details of his estimation procedure for calculating the total number of claims within the relevant universe for non-covered services to his report. *See* Doc. 151–1 at 50.

As a final matter, Dr. Yiannoutsos will estimate the total TRICARE overpayment amount "based on patterns identified in the Medicare sample." (*Id.* at 20). As discussed above, the TRICARE universe is defined as the 5,442 TRICARE claims with corresponding claims in the Medicare universe. Dr. Yiannoutsos explains that the reason he has chosen to estimate any TRICARE overpayment this way is because of the assumption that "the TRICARE claims in the relevant TRICARE universe were filed for the same beneficiaries and for the same conditions as their corresponding Medicare claims." (*Id.*). Dr. Yiannoutsos has attached the details of his estimation procedure for calculating the total number of claims within the TRICARE universe for non-covered services to his report. *See* Doc. 151–1 at 52.

2. Expert Report of Mr. Stefan Boedeker

***8** Mr. Stefan Boedeker was retained by Defendant to opine on the statistical theory, sampling methodology, and data analysis of Dr. Yiannoutsos' expert report. (Doc. 151–3 at 6). Mr. Boedeker is employed as a director at Berkley Research Group in Los Angeles, California. (Doc. 151–3 at 46). As a director, Mr. Boedeker's main area of expertise

is statistics and econometrics, and he "provides statistical and economic consulting to a variety of clients." (*Id.*). Mr. Boedeker received his undergraduate degree in Business Administration and Statistics and his Master's degree in Statistics from the University of Dortmund in Germany and his Master's degree in Economics from the University of California, San Diego. (*Id.*). Mr. Boedeker has also completed the requirements to receive his PhD at the University of California, San Diego, but has not completed his dissertation. (*Id.*). Before his current employment, Mr. Boedeker was employed as an economic research assistant for the German government, an economic and statistical consultant at Arthur Andersen, and held positions with PricewaterhouseCoopers, LLP, Deloitte & Touche LLP, and Navigant Consulting. (*Id.* at 60).

In reviewing and analyzing Dr. Yiannoutsos' report, Mr. Boedeker concluded that the sample universe does not represent the overall universe of Life Care facilities. (*Id.* at 9). Specifically, Mr. Boedeker found the selection of 82 facilities rather than all 225 facilities to depart from the "logical choice." (*Id.* at 10). Rather, Mr. Boedeker noted that the "actual universe during this time period included 225 individual Life Care facilities ... and included 279,913 individual beneficiaries who had 449,691 admissions and 946,592 claims." (*Id.* at 11). Considering Dr. Yiannoutsos' selection of the relevant universe, Mr. Boedeker determined that his sampling plan would "ultimately yield an arbitrary, non-representative, and invalid selection of facilities that will be part of the sampling universe while the rest of the facilities will be ignored." (*Id.* at 12). Mr. Boedeker also concluded that the sample selected by Dr. Yiannoutsos is not representative of the sample universe because it does not account for "the high degree of variation" across and within the Life Care facilities. (*Id.* at 31).

Mr. Boedeker also considered Dr. Yiannoutsos' selection of a beneficiary's admission as a sample unit to be "inappropriate." (*Id.* at 14). The reason that Mr. Boedeker identifies this selection as inappropriate is because it results in "the number of Medicare claims submitted for allegedly non-covered services ... to be estimated indirectly by using the average number of claims in an admission that are alleged to include non-covered services." (*Id.* at 15). Based on the lack of an "appropriate sampling unit," Mr. Boedeker considered Dr. Yiannoutsos' opinions to be unreliable and "below the standards for proper statistical interpretation." (*Id.*).

***9** Mr. Boedeker further found that Dr. Yiannoutsos' analysis was "fundamentally flawed" because he accepted the sample frame given to him by the Government rather than defining his sample universe based on the Complaint in this action. (*Id.* at 16). Mr. Boedeker opines that Dr. Yiannoutsos should have calculated a sample size that was large enough to yield a reliable statistical sample and conducted a probe sample. (*Id.* at 17–18). Mr. Boedeker notes that Dr. Yiannoutsos performed a simulation study "in an attempt to measure the variation of potential overpayments in the underlying universe," but asserts that the simulation was fundamentally flawed because it relied on flawed assumptions. (*Id* . at 19). Mr. Boedeker performed a simulation study in which he altered the flawed assumption related to the percentage of overpayment for each claim and the "result of the simulation study indicated that the margin of error was almost 50% in some cases." (*Id.* at 20). Mr. Boedeker found this large of a margin of error to be "unacceptable." (*Id.*).

Mr. Boedeker also opined that Dr. Yiannoutsos' stratification based on average paid amounts per division was "inappropriate and statistically invalid." (*Id.* at 21). Mr. Boedeker finds the stratification to be inappropriate because of the analyses he has done that indicate "that such stratification does not create homogeneous strata and fails to reduce variation." (*Id.* at 22). In his report, Mr. Boedeker illustrates several analyses he has performed to highlight the flaws in Dr. Yiannoutsos' stratification. *See* Doc. 151–3 at 23–28).

Regarding how Dr. Yiannoutsos generated his random numbers, Mr. Boedeker opined that Dr. Yiannoutsos applied the random number generator incorrectly, which "negates the randomness of the sample selection, rendering it useless and corrupt for extrapolation purposes." (*Id.* at 29). Dr. Yiannoutsos used SAS, a statistical software package, to select the sampling units from the two strata in the relevant universe. However, Mr. Boedeker found Dr. Yiannoutsos' method of sorting the sample frame by stratum and then uniformly distributed number to deviate "from accepted principles of random sampling." (*Id.* at 30).

Mr. Boedeker also found Dr. Yiannoutsos' methodology to be flawed because it relies upon a "highly subjective review" and does not clearly define the rules of evaluating the medical necessity of the reviewed claims. (*Id.* at 40). Mr. Boedeker suggests that a probe sample could have assessed the significance "of patient specific information and medical

professional specific information on the audit process," but points out that Dr. Yiannoutsos failed to conduct such a sample. (*Id.* at 41). Based on these factors, Mr. Boedeker concludes that Dr. Yiannoutsos' analysis could not lead to a reliable estimate about the relevant universe of claims. (*Id* .).

B. *Daubert* Hearing Testimony

***10** The Court held a *Daubert* Hearing on Defendant's Motion to Exclude Expert Testimony of Constantin T. Yiannoutsos on May 13–14, 2014. (Doc. 167). At the Hearing, Defendant raised several issues with Dr. Yiannoutsos' testimony and expert report. The Court will address each issue in turn, but will not restate testimony that mirrors either expert's report, as discussed *supra.*

1. Testimony of Dr. Constantin T. Yiannoutsos

The Government called Dr. Yiannoutsos to the stand and questioned him about the details of his statistical sampling and extrapolation plan. (Doc. 170 at 36). Dr. Yiannoutsos testified that he was retained by the Government in October 2012 "to obtain a statistically valid sample from data involving claims submitted to Medicare by providers operated or owned by Life Care." (*Id.* at 40).

Regarding selection of the sample, Dr. Yiannoutsos testified that he determined that an admission was the appropriate sample unit and then "ended up with a sample size of 400 beneficiary admissions." (*Id.* at 41). The Court requested that Dr. Yiannoutsos clarify any exchange between the Government and Dr. Yiannoutsos regarding the selection of the sample universe, and Dr. Yiannoutsos testified that he "did not alter the universe" identified by the Government. (*Id.* at 42). Dr. Yiannoutsos explained that there are two ways to "mitigate variability:" design and sample size. (*Id.* at 247). Given the size of the sample, Dr. Yiannoutsos "informed the government that it was [his] opinion that this would be a large sample enough to produce sufficiently precise estimates, so they could proceed without a probe sample but to review all 400 admissions." (*Id.* at 58). Dr. Yiannoutsos also explained that he did not remove any outlier data points from the data set, and that the 400 admissions were selected randomly. (*Id.* at 44, 69). Dr. Yiannoutsos testified that, if "you cherry pick the data, you are changing the universe of the analysis." (*Id.* at 231).

Dr. Yiannoutsos testified that the admissions were selected randomly because he generated "uniformly distributed random numbers randomly and then assign[ed] each one of them to each of the 54,396 admissions, and then [took] the 200 smallest, the admissions rather that were associated with the 200 smallest uniformly distributed random numbers as the 200 admissions within each stratum." (*Id.* at 69). Dr. Yiannoutsos described random selection of a sample as "critical" because "it's the strongest assurance that the sample is representative." (*Id.* at 72). From the randomly drawn numbers associated with the admissions, Dr. Yiannoutsos testified that there are "one or two facilities which have no patients from them." (*Id.* at 237). He further testified that "the goal was not to estimate overpayment within a facility." (*Id.*).

The Government questioned Dr. Yiannoutsos about his decision to divide the data into two subgroups, or strata. Dr. Yiannoutsos testified that if the stratification were successful, it could result in the estimates being more precise. He also testified that he did not stratify the data by facility, or factor in considerations related to diagnosis codes or the type of therapy. (*Id.* at 230, 232). If the stratification was not successful and the two subgroups had no relationship with the overpayment amounts, Dr. Yiannoutsos stated that the sample design "would be a simple random sampling situation." Dr. Yiannoutsos also testified that a simple random sampling design is a "valid" and "usual" design. (*Id.* at 55–56).

***11** During his testimony, Dr. Yiannoutsos discussed his use of simulations. He testified that the simulation studies he used indicate that he "will have a pretty good idea of what the level of overpayment" is once the medical review occurs. (*Id.* at 66). Generally, Dr. Yiannoutsos finds an estimate with a precision level of 25 percent and a confidence level of 90 percent to be sufficiently reliable. (*Id.* at 67, 122, 124, 222–223). Dr. Yiannoutsos testified that, depending on the precision he was seeking and how confident he wanted to be, he "may want to be 90 percent confident, [or he] may want to be 95 percent confident." (*Id.* at 89). He used the simulations to address whether he had "assurances that the resulting estimates will have certain precision." (*Id.* at 240). Specifically, his simulations "show that if the overpayment level is between 15 and 17 percent, [the estimate] will be within that 25 percent precision level." (*Id.* at 223).

For his sampling plan, Dr. Yiannoutsos has assumed that the results received from the medical review will be correct. (*Id.* at 86). Dr. Yiannoutsos did not provide any input regarding the standards the medical review team will use "to assess whether the care provided [is] covered or non-covered" because he considers that determination "well beyond [his] expertise." (*Id.* at 166). If Dr. Yiannoutsos

receives information indicating that the results are incorrect, he can submit the new data "to the same procedure and come up with modified estimates of the total overpayment or the total number of claims respectively." (*Id.* at 87). The results of the medical review will determine the margin of error for Dr. Yiannoutsos' estimates. (*Id.* at 250–51).

Dr. Yiannoutsos testified that, while he had been published on statistical sampling and "inference," he has not been published on "using statistical sampling to estimate loss attributable to overpayment." (*Id.* at 172). He further testified that he stood up in a public setting and discussed his simulations and estimates "all of the time." (*Id.* at 173).

2. Testimony of Mr. Stefan Boedeker

Defendant called Mr. Boedeker to the stand and questioned him about the details of Dr. Yiannoutsos' statistical sampling and extrapolation plan. (Doc. 171 at 3). Defendant retained Mr. Boedeker, and he reviewed Dr. Yiannoutsos' report, data files, and the Complaint, interrogatories, and the interrogatory responses so that he had "background knowledge" about the case. (*Id.* at 11). Mr. Boedeker did not generate his own sample with respect to the Medicare data. (*Id.* at 159). Mr. Boedeker testified that the following steps that a statistician would take when hired to formulate a sample and extrapolation plan are: (1) properly define the universe; (2) define the statistical terms in the sampling unit; (3) define the sampling frame; (4) determine the appropriate sample size; (5) define the appropriate sampling methodology; (6) select the items that are part of the sample; and (7) ensure that the sample is representative.

***12** Mr. Boedeker testified that there was a problem with the Government giving Dr. Yiannoutsos a sample size of 400 "because at the end conclusions will be drawn from the sample." (*Id.* at 27). He described a statistical sample as a "decision tool" and testified that "you can statistically calculate the necessary sample size" to get the confidence interval to a certain range. (*Id.* at 27–28). Because of the sample size of 400, Mr. Boedeker testified that he disagreed with Dr. Yiannoutsos that this sample was sufficient to produce a reasonably reliable result. (*Id.* at 28).

Mr. Boedeker also disagreed with Dr. Yiannoutsos' decision to not use a probe sample. (*Id.* at 30). He testified that textbooks "recommend to use a probe sample ... [to] find out the variation in the universe." (*Id.*). He also supported the use of a probe sample in the instant cause because it "is the safest way to address the issue of an unknown variation, because it's a valid random sample in a smaller scope." (*Id.* at 43). Mr. Boedeker further testified that a probe sample helps statisticians calculate the ultimate sample size. (*Id.* at 44). Mr. Boedeker categorized Dr. Yiannoutsos' decision not to use a probe sample as his biggest mistake. (*Id.* at 80). However, during the Government's cross-examination of Mr. Boedeker, he testified that they have been cases in which he has not used a probe sample. (*Id* . at 128, 133).

During his testimony, Mr. Boedeker asserted that "a reasonable and valid statistical sampling plan has to incorporate the facility level." (*Id.* at 65). Mr. Boedeker stated this conclusion after discussing the fact that the Government chose to "whittle down" its case from 225 facilities to 82 facilities. (*Id.*). Thus, Mr. Boedeker concluded that the Government "chose certain facilities for a reason" and those considerations should be taken into account when designing a sampling plan. (*Id.*).

Mr. Bodeker also testified about how the 82 facilities were represented in the statistical sample. (*Id.* at 66). Of the 82 facilities, there are 4 facilities that were not represented in the sample. (*Id.*). Additionally, there were 6 facilities that were represented by one patient file. Mr. Boedeker testified that the lack of representation for these 10 facilities was a problem because "the zero is obviously not represented at all ... [and][t]he one does not enable a statistician to calculate variation." (*Id.* at 67). Mr. Boedeker also identified a facility which was represented 13 times in the sample, which he found problematic because it is "overrepresented in the sample ... [which] will lead to an inflation of the actual point estimate." (*Id.* at 68–69).

Mr. Boedeker found Dr. Yiannoutsos' stratification to result in a "highly unreliable" and unrepresentative sampling plan, which he determined would create an unreliable extrapolation result. (*Id.* at 77, 92). He also discussed Dr. Yiannoutsos' use of simulations and found them to be lacking because of his assumption that "[w]hoever was found to have an overpayment had the same constant overpayment." (*Id.* at 82). As a final matter during his direct examination, Mr. Boedeker testified as to the effect any issues in a statistical sample may have on extrapolation. Mr. Boedeker testified that "everything that was not corrected in the sample, everything that was assumed but not proven with the data now gets magnified by a big multiple." (*Id.* at 91).

***13** Near the end of his testimony, Mr. Boedeker stated that there is not a "one size fits all" approach in statistical

sampling. (*Id* . at 148). Rather, there are "differences in opinions" and it is possible that "there could be competing statistical sampling designs that are statistically valid." (*Id.* at 148–149).

As of the date of the *Daubert* Hearing, Mr. Boedeker had one publication in a book, and he could not "remember if it was peer reviewed under the same level of peer reviews that an article in a scholarly journal would be peer reviewed." (*Id.* at 163). Mr. Boedeker also has been published in the publication of his employer, the *BRG Review*, which he does not count as a publication. (*Id* .).

C. Analysis

As the Court discussed more thoroughly *supra*, it must determine whether Dr. Yiannoutsos' testimony and expert report are both reliable and relevant. After the *Daubert* Hearing, the Court permitted the parties to submit post-hearing briefs, addressing whether the Government has met its burden under the Federal Rules of Evidence and *Daubert.* In its brief, Defendant asserts four reasons that the Government has not met the requirements under the Federal Rules of Evidence and *Daubert:* (1) the Government has not independently validated Dr. Yiannoutsos' testimony; (2) Dr. Yiannoutsos did not testify that his methodology was reliable as applied to the instant case; (3) Dr. Yiannoutsos' methodology is flawed because he did not perform a probe sample, calculate a sample size, account for any variable, set precision requirements up front, and address issues with the medical review; and (4) Mr. Boedeker's testimony established that Dr. Yiannoutsos' sampling plan would result in unreliable estimates. (Doc. 174 at 5–7). In its brief, the Government set forth several reasons why Dr. Yiannoutsos' testimony does meet the requirements under the Federal Rules of Evidence and *Daubert:* (1) the Government's use of sampling is limited to the number of claims for non-covered services and the loss associated with those claims; (2) Defendant's arguments about representativeness are unsupported by statistics, law or logic; (3) a probe sample is not necessary to develop a statistically valid sample; (4) any arguments about issues with the medical review should be directed at the medical review rather than the sample design; and (5) Dr. Yiannoutsos' testimony is supported by well-accepted statistical methods. (Doc. 173 at 5–9). The Court will address these arguments as they relate to the requirements under the Federal Rules of Evidence and *Daubert.*

1. Reliability

The Court's first duty under *Daubert* is to determine whether the proposed evidence and testimony are reliable. *See Daubert,* 509 U.S. at 592 ("Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a), whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue"). The principle of reliability is well-rooted in Federal Rule of Evidence 702, which in part requires that an expert base his testimony on sufficient facts or data, support his testimony with reliable principles and methods, and reliably apply his methodology to the facts of a given case. *See* Fed.R.Evid. 702. In addition to these more generalized considerations, the Court will also consider the specific factors set forth in *Daubert.* [3]

***14** As a preliminary matter, the Court notes that the Government intends to use Dr. Yiannoutsos' testimony solely to (1) estimate the number of claims submitted by 82 Life Care facilities that were for non-covered services; and (2) estimate the amount of loss to the Government associated with those claims. *See* Doc. 173 at 4; Doc. 170 at 292–293. Thus, the Court will not consider or discuss issues raised outside the scope of these parameters.

Daubert first requires that the theory or technique can be and has been tested and that the Court consider the standards controlling the technique's operation. Daubert, 509 U.S. at 593. The two sampling plans that Dr. Yiannoutsos has created are based on theories of statistical sampling and extrapolation. Specifically, he refers to his design plans as a stratified sampling design at the admission level and a combined stratified cluster design at the claim level "where the admission is still the primary sampling unit but it is thought of as a *cluster* of the individual claims it contains." (Doc. 151–1 at 19) (emphasis original).

As discussed above, Dr. Yiannoutsos first became familiar with the databases provided by the Government before forming his statistical plans. *See* Doc. 151–1 at 5 ("A number of tasks were performed in order to process and gain familiarity with the Medicare Database"). Once he performed these tasks as well as cross referencing the Medicare and TRICARE databases, Dr. Yiannoutsos selected the admission as his principle sampling unit and stratified the sample into two strata. (*Id.* at 9). The 8 Life Care divisions encompassing the 82 facilities at issue were divided into 2 strata: the four facilities with the lowest per day average amount paid per admission and the four facilities

with the highest per day average amount paid per admission. (*Id.* at 11). Dr. Yiannoutsos also considered whether a sample size of 400 was sufficient and later "conducted a number of simulations that show a sample size of 400 is likely to yield estimates that meet or substantially exceed established auditing standards." (*Id.* at 11). To determine which admissions would be selected in the sample, Dr. Yiannoutsos used the SAS program to randomly select the admissions. (*Id.* at 14). Once selected, the admissions were sent to a medical review team, who will provide Dr. Yiannoutsos with (1) a yes/no statement regarding whether each claim includes non-covered services; and a dollar amount of the overpayment at the claim level. (*Id.* at 17). As detailed more thoroughly *supra*, once the medical review has been performed, Dr. Yiannoutsos will review the results and estimate the total number of claims made for non-covered services and the loss associated with those claims.

Dr. Yiannoutsos has described the stratified random sampling plan as "random sampling within each stratum. The stratum-specific sampling probability is equal within each stratum and a simple random sampling is conducted within each stratum." (Doc.151–5 at 20). During the *Daubert* Hearing, Dr. Yiannoutsos testified that he endorses the treatise *Elementary Survey Sampling* by Richard L. Scheaffer, William Mendenhall, R. Lyman Ott, and Kenneth G. Gerow ("ESS"). ESS supports Dr. Yiannoutsos' definition and provides that a stratified random sample "is one obtained by separating the population elements into nonoverlapping groups, called strata, and then selecting a simple random sample from each stratum." ESS, at 116. ESS also provides that statisticians use stratified random sampling for the following reasons:

***15** 1. Stratification may produce a smaller bound on the error of estimation than would be produced by a simple random sample of the same size. This result is particularly true if measurements within strata are homogeneous.

2. The cost per observation in the survey may be reduced by stratification of the population elements into convenient groupings.

3. Estimates of population parameters may be desired for subgroups of the population. These subgroups should then be identifiable strata.

ESS at 117.

In addition to the established methodologies in the statistical literature, as the Court has discussed at length in its Order on Defendant's Motion for Summary Judgment, statistical sampling has been used in litigation for decades. *See* Doc. 184. The courts that have considered statistical sampling and extrapolation have concluded that "statistical sampling with an appropriate level of representativeness has been utilized and approved." *In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1020 (5th Cir.1997); *see also E.K. Hardison Seed Co. v. Jones*, 149 F.2d 252, 256 (6th Cir.1945) ("Thus it is that samples are receivable in evidence to show the quality or condition of the entire lot or mass from which they are taken. The prerequisites necessary to the admission in evidence of samples are that the mass should be substantially uniform with reference to the quality in question and that the sample portion should be of such nature as to be fairly representative."); *Republic Servs., Inc. v. Liberty Mut. Ins. Co.*, 2006 WL 2844122 (E.D.Ky. Oct.2, 2006) (collecting cases). In fact, inferential statistics have been considered "an acceptable due process solution" in litigation. *In re Estate of Marcos Human Rights Litig.*, 910 F.Supp. 1460, 1467 (D.Haw.1995) *aff'd sub nom., Hilao v. Estate of Marcos*, 103 F.3d 767 (9th Cir.1996). Statistical methods and analysis have also been described as being "well recognized as reliable and acceptable evidence in determining adjudicative facts." *State of Ga., Dep't of Human Res. v. Califano*, 446 F.Supp. 404, 409 (N.D.Ga.1977). Thus, not only have the statistical principles Dr. Yiannoutsos relies on been established in the mathematical field, they have also been tested and reviewed by the federal court system. The Court finds this sufficient to meet this requirement under *Daubert.*

Next, *Daubert* requires that the methodology must have been subjected to peer review and publication. *Daubert*, 509 U.S. at 593. The parties have presented evidence regarding this matter to the Court with very different approaches. While Defendant argues that Dr. Yiannoutsos' testimony is unreliable and his methodology regarding sampling Medicare fraud has never been peer-reviewed, the Government argues that Dr. Yiannoutsos relies on well-supported statistical methodology. The Court sees some validity in both parties' positions. It is true that the methodology upon which Dr. Yiannoutsos relies is based on principles of statistics, which have been used in litigation for decades. *See State of Ga., Dep't of Human Res.*, 446 F.Supp. at 409. However, given that apparently, a court has not explicitly addressed the issue of statistical sampling and extrapolation in large-scale FCA cases, it is highly unlikely if not impossible that Dr. Yiannoutsos would have been able to have this type of

sampling peer-reviewed or rely on previously-performed statistical sampling and extrapolation plans. *See* Doc. 170 at 174–177. Accordingly, the Court will address Defendant's *Daubert* challenge considering the posture and context of the instant litigation.

***16** It is indisputable that Dr. Yiannoutsos has authored publications relating to the topic of statistical sampling numerous times. *See* Doc. 151–1 at 25–37. Additionally, the publications to which Dr. Yiannoutsos has contributed have been published in academic journals, which have been subject to peer review. *Id.* Regarding these publications, Dr. Yiannoutsos has never been told that one of his stratified random sample designs has been invalid. (Doc. 170 at 50).

Despite Dr. Yiannoutsos' substantial record of publication in peer-reviewed journals, Defendant takes issue with the fact that, of these publications, none of them concern Dr. Yiannousos's methodology for estimating overpayment for Medicare or loss attributable to that overpayment. (Doc. 170 at 172). However, Defendant is also unable to articulate specific publications that would be entirely on point for the instant case. *See id.* at 175 ("One area would be how it actually is done in CIAs, these agreements on doing sampling going forward, maybe not all of the principles necessarily go, but we think some of the principles would be applicable."). Given Dr. Yiannoutsos' distinguished record on statistical sampling and extrapolation along with the lack of peer-reviewed publications on the specific matters at issue in this action, the Court does not find that Dr. Yiannoutsos' lack of publication on estimating overpayment for Medicare and loss attributable to that overpayment renders his testimony inadmissible. Rather, Dr. Yiannoutsos' numerous publications regarding statistical sampling and extrapolation are sufficient to withstand Defendant's *Daubert* challenge on this factor.

Daubert also requires the Court to consider the known or potential rate of error for the methodology being proposed. *Daubert*, 509 U.S. at 594. Because the medical review has not yet been completed, the precision of the estimates attained from Dr. Yiannoutsos' sample design is unknown. Nevertheless, both parties insist that this matter is ripe for review and Dr. Yiannoutsos conducted simulations to determine the potential rate of error for his sampling design. [4]

In his expert report and throughout his testimony, Dr. Yiannoutsos has represented that the rate of error for his sampling plan is likely to fall within a 25 percent precision level "if the overpayment level is between 15 and 17 percent." (Doc. 170 at 223). Dr. Yiannoutsos plans to report the results of the extrapolation "in a variety of ways, including a two-sided 95% confidence interval, a one-sided 95% confidence interval, and a one-sided 90% confidence interval." (Doc. 151–1 at 18). Other courts which have considered the precision level of statistical methodologies have found a margin of error of 43.3 percent to be too high while a margin of error of 20 percent to be sufficiently reliable. *See Duran v. U.S. Bank Nat. Assn.*, 59 Cal.4th 1, 46, 172 Cal.Rptr.3d 371, 325 P.3d 916 (2014) (describing a precision level of 43.3 percent at a 95 percent confidence interval to be "intolerably high."); *Massachusetts Mut. Life Ins. Co. v. Residential Funding Co., LLC*, 989 F.Supp.2d 165, 174 (D.Mass.2013) ("As other courts have concluded, the ± 10 percentage point margin of error does not render Dr. Cowan's methodology unreliable. The margin of error speaks to the persuasive power of the sample, not its admissibility"). Considering other courts that have discussed the admissibility of evidence based on similar confidence intervals and the testimony of both experts at the *Daubert* Hearing, the Court finds the confidence interval and precision level likely to result from Dr. Yiannoutsos' sample design (once the medical review has been performed) to be sufficiently reliable.

***17** *Daubert* further requires the Court to consider whether the theory or technique is generally accepted in the relevant scientific community. Daubert, 509 U.S. at 594. To this factor, Defendant raises the issue that Dr. Yiannoutsos' methodology is flawed because he did not perform a probe sample, he accepted the Government's sample size, he did not account for specific variables, he did not set precision requirements upfront, and he failed to address issues with the medical review. Defendant also argues that Mr. Boedeker's testimony and expert report established that Dr. Yiannoutsos' sampling plan would result in unreliable estimates.

For each of Defendant's concerns, the Government has provided a reasonable and logical response. At the *Daubert* Hearing, Mr. Boedeker testified that the lack of a probe sample in Dr. Yiannoutsos' sampling plan was his biggest mistake. (Doc. 171 at 80). However, regarding the issue of probe samples generally, Mr. Boedeker testified that, depending on his assignment, he has chosen not to do a probe sample in certain studies. (*Id.* at 115). This leads to the logical conclusion that a probe sample, although it could lead to a more precise estimate, is not always necessary. Thus, Defendant's assertion that "it is absolutely necessary

to perform a pilot or probe sample" in the instant case is unsupported by its own expert. (Doc. 138–8 at 19).

Defendant also challenges Dr. Yiannoutsos' use of the 400 admission sample size and his decision not to account for certain variables in his sample. Concerning Dr. Yiannoutsos' acceptance of the Government's sample size, Dr. Yiannoutsos testified that he accepted the sample size because he felt it was more than sufficient to produce a reliable estimate. *See* Doc. 170 at 247 ("I thought I had a very large sample size so I did not go too far into generating a universal and complex model because I thought, and so far all of the evidence is from the simulations show that I'm correct, that the resulting estimates will have sufficient precision .").

Defendant's argument regarding the specific variables that could have been accounted for in Dr. Yiannoutsos' sample is similarly lacking. Considering the testimony presented by both experts, there are a wide variety of ways that this sample could have been designed. Dr. Yiannoutsos considered many of the variables highlighted by Defendant at the *Daubert* Hearing, but "did a number of analyses ... [and] chose to do the stratification ... based on these two strata." (*Id.* at 247). Simply because Dr. Yiannoutsos did not account for certain variables that are not necessarily related to overpayment does not make his design invalid. As the Court has set forth above, an expert "need not base his opinion on the best possible evidence, but upon 'good grounds, based on what is known.' " *Deutsch,* 768 F.Supp.2d at 453. Therefore, as long as Dr. Yiannoutsos has reached his conclusion through a sound methodology, the Court will not deem his testimony inadmissible even if he could have designed the sample based on different variables.

***18** Defendant also challenges Dr. Yiannoutsos' reliance on the medical review. Specifically, Defendant takes issue with Dr. Yiannoutsos' "failure to account for the potential error in the Government's subjective review of the complicated subject of whether a particular therapy claim is medically necessary or related to non-covered services." (Doc. 90 at 26). However, similar to Dr. Yiannoutsos, many statisticians do not have professional expertise in the subject matters they are analyzing. Because of this, another expert such as the medical review team in the instant case can be required. Dr. Yiannoutsos, rather than assuming the medical review would return incorrect results, assumed that the results from the medical review would be correct. If it is the case that error is identified in the medical review, Dr. Yiannoutsos testified that he "can submit them to the same procedure and come up with modified estimates of the total overpayment or the total number of claims respectively." (Doc. 170 at 87). Considering Dr. Yiannoutsos' testimony, the Court could only conclude that Dr. Yiannoutsos' reliance on the medical review's accuracy affected the reliability of his estimate based on speculation. Additionally, even if the Court were to reach that conclusion, any error identified could be accounted for in the sample. Accordingly, the Court does not find that Defendant's argument supports the exclusion of Dr. Yiannoutsos' testimony or expert report.

The Court also finds Defendant's remaining arguments regarding the admissibility of Dr. Yiannoutsos' sample to be lacking. Defendant's arguments merely distinguish other approaches that Dr. Yiannoutsos could have taken rather than identifying significant flaws in the sampling plan. At this juncture in the litigation, concluding that any of Defendant's concerns were fundamental flaws in Dr. Yiannoutsos' sampling plan would be considered premature and is unwarranted. Dr. Yiannoutsos' testimony and expert report were developed based on reliable principles of statistics and his simulations indicate that the results will be within an acceptable degree of precision. In the unlikely event that the findings of the medical review were to return with a degree of uncertainty outside of an acceptable level of precision, Defendant may seek leave of Court to file an additional *Daubert* motion on that basis.

2. Relevance

The Court's second duty under *Daubert* is to determine whether the proposed evidence and testimony are relevant. The Court is tasked with determining the relevance of expert evidence because "[e]xpert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. *Daubert,* 509 U.S. at 591.

Federal Rule of Evidence 401 provides that evidence is relevant if: (1) it has a tendency to make a fact more or less probable; and (2) that fact is "of consequence in determining the action." Fed R. Evid. 401. As a general matter, relevant evidence is admissible unless the United States Constitution, a federal statute, the Federal Rules of Evidence, or rules prescribed by the United States Supreme Court provide otherwise, and irrelevant evidence is inadmissible. Fed.R.Evid. 402. Another factor in determining whether evidence is relevant is set forth in Federal Rule of Evidence 702, which provides that expert testimony may be admissible 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." Fed.R.Evid. 702.

***19** The Government seeks to use Dr. Yiannoutsos' testimony to estimate the number of claims submitted in the relevant universe and estimate the amount of loss suffered by the Government related to those claims. (Doc. 170 at 292–293). Defendant argues that this use of his testimony would not be helpful to the fact finder because it "will not address whether any specific claim was false, resulted in overpayment, or had anything to do with over-billing for rehabilitation therapy." (Doc. 90 at 9).

Based on the reports submitted, the Court finds that Dr. Yiannoutsos is an expert proposing to testify as to scientific knowledge of statistics, which will ultimately assist the trier of fact to determine facts at issue. *See* Fed.R.Civ.P. 104(a); *United States v. Jones*, 107 F.3d 1147, 1152 (6th Cir.1997). The number of claims and the loss associated with those claims are certainly facts of consequence in this action, even if they are not specific elements under the FCA. These facts indicate the size and scope of the Government's case, which further supports them being deemed relevant. Accordingly, consistent with *Daubert*, the Court finds that the proposed testimony and evidence is relevant to the instant case and would be helpful to the fact finder. As the Court has now concluded that Dr. Yiannoutsos' testimony is both reliable and relevant, Defendant's Motion will be **DENIED.**

IV. CONCLUSION

For the reasons set forth herein, the Court hereby **RESERVES RULING** on the Government's Motion to Partially Exclude Testimony of Stefan Boedeker (Doc. 135), and **DENIES** Defendant's Motion to Exclude Expert Testimony of Constantin T. Yiannoutsos (Doc. 137).

SO ORDERED.

Footnotes

1 On May 13–14, 2014, the Court held a *Daubert* hearing to address both parties' motions regarding expert testimony. At that hearing, the parties agreed that the Court could determine the Government's Motion to Partially Exclude Testimony of Stefan Boedeker on the briefs submitted, rather than hearing Mr. Boedeker's testimony as to the issues raised by the Government in its Motion. (Doc. 170 at 9).

2 In the instant action, the Government only seeks to extrapolate the statistical sample "to the 82 facilities from which the sample is taken. It is not to be extrapolated to the remainder of the 220 some facilities...." (Doc. 170 at 5).

3 As the parties do not dispute Dr. Yiannoutsos' qualifications as an expert, the Court will not discuss this issue and, based on Dr. Yiannoutsos' professional background, qualifications, and peer-reviewed publications, finds him to be a qualified expert consistent with Federal Rule of Evidence 702.

4 At the *Daubert* Hearing, the Court asked both parties whether this issue was ripe for review. (Doc. 171 at 32). Defendant responded that its *Daubert* challenge was ripe for review as it concerns "the statistical sampling used to extrapolate ." (*Id.*). The Government also agreed that this issue was ripe for review because the parties agreed to have the Court decide "the discrete issue of sampling early on in this matter." (*Id.* at 33).