



THE HEALTH LAWYER

IN THIS ISSUE

Back to the Future:
Provider-Employer Alliance
Direct Contracting for
Health Benefits 1

Chair's Column..... 2

The Price is Right? What is
“Usual, Customary and
Reasonable” Between
Provider and Payor 12

Section News..... 18

Impact of the Tax Cuts and
Jobs Act of 2017 on Tax-
Exempt Hospitals 20

Extrapolating Liability – An
Analysis of the Potential Use of
Sampling to Establish Liability
in False Claims Act Cases..... 26

Section Calendar.....Back Cover

BACK TO THE FUTURE: PROVIDER-EMPLOYER ALLIANCE DIRECT CONTRACTING FOR HEALTH BENEFITS

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It was the 1990s. Americans were patiently rewinding VHS tapes, belly-lauding (or cringing) at The Ren & Stimpy Show, waiting half a day for America Online to dial-up, whooping to Arsenio Hall, popping Mentos (the freshmaker), and debating the merits of East Coast vs. West Coast rap.

More importantly, perhaps, the cost of healthcare had become the most expensive in the world. The United States was spending about \$4,000 per capita, more than twice the average of other developed countries.¹ Then-President Bill Clinton put healthcare reform on the table, but it failed. Most people were getting their health benefits through employment, and managed care via health maintenance organization (“HMO”) had become the norm. This risk-bearing model, in which an insurer middleman combines healthcare delivery and financing, was designed to control cost while improving quality of care.² But critics, providers and employers alike, were skeptical. They were not benefitting much from the savings, and

cost-control seemed to be compromising, not improving, quality of care.³

With these concerns in mind, employers and providers explored direct contracting, *i.e.* excision of the middleman insurer. Rather than pay premiums to an insurer, employers contracted directly with providers, or more often a network of providers forming a provider sponsored organization (“PSO”), to fulfill employee healthcare needs.⁴ The Buyers Health Care Action Group (“BHCAG”), Minnesota’s mighty coalition of large employers, including Wells Fargo and American Express, led a particularly innovative and promising direct contracting experiment in the Midwest.⁵ And a swarm of large health system PSOs across the nation formed their own provider-sponsored health plans (“PSHPs”) to facilitate direct contracting efforts.⁶

But at the turn of the century, direct contracting quietly sunk back into the managed care abyss from whence it sprung. BHCAG’s ambitious regional project began losing steam in 2000, upon withdrawal of two of its largest employer members and transfer of management; ultimately it was sold to a large health plan in 2004.⁷ Many

continued on page 3

EXTRAPOLATING LIABILITY – AN ANALYSIS OF THE POTENTIAL USE OF SAMPLING TO ESTABLISH LIABILITY IN FALSE CLAIMS ACT CASES

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Introduction

The use of statistical sampling and extrapolation is a growing trend in healthcare legal matters, and it has become a leading tool in the struggle for efficiency when collecting evidence. Many courts have accepted statistical sampling and extrapolation as evidence to estimate damages, and administrative agencies routinely use statistical sampling to determine overpayment amounts. Nevertheless, the acceptance of sampling to establish elements of *liability* in False Claims Act (“FCA”) litigation is openly disputed among counsel, and its evidentiary merit has led to a still-unresolved split among the courts.

Multiple recent federal court decisions have addressed the issue of extrapolating liability in FCA matters, with the majority involving allegations against skilled nursing and hospice providers. This article will provide a summary of these recent rulings along with a discussion of future implications for the use of extrapolation evidence. It will also offer an overview of statistical sampling and technical arguments related to its use in demonstrating FCA liability, with specific attention to the extrapolation of issues involving medical judgment.

Specifically, this article will address four recent FCA decisions: *United States ex rel. Martin v. Life Care Centers of America, Inc.*, *United States ex rel. Paradies v. AseraCare, Inc.*, U.S.

ex rel. Wall v. Vista Hospice Care, Inc., and *United States ex rel. Michaels v. Agape Senior Cmty., Inc.* Each of these decisions analyzed the use of statistical sampling as it related to patient eligibility for hospice and/or skilled nursing care and clinical decision-making. In each case, the government alleged that the provider submitted fraudulent claims to Medicare as part of a scheme to provide medically unnecessary services. The alleged schemes involved improperly admitting or re-certifying patients who failed to meet appropriate reimbursement eligibility for hospice and/or skilled nursing care. The government presented specific evidence as to statistical samples of patient admissions in each case, and with those samples, it sought to extrapolate both liability and damages as to the larger populations of patient admissions. As this article will discuss, these rulings reached different conclusions about the admissibility of extrapolation evidence for the purposes of proving liability.

Sampling Overview

Statistical sampling analysis is most commonly used when one seeks to infer useful information about a relatively large population, without examining every unit in the population, through the examination of only a subset of that population (i.e., a sample). As part of sampling analysis, estimation or *extrapolation* is a procedure by which measured characteristics of a sample yield estimates, inferentially, about unknown characteristics of the population from which the sample was drawn. Sampling methodologies are described at length in textbooks, journals, and various industry guidelines, and are capable of producing useful results when properly applied.¹

While a variety of steps exist to properly design, execute, and interpret valid sampling analysis, this article focuses on the key steps at issue in recent legal rulings in FCA cases.² Despite the narrow focus in this instance, effective sampling demands attention to all steps of the analysis, since poor work in one area may render a study unreliable, even when everything else is performed properly.³

A critical step in properly executing sampling analysis relates to the composition of the sample itself. Since characteristics of a sample will be used to infer characteristics of the broader population, a sample should be reasonably *representative* of the population. 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.”⁴ Conversely, if the sample chosen is not representative of the population, inferences about the population may be irreparably biased and invalid. The methodology anticipated to lead to a representative sample is *random* sample selection. Without using proper randomization to select a sample, the presence of selection bias may prevent a sample from being reasonably representative.⁵

Another key step in sampling analysis is the measurement of sampled units (i.e., the testwork). In healthcare cases, this might involve evaluating whether a sampled patient was treated appropriately, and whether the treatment was coded and submitted for reimbursement appropriately. Whatever the goals of a given sample analysis, it is critical that the parties conducting this analysis are *objective* and do not offer biased or subjective conclusions about each sampling unit.

Such bias has a technical term: *error in measurement*, and it may inject undue error, or even invalidate an analysis entirely.⁶ In an effort to prevent such bias, analysts strive to ensure reliable, relevant and repeatable assessments of the data set, and they often work with evaluators to document and standardize their decision-making criteria.

Considerations for Extrapolating Clinical Judgment

A variety of arguments have been developed to refute the use of sampling analysis as evidence of liability in FCA matters. Most significant among the cases discussed in this article is the argument that relators cannot sufficiently plead and prove *falsity* by means of extrapolation. In hospice and/or skilled nursing care cases, this argument generally manifests in one of two variations, with both focusing on the evaluation of medical decision-making:

Objectivity

First, defendants often argue that *objective* falsity cannot be proven in matters where differences of opinion in clinical decision-making (i.e., subjective disagreements about eligibility for hospice and/or skilled nursing care) are the basis for proving falsehood. Said another way, clinical judgment has subjective aspects, and the conclusions for each patient in a sample could differ depending on the individual medical reviewer who reviews the data (i.e., physician, nurse, etc.). In statistical terms, this argument addresses potential measurement error in the analysis (i.e., whether various examiners could or would reach the same conclusions time and time again) and it suggests that a patient's eligibility for hospice and/or skilled nursing care cannot be measured objectively and reliably, thereby negating the utility of extrapolation.

Notably, this argument is not limited to issues of extrapolation, and

it may be invoked for any claims involving allegations of falsehood due to clinical judgment. However, cases involving sampling often involve a greater number of falsehood claims due to extrapolation and its subsequent magnifying effect.

Representativeness

Second, defendants often argue that the determination of whether individualized care is medically necessary for a particular patient requires an individual assessment of that patient's physical condition and other patient-specific considerations. Therefore, the assessment of only a subset of individual patients cannot be extrapolated across an entire population. Instead, the argument goes, each patient in the population should be analyzed individually (i.e., without sampling) to yield accurate conclusions about the total population. The issue raised here is that the decisions rendered for a particular sample might be materially different from those of the entire population. To use statistical terminology, this is an issue of the sample's representativeness.

Both of these arguments enjoy legal as well as statistical merit, and the issues underlying each argument may be so severe from a statistical standpoint, if they do exist in a given sample, to invalidate the entire extrapolation. However, these arguments have not been universally effective in rebutting the use of statistical sampling in FCA cases. Relators and the government routinely argue that the use of sampling and extrapolation is widely accepted in complex litigation, including FCA matters.⁷ The government also generally contends that even though unique factors will determine the individual type and amount of therapy received by a patient, such unique factors do not necessarily preclude the use of extrapolation as evidence. Instead, the government has highlighted that the defendant could challenge the extrapolation through cross examination and competing

witness testimony at trial and that the jury will ultimately decide how much weight to give the evidence.⁸

Court Rulings

There have been several court rulings in recent years which have addressed the propriety of using sampling to establish liability in FCA cases.⁹ Some of the most notable recent opinions, which are representative of the analysis on the use of sampling to establish liability, are summarized below:

*United States ex rel. Martin v. Life Care Centers of America, Inc.*¹⁰

In 2012, the federal government intervened in an FCA case against Life Care Centers of America, Inc. ("Life Care"), an operator of over 200 skilled nursing facilities nationwide.¹¹ The government alleged that Life Care engaged in upcoding and provided medically unnecessary, unreasonable, and unskilled services, which resulted in the submission of over 150,000 false claims to the federal government.

The government sought to extrapolate from a random sample of 400 admissions from over 80 Life Care facilities from 2006–2012 to estimate the total number of claims (out of the over 150,000 claims) that resulted in overpayments made by Medicare. The defendant subsequently moved for partial summary judgment on the claims for which the government sought to use statistical sampling to prove their falsity.

In a September 2014 opinion, the United States District Court for the Eastern District of Tennessee found that the government could rely on and use sampling and extrapolation to establish not only FCA damages, but actual FCA liability. The court denied the defendant's motion for summary judgment and found that the government could use statistical sampling to establish the FCA

continued on page 28

Extrapolating Liability – An Analysis of the Potential Use of Sampling

continued from page 27

element of falsity and that if the defendant “wishes to challenge the weight that a fact finder may attribute to the extrapolation, it can employ cross-examination and competing witnesses and testimony to highlight the disparity between claims.”¹² Notably, the *Life Care* court allowed statistical sampling to extrapolate claims to show how the defendant’s services were medically unnecessary – a very specific and individualized professional decision that the defendant argued could not be based on statistical sampling and subsequent extrapolation. Although the court allowed the government to use statistical sampling and extrapolation, *Life Care* could have still contested the government’s process and conclusions regarding its extrapolation evidence at trial.

Ultimately, in October 2016 the parties agreed to enter into a \$145 million settlement.¹³

United States ex rel. Paradies v. AseraCare, Inc.¹⁴

In May 2008, *qui tam* relators filed a complaint against the defendants collectively referred to as “AseraCare,” a nationwide operator of hospice facilities, alleging that AseraCare defrauded the federal government by driving its employees to liberally interpret patient medical records. Specifically, it was alleged that AseraCare was falsely certifying certain patients as “terminally ill” so as to be eligible for hospice care to enable AseraCare to submit hospice claims for more patients. The federal government intervened in the case, claiming that the submission of false hospice benefit claims constituted a violation of the FCA.

AseraCare filed a motion for summary judgment, challenging the government’s use of statistical evidence to demonstrate its claims related to falsely certified hospice services. The government’s expert used a sample of

233 patients from 2,181 claims and determined that approximately half of the claims were “false” under the FCA; the government then sought to extrapolate the expert’s findings to all 2,181 claims. In December 2014, the United States District Court for the Northern District of Alabama denied the defendants’ motion for summary judgment and found that statistical evidence was sufficient to show falsity. The court found that “[s]tatistical evidence is evidence,”¹⁵ but stated that the jury is to determine the weight to be accorded to the statistical evidence.

In June 2015, after having allowed the government to utilize statistical sampling and extrapolation, the court granted AseraCare’s motion to bifurcate the trial into two phases. The first phase was to determine whether the submitted claims were “false” and the second phase was to decide whether AseraCare *knowingly* submitted the false claims.

In October 2015, after a two-month trial on the first phase, the jury returned a verdict in favor of the federal government, finding that 104 of the 123 claims that AseraCare had submitted were “objectively” false claims. In November 2015, however, the district court granted the defendants a new trial based upon the judge’s belief that improper jury instructions had been provided. In that same November 2015 opinion, the district court questioned whether the government, under the correct legal standard, had “sufficient admissible evidence of more than just a difference of opinion to show that the claims at issue [were] objectively false as a matter of law.”¹⁶ Thus, the court found that it would consider a motion for summary judgment to ascertain whether the government could present objective evidence that the claims were false and not just a mere difference of opinion among physicians. In the absence of such objective evidence

of falsity, in March 2016 the court found “that contradiction based on clinical judgment or opinion alone cannot constitute falsity under the FCA as a matter of law” and consequently granted summary judgment in favor of AseraCare.¹⁷

In May 2016, the federal government filed a notice of appeal to seek review by the Eleventh Circuit of three orders from the district court involving the court’s decision to bifurcate the trial, an opinion granting the defendants a new trial, and an award of summary judgment to the defendants. The Eleventh Circuit heard oral arguments in March 2017; the appeal is still pending.

United States ex rel. Wall v. Vista Hospice Care, Inc.¹⁸

United States ex rel. Wall v. Vista Hospice Care, Inc. involved a *qui tam* suit filed in April 2007 against Vista Hospice Care, Inc. (“Vista”), an operator of a chain of hospice facilities in 14 states. The *qui tam* relator alleged that, for a period of time and across multiple Vista facilities, the defendants improperly enrolled ineligible patients for hospice care and submitted false claims for hospice services provided to beneficiaries who were not eligible for hospice benefits. The complaint also alleged that Vista improperly pressured employees to certify false information regarding hospice eligibility. The government declined to intervene in this case.

In 2016, the United States District Court for the Northern District of Texas granted summary judgment in favor of Vista and granted the defendants’ motions to strike the relator’s expert testimony. The court struck the relator’s statistical sampling expert in this case because the court found that statistical sampling was not reliable and could not “establish liability for fraud in submitting claims for ineligible patients, as the underlying

determination of eligibility for hospice is inherently subjective, patient-specific, and dependent on the judgment of involved physicians.”¹⁹ The court also distinguished the case from *AseraCare* because the question in *Vista Hospice Care* was not whether the defendants provided reasonable and necessary services. Rather, the question in *Vista Hospice Care* was whether, “based on the physician’s or medical director’s *clinical judgment* regarding the normal course of the individual’s illness a patient had a life expectancy of 6 months or less.”²⁰ This involved scrutinizing the “subjective clinical judgment” of a number of certifying physicians. Therefore, the court found that sampling and extrapolation in this case could not be used to reliably prove the specific FCA violations that the relator alleged. The court also found that the expert’s process was fundamentally flawed because the chosen sample was not randomly selected and could not be used to infer falsity across the universe of claims.

Vista Hospice Care represents the potential limitations to the use of statistical sampling and extrapolation in FCA cases and provides an example of a situation where extrapolation was not appropriate in an FCA case. The relator has filed a notice of appeal in the Court of Appeals for the Fifth Circuit.

United States ex rel. Michaels v. Agape Senior Cmty., Inc.²¹

The *qui tam* relators in *United States ex rel. Michaels v. Agape Senior Cmty., Inc.* filed their complaint in December 2012 asserting claims against operators of a network of approximately 24 nursing homes throughout South Carolina. The government declined to intervene in the case. In March 2014, the relators filed their Second Amended Complaint, which alleged that the defendants improperly billed federal healthcare programs for hospice services that were either improperly provided to beneficiaries who were

not eligible for the services or not provided at all.

To establish FCA liability and damages, the relators sought to rely on statistical sampling. The United States District Court for the District of South Carolina, however, found that statistical sampling was improper under the facts and circumstances of the case, mainly because the parties had the ability to review each and every medical record since nothing was “destroyed or dissipated.”²² The district court certified an interlocutory appeal of its holdings, including its statistical sampling ruling, and the Fourth Circuit agreed to hear the appeal. The Fourth Circuit had the opportunity to be the first circuit court to clarify and address the statistical sampling issue impacting many recent FCA cases. However, the Fourth Circuit ultimately declined to address whether sampling could be used by relators to establish FCA liability after finding that the question was not a “pure question of law.”²³ In so ruling, the Fourth Circuit did not provide more definitive guidance for FCA litigants on their ability to rely on statistical sampling. In August 2017, the parties agreed to settle the *qui tam* case for \$275,000.²⁴

Legal Implications of Rulings

The healthcare industry continues to be the most significant target of FCA lawsuits, with the government typically recovering more than half of its annual recoveries from healthcare entities.²⁵ One of the unique aspects of FCA cases in the healthcare context pertains to the substantial volume of claims that are submitted annually by healthcare providers. This claims volume will continue to cause relators and the government to pursue the use of sampling to establish damages and, increasingly, to attempt to use sampling to establish liability. However, the potential benefits of sampling in terms of efficiency

may be undercut by the inability to account for variances in physician specific decision-making and in comorbidities and other differences between patients.

Moving forward, the issue of sampling to establish liability will likely continue to be hotly contested – with relators and the government advocating for such sampling and with defendants contesting the propriety of such sampling – until it is resolved by the Supreme Court or by federal circuit courts of appeals.

Statistical Implications of Rulings

For both relators and defendants, these court rulings offer a roadmap for statisticians and analysts to either develop or scrutinize extrapolation analysis. Recall that a variety of steps exist to properly design, execute, and interpret valid sampling analysis. While this article focuses on the key steps at issue in recent legal rulings in FCA cases, effective sampling demands attention to all steps of the analysis, since poor work in one area may render a study unreliable, even when everything else is performed properly.²⁶ Below are key considerations of the recent FCA Court rulings regarding the validity and reliability of a sampling analysis.

Objectivity

First, an analyst should ensure that the review of sampling units (i.e., the measurement) is, in fact, *objective*. Parties should be mindful to scrutinize the work plan, testwork criteria, and credentials of all parties involved with the examination and decision making for sampled units. An entirely independent reviewer may reinforce an analysis’ objectivity, along with carefully documenting the criteria by which sampling units are evaluated by the reviewer. For instance, a patient’s eligibility for care should be determined using published medical decision-making criteria, rather than

continued on page 30

Extrapolating Liability – An Analysis of the Potential Use of Sampling

continued from page 29

simply relying on the provider's subjective opinion. Illustrating how the reviewer explicitly considered each criterion and why each patient did or did not meet such criteria can demonstrate how a seemingly subjective concept can be, in fact, objective. Alternatively, analysis that is not executed objectively may inject incurable subjectivity into extrapolation conclusions, or, at a minimum, introduce immeasurable uncertainty into the conclusions of the analysis.

Representativeness

Second, the analyst should diligently evaluate the selection and composition of the sample to ensure that it is randomly selected and, in fact, reasonably representative of the population in question. While sampling units (i.e., patients) may be unique or diverse according to any number of characteristics, the analyst is primarily concerned with characteristics that might affect the measurements of the analysis. For example, foot size might be a unique characteristic for a population of patients; however, one would not anticipate a selection of patients with disproportionately small feet to be more or less eligible for hospice and/or skilled nursing care. The assessment of such irrelevant characteristics, or ignoring otherwise germane criteria, could result in misleading conclusions about a sample's representativeness.

Instead, the analyst should identify and document the characteristics most believed to affect the measurements of a study, and then evaluate whether those characteristics of the sample are reasonably representative of the total population. For instance, characteristics that could impact a patient's hospice eligibility might include the original physician's criteria for determining eligibility or the facility's processes and protocols for determining eligibility. Consistent application of such determinations or processes can support an analyst's

conclusion that a sample is reasonably representative, without which an analyst may be unable to reach objective and valid conclusions.

Conclusion

Courts have not reached a definitive determination as to whether sampling can be used to establish liability in FCA cases. The propriety of such sampling will depend on patient and physician specific considerations. This will continue to be an important issue to monitor in the future to evaluate whether there is more definitive guidance rendered as to when sampling may be appropriate for purposes of establishing liability.



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Endnotes

- 1 REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, 3RD EDITION, FEDERAL JUDICIAL CENTER 214 (2011), <https://www.fjc.gov/sites/default/files/2015/SciMan3D01.pdf>.
- 2 Christopher L. Haney, *Statistical Sampling; Use and Techniques Including RAT-STATS*, in HEALTH LAW AND COMPLIANCE UPDATE (John E. Steiner ed., 2018); see also *Overview of Statistical Sampling and Extrapolation: Forensus' Framework*, FORENSUS GROUP (2017), <http://forensus.com/overview-of-statistical-sampling-and-extrapolation/>.
- 3 WILLIAM G. COCHRAN, SAMPLING TECHNIQUES 8 (1977).
- 4 ERIC E. CORTY, USING AND INTERPRETING STATISTICS 145 (2007).
- 5 *Id.* at 146.
- 6 W. EDWARDS DEMING, SAMPLE DESIGN IN BUSINESS RESEARCH 64 (1990); see also STEVEN K. THOMPSON, SAMPLING 5 (3d ed. 2012).

- ⁷ See *United States v. Life Care Centers of Am., Inc.*, 114 F. Supp. 3d 549, 571 (E.D. Tenn. 2014).
- ⁸ *Id.* at 567.
- ⁹ A person is liable for violating the False Claims Act (“FCA”) if that person “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval [or] knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.” 31 U.S.C.A. § 3729(a). Thus, a plaintiff must prove that the (1) defendant made a claim or statement to the government for reimbursement, (2) the claim or statement was false or fraudulent, and (3) the defendant knew that the claim or statement was false or fraudulent.
- ¹⁰ *Life Care Centers of Am., Inc.*, 114 F. Supp. 3d at 549.
- ¹¹ The FCA allows private citizens, referred to as “relators,” to file suits based on violations of the FCA on behalf of the government. This type of suit is known as a *qui tam* action. The FCA provides that any *qui tam* complaint must be first filed with the court under seal. 31 U.S.C.A. § 3730(b)(2). While under seal, the government is required to investigate the allegations in the complaint so as to decide whether it will intervene in the applicable FCA case. If the government declines to intervene in the FCA case after its investigation, the relator can proceed with the FCA action on his/her own. If the government intervenes, the FCA provides that the relator is entitled to receive at least 15 percent but not more than 25 percent of the amount recovered. *Id.* at § 3730(d)(1). If the government declines to intervene, however, the relator is entitled to receive between 25 and 30 percent of the amount recovered. *Id.* at § 3730(d)(2).
- ¹² *Id.* at 567.
- ¹³ *Life Care Centers of America Inc. Agrees to Pay \$145 Million to Resolve False Claims Act Allegations Relating to the Provision of Medically Unnecessary Rehabilitation Therapy Services*, U.S. DEP’T OF JUSTICE (Oct. 24, 2016), <https://www.justice.gov/opa/pr/life-care-centers-america-inc-agrees-pay-145-million-resolve-false-claims-act-allegations>.
- ¹⁴ *U.S. ex rel. Paradies v. AseraCare, Inc.*, No. 2:12-CV-245-KOB, 2014 U.S. Dist. LEXIS 167970 (N.D. Ala. Dec. 4, 2014).
- ¹⁵ *Id.* at *10.
- ¹⁶ *U.S. ex rel. Paradies v. AseraCare, Inc.*, 153 F. Supp. 3d 1372, 1385 (N.D. Ala. 2015).
- ¹⁷ *U.S. ex rel. Paradies v. AseraCare, Inc.*, 176 F. Supp. 3d 1282, 1286 (N.D. Ala. 2016).
- ¹⁸ *United States v. Vista Hospice Care, Inc.*, No. 3:07-CV-00604-M, 2016 WL 3449833 (N.D. Tex. June 20, 2016), *reconsideration denied sub nom. United States ex rel. Wall v. Vista Hospice Care, Inc.*, No. 3:07-CV-0604-M, 2017 WL 5483747 (N.D. Tex. Nov. 14, 2017).
- ¹⁹ *Id.* at *11.
- ²⁰ *Id.* at *12 (emphasis in original) (internal quotations omitted).
- ²¹ *U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. 15-2145, 2017 WL 588356 (4th Cir. Feb. 14, 2017).
- ²² *U.S. ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. CA 0:12-3466-JFA, 2015 WL 3903675, at *7 (D.S.C. June 25, 2015), *order corrected*, No. CA 0:12-3466-JFA, 2015 WL 4128919 (D.S.C. July 6, 2015), and *aff’d in part, appeal dismissed in part sub nom. United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, 848 F.3d 330 (4th Cir. 2017).
- ²³ *Michaels*, 2017 WL 588356, at *6. The Fourth Circuit found that review of interlocutory appeals are not appropriate if the question presented “turns on whether there is a genuine issue of fact or whether the district court properly applied settled law to the facts or evidence of a particular case.” *Michaels*, 848 F.3d at 341. The question presented in *Michaels v. Agape Senior Community* was whether the proposed statistical sampling was conducted in a “scientifically proven and accepted manner pursuant to the Supreme Court’s ruling” in *Daubert v. Merrell Dow Pharmaceutical*. *Id.* Because the question presented did not “present a pure question of law that is subject to [the court’s] interlocutory review,” the Fourth Circuit dismissed the statistical sampling aspect of the relator’s appeal. *Id.*
- ²⁴ AGAPE LITIGATION ENDS, DEBORAH B. BARBIER (Aug. 23, 2017), <https://dlbjbjzgnk95t.cloudfront.net/0957000/957059/press%20statement%20on%20settlement.pdf>. The government had previously rejected a larger settlement of \$2.5 million, despite the fact that it did not intervene, demonstrating that the government still has control over the case as the actual party-in-interest even where it declines to intervene. Brian P. Dunphy & Laurence Freedman, *Fourth Circuit Permits DOJ to Reject an FCA Settlement, But Punts Decision on Statistical Sampling*, HEALTH LAW & POLICY MATTERS (Feb. 22, 2017), <https://www.healthlawpolicymatters.com/2017/02/22/fourth-circuit-permits-doj-to-reject-an-fca-settlement-but-punts-decision-on-statistical-sampling/>.
- ²⁵ *Justice Department Recovers Over \$3.7 Billion from False Claims Act Cases in Fiscal Year 2017*, DEPARTMENT OF JUSTICE (Dec. 21, 2017), <https://www.justice.gov/opa/pr/justice-department-recovers-over-37-billion-false-claims-act-cases-fiscal-year-2017>.
- ²⁶ COCHRAN, *supra* note 3, at 8.

Another *Health Lawyer* Article Wins National Award!

Paul Smith, Esq. and **Andrea Frey, Esq.**, with Hooper Lundy & Bookman, PC in San Francisco, are the latest *Health Lawyer* authors to win a coveted Burton Award! Their article, *Modernizing the Common Rule: Federal Agencies Revise Rule on the Protection of Human Subjects* ran in the April 2017 issue of *The Health Lawyer*.

This marks the fifth year in a row that an article from *The Health Lawyer* was selected for a Burton Award!

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Congratulations Paul and Andrea!



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December 9-10, 2018
16th Annual Washington
Health Law Summit
Washington, DC