Nos. 15-2145(L), 15-2147

In The

United States Court of Appeals for the Fourth Circuit

UNITED STATES OF AMERICA *ex rel.* BRIANNA MICHAELS and AMY WHITESIDES,

Plaintiffs-Appellants,

v.

AGAPE SENIOR COMMUNITY, INC. *et al.*,

Defendants-Appellees,

v.

UNITED STATES OF AMERICA,

Intervenor-Appellee,

On Appeal from the United States District Court for the District of South Carolina, No. 0:12-cv-03466-JFA (Hon. Joseph F. Anderson, Jr.)

BRIEF OF AMERICAN HEALTH CARE ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS-APPELLEES

Colin E. Wrabley
M. Patrick Yingling
REED SMITH LLP
225 Fifth Avenue
Suite 1200
Pittsburgh, PA 15222
(412) 288-3548
cwrabley@reedsmith.com

Counsel for Amicus Curiae

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT
DISCLOSURE OF CORPORATE AFFILIATIONS AND OTHER INTERESTS

Disclosures must be filed on behalf of all parties to a civil, agency, bankruptcy or mandamus case, except that a disclosure statement is **not** required from the United States, from an indigent party, or from a state or local government in a pro se case. In mandamus cases arising from a civil or bankruptcy action, all parties to the action in the district court are considered parties to the mandamus case.

Corporate defendants in a criminal or post-conviction case and corporate amici curiae are required to file disclosure statements.

If counsel is not a registered ECF filer and does not intend to file documents other than the required disclosure statement, counsel may file the disclosure statement in paper rather than electronic form. Counsel has a continuing duty to update this information.

No. 15-2145 Caption: U.S. ex rel. Michaels et al. v. Agape Senior Community, Inc., et al.

Pursuant to FRAP 26.1 and Local Rule 26.1,

American Health Care Association
(name of party/amicus)

who is Amicus, makes the following disclosure:
(appellant/appellee/petitioner/respondent/amicus/intervenor)

1. Is party/amicus a publicly held corporation or other publicly held entity? ☐ YES ☑ NO

2. Does party/amicus have any parent corporations? ☐ YES ☑ NO
If yes, identify all parent corporations, including all generations of parent corporations:

3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity? ☐ YES ☑ NO
If yes, identify all such owners:

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation (Local Rule 26.1(b))? ☐YES ☑NO
If yes, identify entity and nature of interest:

5. Is party a trade association? (amici curiae do not complete this question) ☐ YES ☐ NO
If yes, identify any publicly held member whose stock or equity value could be affected substantially by the outcome of the proceeding or whose claims the trade association is pursuing in a representative capacity, or state that there is no such member:

6. Does this case arise out of a bankruptcy proceeding? ☐ YES ☑ NO
If yes, identify any trustee and the members of any creditors' committee:

Signature: /s/ Colin E. Wrabley Date: 3/24/16

Counsel for: American Health Care Association

CERTIFICATE OF SERVICE

****

I certify that on 3/24/16 the foregoing document was served on all parties or their counsel of record through the CM/ECF system if they are registered users or, if they are not, by serving a true and correct copy at the addresses listed below:

/s/ Colin E. Wrabley (signature) 3/24/16 (date)

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Regulations

Other Authorities

I. INTEREST OF *AMICUS CURIAE*[1]

The American Health Care Association (AHCA) is the nation's leading long-term health care organization. It serves as the national representative of more than 12,000 non-profit and proprietary facilities dedicated to improving the delivery of professional and compassionate care to more than 1.5 million frail, elderly, and disabled Americans who live in skilled nursing facilities, assisted living residences, subacute centers, and homes for persons with mental retardation and developmental disabilities. One way in which AHCA serves its mission is by participating as *amicus curiae* in cases with far-ranging consequences for its members—including cases raising important issues under the False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.* *See, e.g., Universal Health Services, Inc. v. U.S. ex rel. Escobar*, No. 15-7 (U.S.) (pending).

AHCA and its members have a substantial interest in the use of statistical sampling and extrapolation to prove liability under the FCA. The federal government funds a substantial percentage of the services provided by AHCA's members, including skilled nursing and hospice services. AHCA's members

[1] Pursuant to Federal Rule of Appellate Procedure 29(c)(5), AHCA states that no counsel for a party authored this brief in whole or in part, and no person other than the *amicus curiae*, its members, or its counsel made a monetary contribution intended to fund the preparation or submission of this brief.

operate long-term care facilities in which hospice care is available to terminally ill patients and in some cases directly provide hospice care to terminally ill patients, including hospice services covered under the Medicare hospice benefit.

AHCA's members also provide skilled nursing facility services to Medicare beneficiaries. Like the hospice benefit, the Medicare skilled nursing facility benefit requires a highly individualized assessment of the individual patient's diagnosis, conditions, ability to engage in activities of daily living, and care needs to determine benefit eligibility. Medicare charges licensed clinical professionals in each facility with classifying each patient's needs through periodic assessments. 42 C.F.R. § 413.343. These assessments—made by physicians, nurses, therapists, licensed social workers, among others—are then reported to the government on a standardized form known as the Minimum Data Set ("MDS"). 42 U.S.C § 1395i-3(b)(3)(A). Completion of the MDS requires complex evaluations of each patient's nursing and therapy needs, ability to perform daily activities, cognitive status, behavioral problems, and medical diagnoses. 42 C.F.R. §§ 413.343, 483.20(b). Using the MDS, each patient is then placed in a reimbursement rate level. 63 Fed. Reg. 26,265 (May 12, 1998).

AHCA has a strong interest in ensuring that its members are not exposed to the FCA's severe penalties, based on the use of sampling, where, as here, FCA claims are based on physicians' medical judgments concerning their patients'

conditions, prognoses, and medical needs. Given the prevalence of attempts to use sampling to prove FCA liability against AHCA's members,[2] and the serious threat of devastating damages, AHCA's interest is acute.

II. PRELIMINARY STATEMENT

The FCA is designed to combat false claims made to the federal government. The statute's requirements are strict—among other things, *qui tam* relators and the government must prove that each alleged false claim is objectively false and that the maker of the claim knew it was false. There is no shortcut around these prerequisites. Nor should there be, given the opprobrium that attaches to a finding of FCA liability and the severe penalties and treble damages the statute can impose.

Yet here—a case based on as many as tens of thousands of unique claims for Medicare reimbursement for hospice care, where the alleged falsity of each claim turns on medical judgments concerning the eligibility of as many as tens of thousands of unique individual patients—the Relators and the government advocate for a novel procedural shortcut: The use of statistical sampling and extrapolation, based on a small sample of alleged false claims relating to a small

[2] *See, e.g., U.S. ex rel. Wall v. Vista Hospice Care*, No. 3-07-CV-0604-M (N.D. Tex.), Doc. No. 236 at 27 (filed March 11, 2016) (contesting use of sampling to prove liability and what relator "claims to be $5 billion" in damages).

sample of patients, to meet their burden of proving FCA liability for a sprawling mass of tens of thousands of unique claims connected to tens of thousands of uniquely different patients. They point to no textual basis in the FCA for this novel shortcut, however, because there is none.

Indeed, no court, absent a defendant's consent, has ever permitted sampling as a substitute for actual proof of FCA *liability* at trial. The U.S. Supreme Court itself has rejected this same "novel project" of using sampling, which it calls—disapprovingly—a "Trial by Formula." *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 2541, 2561 (2011).

Here, the district court properly foreclosed this "proof-by-statistics" end-run around the FCA's requirements, and this Court should do the same. To begin with, far from supporting the use of sampling to prove liability, the FCA—which places the burden of proof expressly on the claimant party—forbids sampling where, as here, it would effectively place the burden of *disproving* its elements, claim-by-claim and patient-by-patient, on defendants like Agape. Relators were required to prove that each allegedly false claim for each patient was (1) actually submitted, (2) objectively false, and (3) knowingly made, or caused to be made, by Agape. Given the significant variations among the many individual claims, patients, and subjective medical judgments involved, however, no statistical methodology could substitute for the claim-by-claim and patient-by-patient evidence required to show

that, *in fact*, a given patient was improperly deemed eligible for hospice care or a given claim was knowingly submitted.

In this way, allowing sampling to establish liability fundamentally shifts the FCA's burden of proof by leaving defendants with no choice—if they wish to defeat liability based on the non-sample, unproved claims—but to carry their own burden to disprove the falsity of each of those claims. It would take a rewriting of the FCA to support that result, but only Congress, not this Court, can do that.

Further, allowing sampling would violate defendants' fundamental due process rights to defend themselves against every claim, or even to know which particular claims out of thousands, or even tens or hundreds of thousands, are alleged to be false. It would also usurp the jury's constitutionally enshrined fact-finding function. And it would be especially improper in FCA cases like this one, which pose a serious threat of imposing the statute's treble damages and penalties—in addition to exclusion from the federal health care reimbursement programs altogether—on health care providers, which struggle to comply with the increasingly byzantine federal regulations that govern their daily operations.

This Court should therefore affirm the district court's decision rejecting the use of sampling to prove liability in this FCA case and FCA cases like it.

III. RELEVANT BACKGROUND

In this *qui tam* FCA action, Relators alleged that Agape orchestrated a scheme to submit false claims to federal health care programs seeking reimbursement for nursing home-related services, including hospice services. The district court estimated that during the alleged time frame, Agape submitted 50-60,000 claims for 10-20,000 patients. JA469-470.

Relators asserted that if they could prove that a certain percentage of randomly selected claims were false and otherwise violated the FCA, they should be permitted to extrapolate that result to the total universe of claims submitted by Agape. The district court rejected this proposal because Relators' claims required a "highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patient." JA484-485.

IV. ARGUMENT

A. Allowing Sampling To Prove FCA Liability Would Impermissibly Shift And Distort The Burden Of Proof The Statute Imposes On *Qui Tam* Relators And The Government.

As a threshold matter, allowing *qui tam* relators and the government to use sampling to prove liability defies the statutory scheme because it relieves claimants of their burden of proof while, at the same time, imposing the burden to disprove liability on defendants such as Agape.

1. The burden of proof under the FCA

The FCA provides that "the United States shall be required to prove all essential elements of the cause of action … by a preponderance of the evidence." 31 U.S.C. § 3731(d). When a relator brings a *qui tam* FCA suit, he assumes this same burden. *See U.S. ex rel. Crews v. NCS Healthcare of Illinois, Inc.*, 460 F.3d 853, 857 (7th Cir. 2006).

The focus of the burden is on the specific false claims alleged because they are the "*sine qua non*" of an FCA violation. *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 878 (6th Cir. 2006) (citation omitted). Thus, relators must prove, "at an individualized transactional level," that actual claims were submitted. *U.S. ex rel. Fowler v. Caremark Rx, LLC*, 496 F.3d 730, 741-42 (7th Cir. 2007) overturned on other grounds, *Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907 (7th Cir. 2009). Falsity requires proof of "an objective falsehood" (*U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 377 (4th Cir. 2008))—a "difference of opinion" or statements "about which reasonable minds may differ cannot be false." *United States v. AseraCare Inc.*, 2015 WL 8486874, at *10 (N.D. Ala. Nov. 3, 2015).

Additionally, relators must prove that a false claim "was made or carried out with the requisite scienter"—*i.e.*, that a person "has actual knowledge of the information; acts in deliberate ignorance of the truth or falsity of the information;

or acts in reckless disregard of the truth or falsity of the information." *U.S. ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 913 (4th Cir. 2003); 31 U.S.C. § 3729(a)-(b). And scienter, like falsity, also must be determined for "each false claim. . . ." *U.S. ex rel. Bunk v. Birkart Globistics GMBH & Co.*, 2010 WL 4688977, at *8 (E.D. Va. Nov. 10, 2010).

Finally, relators must prove materiality—*i.e.*, that each claim had "a natural tendency to influence or [was] capable of influencing,' the Government's decision to pay." *United States v. Triple Canopy, Inc.*, 775 F.3d 628, 637 (4th Cir. 2015) (citation omitted); 31 U.S.C. § 3729(b)(4).

2. Allowing sampling to prove FCA liability would shift the statute's burden of proof to defendants.

If sampling could be used to prove FCA liability for a mass of unspecified claims in cases like this one, that would shift the burden of proof to defendants to have to *disprove* the elements of FCA liability for each unspecified claim.

Here, Relators claim that "Agape provided hospice services to patients who were not eligible for hospice, *i.e.*, they did not have terminal illnesses." Agape Br. at 1. Certification of hospice eligibility turns on a physician's medical judgment that a patient's "life expectancy is 6 months or less." 42 U.S.C. § 1395f(a)(7)(A)(i); 42 U.S.C. § 1395x(dd)(3)(A). That judgment involves "a complex assessment influenced by the unique facts and circumstances associated

with" each patient. JA283-284. A similar process takes place in skilled nursing facilities. *See supra* at 2.

Because physicians must use their medical judgment, "an FCA complaint about the exercise of that judgment must be predicated on the presence of an objectively verifiable act at odds with the exercise of that judgment." *U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, 778 F. Supp. 2d 709, 718 (N.D. Tex. 2011). A mere "difference of opinion among physicians … is insufficient to support a finding that a claim is false." *AseraCare*, 2015 WL 8486874, at *11. Thus, relators must prove that the treating physician "did not or could not have believed, based on his or her clinical judgment, that the patient was eligible for hospice care." *United States ex rel. Geschrey v. Generations Healthcare, LLC*, 922 F. Supp. 2d 695, 703 (N.D. Ill. 2012).

Under these settled standards, Relators would, at a minimum, have to prove the following:

- That each claim was objectively false and actually submitted to the government;
- That those individual Agape employees responsible for submitting claims knew or should have known they were false; and
- That the falsity of the claims submitted was material to the government's decision to pay.

In short, "[t]he likelihood or probability of a false submission is simply not enough"—a relator must make "an individualized, transactional showing." *U.S. ex rel. Turner v. Michaelis Jackson & Associates, L.L.C.*, 2011 WL 13510, at *7 (S.D. Ill. Jan. 4, 2011) (citation omitted).

Were Relators permitted to meet this highly-individualized burden through sampling, the burden would take on a decidedly different character that is contrary to the FCA's plain terms. Relators first would focus discovery on their small selected sample of allegedly false claims, and the parties presumably would produce experts on sampling and conduct expert discovery. To the extent the evidence of the allegedly false claims in the small selected sample survived summary judgment, those claims—and those claims only—would be tried before a jury. Then, depending on whether the jury finds the sample claims false, the jury's liability finding would be extrapolated to the broader universe of the many thousands (or more) of claims outside the sample—subject only to the Court's scrutiny of the sampling experts under *Daubert* and the jury's determination of which of the experts' testimony regarding the sample claims is more credible and persuasive.

As such, Relators would not establish—or have to establish—with any specific and direct proof that any individual claim in the large universe of non-sample claims was objectively false and met the scienter, materiality, and other

elements of FCA liability. The sample proof and application of statistical principles alone would suffice.

But such aggregate proof sheds no light on whether unique "Patient A"—who is not in the non-sample pool, was certified for eligibility by a particular physician, and has her own unique set of physical and medical conditions—was properly certified for the level of hospice care she received. For one thing, there could be "completely innocuous alternative explanations" for why "Patient A" was diagnosed or treated a certain way. *U.S. ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25, 66 (D.D.C. 2007). Thus, the sample would do "nothing to identify [the] cause" for her diagnosis, "let alone establish liability" for fraud. *Id.* at 65. Nor would it show that any claims were submitted despite knowledge that the care provided was excessive. Sampling thereby would allow relators and the government to jettison the burden of proof for the vast majority of claims—those that fall outside of the selected sample.

At the same time, defendants would have only one real option for defending against the non-sample claims: conduct discovery on every single claim for every patient, and then prove at trial that each claim was ***not*** false. This effectively—and impermissibly—would reverse and rewrite the FCA's express allocation of the burden of proof. *See Rosmer v. Pfizer Inc.*, 263 F.3d 110, 115 (4th Cir. 2001)

(courts cannot "rewrite the statute"). And, case law specifically refutes any such rewriting.

In *Crews*, 460 F.3d at 857, for example, the relator argued that because the defendant kept poor records, presenting evidence as to each particular claim would be "impossible," and thus the burden should be shifted to the defendant to show that its actions were legal. *Id.* at 857. The district court granted defendants summary judgment, and the Seventh Circuit affirmed, concluding that the relator had not cited one relevant FCA case "that shifted the burden of actually identifying a false claim from the relator to the defendant." *Id.* The Court further reasoned that, "[i]n effect, [Relator] is arguing that [the defendant] must prove that each and every claim it ever filed [] was lawful, an argument that defies common sense and the plain language of the FCA." *Id.*; *see also* Jill Wieber Lens, *Tort Law's Deterrent Effect and Procedural Due Process*, 50 Tulsa L. Rev. 115, 1118 (2014) (acknowledging the "problem" with sampling in "implicitly shift[ing] the burden of proof as defined by the substantive law").

Here, like the relator in *Crews*, Relators and the government contend that sampling should be permitted because it would be impracticable to prove the many false claims *Relators* chose to allege. Relators' Br. at 10; Gov't Br. at 39, 41-42. As in *Crews*, however, such considerations cannot override the FCA's plain text.

Nor, in any case, is there any truth to the speculation that allowing sampling to establish FCA liability will lead to a more cost-effective resolution for all parties.

Rather, the costs would simply be transferred to Agape, now forced to *disprove* the based-on-statistics-only "falsity" of each of the thousands or tens of thousands of claims not in the sample. This would result in a trial of "monumental proportions" (JA485) every bit as much as if Relators were required in the first instance to prove the non-sample claims with affirmative evidence. The only difference is that the burden would be on the defendant—a result the FCA does not permit.

Just as surely, the alleged broad scope of a "defendant's wrongdoing" cannot be invoked to "shift the burden of proof to the defendant under the FCA" either. *U.S. ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.*, 764 F.3d 699, 714 (7th Cir. 2014). Yet, that is one of the government's principal contentions—without sampling, it claims, "perpetrators of the largest fraudulent schemes" would "escape liability precisely because their fraud was effectively too big to prosecute." Gov't Br. at 19.[3] The government provides no evidence for this purely speculative

[3] The government relies heavily for this claim on *Martin*, Gov't Br. at 39-40, where the district court suggested that the supposed "too big to prosecute" phenomenon would not be "consistent with the purpose and history of the FCA[.]" *Martin*, 114 F. Supp. 3d at 571. But "'vague notions of a statute's 'basic purpose' are ... inadequate to overcome the words of its text regarding the specific issue

Continued on following page

assertion, which runs counter to the government's success in obtaining substantial recoveries in health care FCA cases. *See, e.g.*, DOJ, Press Release, United States Settles False Claims Act Allegations Against 21st Century Oncology For Nearly $34.7 Million, https://www.justice.gov/usao-mdfl/pr/united-states-settles-false-claims-act-allegations-against-21st-century-oncology-nearly.

The government also ignores the administrative Medicare recoupment process for recovering Medicare overpayments. Through that process, the government is expressly authorized by statute to use sampling to prove its right to recovery, *see* 42 U.S.C. § 1395ddd(f)(3), but it is not entitled to the damage multipliers available under the FCA. *See Martin*, 114 F. Supp. 3d at 562-63. In reality, the government is electing to pursue "recoupment" under the FCA more frequently because it can recover far more than it could through the administrative process.

For these reasons alone, the district court's refusal to permit sampling should be affirmed.

Continued from previous page
under consideration.'" *Montanile v. Board of Trustees*, 136 S. Ct. 651, 661 (2016) (citation omitted).

B. Rejecting Sampling To Prove FCA Liability Avoids Serious Constitutional Difficulties.

Serious constitutional concerns arise from the proposed use of sampling to prove FCA liability that this Court should avoid by rejecting any construction of the statute that permits it. *See Vt. Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 787 (2000) (construing FCA to avoid constitutional difficulties). Using sampling where proving FCA liability requires a factfinder to determine whether certain individualized care furnished to uniquely different patients was medically necessary would infringe both the Due Process Clause's protection of the right to assert every defense and the Seventh Amendment's right to a trial by jury on the individualized facts.

1. Using sampling to prove FCA liability would violate the Due Process Clause.

Most troublingly, the sampling advanced by Relators and the government would violate Agape's due process rights to mount every available defense to each alleged false claim.

a. Sampling would violate Agape's due process right to mount every meaningful defense to Relators' FCA claims.

As the Supreme Court has made clear, the Due Process Clause guarantees defendants "an opportunity to present every available defense." *Philip Morris USA v. Williams*, 549 U.S. 346, 353 (2007) (citation omitted); *see also Mullins v. Direct Digital, LLC*, 795 F.3d 654, 669 (7th Cir. 2015) ("It is certainly true that a

defendant has a due process right not to pay in excess of its liability and to present individualized defenses if those defenses affect its liability."); *Carrera v. Bayer Corp.*, 727 F.3d 300, 307 (3d Cir. 2013) (same). This guarantee applies with particular force in FCA cases because the statute imposes "essentially punitive" damages. *Vermont Agency of Nat'l Res.*, 529 U.S. at 784.

As even commentators who support the use of sampling admit, the practice runs afoul of due process. The "linkage between a plaintiff's harm and a defendant's causal contribution to that harm is the only justification for redistribution from a defendant to a plaintiff." Jay Tidmarsh, *Resurrecting Trial by Statistics*, 99 Minn. L. Rev. 1459, 1470 (2015). But "[e]xcept for the sampled cases, trial by statistics eliminates the proof on both sides of this connection"—the defendant's conduct and the plaintiff's injury—thereby violating a defendant's constitutionally protected "ability to contest its liability to each plaintiff. . . ." *Id.* at 1470-72, 1477; *see also* Suzette M. Malveaux, *The Power and Promise of Procedure: Examining the Class Action Landscape After* Wal-Mart v. Dukes, 62 DePaul L. Rev. 659, 661 (2013) ("A defendant must be able to adequately defend itself from individual claims whose aggregation may mask important distinctions and available defenses.").

The use of sampling here likewise would eliminate Agape's due process protections. It would enable Relators to avoid even identifying—much less

establishing with specific and direct proof—exactly which of the tens of thousands of non-sample claims Agape allegedly submitted were false.[4] As a result, Agape would be unable to investigate, develop and present evidence to defend these unspecified false claims.

This is a litigation environment that the Due Process Clause does not tolerate. Far from being able to mount every available defense to every claim, Agape would not even know what claims for payment to defend, why those claims supposedly were false, who was involved in treating the patients and when, and who submitted the claim to the government and when. It is hard to imagine a graver assault on one's right to defend itself, even while the claimants are permitted to "prove" all of their claims through the simple expedient of sampling.

Nor, as the government suggests (Gov't Br. at 42), would Agape's due process rights be effectuated by its mere ability to engage in discovery relating to any proposed sampling expert, to challenge that expert at the *Daubert* stage and through cross-examination at trial, and to proffer its own sampling expert. The government cites no authority for this cramped view of due process, and none appears to exist. For good reason. The opportunity to challenge a sample and an

[4] Relators do not assert that every claim submitted during the relevant timeframe was false. Agape Br. at 4 n.2. This only exacerbates the difficulty of identifying which of the unspecified, non-sample claims are allegedly false and which are not.

expert's credentials and statistical methodology simply does not alleviate the due process problems generated by allowing the results of a small sample to be extrapolated to the expansive, highly-individualized universe of non-sample claims in order to prove liability.[5]

b. Courts have rejected similar efforts to use sampling as a substitute for specific and direct proof of liability.

Relators and the government would have this Court believe that trial by statistics of fraud and other forms of liability in complex cases is commonplace and consistent with due process. *See* Gov't Br. at 37.[6] They are wrong.

Indeed, courts frequently have rejected the use of sampling to prove liability in similar cases because it lacks the due process protections fundamental to the fair administration of justice. In *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 2541 (2011), the U.S. Supreme Court condemned the use of sampling to prove liability

[5] The government's embrace of sampling to prove liability is notable given that it has previously opposed it. *See Bayer Corp. v. United States*, 850 F. Supp. 2d 522, 533 (W.D. Pa. 2012) ("The United States has consistently and vigorously opposed the idea that it can be forced to accept statistical sampling as a means of discovery or as a basis by which Bayer can meet its burden of proof at trial."); Gov't Memo. in Opp., *Bayer Corp. v. United States*, No. 09-CV-351 (W.D. Pa.), Doc. No. 73 at 21 (filed June 6, 2011) (citing Third Circuit decision that "explained why use of statistical sampling to prove damages (even if allowed) does not support the use of statistical sampling to establish liability") (citation omitted).

[6] The government cites only one case where a court, years before any trial, found that sampling potentially could be used to prove FCA liability. Gov't Br. at 39-40 (discussing *Martin*, 114 F. Supp. 3d 549).

in a class action. There, the Ninth Circuit had authorized a procedure whereby Wal-Mart's liability for sex discrimination against a sample set of class members would be determined. "The percentage of [sample] claims determined to be valid would then be applied to the entire remaining class, and the number of (presumptively) valid claims thus derived would be multiplied by the average backpay awards in the sample set to arrive at the entire class recovery." *Wal-Mart*, 131 S. Ct. at 2561. But Wal-Mart, the Court observed, would be limited to "present[ing] individual defenses" only in the "randomly selected sample cases." *Id.* at 2550 (citation and internal quotation marks omitted).

The Supreme Court rejected this approach, making clear that "Wal-Mart is entitled to individualized determinations of each employee's eligibility for backpay." *Id.* at 2560. Criticizing the Ninth Circuit's "novel project" as a "Trial by Formula," the Court held that "a class cannot be certified on the premise that Wal-Mart will not be entitled to litigate its statutory defenses to individual claims." *Id.* at 2561; *see also Tyson Foods, Inc. v. Bouaphakeo*, --- U.S. ---, 2016 WL 1092414, at *10 (U.S. March 22, 2016) (same). *Wal-Mart* thus destroyed the "notion that a court could try a representative sample of monetary claims and

extrapolate the average result to the remainder of the cases. . . ." Tidmarsh, *Resurrecting Trial by Statistics*, *supra*, at 1459, 1477.[7]

This case is not a class action. But the "threats to defendants' rights" from allowing sampling or another "form of aggregate proof" to prove liability arise in any highly individualized case involving numerous plaintiffs or claims, whether a class action, *parens patriae* action,[8] or FCA suit like this one. *See* John C.

---

[7] In *Tyson Foods*, an overtime-pay class action, the Court held that the particular use of sampling there was permissible. But that ruling is inapposite and, by its express terms, does not establish any "general rule[] governing the use of statistical evidence." 2016 WL 1092414, at *11.

The Court there held that sampling was acceptable because (1) "each class member could have relied on th[e] sample to establish liability if he or she had brought an individual action" and (2) "there were no alternative means for the employees to establish their hours worked"—the sample was used "to fill an evidentiary gap created by the employer's failure to keep adequate records." 2016 WL 1092414, at *9. Neither feature is present in this case, or in the typical FCA case like it—the proposed sample here could not be used to prove that any individual claim for payment was false, and there is no suggested "evidentiary gap" created by Agape's records. *See* JA481.

Additionally, the Court did not address the due process implications of sampling, and it distinguished *Wal-Mart* because of the significant variations among the class members there, whereas in *Tyson Foods*, "each employee worked in the same facility, did similar work, and was paid under the same policy." 2016 WL 1092414, at *11. In the end, the Court emphasized that the "fairness and utility of statistical methods in contexts other than those presented here will depend on facts and circumstances particular to those cases." *Id.*

[8] *See, e.g.*, Pet. for Cert. at i, *Exxon Mobil Corp. v. State of New Hampshire*, No. 15-933, 2016 WL 324324 (U.S. filed Jan. 20, 2016) (presenting question "[w]hether the Due Process Clause permits a state to use *parens patriae* standing

Continued on following page

Massaro, *The Emerging Federal Class Action Brand*, 59 Clev. St. L. Rev. 645, 676 (2011). And, though *Wal-Mart* was grounded in the Rules Enabling Act, numerous courts have recognized the due process principles underlying the Court's holding. *See Mullins*, 795 F.3d at 669 (citing *Wal-Mart* to conclude "that a defendant has a due process right not to pay in excess of its liability and to present individualized defenses if those defenses affect its liability"); *Carrera*, 727 F.3d at 307 (same); *Bustillos v. Bd. of Cty. Comm'rs of Hidalgo Cty.*, 310 F.R.D. 631, 660 (D.N.M. 2015) ("Techniques that merely presume away substantive elements that normally must be proven by the plaintiff, or that would impair a defendant's Due Process rights, however, are not permissible. [*Wal-Mart*] has expressly disavowed 'trials by statistics,' or 'trials by formula,' either as to liability or damages.").

Numerous other courts have reached similar conclusions where aggregate proof has been proposed. In *In re Fibreboard*, 893 F.2d 706 (5th Cir. 1990), the Fifth Circuit addressed a trial plan where evidence of liability would be presented for 30 plaintiffs and the jury would then determine damages to the remaining 2,990 class members based on that evidence and expert testimony. Relying on the Due Process Clause, the Fifth Circuit rejected the plan because "[a] contemplated 'trial'

Continued from previous page
and statistical proof to recover hundreds of millions of dollars in a 'Trial by Formula' that eliminated individualized defenses").

of the 2,990 class members without discrete focus can be no more than the testimony of experts regarding their claims, as a group, compared to the claims actually tried to the jury." *Id.* at 712. *See also McLaughlin v. American Tobacco Co.*, 522 F.3d 215, 231-32 (2d Cir. 2008) (rejecting on due process grounds "fluid recovery plan" that would have provided "an initial estimate of the percentage of class members who were defrauded" and then used the estimate to calculate total damages to the class because it would violate the "right of defendants to challenge the allegations of individual plaintiffs"); *Bustillos*, 310 F.R.D. at 660 (concluding that "trials by formula" "violate[] the defendant's right to have (i) each element of (ii) each claim asserted against it by (iii) each class member specifically proven"); *Hilao v. Estate of Marcos*, 103 F.3d 767, 787 (9th Cir. 1996) ("determining causation as well as damages by inferential statistics instead of individualized proof raises more than 'serious questions' of due process") (Rymer, J., dissenting).

More recently, in *Duran v. U.S. Bank Nat'l Ass'n*, 325 P.3d 916 (Cal. 2014), the California Supreme Court, relying on *Wal-Mart*, rejected a similar use of sampling in the class context on due process grounds. There, the trial court had permitted a putative class of 260 employees to prove injury resulting from defendant's violations of overtime laws based on a sample of 21 employees. Relying on testimony from the "small sample group," the trial court "found that the entire class had been misclassified" as exempt from overtime laws and then

"extrapolated the average amount of overtime reported by the sample group to the class as a whole." *Id.* at 920, 935. Citing *Wal-Mart* and the Due Process Clause, the California Supreme Court reversed, holding that the trial "court's decision to extrapolate classwide liability from a small sample … deprived [the bank] of the ability to litigate its exemption defense." *Id*. at 935.

As these authorities demonstrate, the use of sampling to prove FCA liability in a "trial by formula" would violate defendants' due process right to assert every defense and receive an individual assessment of liability. The district court's decision to deny the use of sampling should be affirmed.

2. Using sampling to prove FCA liability would violate Agape's Seventh Amendment right to a jury trial.

Allowing sampling to prove FCA liability not only would violate basic due process rights—it would threaten the equally fundamental principle that juries must determine liability based on specific proof of each asserted unlawful act.

The Seventh Amendment right to a jury trial "extends to causes of action created by Congress[,]" *Chauffeurs, Teamsters & Helpers, Local No. 391 v. Terry*, 494 U.S. 558, 564-65 (1990) (citation omitted), and the Supreme Court has zealously protected it. *See Beacon Theatres, Inc. v. Westover*, 359 U.S. 500, 501 (1959) ("'Maintenance of the jury as a fact-finding body is of such importance and occupies so firm a place in our history and jurisprudence that any seeming

curtailment of the right to a jury trial should be scrutinized with the utmost care.'") (citation omitted). But the use of sampling to prove liability in cases like this one poses a serious threat to this fundamental right.

In *Cimino v. Raymark Indus. Inc.*, 151 F.3d 297 (5th Cir. 1998), for example, the district court (1) certified a class of several thousand, (2) tried liability on a class-wide basis, (3) held a bench trial to determine damages for 160 sample plaintiffs, and (4) awarded the sample plaintiffs $69 million. *Id.* at 299-300. The trial plan provided for extrapolation of the liability verdict to the remaining thousands of class members. The Fifth Circuit rejected the plan. It held that judgments reached through extrapolation "contravene[d]" the Seventh Amendment because findings as to one plaintiff "cannot control the determination of, or afford any basis for denial of [defendants'] Seventh Amendment rights to have a jury determine, the distinct and separable issues of the actual damages of each of the extrapolation plaintiffs." *Id.* at 320-21. *See also In re Fibreboard*, 893 F.2d at 710 (noting that "traditional ways" of "one-on-one" adjudication "reflect far more than habit. They reflect the very culture of the jury trial").

Other courts are in accord. In *Basco v. Wal-Mart Stores, Inc.*, 216 F. Supp. 2d 592 (E.D. La. 2002), for example, the court rejected a sampling plan to determine hours worked off-the-clock for the entire Wal-Mart workforce in Louisiana because such a "representational method … would deprive defendants of

their right to have a jury determine liability and damages." *Id.* at 604. *See also Osuna v. Wal-Mart Stores, Inc.*, 2004 WL 3255430, at *8 (Ariz. Super. Ct. Dec. 23, 2004) (right to jury trial abridged where defendant is denied "the right to examine individual class members and to assert individual defenses, by using formulaic methodologies to establish liability and damages"); *In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1023 (5th Cir. 1997) ("The use of statistical sampling as a means to identify and resolve common issues in tort litigation has [] been severely criticized. Among other things, the technique may deprive nonparties of their Seventh Amendment jury trial right.") (Jones, J., concurring) (citation omitted).

As in these cases, Relators' proposed use of sampling would remove from the jury's domain FCA liability determinations for thousands or tens of thousands of discrete claims outside the sample. The jury would not decide whether Relators made out a *prima facie* liability case with respect to the "distinct and separable issues" for each alleged false claim outside the small sample. *Cimino*, 151 F.3d at 320-21 (Seventh Amendment guarantees "rights to have a jury determine the distinct and separable issues" for each claim). That does not come close to what the Seventh Amendment demands, and it provides an additional reason to affirm the district court's refusal to permit sampling here.

C. Allowing Sampling To Prove FCA Liability Would Magnify The Threat To Health Care Providers Of The Statute's Draconian Penalties And The Enormous Pressure To Settle Meritless Claims.

If Relators are permitted to use their suggested "Trial by Formula" approach to proving FCA liability—an approach relators and the government are invoking with increasing frequency against health care providers nationwide (*see supra* at 3 n.2)—that will amplify, by many orders of magnitude, the serious threat of massive FCA liability and additional adverse consequences that those providers already face.

The escalation of FCA *qui tam* suits is well-chronicled. Between 2000 and 2013, the number of those suits more than doubled. *See* Fraud Statistics—Overview, Civil Div., U.S. Dep't of Justice (Oct. 1, 1987 – Sept. 30, 2015), www.justice.gov/opa/file/796866/download. More staggering are the recoveries—from $2.3 ***million*** in 1998 to nearly $2.8 ***billion*** in 2011. David Freeman Engstrom, *Harnessing the Private Attorney General: Evidence from Qui Tam Litigation*, 112 Colum. L. Rev. 1244, 1270 (2012). The "potential for astronomical profits, as well as the ever-expanding theories of [FCA] liability," are driving this upsurge. Sean Elameto, *Guarding the Guardians: Accountability in Qui Tam Litigation Under the Civil False Claims Act*, 41 Pub. Cont. L.J. 813, 844 (2012).

Health care providers are among the principal targets of these proliferating FCA suits. Of the unprecedented $5.7 billion in FCA settlements and judgments

paid in 2014, $2.3 billion came from the health care industry. DOJ, *Press Release, Justice Department Recovers Nearly $6 Billion from False Claims Act Cases in Fiscal Year 2014* (Nov. 20, 2014). And in 2015, more than half of the $3.5 billion in settlements and judgments—$1.9 billion—came from the health sector. *See* Fraud Statistics—Overview, *supra*.

Indeed, health care providers face substantial FCA exposure. The statute imposes treble damages as well as civil penalties. 31 U.S.C. § 3729(a)(1). It also provides for expenses and attorneys' fees. *Id.* § 3730(d)(1)-(2). These "essentially punitive" damages and penalties, *Vermont Agency of Natural Res.*, 529 U.S. at 784, are prone to reaching "astronomical sums" in health care cases such as this one. Timothy Stoltzfus Jost & Sharon L. Davies, *The Empire Strikes Back*, 51 Ala. L. Rev. 239, 259, 260 (1999). That is because civil penalties apply "per claim," *Graham County Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 545 U.S. 409, 411 (2005), and, as in this case, health care providers, including AHCA's members, typically submit "enormous volumes of claims." Jost & Davies, *supra*, at 259.

That courts have interpreted the FCA's liability provisions broadly has further increased the risks to health care providers. In particular, providers often are targets of "implied-certification" FCA claims, which turn on allegations that, although a provider did not make any affirmative false statement, it is deemed to

have impliedly made one when it sought payment despite knowing that it was in violation of another federal statute or regulation. *See Triple Canopy*, 775 F.3d at 636. Given the "sheer volume of the laws and regulations," only perfect compliance can ward off these suits. Joan H. Krause, *"Promises to Keep,"* 23 Cardozo L. Rev. 1363, 1398, 1399 (2002). But that is not feasible due to the increasingly complex regulatory environment providers occupy and their focus on their primary mission of providing quality patient care. *See Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000) (describing Medicare as "a massive, complex health and safety program … embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations").

Perhaps the greatest threat from extending the FCA's reach is that a finding of liability carries with it the risk of a health care provider's exclusion from the federal health care reimbursement programs. *See, e.g.*, 42 U.S.C. §1320a-7 (2006) (describing exclusion); *see also generally* David W. Ogden & Elisebeth Collins Cook, *The Exclusion Illusion* 20-26 (Oct. 2012). Indeed, "an excluded person or entity is blacklisted in the health care industry for the period of exclusion." William W. Horton, *Key Developments in Provider Reimbursement, Regulation and Enforcement in the New World of the Affordable Care Act*, Aspatore, 2015 WL 9182489, at *4 n.18 (Nov. 2015). And "the government has become … very

willing to use the FCA," in tandem with the government's "exclusion authority," "as vehicles to press for large civil settlements." *Id.* at *4.

Allowing the use of sampling to prove FCA liability—and the exponential multiplying of damages and penalties it entails—will only intensify providers' already-substantial incentives "to settle otherwise unmeritorious suits to avoid risking financial ruin. . . ." *See* Malcolm J. Harkins III, *The Ubiquitous False Claims Act: The Incongruous Relationship Between a Civil War Era Fraud Statute and the Modern Administrative State*, 1 St. Louis U.J. Health L. & Pol'y 131, 174 (2007); Vicki W. Girard, *Punishing Pharmaceutical Companies for Unlawful Promotion of Approved Drugs: Why the False Claims Act Is the Wrong Rx*, 12 J. Health Care L. & Pol'y 119 (2009) ("Companies settle [FCA] cases largely to avoid the potential loss of revenue associated with the exclusion regime"). As the Supreme Court has stressed, costly settlements of "anemic" lawsuits are a sign of an unhealthy justice system and should be reduced—not encouraged. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559 (2007). These developments are particularly troubling because the extraordinary costs of these settlements undermine the central mission of health care providers—to provide high-quality medical care to those most in need of it.

Approving the "Trial by Formula" approach to proving FCA liability advocated by Relators and the government thus threatens systemic harm to health

care providers like Agape and AHCA's members. This is all the more reason to reject it.

V. CONCLUSION

Accordingly, *Amicus Curiae* AHCA respectfully urges this Court to affirm the district court's denial of Relators' proposed use of sampling to prove liability under the FCA.

Respectfully submitted,

/s/ Colin E. Wrabley
Colin E. Wrabley
M. Patrick Yingling
REED SMITH LLP
225 Fifth Avenue
Pittsburgh, PA 15222
Tel: (412) 288-3131
Fax: (412) 288-3063
cwrabley@reedsmith.com

Counsel for Amicus Curiae

Dated: March 24, 2016

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

No. 15-2145 **Caption:** U.S. ex rel Michaels et al. v. Agape Senior Community

CERTIFICATE OF COMPLIANCE WITH RULE 28.1(e) or 32(a)
Type-Volume Limitation, Typeface Requirements, and Type Style Requirements

1. **Type-Volume Limitation:** Appellant's Opening Brief, Appellee's Response Brief, and Appellant's Response/Reply Brief may not exceed 14,000 words or 1,300 lines. Appellee's Opening/Response Brief may not exceed 16,500 words or 1,500 lines. Any Reply or Amicus Brief may not exceed 7,000 words or 650 lines. Counsel may rely on the word or line count of the word processing program used to prepare the document. The word-processing program must be set to include footnotes in the count. Line count is used only with monospaced type.

   This brief complies with the type-volume limitation of Fed. R. App. P. 28.1(e)(2) or 32(a)(7)(B) because:

   ☑ this brief contains 6,888 [*state number of*] words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii), *or*

   ☐ this brief uses a monospaced typeface and contains _____ [*state number of*] lines of text, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. **Typeface and Type Style Requirements:** A proportionally spaced typeface (such as Times New Roman) must include serifs and must be 14-point or larger. A monospaced typeface (such as Courier New) must be 12-point or larger (at least 10½ characters per inch).

   This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because:

   ☑ this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 [*identify word processing program*] in 14 point Times New Roman [*identify font size and type style*]; **or**

   ☐ this brief has been prepared in a monospaced typeface using _____ [*identify word processing program*] in _____ [*identify font size and type style*].

(s) Colin E. Wrabley

Attorney for American Health Care Association

Dated: 3/24/16

CERTIFICATE OF SERVICE

I hereby certify that the foregoing was electronically filed using the Court's CM/ECF system. I certify that all participants are CM/ECF users and that service will be accomplished via CM/ECF system.

/s/ Colin E. Wrabley

Dated: March 24, 2016