

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

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

UNITED STATES 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

**PUBLIC BRIEF FOR THE UNITED STATES
AS INTERVENOR-APPELLEE**

WILLIAM N. NETTLES
United States Attorney

ELIZABETH C. WARREN
Assistant United States Attorney

BENJAMIN C. MIZER
*Principal Deputy Assistant
Attorney General*

MICHAEL S. RAAB
CHARLES W. SCARBOROUGH
Attorneys, Appellate Staff
Civil Division, Room 7244
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530
(202) 514-1927

TABLE OF CONTENTS

	<u>Page(s)</u>
STATEMENT OF JURISDICTION	1
STATEMENT OF THE ISSUES	1
STATEMENT OF THE CASE	3
A. Regulatory Background	3
1. The False Claims Act.....	3
2. Medicare Coverage of Hospice Care	5
B. Proceedings In This Case.....	7
SUMMARY OF ARGUMENT	16
STANDARD OF REVIEW.....	19
ARGUMENT	19
I. THE CONSENT OF THE UNITED STATES IS A PREREQUISITE FOR THE SETTLEMENT AND VOLUNTARY DISMISSAL OF CLAIMS IN DECLINED QUI TAM SUITS.....	19
A. The FCA Expressly And Unequivocally Conditions The Voluntary Dismissal Of A Qui Tam Action Upon The Written Consent Of The Attorney General.....	20
B. The Parties’ Arguments That Courts Have Authority To Determine Whether The Government’s Decision To Withhold Consent To A Settlement Is Reasonable Lack Merit.....	28
II. THE DISTRICT COURT ERRED IN SUGGESTING THAT THE GOVERNMENT’S REFUSAL TO CONSENT TO THE SETTLEMENT WAS LIKELY UNREASONABLE.....	33
CONCLUSION	43

CERTIFICATE OF COMPLIANCE WITH
FEDERAL RULE OF APPELLATE PROCEDURE 32(A)

CERTIFICATE OF SERVICE

ADDENDUM

TABLE OF AUTHORITIES

Cases:	<u>Page(s)</u>
<i>Assured Guar. Mun. Corp. v. Flagstar Bank, FSB</i> , 920 F. Supp. 2d 475 (S.D.N.Y. 2013)	41
<i>Baltimore Gas & Elec. Co. v. FERC</i> , 252 F.3d 456 (D.C. Cir. 2001).....	23
<i>Barnhart v. Sigmon Coal Co.</i> , 534 U.S. 438 (2002)	22, 29
<i>Daubert v. Merrell Dow Pharm., Inc.</i> , 509 U.S. 579 (1993)	42
<i>Heckler v. Chaney</i> , 470 U.S. 821 (1985)	23
<i>Hoyte v. American Nat’l Red Cross</i> , 518 F.3d 61 (D.C. Cir. 2008).....	27
<i>Ignacio v. United States</i> , 674 F.3d 252 (4th Cir. 2012)	19
<i>In re Chevron U.S.A., Inc.</i> , 109 F.3d 1016 (5th Cir. 1997)	38
<i>In re Countrywide Fin. Corp. Mortgage-Backed Sec. Litig.</i> , 984 F. Supp. 2d 1021 (C.D. Cal. 2013)	37, 38, 41
<i>Michigan Dep’t of Educ. v. U.S. Dep’t of Educ.</i> , 875 F.2d 1196 (6th Cir. 1989)	37
<i>Minotti v. Lensink</i> , 895 F.2d 100 (2d Cir. 1990).....	30, 31
<i>Native Angels Home Care Agency, Inc. v. Sebelius</i> , 749 F. Supp. 2d 370 (E.D.N.C. 2010).....	6
<i>Republic Servs., Inc. v. Liberty Mut. Ins. Co.</i> , No. 03-494, 2006 WL 2844122 (E.D. Ky. Oct. 2, 2006).....	41

<i>Ridenour v. Kaiser Hill Co., LLC</i> , 397 F.3d (10th Cir. 2005).....	27
<i>Speed Mining, Inc. v. Fed. Mine Health and Safety Review Comm’n</i> , 528 F.3d 310 (4th Cir. 2008)	23
<i>United States v. Armstrong</i> , 517 U.S. 456 (1996)	23
<i>United States v. Cabrera-Diaz</i> , 106 F. Supp. 2d 234 (D.P.R. 2000).....	38
<i>United States v. Conner</i> , 262 F. App’x 515 (4th Cir. 2008).....	40
<i>United States v. Fadul</i> , No. 11-0385, 2013 WL 781614 (D. Md. Feb. 28, 2013).....	41
<i>United States v. Health Possibilities, P.S.C.</i> , 207 F.3d 335 (6th Cir. 2000)	12, 25, 26, 31, 32
<i>United States v. Jones</i> , 641 F.3d 706 (6th Cir. 2011)	41
<i>United States v. Maceo</i> , 873 F.2d 1 (1st Cir. 1989)	41
<i>United States v. Rogan</i> , 517 F.3d 449 (7th Cir. 2008)	38
<i>United States v. Ukwu</i> , 546 F. App’x 305 (4th Cir. 2013).....	41
<i>United States ex rel. Eisenstein v. City of New York</i> , 556 U.S. 928 (2009)	5, 27
<i>United States ex rel. Killingsworth v. Northrop Corp.</i> , 25 F.3d 715 (9th Cir. 1994)	12, 25, 26, 35
<i>United States ex rel. Landis v. Tailwind Sports Corp.</i> , 98 F. Supp. 3d 8 (D.D.C. 2015).....	26
<i>United States ex rel. Loughren v. UnumProvident Corp.</i> , 604 F. Supp .2d 259 (D. Mass. 2009).....	38

<i>United States ex rel. Martin v. Life Care</i> , 114 F. Supp. 3d 549 (E.D. Tenn. 2014).....	39, 40
<i>United States ex rel. Milam v. University of Texas</i> , 961 F.2d 46 (4th Cir. 1992)	24
<i>United States ex rel. Radcliffe v. Purdue Pharma, LP</i> , 600 F.3d 319 (4th Cir. 2010)	27
<i>United States ex rel. Searcy v. Philips Elecs. North America Corp.</i> , 117 F.3d 154 (5th Cir. 1997)	12, 24, 25, 26, 32
<i>United States ex rel. UBL v. IIF Data Solutions</i> , 650 F.3d 445 (4th Cir. 2011)	27
<i>Vermont Agency of Nat. Res. v. United States ex rel. Stevens</i> , 529 U.S. 765 (2000)	3, 19

Statutes:

False Claims Act, 31 U.S.C. § 3729 <i>et seq.</i>	3
31 U.S.C. § 3729(a)	3
31 U.S.C. § 3729(a)(1)(A).....	3
31 U.S.C. § 3729(a)(1)(B)	3
31 U.S.C. § 3729(b)(1).....	3
31 U.S.C. § 3730(a)	1
31 U.S.C. § 3730(b).....	5
31 U.S.C. § 3730(b)(1).....	9, 11, 16, 19, 20, 23, 28
31 U.S.C. § 3730(b)(2).....	4, 7, 21
31 U.S.C. § 3730(b)(4).....	4
31 U.S.C. § 3730(b)(5).....	8
31 U.S.C. § 3730(c)(1)	4

31 U.S.C. § 3730(c)(2)(A).....	5, 20
31 U.S.C. § 3730(c)(2)(A)-(B).....	4
31 U.S.C. § 3730(c)(2)(B).....	5, 20, 21, 29
31 U.S.C. § 3730(c)(2)(C).....	22
31 U.S.C. § 3730(c)(3).....	4, 8, 20, 22
31 U.S.C. § 3730(c)(4).....	5, 20, 22
31 U.S.C. § 3730(d).....	5
31 U.S.C. § 3730(d)(1).....	5
31 U.S.C. § 3730(d)(2).....	5
31 U.S.C. § 3732.....	1
31 U.S.C. § 3740(b)(4)(B).....	31
Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, § 4(a), 123 Stat. 1621.....	3
Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 10104(j)(2), 124 Stat. 119.....	3
Social Security Act, tit. XVIII, 42 U.S.C. §§ 1395 <i>et seq.</i>	5
42 U.S.C. § 1395f(a)(7)(A)(i).....	6
42 U.S.C. § 1395f(a)(7)(A)(ii).....	6
42 U.S.C. § 1395x(dd)(3)(A).....	6
42 U.S.C. § 1395y(a)(1)(C).....	6
28 U.S.C. § 1292(b).....	1, 2, 11, 15, 16
31 U.S.C. § 232(b)(1976).....	30

Regulation:

42 C.F.R. § 418.22(b)(2)..... 6

Rule:

Fed. R. Evid. 702..... 42

Legislative Material:

S. Rep. No. 345, 99th Cong., 2d Sess. (1986)..... 4

Other Authority:

Ctrs. for Medicare & Medicaid Servs., HHS, *Medicare Benefit Policy Manual*..... 6

STATEMENT OF JURISDICTION

The district court had jurisdiction over this qui tam suit under the False Claims Act (“FCA”) under 31 U.S.C. § 3732. On June 25, 2015, the district court denied a motion to enforce a proposed settlement agreement negotiated by the defendants and the qui tam relators over the objections of the United States. Joint Appendix (“JA”) 468-86. The court also sua sponte certified its order for interlocutory review under 28 U.S.C. § 1292(b). JA 485-86. Defendants and the relators filed petitions for permission to appeal under 28 U.S.C. § 1292(b), which the United States opposed. On September 29, 2015, this Court granted the petitions. JA 577. This Court has jurisdiction over these consolidated appeals pursuant to 28 U.S.C. § 1292(b).

STATEMENT OF THE ISSUES

In this False Claims Act suit, qui tam relators allege that defendants, a group of hospice care providers known collectively as Agape, submitted thousands of false claims to Medicare for hospice services. Relators allege that patients either were not eligible for the hospice services at all or were not eligible for the level or types of services provided. Although the relators and Agape reached a tentative settlement of those claims, the United States objected to the proposed settlement on various grounds.

The district court denied the parties’ motion to enforce the settlement over the government’s objections, holding that the consent of the United States is an absolute prerequisite for the settlement and dismissal of claims under the FCA. However, the

court expressed concerns that the government's veto of the settlement relied at least in part upon statistical sampling – a method of proving liability and damages that the court had previously rejected in this case. The court thus indicated that, if it had authority to assess the reasonableness of the government's objections to the parties' proposed settlement, it would likely find that those objections were not reasonable. JA 477. Faced with the prospect of a lengthy trial in a case that the relators and the defendants wanted to settle, the district court sua sponte certified its order for immediate appeal under 28 U.S.C. § 1292(b), identifying two questions that it believed would benefit from interlocutory appellate review: (1) whether the United States has unreviewable authority to veto settlements in declined qui tam suits, and (2) whether statistical sampling could be used to prove liability and damages in this case. This Court granted petitions filed by the defendants and the relators for permission to appeal. The questions now presented in these consolidated appeals are:

1. Whether the consent of the United States is an absolute prerequisite for the settlement and dismissal of FCA claims in declined qui tam suits.
2. In the alternative, whether the district court erred in finding that the government's refusal to consent to the proposed settlement was likely unreasonable.

STATEMENT OF THE CASE

A. Regulatory Background.

1. The False Claims Act

The False Claims Act (“FCA”), 31 U.S.C. § 3729 *et seq.*, is “the primary vehicle by the Government for recouping losses suffered through fraud.” H.R. Rep. No. 660, 99th Cong., 2d Sess. 18 (1986). The FCA imposes civil liability upon any person who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,” *id.* § 3729(a)(1)(A), or “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim,” *id.* § 3729(a)(1)(B).¹ A person found to have violated the FCA is liable for civil penalties and treble damages. *Id.* § 3729(a).

A civil action under the FCA may be commenced in either of two ways. First, the United States may bring its own suit. 31 U.S.C. § 3730(a). Second, a private person (known as a relator) may bring a *qui tam* action “for the person and for the United States Government.” *Id.* § 3730(b)(1). In such circumstances, “a *qui tam* relator is, in effect, suing as a partial assignee of the United States.” *Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 773 n.4 (2000).

¹ Congress has twice amended the FCA in recent years. *See* Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, § 4(a), 123 Stat. 1617, 1621; Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 10104(j)(2), 124 Stat. 119. None of those amendments is relevant to the issues presented in this appeal and this brief references the current version of the FCA.

The FCA requires that qui tam complaints be filed in camera and served on the government along with written disclosures of all material evidence and information the relator possesses. 31 U.S.C. § 3730(b)(2). The complaint is not served on the defendant at the time of filing, and the case must remain under seal for at least 60 days. *Ibid.* Those procedural requirements are intended to give the government an opportunity to investigate the allegations and make an informed decision regarding whether to intervene in the action before the defendant becomes aware of the case. *See* S. Rep. No. 99-345, at 24 (1986).

After conducting an investigation into the allegations raised in a qui tam complaint, the United States may either “intervene and proceed with the action” or “notify the court that it declines to take over the action,” 31 U.S.C. §§ 3730(b)(2) & (b)(4). If the government elects to intervene, it “shall have the primary responsibility for prosecuting the action, and shall not be bound” by any act of the relator. *Id.* § 3730(c)(1). However, the relator may continue as a party to the action, and is entitled to a hearing before voluntary dismissal and to a court determination of reasonableness before settlement. *Id.* § 3730(c)(2)(A) - (B).

If the government declines to intervene, the relator has “the right to conduct the action.” 31 U.S.C. § 3730(c)(3). Even in these circumstances, however, the United States retains important procedural and substantive rights in such proceedings. For example, the United States may intervene in a declined qui tam suit upon a showing of “good cause,” *id.* § 3730(c)(3), it may seek to stay discovery that would

interfere with its investigation or prosecution of criminal or civil matters arising out of the same facts, *id.* § 3730(c)(4), it may unilaterally dismiss a qui tam suit over the relator's objections, *id.* § 3730(c)(2)(A), and it may settle an action over the relator's objections if a court determines that the settlement is "fair, adequate, and reasonable," *id.* § 3730(c)(2)(B). The FCA also provides that a qui tam "action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting." *Id.* § 3730(b). *See also United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 932 (2009) (noting that government's rights in declined qui tam suits include "vetoing a relator's decision to voluntarily dismiss the action").

If a qui tam action results in the recovery of damages or civil penalties, the award is divided between the government and the relator. 31 U.S.C. § 3730(d). In cases where the government has intervened, the relator is generally entitled to between 15 and 25 percent of the proceeds. *Id.* § 3730(d)(1). In cases where the government has not intervened, the relator receives a larger share of a successful suit, between 25 and 30 percent of the recovery. *Id.* § 3730(d)(2).

2. Medicare Coverage of Hospice Care

Medicare is a federally-subsidized health insurance program for older persons and other eligible individuals, established by Congress as Title XVIII of the Social Security Act, 42 U.S.C. § 1395, *et seq.* Generally speaking, Medicare Part A provides insurance for the costs of inpatient hospital and related services, and Medicare Part B provides insurance for the costs of physician services, medical supplies, diagnostic

tests, and related services. As relevant here, Medicare will pay for hospice care for terminally ill patients, but only pays for items or services that are “reasonable and necessary for the palliation or management of terminal illness.” 42 U.S.C.

§1395y(a)(1)(C). *See generally Native Angels Home Care Agency, Inc. v. Sebelius*, 749 F.

Supp. 2d 370, 376 (E.D.N.C. 2010) (explaining that “Congress amended the Medicare Act in 1982 to provide coverage for hospice care”).

Various statutes, regulations, and guidance from the Centers for Medicare and Medicaid Services (“CMS”) establish the core requirements to qualify for hospice care benefits. Among other things, an individual must be terminally ill, meaning that the “individual’s life expectancy is 6 months or less.” 42 U.S.C. § 1395x(dd)(3)(A). *See Native Angels*, 749 F. Supp. 2d at 376. In order to demonstrate eligibility, a Medicare beneficiary’s physician and either the hospice medical director or a hospice physician must certify that the beneficiary is terminally ill, 42 U.S.C. § 1395f(a)(7)(A)(i), and the beneficiary’s medical records must support such a finding, 42 C.F.R. § 418.22(b)(2). A beneficiary’s eligibility must be recertified every 60 or 90 days. *Id.* § 1395f(a)(7)(A)(ii). *See generally* Ctrs. for Medicare & Medicaid Servs., HHS, Medicare Benefit Policy Manual, ch. 9 (explaining hospice care eligibility requirements, including certification and recertification requirements); *Agape Br.* at 6 (same).

B. Proceedings In This Case

1. This case involves allegations that the Agape chain of hospice and skilled nursing care providers in South Carolina engaged in a widespread fraudulent scheme to bill Medicare for hospice care services while knowing that the prerequisites for receiving payment for those services were not satisfied. The qui tam relators, two former employees at Agape facilities, allege, *inter alia*, that Agape submitted thousands of Medicare claims for routine home hospice care and general inpatient (“GIP”) care that were false because the care was not medically necessary or the certifications required to obtain Medicare reimbursement were falsified. As summarized in the second amended complaint, “[d]efendants knowingly submitted false or fraudulent certifications, recertifications and claims for hospice care for patients whom they knew were not terminally ill or not eligible for hospice care benefits.” JA 164.

As required under the FCA, 31 U.S.C. § 3730(b)(2), the relators filed their initial complaint under seal. JA 49. After the United States declined to intervene in this case, JA 72, the district court issued an order unsealing the complaint, JA 74. The court’s order stated, “should the relators or the defendants propose that this action be dismissed, settled, or otherwise discontinued, either the relators or the defendants will solicit the written consent of the United States before presenting the matter to this court for its ruling or granting its approval.” JA 75. The government’s notice of election not to intervene likewise explained that, if the parties sought to dismiss or discontinue the case, the relators or defendants were required to “solicit the written

consent of the United States before asking this Court to rule on the proposed dismissal.” JA 72.²

Following the government’s decision not to intervene, the relators and Agape engaged in extensive discovery and pre-trial motions practice. As required under 31 U.S.C. § 3730(c)(3), the parties served copies of relevant discovery materials and pleadings on the United States, and the government closely monitored this case. In light of the large number of false claims Agape allegedly submitted (numbering in the tens of thousands), relators made clear that they intended to use some form of statistical sampling to prove their claims. *See* JA 202-21 (transcript of 8/14/14 hearing). Because Agape opposed the use of any form of statistical sampling, the district court ordered the parties to submit briefs on the sampling issue, and allowed the United States to file an amicus brief addressing that issue. JA 220. Pursuant to that order, the relators filed a motion to permit the use of statistical sampling, JA 239-53, and Agape opposed that motion, JA 254-88.³

² After the United States declined to intervene in this case, a new qui tam action was filed making similar allegations against the Agape defendants. *See United States ex rel. Rush v. Agape*, No. 3:13-cv-00666 (D.S.C. filed Mar. 12, 2013). The United States also investigated the allegations in that case and filed a notice of no decision after the court declined to extend the seal. JA 223. Pursuant to 31 U.S.C. § 3730(b)(5), the district court then dismissed the *Rush* complaint on the ground that the relators in this case were the first to file these claims. JA 222-38.

³ Although both the relators’ motion and Agape’s opposition to statistical sampling are included in the joint appendix, the United States’ amicus brief in support of statistical sampling is not in the appendix. It is, however, part of the district court record and available to this Court at ECF No. 167.

The court held a hearing on the use of statistical sampling, JA 289-334, and another hearing to discuss the possibility of conducting a “bellwether” trial of some subset of the claims at issue in this case, JA 336-77. On December 14, 2014, the court scheduled a bellwether trial for 95 patients to commence in May 2015. JA 380. On March 16, 2015, the court also issued a short order finding (without any analysis) that “on the facts of this case, statistical sampling would be improper.” JA 422.

2. At the district court’s urging, JA 332-33, the parties also engaged in settlement discussions at various times. The relators, Agape, and the United States participated in a mediation session on November 25, 2014, which was unsuccessful. In January 2015, the relators and Agape participated in at least one additional mediation session before a magistrate judge. As the district court noted, “the Government was not invited and did not participate” in that mediation. JA 472. In the mediation from which the United States was excluded, the relators and Agape reached a tentative settlement agreement. JA 812 (sealed appendix).

Pursuant to 31 U.S.C. § 3730(b)(1), the United States objected to the proposed settlement of the FCA claims primarily because the settlement amount was just a small fraction of the estimated damages sustained as a result of the conduct for which Agape sought a release, and was therefore inadequate. The settlement amount was also insufficient because [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. The settlement also had terms that were contrary to public policy or inconsistent with long-standing DOJ practices. For example, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Agape filed a motion to enforce the settlement over the government's objections, JA 736-804, and the United States filed a response opposing that motion, JA 805-13. In order to protect the confidentiality of settlement negotiations, Agape's motion and the government's response were both filed under seal, and the district

⁴ In an abundance of caution, the parties have filed all materials relating to the proposed settlement in a sealed appendix in this Court. We note, however, that only the specific terms of the settlement may properly be deemed confidential. The broad contours of the settlement proposed and the bases for the government's objections to that settlement are already in the public domain; indeed, the public version of the district court's order denying the defendants' motion to enforce the settlement agreement discusses the government's objections and only redacts the total amount of money the defendants were willing to pay and what percentage that figure is of the \$25 million in damages the government believed it could potentially recover in this case. JA 472. *See also* ECF No. 303 (granting defendants' motion to retroactively redact specific cites to amount of the proposed settlement). Because both the district court and the parties have discussed the proposed settlement and the government's objections in general terms, the only cites we have redacted from the public version of this brief are references to specific terms in the proposed settlement agreement, which can be found in the sealed appendix at JA 813.

court also sealed the hearings it held on those motions. JA 579-641 (5/7/15 hearing); JA 648-735 (6/16/15 hearing).

3. On June 25, 2015, the district court denied Agape's motion to enforce the settlement agreement over the government's objections. JA 468-86. In addition, the court also sua sponte certified its order for immediate appellate review under 28 U.S.C. § 1292(b). JA 485-86.

The court began its analysis by asserting that it was "faced with a unique dilemma: The Government, claiming an unreviewable veto right over the tentative settlement in this case, objects to a settlement in a case to which it is not a party, using as a basis of its objection some form of statistical sampling that this Court has rejected for use at the trial of the case." JA 473. Because this "dilemma" was created, at least in part, by the court's legal rulings on two key issues, the court concluded that it was appropriate to certify those issues for immediate appeal, which could potentially obviate the need for a time-consuming and expensive trial. To facilitate interlocutory appellate review, the court then set forth the rationale for its rulings that (1) the United States has unreviewable veto authority over settlements in declined qui tam suits, and (2) the relators may not use statistical sampling as a method of proving liability or damages in this case. *Ibid.*

a. The court first held that the plain language of 31 U.S.C. § 3730(b)(1) makes the Attorney General's written consent an absolute prerequisite to dismissal of a qui tam action. JA 473-76. The court stressed that "[t]he statute provides no limitation

on the Attorney General's authority, and no right of this Court to review the Attorney General's objection for reasonableness." JA 474. As a result, the court observed, both the Fifth and Sixth Circuits have held that a *qui tam* suit may not be settled without the government's consent. JA 474-75 (citing *United States ex rel. Searcy v. Phillips Elecs. N. Am. Corp.*, 117 F.3d 154 (5th Cir. 1997), and *United States v. Health Possibilities, P.S.C.*, 207 F.3d 335 (6th Cir. 2000)). While recognizing that the Ninth Circuit has taken a contrary view, holding that the government's veto of a settlement in a *qui tam* suit "is subject to a reasonableness review," JA 474 (citing *United States ex rel. Killingsworth v. Northrop Corp.*, 25 F.3d 715 (9th Cir. 1994)), the district court rejected the Ninth Circuit's approach on the ground that it was contrary to the plain language of the statute, JA 476. "Because the statute under consideration is plain on its face and contains no limitation on the Attorney General's authority to object to a settlement in a *qui tam* action," the district court adopted the rationale of the Fifth and Sixth Circuits and denied the motion to enforce the proposed settlement agreement over the government's objections. *Ibid.*

After holding that courts lack authority to review the reasonableness of the United States' decision to withhold consent to a settlement, the district court stated that its "inquiry is at an end." JA 477. Nevertheless, the court did not end its analysis but instead made a variety of observations about the case. Most notably, the court declared that, if it "did have the authority to review an objection by the Attorney

General for reasonableness in a case of this nature, a compelling case could be made here that the Government's position is not reasonable." *Ibid.*

To support its tentative conclusion that the government's refusal to consent to the settlement proposed by Agape and the relators was unreasonable, the court emphasized the high costs and burdens of litigating the many thousands of claims at issue in the case, asserting that the total costs for experts and trial preparation would likely exceed "the Government's assessment of the value of the case." JA 478. The court also criticized the United States for failing to provide what the court deemed to be an adequate explanation for its estimate of \$25 million as the defendants' potential liability, noting that "the Government has declined to provide its calculations." JA 479. The court acknowledged that it had "reluctantly agreed with the Government that it should not be required to respond to AGAPE's motion for a precise calculation of damages" because the United States is not a party for purposes of discovery requests. *Ibid.* However, the court nonetheless criticized the government's basis for objecting to the settlement, stressing that "the Government has admitted that statistical sampling of the entire universe of claims played a major part in its calculation of the value of this case." *Ibid.* Because the court had previously ruled that statistical sampling could not be used to prove damages or liability in this case, the court suggested that the United States could not properly rely upon sampling to estimate the value of the case and therefore had no proper basis for rejecting the

proposed settlement on the ground that it was too low.⁵ The court did not evaluate the reasonableness of any other grounds raised by the United States for objecting to the proposed settlement. *See* JA 805-16 (Opp. to Mot. to Enforce).

b. In addition to opining that the government's objections to the settlement were likely unreasonable, the court also explained the basis for its prior conclusion that statistical sampling could not be employed to establish liability and damages in this case.⁶ JA 479-85. The court acknowledged that statistical sampling is an appropriate method of proof in some cases, but stressed that "this case is not one where the evidence has dissipated, thus rendering direct proof of damages impossible." JA 480. The court then cited various decisions rejecting and approving the use of statistical sampling in various contexts, concluding that "the cases are legion on each side of the issue." JA 484. Without considering any of the specific methods by which the relators might use random sampling to estimate the number of false claims submitted by the defendants and the amount of the damages, the court

⁵ While acknowledging that the United States had not provided its damages calculations (and was not required to do so), the court criticized those estimates without ever seeing them. For example, the court asserted that the "Government arrived at its potential recovery figure by using an 'error rate' in the '20-60% range' derived from an expert review of what the Government refers to as 'cherry picked' claims." JA 473. That is not an accurate description of the methodology the government used to estimate the value of the claims in this case, and it is not clear why the court believed the government used such unsound techniques.

⁶ As noted, the court had previously issued a two-paragraph order holding that the use of statistical sampling was not appropriate, but that order did not offer any explanation or analysis to support that holding. *See* JA 421-22.

held that sampling was not appropriate in this case because “each claim asserted here presents the question of whether certain services furnished to nursing home patients were medically necessary.” JA 484. The court stressed that “[a]nswering that question for each of the patients involved in this action is [a] highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patient.” *Ibid.* Thus, while recognizing that in some cases sampling “is the only way that damages may be proved,” the court held that this is “not such a case.” JA 485.

c. After explaining the rationale for its rulings with respect to the government’s veto authority over settlements and the use of statistical sampling in this case, the district court concluded with a short discussion of the need for interlocutory appellate review to resolve these issues. JA 485-86. Noting a variety of possible outcomes on appeal that could obviate the need for “a trial of monumental proportions, involving a staggering outlay of expenses by the Plaintiff-Relators and a significant drain on the resources of this Court,” the court declared that “[i]t would be much more judicially efficient to have a ruling on both of the questions before, rather than after, such a monumental trial.” JA 485. The court accordingly certified its rulings for interlocutory appeal pursuant to 28 U.S.C. § 1292(b). JA 486.

4. The relators and Agape each filed petitions in this Court for permission to appeal the district court’s interlocutory ruling. As the real party in interest with respect to the government’s power to disapprove settlement of a *qui tam* action, the

United States filed a response to both petitions, arguing that discretionary interlocutory review under 28 U.S.C. § 1292(b) was not warranted. This Court granted the petitions and consolidated these appeals for briefing and argument.

SUMMARY OF ARGUMENT

1. The qui tam provisions of the False Claims Act allow, and encourage, private persons to bring fraud claims on behalf of the United States. The government has a right to intervene and prosecute such claims, but even in cases where the United States declines to exercise that right, it remains a “real party in interest” and retains important substantive and procedural rights to protect its interests. Because the interests of the United States sometimes diverge from those of an individual relator acting as the “partial assignee” of the government’s claims, these rights are vital to the proper operation of the FCA. As numerous courts have recognized, qui tam relators are typically driven by the prospect of hefty financial awards, which may cause them to manipulate settlements to maximize their own recoveries in ways that can be detrimental to the government’s interests. As a result, one of the most important tools Congress provided to ensure that the United States can adequately protect its interests in the FCA’s unique scheme is a broad and unqualified right to veto the voluntary dismissal of a qui tam action pursuant to a settlement between relators and defendants. *See* 31 U.S.C. § 3730(b)(1).

The district court correctly held that the plain language of Section 3730(b)(1) gives the United States veto authority over the dismissal and settlement of all FCA

claims. As the court recognized, that provision is not qualified temporally or limited in any other way. Moreover, unlike many other provisions of the FCA, Section 3730(b)(1) does not require the government to satisfy any particular standard, or make any specific showing reviewable by a court, in order to withhold its consent to the dismissal of its claims. Indeed, that provision does not require the United States to give any reasons at all when withholding its consent to a dismissal. Thus, both the text of Section 3730(b)(1) and the overall structure of the FCA refute any argument that the reasonableness of the Attorney General's refusal to provide "written consent" to a settlement is subject to judicial review.

The weight of authority also supports this construction of the statute. Both the Fifth and Sixth Circuits have directly addressed this issue, and both rejected the lone decision by the Ninth Circuit to the contrary. As the Fifth and Sixth Circuits each explained, the Ninth Circuit erroneously relied on ambiguous legislative history to impose temporal limitations on the veto authority of the United States that are not present in the statute. Since that time, no other court of appeals has adopted the Ninth Circuit's rationale, and numerous courts, including the Supreme Court and this Court, have indicated in various contexts that the government's consent is an absolute prerequisite for the settlement and dismissal of a qui tam action, even when the United States has declined to intervene.

2. If this Court agrees that the United States has unreviewable authority to veto the settlement of claims in declined qui tam actions, it need not reach any of the

other issues raised in this interlocutory appeal. If, in the alternative, this Court concludes that the government's refusal to consent to the settlement and dismissal of its claims is subject to judicial review to determine if it is "reasonable," the Court should hold that the district court erred in suggesting that the government's refusal to consent to the proposed settlement was likely unreasonable. Although the government was not required to explain its reasons for rejecting the settlement proposed by Agape and the relators, it voluntarily provided an explanation for its position. JA 805-16. The district court failed to even address the United States' objections to certain settlement terms, and it compounded that error by discounting the government's primary objection to the settlement: that the amount was insufficient in light of the broad release demanded by Agape.

The district court erred in stating that the government's veto of the settlement was likely unreasonable based upon its belief (and prior ruling) that statistical sampling could not be used to prove liability and damages in this case. There was no basis for the court to question the analysis the government used to evaluate the worth of the claims in this case because the court never even examined the government's estimates. More importantly, there was no basis for the court to categorically reject the use of statistical sampling as a method to prove liability and damages in this case, much less to reject it as a method by which the government could roughly gauge the settlement value of this case. As explained in Section II, *infra*, statistically-valid random sampling is a well-accepted method of establishing liability and damages in a

variety of contexts. Properly-validated statistical sampling is an especially effective and indispensable tool in False Claims Act cases where the scope of the defendant's fraud makes claim-by-claim review impracticable. To hold otherwise would have the perverse effect of allowing the perpetrators of the largest fraudulent schemes to escape liability precisely because their fraud was effectively too big to prosecute.

STANDARD OF REVIEW

The proper interpretation of the FCA is a question of law subject to de novo review in this Court. *See Ignacio v. United States*, 674 F.3d 252, 254 (4th Cir. 2012).

ARGUMENT

I. THE CONSENT OF THE UNITED STATES IS A PREREQUISITE FOR THE SETTLEMENT AND VOLUNTARY DISMISSAL OF CLAIMS IN DECLINED QUI TAM SUITS.

The False Claims Act authorizes a private person to bring an action “in the name of the Government” to seek civil remedies for fraud against the United States. 31 U.S.C. § 3730(b)(1). In pursuing such claims, qui tam relators seek to redress wrongs done to the United States, not to the relators themselves. *Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 773 n.4 (2000) (explaining that a relator acts “as a partial assignee of the United States”). Given the divergent interests that may arise between a qui tam relator and the United States, the FCA places certain conditions and restrictions on relators in litigating and settling the government's claims, and confers various procedural and substantive rights on the United States,

which ensure that the government can fully protect its interests even in cases where it declines to intervene.

For example, the United States may intervene in a declined qui tam suit upon a showing of “good cause,” 31 U.S.C. § 3730(c)(3), it may seek to stay discovery that would interfere with its investigation or prosecution of criminal or civil matters arising out of the same facts, *id.* § 3730(c)(4), it may unilaterally dismiss a qui tam suit over the relator’s objections, *id.* § 3730(c)(2)(A), and it may settle an action over the relator’s objections if a court determines that the settlement is “fair, adequate, and reasonable,” *id.* § 3730(c)(2)(B). As relevant here, the United States also has the right to veto the voluntary dismissal of a qui tam action: such an “action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.” 31 U.S.C. § 3730(b)(1).

A. The FCA Expressly And Unequivocally Conditions The Voluntary Dismissal Of A Qui Tam Action Upon The Written Consent Of The Attorney General.

1. The text of 31 U.S.C. § 3730(b)(1) makes the consent of the Attorney General an express prerequisite to the voluntary dismissal of a qui tam action pursuant to a settlement between the relator and the defendant. As the district court recognized, “[t]he statute provides no limitation on the Attorney General’s authority, and no right of this Court to review the Attorney’s General’s objection for reasonableness.” JA 474. The court thus correctly held that the FCA’s unambiguous language gives the United States authority to veto a proposed settlement, even in cases

where it has not intervened, and rejected the argument that courts may review the government's exercise of that authority to determine if it is reasonable.

The district court properly declined to read exceptions into the plain language of Section 3730(b)(1). On its face, that provision does not limit the consent requirement to cases in which the United States has intervened under 31 U.S.C. § 3730(b)(2). Rather, the "action" referenced in that provision is *any* action brought under the statute by a private party, without regard to whether the action is prosecuted by the relators or taken over by the government. Nor does that provision give the court authority to pass upon the reasonableness of the government's objections. Indeed, Section 3730(b)(1) does not merely give the United States a right to "object" to voluntary dismissal; it makes the "written consent" of the Attorney General an absolute prerequisite to dismissal. The breadth of this provision contrasts markedly with more qualified language in other provisions of the FCA, which confirm that Congress could have limited the consent requirement in various ways and could have required the government to demonstrate "good cause" or the "reasonableness" of its objections, but elected not to do so.

For example, 31 U.S.C. § 3730(c)(2)(B) gives relators a right to object to (but not veto) settlements agreed to by the United States and a defendant. Unlike Section 3730(b)(1), which states that an action may only be dismissed if the Attorney General gives "written consent," Section 3730(c)(2)(B) states that the government may settle an action "notwithstanding the objections of the person initiating the action [*i.e.*, the

relator] if the court determines, after a hearing, that the proposed settlement is fair, adequate, and reasonable under all the circumstances.” That provision thus makes clear both (1) that a relator may only object to (not veto) a settlement by the United States, and (2) that a court may review the relator’s objections to determine if the settlement is “fair, adequate, and reasonable.” The absence of comparable language in Section 3730(b)(1) is strong textual evidence that courts may not review the reasonableness of a decision by the United States to withhold consent to a settlement agreement. “[W]hen Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.” *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 452 (2002).⁷

The structure of Section 3730(b)(1) confirms this conclusion. Had Congress intended to require the United States to provide reasons for refusing to consent to a settlement – which a court could review for reasonableness – it would have said so in

⁷ Numerous other provisions of the FCA likewise permit certain actions only upon specified showings subject to review by a court. For example, the United States may limit the participation of a relator in a qui tam suit upon a showing that litigation by that person “would interfere with or unduly delay the Government’s prosecution of the case,” 31 U.S.C. § 3730(c)(2)(C), the government may intervene in a qui tam suit after the initial period for intervention has expired upon a showing of “good cause,” *id.* § 3730(c)(3), and the government may seek to stay discovery upon a showing that it would interfere with its investigation or prosecution of criminal or civil matters arising out of the same facts, *id.* § 3730(c)(4). The presence of express language requiring judicial approval for certain actions in these provisions underscores the telling absence of comparable language in Section 3730(b)(1).

Section 3730(b)(1). But that provision only requires the government to provide reasons when it *consents* to settlement, not when it withholds its consent. *See* 31 U.S.C. § 3730(b)(1) (stating that an action may be dismissed only where the Attorney General gives “reasons for consenting”). The statutory structure thus strongly indicates that the government’s decision to veto a settlement is unreviewable because the United States has no duty to provide reasons for its decision not to consent to a settlement.

The nature of the action – a discretionary judgment that a proposed settlement does not adequately advance the government’s interests, taking into account litigation risks and myriad other factors – likewise supports this construction of the statute. While courts sometimes assess whether settlements are “fair and reasonable” in certain contexts, they have no authority to judge exercises of prosecutorial discretion, *see United States v. Armstrong*, 517 U.S. 456, 464 (1996), decisions to settle cases, *see Baltimore Gas & Elec. Co. v. FERC*, 252 F.3d 456, 461-62 (D.C. Cir. 2001), or decisions not to take enforcement action, *see Heckler v. Chaney*, 470 U.S. 821 (1985); *Speed Mining, Inc. v. Federal Mine Health and Safety Review Comm’n*, 528 F.3d 310, 317-19 (4th Cir. 2008) (finding Secretary’s decision not to issue citation to crane operator was unreviewable). It would thus be highly anomalous for a court to determine that it was not “reasonable” for the Attorney General to withhold the “written consent” that is a prerequisite under Section 3730(b)(1) to the dismissal of the government’s claims.

Finally, the government’s right to veto a proposed settlement of FCA claims negotiated by a relator and a defendant is vital to the proper operation of the statute.

The qui tam provision of the FCA reflects Congress's recognition that the government lacks the resources to uncover, investigate, and pursue every instance of fraud against the United States and thus gives private relators a financial incentive to supplement the government's enforcement efforts. *See United States ex rel. Milam v. Univ. of Texas*, 961 F.2d 46, 49 (4th Cir. 1992). But the powerful financial incentives in qui tam cases may lead some relators to try to broker settlements that benefit them individually at the expense of the government's interests. For example, a relator may attempt to boost the settlement value of his qui tam suit by bargaining away claims on behalf of the United States for which he is not receiving fair value or which he has no authority to release. As a result, it is essential for the United States to have broad authority to veto "sweetheart" settlements that result in dismissals advantageous to the relators and the defendants but detrimental to the government's interests.

2. In light of the foregoing textual and practical considerations supporting the view that Section 3730(b)(1) gives the United States veto authority over settlements in qui tam cases, several judicial decisions also support this construction of the statute. Two of the three courts of appeals that have directly addressed this issue have held that the United States has an unreviewable right to withhold consent to the settlement of a qui tam action, and numerous other courts (including this Court and the Supreme Court) have indicated that they agree with this reading of the statute.

In *United States ex rel. Searcy v. Philips Electronics North America Corp.*, 117 F.3d 154 (5th Cir. 1997), for example, the Fifth Circuit declared that the statutory provision

supporting the government's right to veto a settlement is "as unambiguous as one can expect." *Id.* at 159. Moreover, in analysis directly applicable here, the court reasoned that restrictions on the government's veto power would enable relators to enrich themselves at the government's expense by trading away the government's right to bring future claims in order to secure a favorable settlement of the claims it has chosen to press in the litigation. *Id.* at 160.

The Sixth Circuit reached the same result in *United States v. Health Possibilities, P.S.C.*, 207 F.3d 335 (6th Cir. 2000). Explaining that the plain language of Section 3730(b)(1) clearly vests the government with a right to veto a relator's settlement, without regard to whether the government has intervened, *id.* at 338-39, the court stressed that "the power to veto a privately negotiated settlement of public claims is a critical aspect of the government's ability to protect the public interest in qui tam litigation." *Id.* at 340.

Only the Ninth Circuit has taken a contrary view. In *United States ex rel. Killingsworth v. Northrop Corp.*, 25 F.3d 715 (9th Cir. 1994), a decision issued several years before the Fifth and Sixth Circuit's decisions, the Ninth Circuit held that allowing the government to veto a settlement after it has decided not to intervene in a qui tam suit would be inconsistent with Congress's intent to vest relators with full responsibility for litigating such cases. Thus, while acknowledging that Section 3730(b)(1) provides veto authority before the government has made an election decision, *id.* at 722, the Ninth Circuit concluded that the government's objections to a

settlement after it has declined to intervene may be sustained only if the court finds the government has “good cause” for its objections, *id.* at 724.

As the district court noted, “*Killingsworth* has not fared well in the intervening years.” JA 475 (quoting *United States ex rel. Landis v. Tailwind Sports Corp.*, 98 F. Supp. 3d 8, 11 (D.D.C. 2015)). The temporal limitation the Ninth Circuit imposed on the government’s veto authority cannot be reconciled with the plain language of the statute, and the Fifth Circuit thus found the Ninth Circuit’s reasoning “unpersuasive.” *Searcy*, 117 F.3d at 159. Moreover, the Ninth Circuit erred in relying on legislative history accompanying the 1986 amendments to the FCA to override the plain language of the statute. *See Killingsworth*, 25 F.3d at 722 (finding that legislative history indicated that Congress intended “to place full responsibility for False Claims Act litigation on private parties,” and asserting that an absolute veto right was inconsistent with this goal). As the Sixth Circuit summarized, nothing in the legislative history cited by the *Killingsworth* court indicates that Congress intended to limit the consent required under Section 3730(b)(1) to the period in which the United States might intervene and take over the action, and “[w]ithout such a clearly expressed purpose, we cannot amend the plain language of a statute.” *Health Possibilities*, 207 F.3d at 335.

In the more than twenty years since *Killingsworth* was decided, it has not been followed by any other court of appeals. On the contrary, the Supreme Court, this Court, and other courts of appeals have (at least implicitly) rejected the analysis in *Killingsworth* and endorsed the majority view that the government’s consent is a

prerequisite for the settlement and dismissal of a qui tam action, even when the government has declined to intervene.

Most notably, the Supreme Court has stated that, even if the United States declines to intervene in a qui tam suit, its rights in the proceeding still include “vetoing a relator’s decision to voluntarily dismiss the action.” *United States ex rel. Eisenstein*, 556 U.S. at 932. This description of the government’s authority as a “veto” right suggests unfettered discretion to block a settlement, not a more qualified right simply to object.

This Court has likewise described the consent requirement in Section 3730(b)(1) in broad and unqualified terms. For example, in *United States ex rel. UBL v. IIF Data Solutions*, 650 F.3d 445 (4th Cir. 2011), this Court observed that the FCA “provides that the government must consent to a dismissal of an FCA claim brought by a private party,” *id.* at 449, a statement incompatible with the temporal limitation the Ninth Circuit read into the statute. Similarly, in *United States ex rel. Radcliffe v. Purdue Pharma, L.P.*, 600 F.3d 319 (4th Cir. 2010), this Court stated that “[t]he FCA clearly provides that once a *qui tam* action is filed, the relator and the defendant may not settle (or at least may not voluntarily dismiss) the action.” *Id.* at 326. Other courts have made similar observations. *See, e.g., Hoyte v. American Nat’l Red Cross*, 518 F.3d 61, 63 n.2 (D.C. Cir. 2008) (“a motion to dismiss by the relator requires the consent of both the Government and the court, even where the Government has declined to intervene”); *Ridenour v. Kaiser-Hill Co., LLC*, 397 F.3d 931 n.8 (10th Cir. 2005)(same); *Taiwind Sports*, 98 F. Supp. 3d at 11.

B. The Parties' Arguments That Courts Have Authority To Determine Whether The Government's Decision To Withhold Consent To A Settlement Is Reasonable Lack Merit.

Agape and the relators acknowledge that 31 U.S.C. § 3730(b)(1) gives the United States a broad right to reject settlements even in declined qui tam actions. *See* Agape Br. 16; Relator Br. 18-19. Indeed, the relators appear to recognize that this veto right is absolute and unreviewable in a “typical” FCA case where the government has declined to intervene. Nevertheless, the relators contend that “under the unique circumstances of this case, the Government should not be permitted to block the parties’ settlement.” Relator Br. 19. That argument lacks merit. Nothing in the text, structure, or purpose of the FCA suggests that the government forfeits its veto authority by “actively participating” in a declined qui tam suit. On the contrary, Section 3730(b)(1) unequivocally conditions the settlement and dismissal of claims in any action upon the government’s consent. It makes no difference whether the government “has interposed itself” into the case without becoming a party; the statute does not limit the government’s veto authority to cases where the United States has not actively asserted an interest in the claims. If anything, the government’s active involvement in this case underscores the critical role Section 3730(b)(1) plays in ensuring that the United States can prevent relators from improperly maximizing their private interests in a settlement at the expense of the public interest.

Agape advances broader legal arguments than the relators. While conceding that the United States has a statutory right to withhold consent to the voluntary

settlement and dismissal of claims in a declined qui tam action, Agape contends that courts may determine whether the government's objections are "reasonable" and overrule them if the court believes they are not. *See* Agape Br. 16 (arguing that government is limited to "reasonable" objections). That argument fails at every turn.

As an initial matter, there is no basis in the text or structure of the FCA to impose a requirement that the government's refusal to consent to the dismissal of its own claims must be "reasonable." On the contrary, as explained above, Section 3730(b)(1) broadly authorizes the Attorney General to withhold consent to a settlement without providing *any* reasons. Moreover, unlike other provisions in the statute, which expressly authorize courts to assess whether a settlement is "fair, adequate, and reasonable," *see* 31 U.S.C. § 3730(c)(2)(B), Section 3730(b)(1) contains no comparable language. Under well-settled principles of statutory construction, the absence of such language is compelling evidence that Congress did not intend for courts to determine whether the government's decision to withhold consent to a settlement is reasonable. *See Barnhart*, 534 U.S. at 452 (omission of language included in another part of the same statute raises inference that omission was intentional).

Agape largely ignores the broad language of Section 3730(b)(1), which forms the basis for the Fifth and Sixth Circuits' decisions holding that the government has unreviewable veto authority in declined qui tam actions. As Agape notes, the Ninth Circuit held in *Killingsworth* that the government's authority to veto settlements in declined qui tam actions is limited and subject to review for "good cause." But

Agape's reliance on *Minotti v. Lensink*, 895 F.2d 100 (2d Cir. 1990) is misplaced. As explained below, that decision supports the distinction recognized by the Fifth and Sixth Circuits between voluntary and involuntary dismissals and thereby confirms the government's broad authority to veto voluntary dismissals.

In *Minotti*, the Second Circuit considered, and rejected, a qui tam relator's attempt to use the consent requirement in Section 3730(b)(1) as a shield to preclude the *involuntary* dismissal of his qui tam suit for failure to comply with discovery orders. In response to the relator's argument that the district court could not dismiss his claims without first obtaining the consent of the Attorney General, the Second Circuit held that the consent requirement "applies only in cases where a plaintiff seeks voluntary dismissal of a claim or action brought under the False Claims Act, and not where the court orders dismissal." 859 F.2d at 103. The court found support for this conclusion both in prior versions of the FCA providing that a claim shall not be "withdrawn or discontinued" without the consent of the United States, *id.* (citing 31 U.S.C. § 232(b)(1976)), and also in the language of Section 3730(b)(1) itself. The court stressed that, if that provision were construed "to apply even to court-ordered dismissals, its language requiring permission of the court, as well as of the Attorney General, before dismissal of a private action would make little sense." *Id.* at 104 n.1.

Minotti refutes Agape's contention that "the plain language of the statute would require the district court to obtain the Government's consent before dismissing a qui tam action for failure to state a claim." Agape Br. 23. Characterizing that result as

“obviously untenable,” because it “would violate the separation of powers,” Agape asserts that it is therefore “clear . . . that the text of § 3730(b)(1) is not alone sufficient to resolve the issue presented by this appeal.” *Ibid.* These arguments again rest on the faulty premise that the text of Section 3730(b)(1) requires the government’s consent to *any* form of dismissal on the merits, not merely a voluntary dismissal. As the Second Circuit explained in *Minotti*, the language in that provision, requiring both the Attorney General *and* the court to consent to dismissal, makes clear that this provision applies only to voluntary dismissals, *Minotti*, 895 F.2d at 104 n.1, and prior versions of this provision confirm this view. *See also Health Possibilities*, 207 F.3d at 341 (citing *Minotti* and holding that consent requirement does not apply to involuntary dismissals).

Agape’s other attempts to minimize or override the plain language of Section 3730(b)(1) are similarly unavailing. For example, Agape stresses that 31 U.S.C. § 3740(b)(4)(B), gives the relator the “right to conduct the action” – a right Agape contends would be “meaningless” if it did not include the right to settle the case. Agape Br. 23-24. That argument is hyperbolic; the right of a relator to conduct a qui tam action on behalf of the United States is quite meaningful even though the United States has ultimate veto authority over settlements. Successful litigation by relators in declined qui tam cases underscores this point.

Moreover, the “right to conduct the action” must be interpreted in harmony with other provisions of the statute, including the more specific requirement that an

action may be dismissed only with written consent of the Attorney General. As both the Fifth and Sixth Circuits recognized in rejecting the same argument, “[n]othing in the statute suggests that the right to ‘conduct’ an action provides the relator with unilateral and ultimate settling authority.” *Health Possibilities*, 207 F.3d at 344. *See also Searcy*, 117 F.3d at 160 (noting that “[a] relator has ‘conducted’ an action if he devises strategy, executes discovery, and argues the case in court, even if the government frustrates his settlement efforts”). In short, the general “right to conduct the action” cannot override the more specific requirement that an action may not be dismissed without the consent of the United States.

Agape’s contention that “[a]bsolute and unreviewable veto authority is also incompatible with § 3730(d)(2),” Agape Br. 24, is similarly flawed. That provision states that “the person bringing the action or settling the claim shall receive an amount which the court determines is reasonable for collecting the civil penalty and damages.” 31 U.S.C. § 3730(d)(2). As the Fifth Circuit explained, however, “the government’s power to block settlements does not mean that the relator will never be the person settling the claim.” *Searcy*, 117 F.3d at 160. Section 3730(d)(2) therefore cannot reasonably be understood to confer an unfettered right to settle on relators, particularly given the more specific consent requirement in Section 3730(b)(1).

In the end, Agape is reduced to making policy arguments for the imposition of an extra-textual “reasonableness” limitation on the government’s authority to withhold consent to the settlement and voluntary dismissal of qui tam claims. *See*

Agape Br. 25-27. While recognizing that the consent requirement is premised on legitimate concerns about relators and defendants negotiating settlements that are detrimental to the interests of the United States, Agape insists that these concerns can adequately be addressed “without giving the Government unlimited veto authority.” *Id.* at 25. But that is a matter for Congress to decide. As explained above, the plain language of the statute Congress enacted does not require the United States to provide any reasons at all for withholding its consent to the settlement of qui tam claims, much less to justify its actions under “good cause” or “reasonableness” standards which appear in other provisions of the statute.

II. THE DISTRICT COURT ERRED IN SUGGESTING THAT THE GOVERNMENT’S REFUSAL TO CONSENT TO THE SETTLEMENT WAS LIKELY UNREASONABLE.

If this Court concludes that the United States has unreviewable authority to withhold consent to the settlement and dismissal of qui tam claims brought on its behalf, the Court need not reach any of the other issues raised in this case. But if this Court were to conclude that courts may assess whether the United States has acted reasonably in withholding consent to the settlement of claims in qui tam suits, the Court should then hold that the district court erred in finding that the government’s veto of the settlement negotiated by Agape and the relators was likely unreasonable.

The district court fundamentally erred in pre-judging the reasonableness of the government’s refusal to consent to the settlement in this case. As an initial matter, the district court should never have reached this issue – a point it appeared to recognize

in stating that its “inquiry is at an end,” JA 477, after holding that the government’s veto authority over qui tam settlements is absolute and unreviewable. As explained above, the text of Section 3730(b)(1) only requires the Attorney General to provide reasons when it consents to a settlement, not when it withholds consent. In opposing Agape’s motion to enforce the settlement, however, the United States went beyond the minimum requirements of the statute and provided a detailed explanation as to why the proposed agreement was unacceptable. *See* JA 805-16. The district court recognized that it lacked the authority to pass judgment on the reasonableness of those objections, while nevertheless suggesting that the government’s position was not reasonable. If this Court reaches this issue, it should hold that the government’s objections were reasonable and direct the district court to reject the settlement.

As explained in the government’s opposition to Agape’s motion to enforce the settlement, JA 805-16, the United States opposed the settlement negotiated by Agape and the relators not merely because it believed the amount was insufficient – the sole issue the district court addressed– but also because the proposed agreement

[REDACTED]

[REDACTED]

[REDACTED]

8 [REDACTED]

Continued on next page.

The United States also refused to consent to the proposed settlement because it purported to [REDACTED]

[REDACTED]

[REDACTED] There is nothing unreasonable about such objections. As the Ninth Circuit recognized in *Killingsworth*, it is perfectly appropriate for the United States to raise questions as to “whether the total proceeds of the settlement have been fairly allocated so as to give the government its due.” *Killingsworth*, 25 F.3d at 725. That is especially true where (as here) the defendant seeks a very broad release of liability in exchange for a small settlement amount.⁹

[REDACTED]

[REDACTED]

[REDACTED]

More fundamentally, the district court erred in suggesting that the government's refusal to consent to the settlement negotiated by the relators and Agape was unreasonable based upon speculation that the government must have used statistical sampling to estimate the value of the claims in this case. *See* JA 479 (asserting that "the Government has admitted that statistical sampling of the entire universe of claims played a major part in its calculation of the value of this case").

As an initial matter, there was no basis for the court to question the methodology the government used to evaluate the worth of this case. The court itself agreed that the United States was not required to provide "a precise calculation of damages" because it was not a party for purposes of discovery. JA 479. Having made that evidentiary ruling, the court could not then reject the government's rationale based solely upon speculation that the government must have relied on some form of flawed statistical sampling. *See* JA 473 (asserting that the government calculated an "error rate" by using "cherry picked" claims).

In addition, there was no basis for the court to categorically reject the use of statistical sampling as an appropriate method to roughly gauge the value of the claims in this case for the purpose of evaluating the sufficiency of the settlement amount in relation to the scope of the release sought by the defendant. Although the court had previously held that the relators could not rely upon statistical sampling to prove liability or damages in this case, JA 422, that interlocutory evidentiary ruling could not preclude the United States from relying on some form of sampling to estimate the

value of the claims in this case for purposes of evaluating the settlement. In any event, the court's stated rationale for rejecting the use of statistical sampling in this case does not withstand even passing scrutiny.

The district court acknowledged that numerous courts have approved the use of statistical sampling to prove damages and liability in FCA cases and other contexts. JA 482-84 (citing cases). Nevertheless, the court appeared to believe that sampling was only appropriate in cases "where the evidence has dissipated, thus rendering direct proof of damages impossible." JA 480. Because "nothing has been destroyed or dissipated in this case," JA 481, the court suggested that statistical sampling could not be used in this case. The district court also found that sampling was inappropriate in this case because each claim "presents the question of whether certain services furnished to nursing home patients were medically necessary," which the court stated would require a "highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patient." JA 484.

The reasons the district court gave for rejecting the use of statistical sampling in this case reflect a fundamental misunderstanding of the nature, purpose, and utility of that evidentiary tool. Sampling is a common, mathematically-proven technique by which estimates of a characteristic of a population can be made based on a sample of that population. *See Michigan Dep't of Educ. v. U.S. Dep't of Educ.*, 875 F.2d 1196, 1205 (6th Cir. 1989). As numerous courts have recognized, "the purpose of using a sample is to extrapolate results from a small sample to a large population." *In re Countrywide*

Fin. Corp. Mortgage-Backed Sec. Litig., 984 F. Supp. 2d 1021, 1038 (C.D. Cal. 2013). So long as scientifically-accepted methods are used to design and execute a sampling plan, statistical sampling provides a reliable mechanism to “confidently draw inferences about the whole from a representative sample of the whole.” *In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1019-20 (5th Cir. 1997).

Statistical sampling is vital to ensuring that defendants can be held accountable for the entirety of their fraudulent conduct, as an intensive claim-by-claim review of thousands of claims is effectively impossible in many cases. As a result, courts have approved the use of statistical sampling in numerous False Claims Act cases. *See, e.g., United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008) (rejecting argument that district court had to address each of the 1,812 claims forms on the ground that “[s]tatistical analysis should suffice”); *United States ex rel. Loughren v. UnumProvident Corp.*, 604 F. Supp. 2d 259, 261 (D. Mass. 2009) (holding that “extrapolation is a reasonable method for determining the number of false claims so long as the statistical methodology is appropriate”); *United States v. Cabrera-Diaz*, 106 F. Supp. 2d 234 (D.P.R. 2000) (holding that extrapolation from 461 sampled claims could be used to prove elements of FCA liability in case involving fraudulent Medicare claims). These and other courts have uniformly recognized that properly-validated sampling is a reliable and necessary tool for the effective prosecution of fraud claims involving large numbers of individual claims.

The district court's recent decision approving the use of statistical sampling in *United States ex rel. Martin v. Life Care*, 114 F. Supp. 3d 549 (E.D. Tenn. 2014), illustrates just how indispensable sampling has become to the government's efforts to combat increasingly widespread and systemic health care fraud. As in this case, *Life Care* involved claims that a provider of nursing home services submitted tens of thousands (if not more) false claims to Medicare for "unreasonable and unnecessary" services, and the government sought to use statistical sampling to prove both liability and damages. *Id.* at 553-55 (reciting allegations in complaint). In a comprehensive opinion, the district court examined the basic principles of statistical sampling, *id.* at 559-60, and the many cases permitting the use of sampling in a variety of contexts, *id.* at 562-65, and concluded that sampling could properly be used to prove all the elements of FCA liability in that case, *id.* at 565-70.

The *Life Care* court observed that "the purpose of statistical sampling is precisely for these types of instances in which the number of claims makes it impracticable to identify and review each claim and statement," *id.* at 565, and stressed that requiring "claim-by-claim review" in all FCA cases would have the pernicious effect of immunizing the largest perpetrators of fraud, *id.* at 571. "Armed with the knowledge that the government could not possibly pursue each individual false claim," the court summarized, "large-scale perpetrators of fraud would reap the benefits of such a system." *Ibid.* Because the court concluded that such a result would not be "consistent with the purpose and history of the FCA," the court held

that statistical sampling could be used to prove both liability and damages under the FCA, while noting that the defendant would remain free to advance arguments “regarding the inherent limitations associated with statistical sampling” to limit the weight that a “fact finder may accord to the extrapolated evidence.” *Id.* at 571-72.¹⁰

The primary reason the district court gave for holding that statistical sampling could not be used in this case was that each claim Agape submitted for hospice care services is “unique” and must be evaluated individually. JA 484 (stating that each claim “presents the question of whether certain services furnished to nursing home patients services were medically necessary”). That argument is not only flawed, but actually dismisses the entire field of inferential statistics, because the whole purpose of sampling is to extrapolate from a sample to a larger but non-identical universe.

Statistical sampling is well-accepted and commonly employed in health care fraud cases. For example, in *United States v. Conner*, 262 F. App’x 515 (4th Cir. 2008), this Court recognized that extrapolation from a sample of Medicare and Medicaid claims “is an acceptable method to use in making a reasonable estimate of the amount of loss under the sentencing guidelines.” *Id.* at 519. Likewise, a district court in this Circuit recently observed that “[c]ourts have routinely endorsed sampling and

¹⁰ The district court in *Life Care* also specifically held “that the use of statistical sampling and extrapolation in this action does not violate Defendant’s due process rights.” *Id.* at 570. That analysis applies equally to Agape’s argument that the use of sampling “would deprive them of their constitutional right to a jury trial,” which the district court simply noted without comment in its opinion. JA 485 n.4.

extrapolation as a viable method of proving damages in cases involving Medicare and Medicaid overpayments where a claim-by-claim review is not practical.” *United States v. Fadul*, No. 11-0385, 2013 WL 781614, at *14 (D. Md. Feb. 28, 2013). The district court’s view that statistical sampling cannot be used where each claim or file is unique, JA 484, cannot be squared with these and other decisions approving the use of sampling in precisely these circumstances. *See also Assured Guar. Mun. Corp. v. Flagstar Bank, FSB*, 920 F. Supp. 2d 475, 512 (S.D.N.Y. 2013) (allowing sampling in case where each loan file was potentially unique); *Countrywide*, 984 F. Supp. 2d at 1032 (allowing sampling where the process of underwriting mortgages requires individual judgment applied to unique loan files).¹¹

The district court’s categorical rejection of statistical sampling in this case cannot be reconciled with *Life Care* or any of the other decisions approving the use of statistical sampling in FCA cases and other contexts. As these cases make clear, sampling is a reliable and necessary tool that courts routinely use where (as here) the scope of the fraud alleged makes it impracticable to identify and review each

¹¹ The use of statistical sampling has likewise been upheld in a variety of other settings. *See, e.g., United States v. Ukwu*, 546 F. App’x 305 (4th Cir. 2013) (upholding sampling in a criminal tax fraud case in which each fraudulent tax return the defendant filed was arguably different); *United States v. Jones*, 641 F.3d 706 (6th Cir. 2011) (upholding the use of sampling to calculate loss in a criminal health care fraud case); *United States v. Maceo*, 873 F.2d 1 (1st Cir. 1989) (upholding use of sampling in criminal trial); *Republic Servs., Inc. v. Liberty Mut. Ins. Co.*, No. 03-494, 2006 WL 2844122 (E.D. Ky. Oct. 2, 2006) (upholding use of statistical extrapolation to determine whether thousands of workers’ compensation claims were properly handled).

potentially false claim. The district court fundamentally erred in ruling out the application of that critical tool in this case based upon its erroneous belief that sampling was not appropriate in cases involving “unique” claims or cases where the evidence was not “dissipated” in some way. The entire premise of sampling is that reliable conclusions may be drawn from a properly-selected subset of a larger universe, and the district court erred in rejecting this basic premise. At a minimum, the court erred in finding that the government’s veto of the settlement was likely unreasonable based upon its rejection of sampling. On remand, the district court may, of course, review any sampling methodology proposed in this case to ensure that it passes muster under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), but the court’s wholesale rejection of the entire field of inferential statistics was both unnecessary and erroneous.

CONCLUSION

For the foregoing reasons, the district court's interlocutory decision holding that the United States has an absolute and unreviewable right to veto the settlement of FCA claims in declined qui tam suits should be affirmed. If the Court agrees, it need not reach any other questions presented in this interlocutory appeal. If the Court disagrees, however, it should hold that the district court erred in suggesting that the government's objections to the settlement were likely unreasonable.

Respectfully submitted,

WILLIAM N. NETTLES
United States Attorney

BENJAMIN C. MIZER
*Principal Deputy Assistant
Attorney General*

ELIZABETH C. WARREN
Assistant United States Attorney

MICHAEL S. RAAB
/s/ Charles W. Scarborough
CHARLES W. SCARBOROUGH
Attorneys, Appellate Staff
Civil Division, Room 7244
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530
(202) 514-1927

MARCH 2016

**CERTIFICATE OF COMPLIANCE
WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(A)**

I hereby certify that this brief complies with the requirements of Fed. R. App. P. 32(a)(5) and (6) because it has been prepared in 14-point Garamond, a proportionally spaced typeface.

I further certify that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 11,521 words, excluding the parts of the brief exempted under Rule 32(a)(7)(B)(iii), according to the count of Microsoft Word.

s/ Charles W. Scarborough
CHARLES W. SCARBOROUGH
Counsel for the United States

CERTIFICATE OF SERVICE

I hereby certify that on March 17, 2016, I electronically filed the foregoing public brief with the Clerk of Court for the United States Court of Appeals for the Fourth Circuit by using the appellate CM/ECF system.

The participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

s/ Charles W. Scarborough
CHARLES W. SCARBOROUGH
Counsel for the United States

ADDENDUM

31 U.S.C. § 3730(a) – (d)

§ 3730. Civil actions for false claims

(a) Responsibilities of the Attorney General.--The Attorney General diligently shall investigate a violation under section 3729. If the Attorney General finds that a person has violated or is violating section 3729, the Attorney General may bring a civil action under this section against the person.

(b) Actions by private persons.--

(1) A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

(2) A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure. The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

(3) The Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal under paragraph (2). Any such motions may be supported by affidavits or other submissions in camera. The defendant shall not be required to respond to any complaint filed under this section until 20 days after the complaint is unsealed and served upon the defendant pursuant to Rule 4 of the Federal Rules of Civil Procedure.

(4) Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall--

(A) proceed with the action, in which case the action shall be conducted by the Government; or

(B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.

(5) When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.

(c) Rights of the parties to qui tam actions.—

(1) If the Government proceeds with the action, it shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action. Such person shall have the right to continue as a party to the action, subject to the limitations set forth in paragraph (2).

(2) (A) The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.

(B) The Government may settle the action with the defendant notwithstanding the objections of the person initiating the action if the court determines, after a hearing, that the proposed settlement is fair, adequate, and reasonable under all the circumstances. Upon a showing of good cause, such hearing may be held in camera.

(C) Upon a showing by the Government that unrestricted participation during the course of the litigation by the person initiating the action would interfere with or unduly delay the Government's prosecution of the case, or would be repetitious, irrelevant, or for purposes of harassment, the court may, in its discretion, impose limitations on the person's participation, such as--

(i) limiting the number of witnesses the person may call;

(ii) limiting the length of the testimony of such witnesses;

(iii) limiting the person's cross-examination of witnesses; or

(iv) otherwise limiting the participation by the person in the litigation.

(D) Upon a showing by the defendant that unrestricted participation during the course of the litigation by the person initiating the action would be for purposes of harassment or would cause the defendant undue burden or unnecessary expense, the court may limit the participation by the person in the litigation.

(3) If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action. If the Government so requests, it shall be served with copies of all pleadings filed in the action and shall be supplied with copies of all deposition transcripts (at the Government's expense). When a person proceeds with the action, the court, without limiting the status and rights of the person initiating the action, may nevertheless permit the Government to intervene at a later date upon a showing of good cause.

(4) Whether or not the Government proceeds with the action, upon a showing by the Government that certain actions of discovery by the person initiating the action would interfere with the Government's investigation or prosecution of a criminal or civil matter arising out of the same facts, the court may stay such discovery for a period of not more than 60 days. Such a showing shall be conducted in camera. The court may extend the 60-day period upon a further showing in camera that the Government has pursued the criminal or civil investigation or proceedings with reasonable diligence and any proposed discovery in the civil action will interfere with the ongoing criminal or civil investigation or proceedings.

(5) Notwithstanding subsection (b), the Government may elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty. If any such alternate remedy is pursued in another proceeding, the person initiating the action shall have the same rights in such proceeding as such person would have had if the action had continued under this section. Any finding of fact or conclusion of law made in such other proceeding that has become final shall be conclusive on all parties

to an action under this section. For purposes of the preceding sentence, a finding or conclusion is final if it has been finally determined on appeal to the appropriate court of the United States, if all time for filing such an appeal with respect to the finding or conclusion has expired, or if the finding or conclusion is not subject to judicial review.

(d) Award to qui tam plaintiff.—

(1) If the Government proceeds with an action brought by a person under subsection (b), such person shall, subject to the second sentence of this paragraph, receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action. Where the action is one which the court finds to be based primarily on disclosures of specific information (other than information provided by the person bringing the action) relating to allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, the court may award such sums as it considers appropriate, but in no case more than 10 percent of the proceeds, taking into account the significance of the information and the role of the person bringing the action in advancing the case to litigation. Any payment to a person under the first or second sentence of this paragraph shall be made from the proceeds. Any such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(2) If the Government does not proceed with an action under this section, the person bringing the action or settling the claim shall receive an amount which the court decides is reasonable for collecting the civil penalty and damages. The amount shall be not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement and shall be paid out of such proceeds. Such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(3) Whether or not the Government proceeds with the action, if the court finds that the action was brought by a person who planned and

initiated the violation of section 3729 upon which the action was brought, then the court may, to the extent the court considers appropriate, reduce the share of the proceeds of the action which the person would otherwise receive under paragraph (1) or (2) of this subsection, taking into account the role of that person in advancing the case to litigation and any relevant circumstances pertaining to the violation. If the person bringing the action is convicted of criminal conduct arising from his or her role in the violation of section 3729, that person shall be dismissed from the civil action and shall not receive any share of the proceeds of the action. Such dismissal shall not prejudice the right of the United States to continue the action, represented by the Department of Justice.

(4) If the Government does not proceed with the action and the person bringing the action conducts the action, the court may award to the defendant its reasonable attorneys' fees and expenses if the defendant prevails in the action and the court finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment.