

No. 24-2180

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IN THE  
**United States Court of Appeals  
for the Ninth Circuit**

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UNITED STATES OF AMERICA,  
*Plaintiff,*

*ex rel.* ADVENTIST HEALTH SYSTEM OF WEST,  
*Plaintiff/Relator-Appellant,*

– v. –

ABBVIE INC., ET AL.,  
*Defendants-Appellees.*

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On Appeal from the United States District Court  
for the Central District of California  
Case No. 2:21-cv-04249-DSF-SK  
Hon. Dale S. Fischer

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**BRIEF OF THE ANTI-FRAUD COALITION AS *AMICUS CURIAE*  
IN SUPPORT OF APPELLANT AND REVERSAL**

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**DISCLOSURE STATEMENT**

The Anti-Fraud Coalition is a 501(c)(3) nonprofit organization with no parent corporation/(s) and no publicly held shares or stock.

Dated: July 26, 2024

By: /s/ Agatha M. Cole

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## **INTRODUCTION AND INTEREST OF AMICUS CURIAE**<sup>1</sup>

The Anti-Fraud Coalition (“TAF Coalition”) is a nonprofit, public interest organization dedicated to combating fraud against the government and protecting public resources through public-private partnerships. The organization has worked to publicize the *qui tam* provisions of the federal False Claims Act (“FCA”), has participated in litigation as a *qui tam* relator and as *amicus curiae*, and has provided testimony to Congress about ways to improve the FCA. TAF Coalition has a strong interest in defending the FCA and ensuring its proper interpretation and application.

The federal False Claims Act (“FCA”), 31 U.S.C. § 3729 *et seq.*, is an extraordinarily effective tool for facilitating the recovery of taxpayer dollars fraudulently obtained from the United States—which it achieves, in part, by authorizing *qui tam* actions brought on the government’s behalf, 31 U.S.C. § 3730(b)(1) (“[a] person may bring a civil action for

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<sup>1</sup> Pursuant to Fed. R. App. P. 29(a)(2), consent for the filing of this *amicus* brief has been obtained from all parties to this appeal. No party, counsel for the parties, or other persons—aside from TAF, its members, and its counsel—has contributed to the authorship, preparation, submission, or funding of this brief.

[violations of § 3729] ... for the United States ... in the name of the Government.”).

In 2023 alone, the government recovered nearly \$2.7 billion from FCA settlements and judgments, of which over \$1.8 billion was attributed to fraud in the healthcare sector.<sup>2</sup> As the Department of Justice stated in commenting upon these recent statistics, “[w]e are grateful for the hard work and courage of whistleblowers who play a critical role in identifying fraud, often at substantial risk to themselves...[o]ur efforts to ensure that public funds are spent properly continues to benefit greatly from their actions.”<sup>3</sup>

In this *qui tam* action, it is alleged that several of the most profitable drug manufacturers in the world lined their pockets with taxpayer dollars by fraudulently overcharging government-funded healthcare facilities for medications purchased under Medicare’s 340B program.

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<sup>2</sup> False Claims Act Settlements and Judgments Exceed \$2.68 Billion in Fiscal Year 2023 (Feb. 22, 2024), <https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-268-billion-fiscal-year-2023>.

<sup>3</sup> *Id.*

The district court dismissed the action pursuant to the Supreme Court’s holding in *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011), which recognized that “covered entities have no right of action under § 340B.” *Id.* at 117 (“[A]ny private right of action for violating a federal statute ... must ultimately rest on congressional intent to provide a private remedy.”) (internal citations omitted); accord *U.S. ex rel. Adventist Health Sys. v. AbbVie, Inc.*, No. 2:21-cv-4249, 2024 WL 1169888, at \*3 (C.D. Cal. Mar. 18, 2024) (finding “that *Astra* [also] bars FCA claims”). But *Astra* has no bearing on the viability of *qui tam* actions brought under the False Claims Act.

As explained herein, private causes of action like the claims asserted in *Astra* are wholly distinguishable from *qui tam* claims under the FCA, which are brought on the government’s behalf and seek redress for public harm, as opposed to private wrongs. The Supreme Court’s decision in *Astra* merely precludes private healthcare operators that purchase medications under the 340B drug pricing scheme from suing drug manufacturers as “third-party beneficiaries” of government contracts entered pursuant to that program. *Astra* says nothing of actions brought by the government directly, or on its behalf, under the FCA, and

does not purport to characterize such suits as private actions. Moreover, courts routinely allow *qui tam* claims to proceed on allegations of fraud that would not give rise to a private right of action—and the mere existence of a parallel administrative enforcement scheme does not preclude, preempt, or otherwise displace the FCA.

If left uncorrected, the district court’s ruling would undermine decades of well-established FCA jurisprudence in which courts have consistently approved of the *qui tam* mechanism as functioning alongside other complex federal regulatory regimes.

## ARGUMENT

### **I. THE FALSE CLAIMS ACT IS THE GOVERNMENT’S PRINCIPAL ENFORCEMENT TOOL FOR RECOVERING TAXPAYER DOLLARS LOST TO FRAUD**

The central aim of the federal False Claims Act (“FCA”), 31 U.S.C. §§ 3729–33, is to “protect the funds and property of the Government from fraudulent claims, regardless of the particular form, or function, of the government instrumentality upon which such claims were made.” *Rainwater v. United States*, 356 U.S. 590, 592 (1958); *accord United States v. Neifert-White Co.*, 390 U.S. 228, 233 (1968) (observing that the statute is “remedial” in nature and “reaches beyond ‘claims’

which might be legally enforced, to all fraudulent attempts to cause the Government to pay out sums of money.”). “Congress wrote [the statute] expansively... ‘to reach all types of fraud, without qualification, that might result in financial loss to the Government’,” *Cook Cnty., Ill. v. U.S. ex rel. Chandler*, 538 U.S. 119, 129 (2003) (quoting *Neifert-White*, 390 U.S. at 232), and imposed appropriately severe consequences for violations of the Act; the statute provides for “treble damages,” in addition to statutory penalties and costs. *Cook Cnty.*, 538 U.S. at 122-123 (citing 31 U.S.C. § 3729(a)).

In order to foster the public-private partnership that Congress deemed essential to effective enforcement, the FCA’s *qui tam* provisions incentivize suits by private citizens seeking to protect or recover taxpayer dollars from fraud. Accordingly, FCA actions may be prosecuted by “private person[s]” (often referred to as a relators, or whistleblowers) who bring an action in the government’s name. 31 U.S.C. § 3730(b). As the Supreme Court recently explained,

“[t]he FCA has [always] been enforced through a unique public-private scheme... Federal prosecutors may of course sue an alleged violator, all on their own... But private parties—again, relators—may also ... [bring] so-called *qui tam* actions... in the name of the Government.”

*U.S. ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 424 (2023) (cleaned up; citations omitted).

The relator in a successful *qui tam* suit does not recover any damages to redress his or her own injury, but rather receives a portion of the government's recovery, as compensation for bringing and pursuing the case on the government's behalf. Pursuant to 31 U.S.C. § 3730(d), a successful *qui tam* relator is entitled to receive between 10% to 30% of the government's proceeds from the action or settlement of the claim. This ensures that *qui tam* relators are compensated for their efforts towards the successful recovery of taxpayer dollars without encroaching upon the government's ability to be made whole. *See Cook Cnty.*, 538 U.S. at 130.

The statute has been extraordinarily effective. Since 1986, *qui tam* actions have returned over \$75 billion in wrongfully diverted taxpayer funds dollars to publicly financed programs. And many of these cases involve conduct that the government could also pursue under parallel enforcement schemes. For example, in 2013, AmerisourceBergen Corporation paid \$625 million to settle allegations that it caused providers to overbill government healthcare programs by submitting

claims for repackaged, prefilled syringes of cancer drugs that were not approved for use or sale by the U.S. Food and Drug Administration.<sup>4</sup> The scheme allegedly involved removing the drugs from the original glass vials and pooling them in untested plastic containers, then extracting the drug and the overfill, and repackaging into syringes to create additional doses. *See id.* The government also has the option of pursuing this type of conduct under the Food, Drug, and Cosmetic Act, which prohibits “the introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.” 21 U.S.C. 331(a).

FCA cases have also returned funds wrongfully taken from the Treasury for improper sales and marketing of opioids, while the same

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<sup>4</sup> *See* Settlement Resolves Federal and State False Claims Act Claims Arising from ABC’s Operation of a Sham Pharmacy that Illegally Repackaged Injectable Drugs Under Insanitary Conditions to Profit from Overfill, *available at* <https://www.justice.gov/usao-edny/pr/amerisource-bergen-corp-pay-625-million-settle-civil-fraud-allegations-resulting-its>

conduct has been addressed under several criminal and civil enforcement schemes at the state and federal level.<sup>5</sup>

The FCA has also been used alongside criminal proceedings, to enforce federal antitrust laws. For example, in 2018, Korean oil companies Hyundai Oilbank and S-Oil paid \$52 million to resolve FCA allegations that they made false statements to the U.S. government in connection with their agreement not to compete, causing the government to overpay for oil, while the same conduct was subject to antitrust enforcement.<sup>6</sup>

These examples, and countless others, demonstrate not only the vital importance of the FCA to the government's fraud enforcement efforts, but also the extent to which the statute complements other complex federal regulatory regimes.

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<sup>5</sup> See Opioid Manufacturer Endo Health Solutions Inc. Agrees to Global Resolution of Criminal and Civil Investigations into Sales and Marketing of Branded Opioid Drug, *available at*, <https://www.justice.gov/opa/pr/opioid-manufacturer-endo-health-solutions-inc-agrees-global-resolution-criminal-and-civil>.

<sup>6</sup> See More Charges Announced in Ongoing Investigation into Bid Rigging and Fraud Targeting Defense Department Fuel Supply Contracts for U.S. Military Bases in South Korea, *available at*, <https://www.justice.gov/opa/pr/more-charges-announced-ongoing-investigation-bid-rigging-and-fraud-targeting-defense>.

## II. *QUI TAM* CLAIMS SEEK TO REDRESS PUBLIC HARM

A *qui tam* relator is “no ordinary civil plaintiff.” *U.S. ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 425 (2023). The *qui tam* device finds its origins in the common law traditions of England, which permitted private individuals to sue on behalf of the King and to obtain a reward.<sup>7</sup> Then, as now, the characteristic feature of a *qui tam* action is that it seeks to redress public harm; the injury alleged is to the government, and to the public it serves. *See, e.g., U.S. ex rel. Eisenstein v. City of New York, New York*, 556 U.S. 928, 930 (2009) (explaining that the “real party in interest” in an FCA action is the United States); *accord Polansky*, 599 U.S. at 425 (“[The] injury assert[ed]... [in a *qui tam* action] is exclusively to the Government.”); *see also Vermont Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 773 (2000) (explaining that the relator brings the case on a “partial assignment of the Government’s damages claim.”). For that reason, *qui tam* actions under the FCA are distinguishable from private actions for contract damages like the one

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<sup>7</sup> “Qui tam” is short for the Latin phrase meaning “who pursues this action on our Lord the King’s behalf as well as his own.” *Vermont Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 768 n. 1 (2000).

at issue in *Astra USA, Inc. v. Santa Clara Cnty., Cal.*, 563 U.S. 110, 118 (2011).

In addition, the role of a *qui tam* relator in an FCA action is hardly analogous to that of a private plaintiff in ordinary civil litigation. Because the “real party in interest” in a *qui tam* action is the government, the statute contains various procedural mechanisms that enable the government to control the litigation. *Id.* at 425-26 (citing 31 U.S.C. §§ 3730(b)(2),(3),(c)(3)) (explaining that the relator “must file his complaint under seal” so that the government can investigate the allegations and decide whether to take over the litigation from the outset, which it may also do at any later point in time with a showing of “good cause” for the intervention).

Because FCA cases seek to redress fraud on the government, *qui tam* actions routinely proceed on allegations that would not otherwise give rise to a private right of action. For example, courts have consistently recognized that false certifications of compliance with the Anti-Kickback Statute (AKS) can serve as the basis for an FCA action, notwithstanding the fact that AKS “provides no private right of action.” *U.S. ex rel. Nunnally v. W. Calcasieu Cameron Hosp.*, 519 F. App’x 890,

893 & n.5 (5th Cir. 2013) (“private plaintiff[s] may not sue... health care provider[s]... under the AKS alone... [but] violations of the AKS can serve as the basis for a FCA claim when the Government has conditioned payment of a claim upon the claimant’s certification of compliance with the statute, and the claimant falsely certifies compliance.”). *See also, e.g., U.S. ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612 (N.D. Ill. 2003) (finding “that since AKS is a critical provision of the Medicare statute, compliance with it is material to the government’s treatment of claims for reimbursement”); *compare U.S. v. General Dynamics Corp.*, 19 F.3d 770 (2d Cir. 1994) (finding that the Anti-Kickback Act “does not preempt remedies of the United States under the FCA and federal common law...”); *U.S. ex rel. Garrison v. Crown Roofing Services, Inc.*, 2011 WL 1005062 (S.D. Tex. 2011) (declining to dismiss the government’s AKA claims regarding a subcontractor because the court would not limit the scope of the Act).

This Court likewise recognized the critical distinction between *qui tam* claims and private causes of action in *U.S. ex rel. Sutton v. Double Day Office Servs., Inc.*, 121 F.3d 531 (9th Cir. 1997), which concerned the viability of a claim brought by a *qui tam* relator alleging that his

employer had falsely certified its compliance with minimum wage requirements under the Service Contract Act (“SCA”), 41 U.S.C. §§ 351–58.<sup>8</sup>

In *Sutton*, as here, defendants moved to dismiss, arguing that because the SCA “does not confer a private right of action to employees,” and may only be enforced by the Secretary of Labor, allowing plaintiffs to proceed “under the guise of another statute” would be functionally “equivalent” to authorizing a private suit for damages under the SCA. *Id.* at 533. This Court flatly rejected that argument, noting the critical distinction between defendants’ predicate violations of the SCA, and the false certifications giving rise to liability under the FCA:

[Defendant’s] failure to pay ... prevailing wages was a violation of the SCA ... [But] it was *not* a violation of the FCA ... [until] it submitted a claim for payment to the United States falsely stating that it *had* complied with the SCA.

*Sutton*, 121 F.3d at 534 (emphasis added).

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<sup>8</sup> The SCA is designed “to ensure that service employees working on government contracts are not paid [below the prevailing wage that is ordinarily paid] by non-government contractors” in any given locality, and applies to any “federal government service contract exceeding \$2,500.” *U.S. ex rel. Sutton v. Doubleday Off. Servs., Inc.*, No. 92-cv-1909, 1996 WL 207766, at \*2 (N.D. Cal. Apr. 23, 1996), *rev’d sub nom.*, 121 F.3d 531 (9th Cir. 1997).

The actionable conduct, the Court explained, is “knowingly induc[ing] the United States to make payment,” based on the false certification, *Sutton*, 121 F.3d at 533; “[t]he FCA attaches liability to the claim for payment,” as opposed “to the underlying activity,” so “it is the false certification of compliance [that matters]... when [that] certification is a prerequisite to obtaining [payment].” *Sutton*, 121 F.3d at 534 (quoting *U.S. ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir.1996)). Because the *qui tam* relator “brings this action ... to recover for damage to the United States,” as opposed to seeking damages in the form of lost wages “for himself,” and because “[the] FCA claim is based on different actions,” separate and apart from the alleged wage violations, the Court reasoned, “his suit is not barred by the SCA’s bar on private rights of action.” *Sutton*, 121 F.3d at 534; accord *U.S. ex rel. Conteh v. IKON Off. Sols., Inc.*, 27 F. Supp. 3d 80, 87 (D.D.C. 2014).

Here, as in *Sutton*, defendants bid for dismissal fundamentally misconstrues the nature of the *qui tam* mechanism—which does not give rise to a private action to redress private harm, but instead seeks to return fraudulently obtained public funds to the government. *Sutton*, 121 F.3d at 534 (“[h]olding that [the relator] ... lacks standing ... would

frustrate the purpose of the FCA, which was ‘intended to reach all kinds of fraud, without qualification, that might result in financial loss to the Government.’”) (quoting *U.S. v. Neifert–White*, 390 U.S. at 232).

As the decision below conceded, no other court has ever applied *Astra* in the context of a *qui tam* action. *U.S. ex rel. Adventist Health Sys. v. AbbVie, Inc.*, No. 2:21-cv-4249, 2024 WL 1169888, at \*3 (C.D. Cal. Mar. 18, 2024) (“[p]erhaps surprisingly, the application of *Astra* to FCA claims appears to be a matter of first impression.”). That should not have been “surprising” at all, however; after all, a bar on private actions should have no bearing on the viability of an “action ... to recover for damage to the United States.” *Sutton*, 121 F.3d at 534.

### **III. THE FALSE CLAIMS ACT FUNCTIONS ALONGSIDE OTHER COMPLEX REGULATORY SCHEMES AND PARALLEL ENFORCEMENT IS COMMON**

The district court’s concern for the potential overlap between *qui tam* actions and the 340B administrative enforcement scheme was also misplaced, as redundancies across statutes are not unusual.

Absent an express prohibition or positive repugnancy between two statutes, courts must give effect to both. *Connecticut Nat. Bank v. Germain*, 503 U.S. 249, 253 (1992). As always, that analysis should

“begin with the text” of the relevant provisions, *Maine Community Health Options v. United States*, 590 U.S. 296, 310 (2020)—in this case, the *qui tam* provisions of the FCA, 31 U.S.C. § 3729, and the statute implementing the 340B drug pricing program, 42 U.S.C. § 256b.

The FCA contains only a few express limits on the subject matter of *qui tam* actions. First, a case may not be based on “claims, records, or statements made under the Internal Revenue Code of 1986,” 31 U.S.C. § 3729(d). Pursuant to that provision, allegations related to federal tax evasion schemes are not actionable under the FCA.<sup>9</sup> The FCA also precludes certain actions against members of the military, 31 U.S.C. § 3730(e)(1), or public officials, 31 U.S.C. § 3730(e)(2), and has limitations on actions based on certain public disclosures of information, 31 U.S.C. § 3730(e)(4), or previously initiated actions, 31 U.S.C. § 3730(b)(5).

Aside from these specific carve outs, the FCA’s capacious language extends broadly to address all manner of fraud, “without qualification, that might result in financial loss to the Government.” *Cook County v.*

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<sup>9</sup> Such claims may instead be pursued through a separate whistleblower program established by the IRS pursuant to 26 U.S.C. § 7623.

*U.S. ex rel. Chandler*, 538 U.S. 119, 129 (2003) (quoting *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968)); accord *U.S. ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 899 (9th Cir. 2017) (“We construe the Act broadly, as ... reach[ing] all types of fraud.”).

The relevant statutory provisions and implementing regulations of the 340B program are likewise silent on the precise question presented in this case. Although 42 U.S.C. § 256b directs the Department of Health and Human Services to develop formal procedures for resolving overcharge claims, neither the statute nor regulations purport to provide an exclusive remedy or otherwise displace the FCA.

Nor does the 340B statute impliedly repeal the FCA. As this Court recognized in *Sutton*, the district court’s logic in the decision below requires the conclusion” that the 340B statute “impliedly preempts the FCA.” *Sutton*, 121 F.3d 531, 535 (9th Cir. 1997).<sup>10</sup> But “repeals by implication” are generally disfavored, and courts must give effect to both

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<sup>10</sup> See also Claire M. Sylvia, FALSE CLAIMS ACT: FRAUD AGAINST THE GOVERNMENT § 10.22 (4<sup>th</sup> Ed. 2023) (“[The] [d]isplacement of one federal law by another federal law involves the doctrine of ‘repeal by implication’”) (citing *Radzanower v. Touche Ross & Co.*, 426 U.S. 148 (1976)).

statutes in the absence of “clear and manifest” Congressional intent to displace a prior law through more recent enactments. *Swinomish Indian Tribal Cmty. v. BNSF Ry.*, 951 F.3d 1142, 1156 (9th Cir. 2020) (internal citations and quotation marks omitted).

With respect to the FCA, courts have been especially “reluctant to find pre-emption[,] ... even where other laws provide closely related regulation and remedies.” *U.S. ex rel. Fallon v. Accudyne Corp.*, 880 F.Supp. 636, 639 (W.D. Wis. 1995) (collecting cases) (explaining false certifications of environmental compliance are actionable under the FCA and not barred by more specific remedial provisions in environmental statutes); *U.S. ex rel. Sutton v. Double Day Off. Servs., Inc.*, 121 F.3d 531, 534 (9th Cir. 1997) (Service Contract Act does not preempt the FCA); *see also, U.S. ex rel. Miller v. Bill Harbert Int’l Const., Inc.*, 608 F.3d 871, 885-886 (D.C. Cir. 2010) (finding that the Foreign Assistance Act did not preempt the FCA and holding that “when two statutes are capable of co-existence, it is the duty of the courts... to regard each as effective... [When] the Government could bring suit under either the FCA or [another statute] ... [that] choice does not create a conflict, let alone an ‘irreconcilable conflict’... [a]lthough the false claims provisions ...

overlap, the two statutes are fully capable of coexisting.”); *U.S. ex rel. Augustine v. Century Health Servs., Inc.*, 289 F.3d 409 (6th Cir. 2002) (finding that government could recover damages under both the FCA and ERISA).

As a practical matter, allegations giving rise to FCA liability nearly always involve or relate to the application of other federal laws and regulations because the misrepresentation of compliance with a statute that was material to the government’s decision to pay is often the basis of the fraud allegation. Indeed, one of the most common types of cases under the Act involves “a claim for goods or services.. provided in violation of ... statute or regulation.” False Claims Amendments Act of 1986, S. Rep. No. 99-345, at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274; *see also Universal Health Services, Inc., v. U.S. ex rel. Escobar*, 579 U.S. 176, 189-90 (2016) (FCA reaches specific representation about goods or services provided where a statutory, regulatory, or contractual requirement makes the representation a misleading half-truth).

Consistent with that understanding, federal courts have universally recognized that the FCA functions alongside other complex

federal regulatory regimes and upheld the viability of *qui tam* actions in contexts where more specific administrative enforcement and remedial schemes have been implemented. *See, e.g., U.S. ex rel. Onnen v. Sioux Falls Indep. Sch. Dist. No. 49-5*, 688 F.3d 410, 414-15 (8th Cir. 2012) (rejecting argument that “complex regime of regulatory sanctions” in Higher Education Act precludes or displaces the FCA’s *qui tam* provisions); *U.S. ex rel. Miller v. Bill Harbert Int’l Const., Inc.*, 608 F.3d 871, 877 (D.C. Cir. 2010) (acknowledging that Foreign Assistance Act, 22 U.S.C. § 2151, gives rise to a separate and more specifically tailored remedial scheme for addressing false claims in the foreign aid context, but rejecting the argument that *qui tam* action was precluded on that basis); *U.S. ex rel. Taylor v. Gabelli*, 345 F. Supp. 2d 313, 334 (S.D.N.Y. 2004) (“[r]emedial scheme to address violations of FCC regulations... [does not] ‘preempt’ remedies under the FCA”); *U.S. ex rel. Totten v. Bombardier Corp.*, 286 F.3d 542, 544 (D.C. Cir. 2002) (“[Amtrak Reform and Accountability Act] erects no per se bar preventing individuals from bringing FCA actions.”); *Costner v. URS Consultants, Inc.*, 153 F.3d 667, 674–75 (8th Cir. 1998) (CERCLA does not bar False Claims Act suit); *Brooks v. United States*, 64 F.3d 251, 253-54 (7th Cir. 1995) (per curiam)

(affirming FCA judgment alongside the imposition of administrative penalties under Department of Agriculture regulations); *United States v. General Dynamics Corp.*, 19 F.3d 770 (2nd Cir.1994) (rejecting the view that Anti Kickback Act pre-empts claims under the FCA); *United States v. Foster Wheeler Corp.*, 447 F.2d 100, 101 (2d Cir. 1971) (“[T]he Truth-In-Negotiation Act... does not supersede the False Claims Act.”); *accord U.S. ex rel. Hendrickson v. Bank of America, N.A.*, 343 F. Supp. 3d 610 (N.D. Tex. 2018), *aff’d*, 779 Fed. Appx. 250 (5th Cir. 2019) (rejecting argument that FCA was preempted by banking regulations). Here, as in those cases, the FCA can co-exist with the 340B program’s administrative remedies and enforcement framework. There is simply no evidence, let alone “clear and manifest” evidence, that Congress intended to extinguish or abrogate the FCA by implementing the administrative oversight and enforcement measures at 42 U.S.C. § 256b(d). And there is no basis for expanding *Astra’s* holding to a wholesale declaration that 42 U.S.C. § 256b(d) precludes an action to recover taxpayer dollars in instances of fraud on the 340B program.

The FCA is also routinely invoked in connection with violations of other federal drug pricing programs that have complex administrative

enforcement and remedial schemes. For example, Medicare Part D is a federal prescription-drug program administered by the Department of Health and Human Services through the Centers for Medicare & Medicaid Services (“CMS”). Pursuant to 42 C.F.R. § 423.505(n),(o), CMS is authorized to initiate compliance actions and impose sanctions on entities that fail to comply with the applicable drug pricing rules and other regulations under Medicare Part D. As this Court has previously observed, Congress did not authorize private rights of action in the Medicare Act, and the regulations promulgated thereunder only speak to administrative enforcement tools and remedies available to CMS. *See generally Parra v. PacifiCare of Arizona, Inc.*, 715 F.3d 1146, 1152-55 (9th Cir. 2013) (explaining that Medicare statute does not authorize private rights of action). According to the district court’s logic in the present case, any *qui tam* action concerning fraud in the context of Medicare Part D would therefore be barred. And yet, the Supreme Court recently permitted a *qui tam* action to proceed against pharmacies accused of falsely reporting their usual and customary drug prices to secure higher reimbursement rates under Medicare Part D. *See U.S. ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739 (2023).

In fact, this Court has evaluated many *qui tam* actions in the Medicare context, where parallel administrative enforcement and remedies also exist. *See, e.g., U.S. ex rel. Silbersher v. Valeant Pharms. Int'l, Inc.*, 89 F.4th 1154 (9th Cir. 2024) (finding that the a case regarding patent fraud could proceed under the FCA despite having several previous patent prosecutions); *U.S. ex rel. Hartpence v. Kinetic Concepts, Inc.*, 44 F.4th 838 (9th Cir. 2022) (reversing the district court's grant of summary judgment in favor of the defendant and finding that there were disputes of material fact as to whether a medical device manufacturer's false certification of compliance with coverage requirements was material); *U.S. ex rel. Winter v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108 (9th Cir. 2020) ("hold[ing] that a false certification of medical necessity can give rise to FCA liability."); *U.S. ex rel. Godecke v. Kinetic Concepts, Inc.*, 937 F.3d 1201 (9th Cir. 2019) (finding that a relator could bring a case regarding the defendant's failure to obtain written orders from physicians before delivering durable medical equipment devices to Medicare patients); *U.S. ex rel. Anita Silingo v. WellPoint, Inc.*, 904 F.3d 667, 681 (9th Cir. 2018) (reversing the district court's ruling granting the defendant's motion to dismiss and finding that

the relator sufficiently plead that the Medicare Advantage Organization was submitting false data in order to inflate its government reimbursements).

And while this Court has yet to expressly opine on the viability of FCA actions relating to the 340B program, the few courts that have did so without any expression of doubt concerning the *qui tam* relator's standing to bring such an action. *See, e.g., United States v. Janssen Biotech, Inc.*, 576 F. Supp. 3d 212, 227 (D.N.J. 2021); *U.S. ex rel. Banigan v. Organon USA Inc.*, 883 F. Supp. 2d 277 (D. Mass. 2012), *rev'd*, 950 F.3d 134 (1st Cir. 2020); *U.S. ex rel. Schumann v. Astrazeneca Pharms. L.P.*, 769 F.3d 837 (3d Cir. 2014); *U.S. ex rel. Foster v. Bristol-Myers Squibb Co.*, 587 F. Supp. 2d 805 (E.D. Tex. 2008).

\* \* \*

In sum, the FCA has long been an effective mechanism of redressing fraud against the government, notwithstanding the availability of parallel enforcement schemes. Taken to its logical extreme, the district court's decision would dramatically undermine Congress's decision to create a robust public private enforcement mechanism for detecting and remedying fraud against the government.

**CONCLUSION**

For these reasons, the TAF Coalition respectfully submits that the decision below should be reversed.

Dated: July 26, 2024

Respectfully submitted,

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