25-2257-cv(L), 25-2259-cv(CON)

United States Court of Appeals

for the

Second Circuit

UNITED STATES OF AMERICA *ex rel.* Uri Bassan, STATE OF CALIFORNIA, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, STATE OF FLORIDA, STATE OF GEORGIA, STATE OF HAWAII, STATE OF ILLINOIS, STATE OF INDIANA, STATE OF IOWA, STATE OF LOUISIANA, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF MONTANA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF NEW YORK, STATE OF NORTH CAROLINA, STATE OF OKLAHOMA, STATE OF RHODE ISLAND, STATE OF TENNESSEE, STATE OF TEXAS, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WASHINGTON, STATE OF WISCONSIN, DISTRICT OF COLUMBIA,

Plaintiffs-Appellees,

UNITED STATES OF AMERICA,

Intervenor-Plaintiff-Appellee,

(For Continuation of Caption See Inside Cover)

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK (NEW YORK CITY)

BRIEF FOR *AMICUS CURIAE* CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA IN SUPPORT OF DEFENDANTS-APPELLANTS CVS HEALTH CORPORATION AND OMNICARE, INC.

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STATE OF MARYLAND,

Plaintiff,

– v. –

CVS HEALTH CORPORATION, OMNICARE, INC.,

Defendants-Appellants.

CORPORATE DISCLOSURE STATEMENT

The Chamber of Commerce of the United States of America ("Chamber") is a nonprofit, tax-exempt organization incorporated in the District of Columbia. The Chamber has no parent corporation, and no publicly held company has 10% or greater ownership in the Chamber.

Dated: January 27, 2026

/s/ Jeremy M. Bylund

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INTEREST OF *AMICUS CURIAE*[1]

The Chamber of Commerce of the United States of America is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

Many American businesses—including many Chamber members—contract directly or indirectly with the federal government for the provision of goods and services, and as a result are subject to the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq*. The Chamber's members have a strong interest in courts' faithfully applying the guardrails in the Constitution and in the FCA to ensure that the Act is used for its

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[1] No counsel for any party authored this brief in whole or in part, and no entity or person, aside from *amicus curiae*, its members, or its counsel, made any monetary contribution intended to fund this brief's preparation or submission. Counsel for all parties consented to this brief's filing.

intended purpose: punishing those who engage in frauds on the government, as enumerated in the statute.

INTRODUCTION AND SUMMARY OF ARGUMENT

The jury's verdict in this case, and the draconian penalties the district court imposed, combine to highlight the peril of turning the FCA into a general-purpose enforcement tool for regulatory violations, particularly when the government still received the benefit of its bargain. The FCA's use to penalize such violations is far afield from its core objective—policing and preventing *fraud* against the government. The government has at its disposal a wide range of regulatory-enforcement tools that are much more appropriate and better suited to addressing regulatory fouls of the type purportedly committed here than is the inherently punitive FCA.

Here, the government pursued FCA claims against Omnicare and its indirect corporate parent CVS Health Corporation ("CVSHC") based on Omnicare's dispensing of medications in assisted-living facilities, allegedly without refill prescriptions that were valid under various states' laws. This was, in the government's own telling, little more than a regulatory infraction—the government did not allege that Omnicare

gave patients medications they did not need or that Omnicare harmed any patient's health, and the government did not contend that Omnicare charged the government for medications that had not been dispensed. Instead, the government's contention is that refill orders and other prescription documentation were lacking when Omnicare continued to provide needed medications.

In assessing those claims and instructing the jury, the district court disregarded multiple legally required guardrails meant to cabin overuse of the FCA. In a cascading series of errors, the district court improperly expanded the FCA's reach in multiple dimensions: it allowed the jury to find liability for claims that were not proven false, including against an entity that did not cause Omnicare to submit those claims, and then allowed the jury to award statutorily excessive damages and used those damages to bootstrap constitutionally excessive penalties.

To prove its claims, the government did not ask the court to interpret and apply the state prescription statutes it contended Omnicare had violated, but instead merely put an expert witness on the stand to opine that Omnicare had broken the law. The court acquiesced, expressly treating the meaning of the state laws at issue as a matter of fact and

declining to instruct the jury as to those laws' requirements. Similarly, the court allowed the same witness to offer, as evidence of falsity, a dubious statistical sample representing less than one percent of the claims at issue—and then allowed a different witness to extrapolate from that sample a falsity rate that the witness applied across the board to all the challenged claims.

The jury deferred to the experts' improper conclusions and found Omnicare liable. Based on an erroneous instruction from the district court, the jury disregarded the value of the medications Omnicare dispensed and assessed damages as the *entire* amount the government paid for all the purportedly false claims Omnicare had submitted. The district court then used that inflated damages number to justify a further $542 million in statutory penalties. Of that $542 million, it held CVSHC, a holding company that had no employees or day-to-day operations and that the jury had expressly found liable for *zero* damages, jointly and severally liable for $165 million—a maneuver that did not so much pierce the corporate veil as shred it entirely.

Because the FCA is fundamentally punitive, it is essential that courts strictly observe and enforce the guardrails Congress built into the

statute and those in the Constitution. The district court failed to do that here, and it is therefore up to this Court to reinforce those guardrails.

ARGUMENT

I. The FCA's "Essentially Punitive" Nature Demands Strict Enforcement of Constitutional and Statutory Limitations.

The FCA was never meant to be a general-purpose tool to police alleged regulatory missteps. Instead, Congress passed and President Lincoln signed the FCA in 1863 "to prevent and punish *frauds* upon the Government of the United States." Cong. Globe, 37th Cong., 3d Sess. 348 (1863) (statement of Sen. Wilson) (emphasis added). The Act was a response to allegations of rampant war profiteering during the Civil War. *United States v. McNinch*, 356 U.S. 595, 599 (1958). Private contractors supporting the Union Army were accused of defrauding the federal treasury through flagrantly wrongful acts: "For sugar, [the government] often got sand; for coffee, rye; for leather, something no better than brown paper; for sound horses and mules, spavined beasts and dying donkeys; and for serviceable muskets and pistols, the experimental failures of sanguine inventors, or the refuse of shops and foreign armories." *United States ex rel. Newsham v. Lockheed Missiles & Space Co.*, 722 F. Supp.

607, 609 (N.D. Cal. 1989) (quoting 1 F. Shannon, *The Organization and Administration of the Union Army*, *1861–1865*, at 58 (1965)).

Since then, Congress has made clear time and again that the FCA's unremitting focus is to root out and punish those who use underhanded means to steal from the public fisc—and to discourage others from doing so. *See, e.g.*, S. Rep. No. 99-345, at 4 (1986) ("[T]his statute has been used more than any other in *defending the Federal treasury* against unscrupulous contractors and grantees.") (emphasis added); S. Rep. No. 111-10, at 10 (2009) ("[The FCA] is an extraordinary civil enforcement tool used to *recover funds lost to fraud and abuse*.") (emphasis added). In line with that straightforward purpose, courts have long recognized that the FCA's regime of treble damages and penalties is "essentially punitive in nature." *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784 (2000).

The specter of FCA liability already touches a broad cross-section of American business.[2] And meritless FCA claims are "downright

[2] *See, e.g.*, *United States ex rel. Lesnik v. ISM Vuzem d.o.o.*, 112 F.4th 816 (9th Cir. 2024) (visas for automobile-plant workers); *Miller v. United States ex rel. Miller*, 110 F.4th 533 (2d Cir. 2024) (credit cards); *United States ex rel. Angelo v. Allstate Ins. Co.*, 106 F.4th 441 (6th Cir. 2024) (car insurance); *United States ex rel. Zotos v. Town of Hingham*, 98 F.4th 339

harmful" to the business community (to say nothing of their effect on courts' already-clogged dockets). *See Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 298 (2010). Setting aside the prospects of adverse judgments, simply *defending* an FCA case requires a "tremendous expenditure of time and energy." Todd J. Canni, *Who's Making False Claims, The* Qui Tam

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(1st Cir. 2024) (municipal road design); *United States ex rel. Vt. Nat'l Tel. Co. v. Northstar Wireless, LLC*, 34 F.4th 29 (D.C. Cir. 2022) (telecommunications services); *United States ex rel. Schweizer v. Canon, Inc.*, 9 F.4th 269 (5th Cir. 2021) (office equipment); *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445 (7th Cir. 2016) (higher education); *United States ex rel. Bias v. Tangipahoa Par. Sch. Bd.*, 816 F.3d 315 (5th Cir. 2016) (public-school JROTC programs); *United States ex rel. Steury v. Cardinal Health, Inc.*, 735 F.3d 202 (5th Cir. 2013) (medical-device manufacturing); *United States ex rel. Anti-Discrimination Ctr. of Metro N.Y., Inc. v. Westchester Cnty.*, 712 F.3d 761 (2d Cir. 2013) (housing); *United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163 (10th Cir. 2010) (waste disposal); *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257 (D.C. Cir. 2010) (consulting); *United States ex rel. Pritzker v. Sodexho, Inc.*, 364 F. App'x 787 (3d Cir. 2010) (public-school student meals); *Grand Union Co. v. United States*, 696 F.2d 888 (11th Cir. 1983) (groceries); *United States ex rel. TZAC, Inc. v. Christian Aid*, No. 17-cv-4135, 2021 WL 2354985 (S.D.N.Y. June 9, 2021) (charitable aid); *United States ex rel. Shemesh v. CA, Inc.*, 89 F. Supp. 3d 36 (D.D.C. 2015) (software development); *United States v. Americus Mortg. Corp.*, No. 12-cv-02676, 2014 WL 4273884 (S.D. Tex. Aug. 29, 2014) (mortgage lending); *United States ex rel. McLain v. Fluor Enters., Inc.*, 60 F. Supp. 3d 705 (E.D. La. 2014) (disaster relief); *United States ex rel. Landis v. Tailwind Sports Corp.*, 51 F. Supp. 3d 9 (D.D.C. 2014) (athletic sponsorship).

Plaintiff or the Government Contractor? A Proposal to Amend the FCA to Require that All Qui Tam *Plaintiffs Possess Direct Knowledge*, 37 Pub. Cont. L.J. 1, 11 n.66 (2007). For example, pharmaceutical, medical devices, and health care companies "spend billions each year" dealing with False Claims Act investigations. John T. Bentivoglio *et al.*, *False Claims Act Investigations: Time for a New Approach?*, 3 Fin. Fraud L. Rep. 801, 801 (2011).

Nor is the FCA an appropriate vehicle for deploying novel legal theories to punish alleged regulatory violations even where the government enjoyed the benefit of the bargain. The prospect of facing draconian penalties for a large number of minor regulatory violations has a real and predictable chilling effect on companies and individuals that are evaluating whether to do business with the federal government. In turn, a reduction in qualified entities and individuals willing to deal with the government deprives the government of choice. Reduced competition means that the government very likely will pay higher prices, receive less valuable products or services, or both. *See, e.g.*, *United States v. Data Translation, Inc.*, 984 F.2d 1256, 1262 (1st Cir. 1992) (Breyer, C.J.) ("[S]ignificantly increasing competitive firms' cost of doing federal

government business[] could result in the government's being charged higher … prices."); Michael D. Granston, Dir., Commercial Litig. Branch, Fraud Section, U.S. Dep't of Justice, *Memorandum to Attorneys, Commercial Litig. Branch, Fraud Section*, at 5 (Jan. 10, 2018) ("[T]here may be instances where an action is both lacking in merit and raises the risk of significant economic harm that could cause a critical supplier to exit the government program or industry.").

For all these reasons, holding FCA plaintiffs—whether the government or relators—to their burden of proof on every element of their claims is an essential safeguard for those who choose to do business with the government. Among other things, FCA plaintiffs must prove that the claims for which they seek to exact punitive redress were *actually* false (including, where the claim is one of legal falsity, by showing that the law *actually* forbids the challenged claims) and that the entity from which they seek to exact that redress *actually* is responsible for those claims. *See infra* Sections II and III. Even when liability is warranted, courts must ensure that the remedy is based on damages the government *actually* incurred and that the penalties assessed are not constitutionally excessive. *See infra* Section IV.

II. The District Court's Falsity Errors Impermissibly Expanded Liability.

Strictly applying the falsity standard to each claim alleged to be false is necessary to cabin liability under an inherently punitive statute. As relevant here, the FCA imposes civil liability on "any person" that (A) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or (B) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)–(B). A "claim" must be a "request or demand, whether under a contract or otherwise, for money or property" to either a federal official or a recipient of federal funds. *Id.* § 3729(b)(2)(A). Falsity is an essential element that must be proved for each claim.

Though the FCA does not specifically define the terms "false" or "fraudulent," the Supreme Court has concluded that the "well-settled" common-law meanings of those terms—encompassing statements and omissions that are misleading—are incorporated in the statute. *Univ. Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 187 (2016). The words "false" and "fraudulent" are crucial to the conduct at the core of the FCA provisions relevant to this case—the knowing

submission of wrongful claims for government payment, or knowingly untrue statements to induce such payments. 31 U.S.C. § 3729(a)(1)(A), (B). Either way, the central action is a demand for money that the government would rightfully choose not to pay absent an untrue or deceptive statement or omission. *See Escobar*, 579 U.S. at 187–88.

As the Court explained in emphasizing the importance of the FCA's "demanding" materiality standard, the FCA is not a catch-all "vehicle for punishing garden-variety breaches of contract or regulatory violations." *Id.* at 194. But the government has increasingly sought to bend it to that purpose. And ensuring that the government and relators must muster proof that each of the challenged claims is *false* is an essential safeguard—no less fundamental than the requirement that any falsehood be *material*—against multiplying liabilities for regulatory infractions that the government could address through other, less punitive means.

Here, the government's central falsity theory was that Omnicare submitted claims that were false because Omnicare had not complied with states' medication-prescription laws. That is a textbook example of a purported "*regulatory* violation[]." *Id.* (emphasis added). There was no

suggestion that Omnicare submitted claims for medications it did not dispense, nor that Omnicare submitted claims for medications patients did not need or that the medications it provided harmed anyone or went to waste. Indeed, the district court conceded that "many, perhaps even most, of the medications in question would have been covered" by "Medicaid, Medicare, or Tricare" had the purported regulatory infractions not occurred. R.779 at 10.

In such circumstances, when the government is threatening a defendant with the outsized club of treble damages and massive civil penalties, the court at a minimum owes the defendant a careful look at whether the claims for payment were even false. The district court abdicated that duty in two ways.

First, the district court outsourced to an expert its duty to instruct the jury on the law. "It is a well-established rule in this Circuit that experts are not permitted to present testimony in the form of legal conclusions." *United States v. Articles of Banned Hazardous Substances Consisting of an Undetermined Number of Cans of Rainbow Foam Paint*, 34 F.3d 91, 96 (2d Cir. 1994). "[E]xpert testimony that usurps … the role of the trial judge in instructing the jury as to the applicable law" is

inadmissible because it "undertakes to tell the jury what result to reach, and thus attempts to substitute the expert's judgment for the jury's." *Nimely v. City of N.Y.*, 414 F.3d 381, 397 (2d Cir. 2005) (cleaned up).

Here, though, the district court declined its law-instructing role, instead leaving key portions of it to the government's expert. The government employed Dr. Smith to opine to the jury on the content of state-law medication-dispensing requirements for forty-two states. *See* JA1261–62, 1277. The court ruled that those state laws' requirements were a question of fact for the jury to decide and did not instruct the jury on those laws. *See* JA1252.

The district court's abdication of its responsibility to say what the law is—if affirmed—would leave FCA defendants in this Circuit at the mercy of the government's, or even a relator's, self-interested view of the law. Allowing FCA liability based on an expert witness's recounting of what she believes the law requires would encourage and reward gamesmanship; reduce or eliminate legal predictability; and all but guarantee the expansion of the FCA's improper use as a tool to advance baseless claims and to improperly expand liability for those based in some regulatory misstep.

And, second, instead of demanding that the government *prove* falsity, the court allowed the government to gesture broadly at the claims' purported falsity by having an expert, Dr. W. Thomas Smith, take a small sample—87,000 of the 24 *million* claims at issue, comprising less than *one half of one percent* of the total claims—and determine what proportion of that sample were "false" according to the government's theory. *See* R.830 at 4. A second expert then extrapolated the first expert's dubious "falsity" rate across the entire set of challenged claims, providing evidence not about specific characteristics of allegedly false claims but only a statistical probability that they were in some way false. *Id.* (tying the 30% rate of "prescriptions [*sic*] in [the expert's] sample [that] were not supported by any sort of prescription" to the jury's finding that "just under 30% of the 11,516,060 claims challenged by the Government as false were … false").

Though the district court cited a handful of other evidentiary sources that it speculated might have justified the jury's findings, the problem remains that the jury never heard more than conjecture concerning the vast majority of the claims at issue—over 99% of them—for which it found Omnicare liable. Despite the precise number the jury

put on the falsity finding (3,341,032), the jury can only have taken a wild stab at the actual number of claims that were false, because the number of claims on which it actually heard "evidence" amounted to a rounding error in its final liability total.

The government, in other words, merely asked the jurors to *assume* that claims were uniformly false across a wide geographic swath, over multiple years under the laws of dozens of different jurisdictions—and the jury acquiesced. The district court then rubber-stamped that estimate. Given the draconian penalties the FCA authorizes—and the breathtaking penalties the district court imposed here—the court should at least have confirmed that each claim for which the jury found liability was in fact false.

III. The District Court Failed to Recognize Corporate Separateness.

The expansion of FCA liability beyond the entities accused of having submitted the claims to those entities' corporate relatives, without any evidence of the latter parties' involvement in the conduct at issue in the case, is likewise problematic. The most basic and uniform premise of black-letter corporate law is that the corporation is a distinct and separate entity from its shareholder owners. *Cedric Kushner*

Promotions, Ltd. v. King, 533 U.S. 158, 163 (2001) ("[I]ncorporation's basic purpose is to create a distinct legal entity, with legal rights, obligations, powers, and privileges different from those of the natural individuals who created it, who own it, or whom it employs."). The corollary of this premise is the principle of limited liability—shareholders are not liable for their corporation's acts. *N.L.R.B. v. Deena Artware, Inc.,* 361 U.S. 398, 402–03 (1960); Wm. Meade Fletcher et al., 1 Fletcher Cyc. Corp. § 25 (2025).

This same principle extends to *corporate* shareholders who own subsidiary corporations. *See United States v. Bestfoods*, 524 U.S. 51, 61 (1998) ("It is a general principle of corporate law deeply ingrained in our economic and legal systems that a parent corporation … is not liable for the acts of its subsidiaries.") (cleaned up). The law, in other words, treats the corporate parent just as it would any other shareholder, limiting its liability the same way it would the liability of any shareholder. 10 Fletcher Cyc. Corp. § 4878; 13 Fletcher Cyc. Corp. § 6222; *Am. Protein Corp. v. AB Volvo,* 844 F.2d 56, 60 (2d Cir. 1988).

That is so even though parent corporations routinely participate in and control the activities of their subsidiaries—a common practice

throughout the country. "In reality, in the normal course of operations a corporate parent will have both an ownership interest in the subsidiary and effective control over the management and operations of the subsidiary." Richard G. Dennis, *Liability of Officers, Directors and Stockholders Under CERCLA: The Case for Adopting State Law*, 36 Vill. L. Rev. 1367, 1436 (1991). But that is not sufficient to eradicate the distinction between the two separate legal entities of parent and subsidiary. 1 Fletcher Cyc. Corp. §§ 25, 43; William O. Douglas & Carrol M. Shanks, *Insulation from Liability Through Subsidiary Corporations,* 39 Yale L.J. 193, 196 (1929–30). If it were, nearly every subsidiary would be an alter ego of its parent. *See United States v. Jon-T Chems., Inc.*, 768 F.2d 686, 691 (5th Cir. 1985).

And regardless of ownership structure, the benefits of limited liability serve the interests of economic efficiency and judicial certainty. *See, e.g.*, Frank H. Easterbrook & Daniel R. Fischel, *Limited Liability and the Corporation*, 52 U. Chi. L. Rev. 89, 93–97 (1985).

Limited liability enhances economic efficiency in numerous ways. First, it promotes efficiency in economic production by reducing agency and capital costs. *See id.* at 94–95. Second, it creates a pathway through

which corporations can achieve economies of scale without proportionally increasing their exposure to liabilities. *See* William A. Voxman, *Jurisdiction over a Parent Corporation in Its Subsidiary's State of Incorporation*, 141 U. Pa. L. Rev. 327, 343 (1992). Third, it reduces litigation costs by ensuring that parent corporations are not required to shoulder the burden of defending themselves against separate liability for the actions of their subsidiaries on top of the costs of defending the subsidiaries themselves. *See* Steven L. Schwarcz, *Collapsing Corporate Structures: Resolving the Tension Between Form and Substance*, 60 Bus. L. 109, 129 (2004). The cost savings afforded by these efficiencies benefit both consumers and investors.

As to legal certainty, a healthy business climate requires that corporations be able to "predict[] how a court might decide a particular set of facts facing [them] should [they] be required to defend their actions or enforce their rights." Glenn D. West & Stacie L. Cargill, *Corporations*, 62 SMU L. Rev. 1057, 1058 (2009). If a legal regime repeatedly and unpredictably fails to respect the corporate form, businesses have no way to forecast when the actions of their subsidiaries will expose the parent entities to liability, "seriously diminish[ing]" the "effectiveness of the law

as a tool to regulate society's behavior." *Id.* (cleaned up). Limited corporate liability thus promotes stability and predictability in the law. *See id.*

Here, the district court rejected a motion for directed verdict filed by CVSHC, Omnicare's ultimate parent, on the ground that a "jury might reasonably find that CVSHC, acting through its agent, 'knowingly ratified' the conduct of Omnicare sufficient for CVSHC to incur liability under" the FCA. R.768 at 23. But when the jury declined to find that CVSHC's actions caused the government any damages, the district court nevertheless imposed joint and several liability on CVSHC for $165 million of civil penalties. R.779 at 12.

In so doing, the district court expressly treated a CVSHC subsidiary as the *agent* of its shareholder—CVSHC. *See* R.768 at 22–23. This is a dramatic break with fundamental corporate-law principles. A subsidiary corporation is not the agent of its parent or the parent's shareholders, regardless of the fact that it ultimately functions in their interests, as subsidiaries are appropriately expected to do. *E.g.*, *Moline Props. v. Comm'r of Internal Revenue*, 319 U.S. 436, 440 (1943) ("[T]he mere fact of the existence of a corporation with one or several stockholders,

regardless of the corporation's business activities, does not make the corporation the agent of its stockholders."). Holding otherwise would contradict the most fundamental principle of corporate law—separation between owner and corporation—and would extend FCA liability to a host of entities that, like CVSHC, did not play any role in the submission of the claims at issue.

IV. The District Court Compounded Those Errors with Statutorily Excessive Damages and Unconstitutionally Excessive Penalties.

A. The district court's erroneous damages award allowed the government to recover more than the damages the FCA allows.

Given the fundamentally punitive effect of trebling a damages award, it is at a minimum incumbent on a district court assessing FCA liability to hew to the text of the FCA and calculate the compensatory baseline (*i.e.*, pre-trebling) damages award as only the "amount of damages which the government sustains because of the act" of the defendant. 31 U.S.C. § 3279(a)(1)(G).

The Supreme Court has explained that the FCA's treble damages provision is a "*ceiling* on damages recoverable" under the Act. *Cook Cnty. v. U.S. ex rel. Chandler*, 538 U.S. 119, 130 (2003) (emphasis added); *see also Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 182

(2016) (noting that, under the FCA, "[d]efendants are subjected to treble damages plus civil penalties"). The Court in *Cook County* reasoned that this was one of the reasons why adding treble damages to the FCA did not improperly expand municipal liability: the FCA's treble damages were expressly limited as such and did not allow an "open-ended" recovery as do "classic punitive damages." 538 U.S. at 131–32. There was thus no concern that more than treble damages would be imposed against defendant municipalities. *Id.* at 132.

Other courts have also described the FCA as imposing a hard limit on damages. *See, e.g.*, *United States v. Mackby*, 339 F.3d 1013, 1018 (9th Cir. 2003) (characterizing the FCA as imposing a "*maximum* treble damage award") (emphasis added). Interpreting the FCA's treble-damages provision as a statutory limit is consistent with the plain language of the Act, which speaks of "3 times the amount of *damages*" sustained, 31 U.S.C. § 3729(a)(1) (emphasis added)—not of restitution, rescission, or disgorgement. These latter, equitable remedies are "distinct from compensable damages." *SEC v. Cavanagh*, 445 F.3d 105, 119 (2d Cir. 2006) (internal citation omitted); *cf. United States v. Novo A/S*, 5 F.4th 47, 56 (D.C. Cir. 2021) (reiterating that "restitution" under

the Food, Drug, and Cosmetic Act "is different from traditional damages" such as those authorized under the False Claims Act). Unlike some other remedies, damages are designed to compensate a plaintiff for a legally recognized loss. *E.g.*, *In re Methyl Tertiary Butyl Ether (MTBE) Prods. Liab. Litig.*, 725 F.3d 65, 126 (2d Cir. 2013) (under New York law, "[t]he goal" of a compensatory damages award "is to restore the injured party, to the extent possible, to the position that would have been occupied had the wrong not occurred"). A plaintiff should recover for its loss but not any additional windfall. *See id.* at 127 (rejecting purportedly compensatory damages in excess of the jury-determined cost to the plaintiff as a "windfall").

In other words, because it expressly refers to "the amount of damages," the FCA's "plain language" indicates that "[t]he only allowable remedy" (aside from statutory penalties) is a statutory multiplier of "compensatory damages." *United States ex rel. Taylor v. Gabelli*, 2005 WL 2978921, at *7 (S.D.N.Y. 2005); *see also United States ex rel. Tyson v. Amerigroup Ill., Inc.*, 488 F. Supp. 2d 719, 732 (N.D. Ill. 2007) ("Disgorgement of profits is not a remedy recoverable under the FCA."). In sum, settled judicial interpretations of the Act confirm that the treble

damages provision of the FCA is an express "*ceiling* on damages recoverable" under the Act, consistent with the text and structure of the statute. *Cook Cnty.*, 538 U.S. at 130 (emphasis added).

But here, the district court assessed baseline damages that, when trebled, far exceeded the statutory limit. The district court instructed the jury to calculate the damages not as the difference in value between the bargained-for medications and the medications actually dispensed—*i.e.*, the actual harm that the government suffered from the FCA violations the jury found—but as the *full* amount of the government's reimbursement. In other words, the jury was told to find damages equal to the entire value of each claim Omnicare submitted, even though the government had in fact received the benefit of its bargain. That was error. *See, e.g.*, *Schonfeld v. Hilliard*, 218 F.3d 164, 175–76 (2d Cir. 2000) ("when the promised performance is the delivery of goods, … damages are measured by the difference between the contract price and the value of the goods at the time of the breach"). Omnicare's purported failure to comply with certain state statutory prescription requirements did not render the medications it provided valueless, but the district court treated them as though it had. And the result was, in the government's

own words, "one of the largest damages verdicts rendered by a jury in a False Claims Act case." U.S. Dep't of Justice, *Statement of U.S. Attorney Jay Clayton on the Verdict in U.S. v. Omnicare and CVS Health Corporation* (April 29, 2025), https://tinyurl.com/3vwz6n2a.[3] When the deck is stacked to this degree—and key limits on FCA liability are ignored—one could scarcely expect otherwise.

B. The massive civil penalties the district court imposed were constitutionally excessive.

The judgment here was unconstitutional under both the Due Process Clause of the Fifth Amendment and the Excessive Fines Clause of the Eighth Amendment.

Unlike the treble-damages provision, which has at least a partly compensatory purpose, the civil-penalty provision of the FCA is "completely punitive." *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 388 (4th Cir. 2015) (citing *United States v. Mackby*, 261 F.3d 821, 830 (9th Cir. 2001)). In assessing the propriety of punitive damages under the Due Process Clause, the Supreme Court has observed that "an

[3] Such statements by the United States heighten the concern that obtaining an extraordinarily high monetary award can become—at least in part—a source of motivation for the government in cases like this one.

award of more than four times the amount of compensatory damages might be close to the line of constitutional impropriety." *State Farm Mut. Auto. Ins. Co. v. Campbell,* 538 U.S. 408, 425 (2003). While the district court determined that *State Farm* was not controlling because it concerned only punitive damages instead of the Eighth Amendment's Excessive Fines clause, "it's hard to see why the Supreme Court's approach to punitive damages under the Fifth Amendment would differ dramatically from analysis under the Excessive Fines Clause." *Grant ex rel. United States v. Zorn*, 107 F.4th 782, 798 (8th Cir. 2024) (cleaned up; quoting *United States v. Rogan*, 517 F.3d 449, 454 (7th Cir. 2008)).

Here, though the district court purported to hew to the four-to-one ratio that *State Farm* says marks the outer bounds of constitutional acceptability, its reasoning in fact pulled the number significantly higher. Working from its already improperly inflated baseline compensatory-damages number, *see supra* Section IV.A, the district court treated *only* the civil penalties as "punitive" and reasoned that it was imposing a "4:1 penalty-to-actual-damages ratio." R.779 at 10. But that calculation did not take into account the non-compensatory (and thus punitive) portion of the trebled damages—meaning that the punitive

portion of the government's recovery was actually closer to *six* times the inflated "compensatory" damages.

Excessively punitive awards are particularly problematic in the healthcare industry. *See, e.g.*, *Zorn*, 107 F.4th at 799–800. After all, "[w]hen numerous small claims are at issue, the FCA's per claim fines can metamorphize from rough remedial justice to grossly disproportionate penalties." Melissa Ballengee, Bajakajian*: New Hope for Escaping Excessive Fines Under the False Claims Act*, 27 J.L. Med. & Ethics 366, 368 (1999). And medical providers "tend to submit a large number of relatively small claims each year." Joan H. Krause, *"Promises to Keep": Health Care Providers and the Civil False Claims Act*, 23 Cardozo L. Rev. 1363, 1370 (2002). Accordingly, "the statutory penalties quickly can reach astronomical proportions." *Id.*

This case provides a prime example: the district court used the large number of purportedly false claims to justify an outsized penalty on Omnicare and CVSHC. In addition, even the district court recognized that it was "undoubtedly true that many, perhaps even most, of the medications in question would have been covered" by the relevant government programs, R.779 at 10—meaning that the harm alleged here

was far "less reprehensible" than conduct alleged to "endanger[ed] the health or safety of others." *Zorn*, 107 F.4th at 799; *see State Farm*, 538 U.S. at 419.

Nor can Congress's own authorization of excessive punishment be seen as justifying the district court's acquiescence in that punishment. Courts "must be mindful not to give 'undue deference' to legislative judgments about excessiveness." *Zorn*, 107 F.4th at 800.

CONCLUSION

For the foregoing reasons and those in the defendants' briefs, this Court should reverse the judgment below.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations in Fed. R. App. P. 29(a)(5), because it contains 5,498 words, which is less than one-half the maximum length authorized in Fed. R. App. P. 32(a)(7)(B)(i) for a party's principal brief.

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