No. 25-1818

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

UNITED STATES OF AMERICA, et al., ex rel. JESSICA PENELOW and CHRISTINE BRANCACCIO,

Plaintiffs-Appellees,

v.

JANSSEN PRODUCTS, LP,

Defendant-Appellant.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CASE NO. 3:12-CV-07758
THE HON. ZAHID N. QURAISHI

REPLY BRIEF FOR DEFENDANT-APPELLANT JANSSEN PRODUCTS, LP

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INTRODUCTION

The United States—the real party in interest under the federal False Claims Act ("FCA")—agrees with Janssen that the district court's legal errors prevent this Court from affirming the unprecedented $1.64 billion judgment. From its inception, this case proceeded on the erroneous theory that Relators could establish an FCA violation simply by convincing a jury that Janssen marketed Prezista and Intelence for purported "off-label" uses. Adopting Relators' false predicate, the district court inserted "on the label" into a jury instruction addressing whether claims were eligible for reimbursement—even though that phrase is found nowhere in the relevant statute. And in upholding the jury verdict, the district court made explicit its view that off-label marketing alone violates the FCA by holding that such marketing violates an *express condition of payment*. In its amicus brief, the Government confirms that the district court erred in instructing the jury and in upholding the verdict based on evidence of purported "off-label" marketing.

Relators do not defend the "express condition of payment" holding. They instead summarily assert that Janssen's marketing was not just "off-label" but also "fraudulent." That gets Relators nowhere. Absent a certification about *marketing* in a reimbursement claim, the veracity of marketing cannot render a claim false. As the Government explains, the reimbursement claims for Prezista and Intelence made

no representation about the marketing messages—whether off-label or on-label, false or truthful—that a physician received.

Without any purported certification regarding off-label marketing, the reimbursement claims at issue necessarily cannot contain a *material* misrepresentation regarding marketing. Relators thus necessarily failed to prove materiality as a matter of law. And even if the claims made representations regarding off-label marketing, those representations were not material because the Government has always paid and continues to pay Prezista and Intelence claims with full knowledge of Relators' allegations and evidence. As this Court's precedent makes clear, the core question for materiality is whether the alleged fraud would have affected the Government's decision to pay for Prezista and Intelence. Over a decade of experience teaches that the answer is "no."

Relators fare no better on falsity. Again, because the reimbursement claims made no representation as to marketing, the veracity of any off-label marketing has no bearing on "falsity" under the FCA. Relators are left to argue that Prezista and Intelence were not prescribed for medically accepted indications and not reasonable and necessary for treatment. That argument fails because Relators did not prove that those were conditions of payment for the government payors at issue or that such conditions were violated. Contrary to Relators' assertion, there was no evidence of patient harm from the prescriptions of these life-saving drugs. Rather, the record

shows that physicians used their expert medical judgment in evaluating the truthful information provided on the drugs' labels and by Janssen representatives to prescribe the right drugs to the right patients. In deciding whether to reimburse claims for prescriptions, government payors do not attempt to interfere with physicians' medical judgment, nor do they categorically bar reimbursement for "off-label" uses.

If this Court does not reverse the judgment on these grounds, it should hold that the FCA's *qui tam* provisions are unconstitutional because they vest Relators with executive authority the Constitution entrusts to the President. This case—in which Relators are pursuing a legal theory that the Government disavows—is a prime illustration of that constitutional problem. The delegation of the Executive Branch's authority and prosecutorial discretion to private individuals is improper and causes grave harm, which is only exacerbated by the astronomical and unconstitutional penalties imposed. The judgment should be reversed.

ARGUMENT

I. As the Government Confirms, the District Court Erred in Holding That Relators Could Prove FCA Violations Based Solely on "Off-Label" Marketing.

To prove an FCA violation for claims submitted for Prezista and Intelence, Relators needed to show that "[t]he claims themselves" were "false or fraudulent." *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 765 (3d Cir. 2017). Because Relators sought to establish "legal" falsity, they needed to prove that each

claim falsely certified compliance "with a statute or regulation the compliance with which is a condition for Government payment." *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 486 (3d Cir. 2017) (cleaned up). The district court upheld the jury verdict on an express certification theory: The court held that Relators presented evidence of "[off-label] marketing" and that "[off-label] marketing violate[s] an express condition of payment for reimbursement." Appx244.

No one defends the district court's reasoning. The court did not identify the source of this purported "express condition of payment," and none exists. The Government acknowledges that, given this error, this Court cannot affirm the district court's judgment. U.S. Br. 41. Relators attempt to avoid this result by advancing other arguments for why off-label marketing renders claims false and by downplaying their disagreement with the Government and the significance of the district court's errors. Those attempts all fail.

A. Parting ways with the Government, Relators contend that "off-label" marketing can render claims false because the absence of improper marketing is a "de facto condition of … payment." Relators Br. 34 (quoting *United States ex rel. Int'l Bhd. of Elec. Workers v. Farfield Co.*, 5 F.4th 315, 345 (3d Cir. 2021)). But a false certification must be either express or implied. *See, e.g., Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 186 (2016). No court has ever recognized

a "de facto" false certification theory. Nor has any court held that the Government imposes a particular condition of payment where, as here, the Government specifically denies that it imposes any such condition.

Although Respondents allude (at 17, 26, 33) to "implied" conditions, they do not develop an implied certification argument, and for good reason. To prove falsity under that theory, Relators needed to show that the reimbursement claims "omitt[ed] critical qualifying information." *Universal Health Servs.*, 579 U.S. at 190. Whether a prescribing physician was exposed to off-label marketing does not meet that standard because, as the Government explains, "[t]he FDCA's misbranding provisions govern how drugs may be marketed; they do not govern whether federal healthcare programs will reimburse for the drugs." U.S. Br. 15. "In other words, compliance with the FDCA is not a condition of Medicare reimbursement. And it is likewise not a condition of reimbursement for state Medicaid and ADAP programs." *Id.* at 36-37. The district court's error thus was not merely that it characterized "off-label" promotion as an "express condition of payment"; the error was treating it as any sort of condition of payment—express, implied, or "de facto."

Relators' "de facto" argument conflates falsity and materiality. The case Relators cite, *Farfield*, involved an allegedly false express certification, and the Court analyzed—for materiality purposes—whether that certification involved noncompliance with a legal requirement that was a "condition of payment," or was

merely another requirement imposed on government contractors. 5 F.4th at 345. In doing so, the Court recognized that a "legal requirement[]" need not be "expressly call[ed] … a condition of payment" for violation of that requirement to be material to the Government's payment decision. *Id.* (citation omitted). But that question—whether the false certification involved compliance with a "condition of payment"—is relevant only if there has first been a false compliance certification.

As the Government acknowledges, the reimbursement claims at issue here did not certify compliance by manufacturers with the FDCA or that manufacturers did not make off-label marketing statements. That is because the reimbursement claims submitted to government payors are not conditioned on manufacturers' compliance with FDA's marketing regulations.

B. Relators accuse the Government of misunderstanding the district court's reasoning. Relators Br. 49. According to Relators, the district court "never suggested off-label marketing, 'without more,' satisfies falsity." *Id.* Rather, "it concluded Relators showed 'more' by proving Janssen lied to doctors about the safety and efficacy of its drugs." *Id.* That argument is flawed in several respects.

First, the district court required only that the jury find that Janssen engaged in "off-label" marketing. None of the references to "off-label" marketing in the jury instructions limited that term—or even referred at all—to "false" or "fraudulent" marketing. *See, e.g.*, Appx2202. Nor did the district court rely on similar qualifiers

in upholding the verdict. Instead, it held that the jury could find for Relators because they "introduced evidence that demonstrated Janssen's marketing of Prezista and Intelence w[as off-label]." Appx244; *see also* Appx243.

Relators attempt to sidestep this point by incorrectly asserting (at 41) that Janssen has conceded that it engaged in fraudulent marketing. Relators point to promotional statements that departed in trivial ways from the drugs' labels. Relators Br. 11-12 (discussing promotion of Prezista as "lipid-friendly," and providing physicians with "off-label studies" that used small sample sizes, were not double-blind, or were authored, with full disclosure, by researchers Janssen had compensated). But that is not evidence that Janssen's promotion for these uses was knowingly false or deceptive. Indeed, Relators identify no specific false statements Janssen allegedly made, and they do not deny that physicians were able to evaluate Janssen's promotional messaging for themselves, including by consulting the Prezista and Intelence product labels. Many of the marketing messages that Relators now call fraudulent were submitted to the FDA by Janssen well over a decade ago.[1] *See* Appx1231, 1678, 1921.

[1] Relators also assert that the "FDA cautioned Janssen against promoting Prezista as having a 'low impact' on lipid levels." Relators Br. 47 (quoting Appx1649). But they omit that the FDA's guidance responded to a direct-to-consumer advertisement. Appx3546-49; *see also* Appx1634. FDA did not similarly respond—or, indeed, respond at all—to similar statements in other marketing material Janssen submitted to the FDA. Janssen Br. 44.

Second, calling Janssen's marketing "false" and "fraudulent" in addition to "off-label" does not solve the fundamental problem with Relators' theory: No variety of improper marketing—standing alone—suffices to establish FCA liability. *See supra* pp. 5-6. Again, as the Government explained, "compliance with the FDCA is not a condition of" reimbursement imposed by any of the government payors here. U.S. Br. 36-37. And that is true regardless of whether a relator alleges that the defendant engaged in truthful off-label promotion or fraudulent off-label promotion. "[F]alse marketing" does not itself "make [a] claim false"—"non-reimbursability" does. U.S. Br. 37-38. That is because the FCA's focus is not on "whether the alleged fraud deceived the prescribing physicians, but rather whether it affected [the Government's] payment decision." *Petratos*, 855 F.3d at 492.

None of Relators' cases (at 32-34 & n.13) support their contention that "prescriptions caused by false and misleading promotion" are necessarily non-reimbursable. Rather, those cases confirm that improper marketing does *not* alone render a prescription non-reimbursable. For example, Relators' lead case on this point—*United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39 (D. Mass. 2001)—allowed a complaint to survive dismissal because it alleged an FCA violation "not from unlawful off-label marketing activity itself," but instead from the allegedly resulting "submission of Medicaid claims for *uncovered* off-label uses"

of epilepsy and hypertension drugs to treat entirely different conditions. *Id.* at 52; *see also id.* at 45.[1]

Third, Relators overlook the Government's explanation of the "something more" that is necessary to render a claim false: A claim would be false if "off-label" marketing caused a physician or pharmacy to make a false certification in connection with the claim—for example, if it caused a claim to be submitted to Medicare that was not for a "medically accepted indication." U.S. Br. 37. Relators' hypothetical—in which a pharmaceutical manufacturer fraudulently promotes a painkiller as a cancer treatment, causing doctors to "prescribe it as a chemotherapy alternative"—underscores the point. Relators Br. 34-35. Off-label marketing could result in FCA liability in that circumstance because cancer would not be a medically accepted indication (and thus the prescription would not be reimbursable), not because of the "off-label" marketing.

C. Relators contend that vacating the judgment and remanding the case would "waste judicial resources" because the district court could merely "revise the

[1] Relators' other cited cases are similar. *See, e.g, United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 902-04 (9th Cir. 2017) ("Our focus here should not be whether the alleged fraud deceived the prescribing physicians, but rather whether it affected CMS's payment decisions" (cleaned up) (citation omitted)); *United States ex rel. Hinkle v. Caris Healthcare, L.P.*, 2017 WL 3670652, at *2, 5-6 (E.D. Tenn. May 30, 2017) (relator adequately alleged falsity where relevant certifications were unsupported by medical records).

cited wording … without altering the underlying judgment." Relators Br. 50. But again, the district court's conflation of off-label marketing with FCA liability was the only basis on which it upheld the jury's verdict, and the district court's misunderstanding of the law infected the whole trial, including how it mistakenly instructed the jury. *See infra* Part II.B.3. Even the Government—which would reap more than $1 billion if the Court affirms the judgment—admits that the judgment *cannot* be affirmed. For the reasons discussed below, the judgment must be reversed, because without the erroneous off-label theory, Relators could not—and did not—prove the elements of their claims.

II. Relators Failed to Establish the Elements of Their Claims.

Without the erroneous "off-label" marketing theory, Relators cannot prove their claims as a matter of law. Perhaps in recognition of this fact, Relators repeatedly attempt to shift the burden of proof to Janssen and claim forfeiture at every turn. None of those arguments have merit.

A. Relators Did Not Establish Materiality.

The district court held that Relators proved materiality based solely on evidence related to "off-label" marketing. Appx243. The reimbursement claims at issue did not make a material misrepresentation about "off-label" marketing because, as the Government confirms, they made no representations regarding marketing. In any event, any misrepresentation regarding marketing could not be

material given the undisputed evidence that the Government continued to reimburse for all relevant claims after learning of the alleged noncompliance. Relators cannot overcome that critical fact.

1. Because the Claims Contain No Representation Regarding Marketing, They Necessarily Lack Any "Material" Misrepresentation Regarding Marketing.

The FCA's falsity and materiality elements are closely linked in this case. To establish falsity, Relators needed to prove that claims for Prezista and Intelence included a false certification regarding compliance with a statute, regulation, or government contract. *Petratos*, 855 F.3d at 486. And to establish materiality, Relators needed to prove that the "misrepresentation about [such] compliance … was material to the government's payment decision." *Universal Health Servs.*, 579 U.S. at 192.

Given the overlap between the two elements, the district court's erroneous falsity holding also undermined its materiality analysis. As discussed above, the court incorrectly believed that "off-label marketing" violates an "express condition of payment." Appx244. The district court then upheld the jury's finding on materiality based on purported evidence that Janssen's "marketing violations were material to the Government's reimbursement decisions." Appx243. But that holding is necessarily wrong as a matter of law: A misrepresentation regarding marketing cannot be material if no such certification was ever made.

For the claims at issue, the jury was instructed on only one theory of materiality: that "off-label marketing violations were material to the Government's payment decision." Appx2214. And in its post-trial ruling, the district court relied solely on evidence regarding "off-label" promotion to uphold the jury's finding of materiality. Appx243. Because "off-label" promotion is not a "condition of payment," *see supra* Part I, it necessarily cannot be material to the payment decision. Given Relators' failure to prove materiality, the judgment must be reversed.[2]

2. The Government's Continued Payment of Claims for Prezista and Intelence Also Defeats Materiality.

Even if the FDCA's marketing requirements were a condition of payment and the claims here falsely certified compliance with them, Relators failed to prove that those purported misrepresentations were material.

a. Relators' materiality arguments largely ignore *Petratos*, this Court's most relevant materiality decision. *Petratos* affirmed the dismissal of an FCA action at the pleading stage—even though the relator adequately alleged falsity under Medicare Part B's "reasonable and necessary" requirement—because the relator

[2] Relators present alternative grounds (at 36-41) for upholding the jury's falsity finding—e.g., that the reimbursement claims were not for a "medically accepted indication." But they have never suggested they could prove materiality based on those alternative theories. Relators have not, for example, pointed to any evidence that a government payor would have denied claims for Prezista or Intelence if it had known that a particular patient had elevated lipids or was taking a drug once, rather than twice, per day.

disclosed "material, non-public evidence" to the Government, which continued to pay claims for the drug, indicated no change in its position, and did not initiate any enforcement actions. 855 F.3d at 490. *Petratos* controls because it is undisputed that the Government continued to pay claims for Prezista and Intelence for over a decade after learning of Relators' allegations *and evidence*—and has, even now, "signaled no change in position," *Universal Health Servs.*, 579 U.S. at 195.

The Government even explains why it continues to pay the claims despite Relators' allegations of off-label marketing: "[t]he FDCA's misbranding provisions … do not govern whether federal healthcare programs will reimburse for the drugs." U.S. Br. 15. This approach makes sense given that "the FDCA does not regulate the practice of medicine," and "physicians may lawfully prescribe drugs for off-label uses." *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 240 (3d Cir. 2012). Put another way, permitting "off-label" use of FDA-approved drugs is an "accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (cleaned up).

Relators err in contending (at 28-29) that the Government's payment of claims cannot defeat materiality until noncompliance has been proven at trial. This Court has resolved materiality both at the pleading stage (*Petratos*) and at summary judgment (*Spay*), and courts have concluded that noncompliance was not material

even where relators disputed "actual knowledge," *see, e.g., United States ex rel. Foreman v. AECOM*, 19 F.4th 85, 113 (2d Cir. 2021). In any event, the Government had "actual knowledge" of the alleged noncompliance here long before trial. Relators provided their evidence to the Government at the onset of the case. *See, e.g.*, Janssen Br. 35. A lengthy multi-year discovery period followed, and in their opposition to Janssen's summary judgment motion, Relators relied on the same evidence they presented at trial, including Relators' own testimony, their expert reports, and testimony from Janssen executives and former employees. ECF 287 at 7-9, 26-30, 37-39; ECF 287-3.

The Government was undoubtedly aware of this evidence: It filed three statements of interest in the district court, Appx350-59; Appx2299-2306; ECF 484. And despite its knowledge, the Government did not halt payments, demand repayment, take enforcement action, or revoke approvals. Even now, on appeal, the Government does not contend that "off-label" marketing is material to its payment decisions. Quite the opposite: It clearly states that such marketing is not part of the reimbursement decision. U.S. Br. 15.

Relators also contend (at 27) that *Farfield* "held" that "the government's payment of claims during [a] litigation" does not "defeat[] materiality." *Farfield* does not stand for that proposition. Unlike the overwhelming evidence of Government inaction here, there was "no record evidence" in *Farfield* "showing that

the Government … pays claims like those at issue" despite its knowledge of noncompliance. 5 F.4th at 346. In other words, the parties proffered "[n]o evidence of past relevant Government (in)action." *Id.* That is not the case here.

b. Faced with "very strong evidence" defeating materiality, *Universal Health Servs.*, 579 U.S. at 194-95, Relators resort to distractions.

Though they insist otherwise (at 28), Relators shoulder the "initial burden" "to show materiality," *United States v. Care Alternatives*, 81 F.4th 361, 374 (3d Cir. 2023), and they cannot discharge that burden with unsubstantiated assertions. For example, Relators contend (at 22) that the prescriptions at issue "endanger[ed] HIV patients." But Relators identify no evidence of any patient harm; indeed, trial evidence was directly contrary. *See, e.g.*, ECF 469 at 6761:9-13 (Prezista was a "game changing advance in the field of HIV therapeutics"); Appx1927 ("[T]hese medications really saved lives"). Nor can Relators meet their burden by citing evidence irrelevant to the materiality inquiry. For example, the cited settlements and corporate integrity agreements, *see* Relators Br. 24-25, 32, concerned other drugs and prescriptions for non-approved conditions, *see, e.g.*, Appx3453-54. FCA liability in those cases arose because the claims allegedly violated a condition of payment—for example, they were not for a "medically accepted indication"—not merely because "off-label" marketing was involved.

Nor does it assist Relators to contend (at 21-22) that the claims must be material because—when aggregated—they amount to a significant monetary sum. The amount here is high precisely *because* the Government continued paying claims for over a decade, which underscores the lack of materiality. *Cf. Farfield*, 5 F.4th at 346-47 ("refus[ing] to measure materiality based only on the monetary value of [defendant's] wrongdoing" because that would involve "difficult, if not impossible, line-drawing").

Finally, Relators point (at 23-24) to Janssen's alleged knowledge, but that argument conflates materiality with scienter. *See Universal Health Servs.*, 579 U.S. at 191. The testimony on which Relators rely was not specific to the particular noncompliance alleged here. It addressed only whether the Government tends to care about off-label marketing. *See* Appx1354; ECF 465 at 2714:1-5; Appx994-95 (Iacobellis). But the question is not whether the Government generally cares about "off-label" marketing; it is whether government payors "would not have paid *these claims* had it known of *these violations*." *Universal Health Servs.*, 579 U.S. at 196 (emphases added). Because Relators' evidence failed to make that showing, the judgment should be reversed.

B. Relators Did Not Establish Falsity.

Because "off-label" marketing is not a condition of payment and therefore cannot establish that any claim for Prezista or Intelence is false, *see supra* Part I,

Relators fall back on the argument that the claims were not for a "medically accepted indication" or not "reasonable and necessary." That argument cannot save their claims because Relators failed to establish that each government payor required compliance with such conditions or that those conditions were violated.

1. Relators Failed to Establish That "Medically Accepted Indication" and "Reasonable and Necessary" Are Conditions of Payment for All Government Payors.

a. Medicare Part D may treat "medically accepted indication" as a condition of payment, but Relators failed to establish that Medicaid and AIDS Drug Assistance Programs ("ADAP") impose that condition.

Relators' contrary contention about Medicaid (at 37) is based on the definition of "covered outpatient drug." But the statute provides that States "may" exclude coverage under Medicaid if "the prescribed use is not for a medically accepted indication," and that this is a "[p]ermissible restriction" that States may impose.[3] 42 U.S.C. § 1396r-8(d)(1)(B)(i). Relators' assertion that "may" means "must" is grounded only in a nonbinding decision that itself acknowledges that coverage "may be denied" if not "for a 'medically accepted indication.'" *In re Vioxx Prods. Liab. Litig.*, MDL No. 1657, 2010 WL 2649513, at *11 (E.D. La. June 29, 2010). Relators

[3] Other courts have also questioned whether "medically accepted indication" is a condition of payment under Medicaid. *See, e.g., United States ex rel. King v. Solvay Pharms., Inc.*, 871 F.3d 318, 328 n.7 (5th Cir. 2017); *United States ex rel. Booker v. Pfizer, Inc.*, 847 F.3d 52, 59 n.7 (1st Cir. 2017).

are also incorrect that ADAP programs are subject to the same requirements. Relators assert (at 37) that state ADAP programs, as 340B entities, "must procure covered outpatient drugs" which can only be prescribed for a "medically accepted indication." But ADAPs are not required to purchase drugs through the 340B program. *See* HHS, *ADAP Manual*, at 79 (2012), https://tinyurl.com/2bcceurp. And Relators cannot disguise the flaws in their case (at 37) by improperly shifting the burden to Janssen to offer evidence that ADAP programs *would* reimburse.

b. Relators' support for the "reasonable and necessary" condition is equally flawed. As to Medicare Part D, Relators rely on *Petratos*, Relators Br. 38, but that case concerned Part *B*, not Part D. 855 F.3d at 488. The statute at issue there—42 U.S.C. § 1395y(a)—provides that "no payment may be made under part A or part B" for drugs that are not reasonable and necessary. The provision at issue *here* clearly provides that Part D plans "may exclude" from coverage drugs that were not reasonable and necessary but are not required to do so. 42 U.S.C. § 1395w-102(e)(3)(A).

As for Medicaid and ADAP, Relators point (at 39) to other provisions of federal law that generally limit federal programs to "reasonable" services. But Relators make no effort to tie those requirements to the theory on which the jury was instructed, which was that a claim must be "reasonable and necessary for the

diagnosis or treatment of illness or injury," language lifted from the statute addressing Medicare Parts A and B. Appx2202.

Nor does any trial testimony "fill th[e] gap." Relators Br. 39-40, 43. For one, a condition of payment must stem from a "statute or regulation," *Petratos*, 855 F.3d at 486; unsubstantiated testimony cannot establish a condition of payment. For another, the trial testimony Relators point to, Appx1502, is steeped in an "off-label" marketing theory that must be rejected, *see supra* Part I. And, indeed, a different witness for Relators acknowledged that "each individual state has different requirements for what they allow to be paid under Medicaid." Appx955.

2. Relators Failed to Establish That the Claims Violated Any "Medically Accepted Indication" and "Reasonable and Necessary" Conditions.

Even assuming the "medically accepted indication" and "reasonable and necessary" conditions applied, Relators failed to establish violations of either requirement.

a. As the Centers for Medicare & Medicaid Services ("CMS") explain, "medically accepted indication" refers to "the *diagnosis or condition* for which a drug is being prescribed." CMS, *Medicare Prescription Drug Benefit Manual* ch. 6, § 10.6 (rev. 2010) ("Part D Manual") (emphasis added). Yet it is undisputed that the claims here involved prescriptions of lifesaving HIV medicines for patients with HIV. All the relevant claims were therefore for a "medically accepted indication."

Relators' response (at 44) that "indications" covers "contra-indications, limitations of use, use by specific populations, and dosage instructions" misquotes *United States ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613 (2d Cir. 2016). That decision states that a drug's "label" includes that information. *Id.* Relators also cite (at 44) FDA's drug labeling regulations, but those require drug labels to have both an "[i]ndications" section containing "[a] concise statement of each of the product's indications" *and* a "usage" section containing the "[m]ajor limitations of use." 21 C.F.R. § 201.57(a)(6).

Relators' approach becomes even more untenable when applied to the particular claims here. The lipid-based claims represent the majority of the claims, *see* Appx1820-22, but the Prezista label mentions lipid-related risks only among dozens of other possible side effects listed in the "Adverse Reactions" section, nearly twenty pages after the "Indications and Usage" section. *See* Appx3220 (Prezista 2006 label). Relators' witness Dr. Glatt accordingly testified that the label does not prohibit use in patients with lipid conditions, Appx1244, and Relators conceded at trial (and therefore have waived) any other contention that those prescriptions were not for "medically accepted indications."

Relators also argue (at 41) that once-daily dosing "contradicted [Intelence's] label," but again, Relators conflate the FDA-approved "indications" for Intelence with the entirety of the label. The label addresses dosage instructions in a "Dosage

and Administration" section that is separate from the "Indications and Usage" section, Appx3073-74, and CMS has explained that "medically accepted indication" does not refer to "the dose being prescribed." Part D Manual ch. 6, § 10.6.

b. Relators likewise cannot point to a single claim that was not "reasonable and necessary" both at the national-level and for the "individual patient," as *Petratos* requires. 855 F.3d at 487-88. At the first step, Relators do not dispute that Prezista and Intelence are FDA-approved, that they are part of CMS's protected class of drugs, and that data supporting their use in each of the four ways at issue here was included in the treatment guidelines. *See* Relators Br. 46.

Relators attempt to overcome their lack of evidence regarding any individual patient by selectively quoting *Petratos* to suggest that individualized proof is unnecessary. *See id.* at 47. But *Petratos* explains that a drug is "reasonable and necessary" for an individual patient "based on accepted standards of medical practice" *and* "the medical circumstances of the individual case." 855 F.3d at 488.

Although Relators point to testimony from witnesses who analyzed claims data, Relators identify no physician testimony based on individualized determinations that any prescriptions were not "reasonable and necessary." *Id.*

(noting that physicians play a "critical role" in such determinations).[4] In fact, Dr. Glatt acknowledged that prescribing Prezista and Intelence in each of the four ways at issue here could be reasonable and necessary. *See* Janssen Br. 36-37. Relators attempt to downplay the significance of that testimony as hypothetical, Relators Br. 48, but it was Relators' choice to argue that all the claims were unreasonable and unnecessary based on generalized evidence. They cannot dodge that decision now. In short, Relators have not met their burden to "provide evidence of at least one false claim." *See United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 99 (3d Cir. 2018). The judgment should be reversed on that ground.

3. As the Government Confirms, the District Court Erred in Instructing the Jury.

Instruction 17 contains three misstatements of law: (1) it inserts "on the label" into the definition of "medically accepted indication," even though the statutory definition does not include that term; (2) it requires a "medically accepted indication" to be FDA-approved *and* supported by a compendia, even though the statutory definition sets forth those requirements in the disjunctive; and (3) it states that Prezista and Intelence claims are reimbursable only if they are for a "medically accepted indication" and "reasonable and necessary," even though Relators did not

[4] Other HIV medicines had side effects as well, *see, e.g.*, ECF 465 at 2444:15-24, highlighting the importance of physicians determining in their medical judgment the appropriate treatment for their patients.

establish that the government payors impose those conditions of payment. *See supra* Part II.B.1. The Government agrees that the district court erred in giving this instruction. U.S. Br. 38-39. Those errors warrant a new trial.

Relators and the Government attempt to avoid that result by asserting that Janssen forfeited this challenge. Relators Br. 50-51; U.S. Br. 39-41. But Janssen repeatedly objected to Instruction 17 on these grounds. It submitted alternative jury instructions and briefing that proposed correct articulations of the law, and at the charge conference, Janssen explicitly raised Instruction 17's misstatements of law, citing the record and case law to support its objections. *See, e.g.*, ECF 424-1 at 29; ECF 424-2 at 1-2. And the district court even reassured the parties that past objections to jury instructions "are noted" and "not waived." ECF 454 at 7853:5-7854:6. The inapposite case upon which the Government relies addressed a garbled objection without any cited legal basis. *See* U.S. Br. 40 (citing *Lesende v. Borrero*, 752 F.3d 324 (3d Cir. 2014)). Conversely, Janssen explicitly objected to Instruction 17 because its definition of "medically accepted indication" "doesn't track the statute or the policy manual." Appx2131-32.

Regardless, the district court committed plain error because Instruction 17 left the jury "without adequate guidance on a fundamental question." *Harvey v. Plains Twp. Police Dep't*, 635 F.3d 606, 612 (3d Cir. 2011) (cleaned up). As the Government acknowledges, Instruction 17 "suggested incorrectly that FDA

approval of a drug for a particular indication is necessary for the drug to be medically accepted for that indication." U.S. Br. 38-39. Put differently, the instruction provided incorrect "guidance on the fundamental question of what [the jury] needed to find" to determine falsity. *Forrest v. Parry*, 930 F.3d 93, 119 (3d Cir. 2019). Nor is it "highly probable" that the error did not affect the judgment. *Harvey*, 635 F.3d at 612. By conflating off-label marketing standards and reimbursement, Instruction 17 endorsed the fundamental error in Relators' case and is far from harmless.

C. Relators Did Not Establish Causation.

The FCA incorporates common-law tort principles, which require but-for causation. The district court's instruction on causation erroneously permitted the jury to hold Janssen liable without finding that Janssen's conduct was a but-for cause of the submission of any false claims. Relators offer no meaningful response.

Relators first point (at 53) to *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235 (3d Cir. 2004). But in addressing causation, *Schmidt* invoked the Restatement of Torts, just like Janssen. *See id.* at 244; *cf. Universal Health Servs.*, 579 U.S. at 193 (using Restatements to address materiality). The Second Restatement adopts a but-for causation requirement as part of the "substantial factor" test. Janssen Br. 39; Appx2250; *see generally June v. Union Carbide Corp.*, 577 F.3d 1234, 1239-44 (10th Cir. 2009) (explaining that Second Restatement generally requires but-for causation and interaction with "substantial factor" test). *Schmidt*

had no cause to address the but-for component of the substantial factor analysis. It instead addressed only whether intervening forces could break the causal chain. *See* 386 F.3d at 244.

Turning next to *Petratos* and *United States v. Hibbs*, 568 F.2d 347 (3d Cir. 1977), Relators ask the Court to ignore any discussion of causation. For example, Relators observe that *Petratos* "rejected the relator's argument that he could prove materiality by proving 'the alleged fraud was the 'but for' cause of the submitted claim.'" Relators Br. 54 (emphasis omitted) (quoting *Petratos*, 855 F.3d at 491). But Relators gloss over *why* the Court rejected that argument: because even "the causation element cannot be met merely by showing 'but for' causation." *Petratos*, 855 F.3d at 491. Similarly, Relators assert (at 54) that *Hibbs* did not address causation at all, but the Court expressly stated the case concerned the "element of causation," which it held required more than showing but-for causation. 568 F.2d at 349, 351. As other courts have recognized, *Hibbs* establishes that the FCA also requires proximate causation. *See United States v. Luce*, 873 F.3d 999, 1010-14 (7th Cir. 2017).

Relators further argue that this Court has not previously required but-for causation instructions in FCA cases. But this Court has never decided whether a jury instruction without but-for causation is permissible. Relators are equally wrong (at 53-54) that the meaning of "substantial factor" is "plain." "Substantial factor" is

a legal term of art lacking plain meaning to lay jurors. *See United States v. Bowen*, 414 F.2d 1268, 1272 n.8 (3d Cir. 1969) (jury not presumed to understand legal terms of art); *Doe v. N.Y.C. Dep't of Soc. Servs.*, 649 F.2d 134, 143-44 (2d Cir. 1981) (same). Indeed, the use of "substantial factor" in the Second Restatement engendered so much "misunderstanding" that the Third Restatement abandoned it. *See June*, 577 F.3d at 1239. The district court's barebones "substantial factor" instruction invited the jury to hold Janssen liable even if every challenged prescription would have been written absent the alleged marketing. Janssen Br. 40. Because the instruction thus "failed to state a proper legal standard" and was at least "misleading," a new trial is warranted. *DiFiore v. CSL Behring, LLC*, 879 F.3d 71, 75 (3d Cir. 2018).

Relators' problems run even deeper. Relators claim only that the evidence they submitted at trial satisfied a looser standard. Relators Br. 52-53. Evaluating the evidence before the jury under the proper standard makes plain that reversal is warranted. Relators are wrong to suggest (at 52) that a heightened standard applies to review of evidentiary sufficiency as to causation. *See ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 268 (3d Cir. 2012) (employing ordinary standard of review). That "[c]ausation is a fact question" for a jury at trial, Relators Br. 52, also does not alter the standard of review. The district court made a legal error, and reversal is

required where, as here, the party bearing the burden did not present sufficient evidence to the jury under the proper standard.

Relators' cursory defense of their causation evidence (at 53-55) incorrectly suggests that Janssen believes statistical evidence is off-limits. If Relators rely on statistical inferences, however, the statistics must at least *try* to show but-for causation. Janssen Br. 42-43. By Shaked's own admission, however, his testimony, like everything else Relators presented to the jury, *see* Janssen Br. 41-43, established at most that physicians not exposed to Janssen's marketing had "less tendency" to prescribe "off-label." Appx1782. That testimony should not even have been admitted, because it was based on flawed assumptions Relators do not try to defend to this Court. Relators Br. 55 (resting on district court's rulings alone). Relators have identified nothing in the trial record establishing the but-for causation the FCA demands, and the judgment should be reversed.

D. Relators Did Not Establish Scienter.

Relators erroneously assert, without support, that they proved Janssen acted with the requisite scienter. Relators Br. 56. But the district court instructed the jury to effectively disregard Dr. Patel's testimony, which was critical to Janssen's knowledge about allegedly unlawful marketing. Janssen Br. 44-45.

Relators again mistakenly argue forfeiture. Relators Br. 56. In its motion for a new trial, Janssen argued that Instruction 22 "was improper in ways that bear on

both falsity and scienter," ECF 474-1 at 32, which the district court explicitly acknowledged in its post-trial opinion, Appx258-59 (acknowledging Janssens' argument that "language improperly influenced the jury to find scienter").

Relators next assert that the "charge, taken as a whole, was complete and accurate." Relators Br. 56-57 (citation omitted). But by omitting Janssen's curative language, "the jury may have been misled into believing that" Janssen's failure to receive explicit approval of its marketing materials meant that Janssen knew its materials *lacked* approval. *Ayoub v. Spencer*, 550 F.2d 164, 168-69 (3d Cir. 1977). That the jury asked, in its first substantive question, about the relevance of FDA's silence, Appx2171, only underscores that Instruction 22 "left the jury without guide or compass to aid it in rationally reaching [its] decision," *Ayoub*, 550 F.2d at 169. Relators read too much into Janssen's statement that adding "or disapproved" would "not 'change the meaning of the instruction.'" Relators Br. 56 (citing Appx2139). Immediately after, Janssen clarified that this language "does give it greater balance," because otherwise the instruction "could be read to say, 'Disregard Dr. Patel's testimony.'" Appx2139.

E. Failure of Any Liability Theory Warrants a New Trial.

Relators do not contest that should any of their twelve theories of liability fail, it would be impossible to tell whether the jury relied on invalid theories; what damages were awarded based on such theories; and what portion of the civil

penalties award was affected. Janssen Br. 45-47. The "proper course" is therefore "to remand for a new trial rather than attempt to divine the basis of the jury's verdict." *Brokerage Concepts v. U.S. Healthcare, Inc.*, 140 F.3d 494, 534 (3d Cir. 1998).

Relators instead ask the Court to ignore this rule, insisting that Janssen forfeited the argument. Relators Br. 61 (citing *Frank C. Pollara, LLC v. Ocean View Inv. Holding, LLC*, 784 F.3d 177, 191 (3d Cir. 2015)). That is wrong both legally and factually.

"[I]nconsistenc[ies] in a general verdict" must be raised before the jury is discharged. *Pollara*, 784 F.3d at 191-92. Here, the problem is not inconsistency—rather, the court could not "determine whether the jury based its verdict on an improper ground." *Wilburn v. Maritrans GP Inc.*, 139 F.3d 350, 361 (3d Cir. 1998) (ordering new trial where jury may have relied on factually deficient theory). This Court has never required preservation of *that* sort of objection. Unlike an objection to an inconsistency, "either side" can insist on a special verdict breaking down liability by particular theory—and "if no one does, the judge can insist." *Gillespie v. Sears, Roebuck & Co.*, 386 F.3d 21, 31 (1st Cir. 2004). Relators' preservation rule penalizing only the appellant makes no sense in this context.

At any rate, Janssen initially proposed a verdict form that would have required the jury to separately identify damages and false claims for each of Relators' four

Medicare theories. *See* ECF 357 at 6-7. Janssen did not ask the same for the Medicaid and ADAP theories only because Janssen simultaneously argued that the Court should not submit those theories to the jury, given Relators' failure to establish coverage requirements. *See* ECF 358 at 7-8.

Beyond their flawed preservation argument, Relators respond only that "the factual insufficiency of any individual theory would be harmless error." Relators Br. 62. But Janssen also identified *legal* infirmities—for example, that certain supposed conditions of payment do not exist and that key jury instructions were flawed. *See* Janssen Br. 30-33, 37-39, 44-45. *Cf. Griffin v. United States*, 502 U.S. 46, 59 (1991) (rejecting harmless error analysis for legally deficient theories because "[j]urors are not generally equipped to determine whether a particular theory of conviction submitted to them is contrary to law"). In any event, harmless error depends on the Court being "reasonably sure that the jury in fact relied upon a theory with adequate evidentiary support." *Gillespie*, 386 F.3d at 30.

The Court has no such assurance here. As a matter of arithmetic, the jury necessarily found Janssen liable for at least *some* false claims involving lipid conditions. *See* Janssen Br. 47. And if no lipid claims were false, then there are claims within the verdict for which there is *no* factually adequate basis. The rationale for holding factual insufficiencies harmless—that jurors may not have "rel[ied] upon

a factually inadequate theory" when also presented with factually adequate theories, *Griffin*, 502 U.S at 59—disappears entirely.

III. The *Qui Tam* Provisions of the False Claims Act Are Unconstitutional.

Neither the Government nor Relators offer a compelling defense of the constitutionality of the FCA's *qui tam* provisions. Nor can either contest that the constitutionality of the *qui tam* device is an open question in this Court and that three Supreme Court Justices have recently observed that "[t]here are substantial arguments that the *qui tam* device is inconsistent with Article II." *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 442 (2023) (Kavanaugh, J., concurring).

This case demonstrates the stark conflict between Article II and the FCA's *qui tam* device. Relators were awarded a billion-dollar judgment on a legal theory that the Government, the real party in interest, has historically rejected and expressly rejected here. *See* U.S. Br. 37 (listing briefs). Because the FCA's *qui tam* device violates Article II by vesting unelected, financially motivated private parties with sweeping executive authority, this Court should reverse the judgment of the district court.

A. Because Relators Serve as Unappointed Officers, the False Claims Act *Qui Tam* Provisions Violate the Appointments Clause.

The FCA's *qui tam* device violates Article II's Appointments Clause because relators function as unconstitutionally appointed "officers" when they litigate *qui*

tam suits. Janssen Br. 49-51. The Government and Relators erroneously urge that relators are not "officers" because relators neither exercise significant authority nor occupy "continuing positions." U.S. Br. 18-27; Relators Br. 58.

The Government's attempts to minimize relator's significant authority fail. The Government contends that *qui tam* suits are "fundamentally personal rather than governmental in nature" because relators "pursue a personal monetary recovery." U.S. Br. 24-25. But that wholly disregards the FCA's text and purpose. Under the FCA, relators bring suit "for" and "in the name of the Government." 31 U.S.C. § 3730(b)(1). The FCA prohibits the submission of false claims to the Government and authorizes recovery for damages "the Government sustains." 31 U.S.C. § 3729(a)(1), (b)(2). Indeed, relators only have standing to sue because of the Government's "injury to its sovereignty" and its "proprietary injury resulting from the alleged fraud." *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 771 (2000). Despite the Government's representations otherwise, "[t]he fact that the government delegates some portion of [its] power to private litigants does not change the governmental character of the power exercised." *Edmonson v. Leesville Concrete Co., Inc.*, 500 U.S. 614, 626 (1991).

The Government falls back on its authority to review relators' lawsuits before they are unsealed and its ability to intervene in an action and either proceed or dismiss. U.S. Br. 26. But Government review and the possibility of intervention do

nothing to diminish the fact that relators independently decide whether to commence litigation on behalf of the United States, what defendants to sue, and which legal theories to pursue. No matter what the United States ultimately decides to do in a particular case, relators have still forced the Government to investigate and act. *See* 31 U.S.C. § 3730(b)(1)-(2). Indeed, in *Lucia v. Securities & Exchange Commission*, the Supreme Court held that SEC administrative law judges were "officers" even though the Commission could review their decisions because the Commission could "decide against reviewing a[] [judge's] decision at all." 585 U.S. 237, 249 (2018). The Government's potential involvement does not diminish relators' exercise of significant authority.

The Government's argument that relators do not occupy a "continuing position" also lacks merit. Whether a position is "continuing" depends on whether its "tenure" and "duration" are of a "continuing and permanent" nature. *United States v. Germaine*, 99 U.S. 508, 511-12 (1879). Relators fill a "continuing and permanent" office because they proceed in the name of the Government and fulfill their duties as defined in the FCA for the compensation the statute provides. An office may be "continuous" "even if it is not continually filled." *United States ex rel. Zafirov v. Fla. Med. Assocs., LLC*, 751 F. Supp. 3d 1293, 1314 (M.D. Fla. 2024), *appeal docketed*, No. 24-13581 (11th Cir. Oct. 30, 2024).

The Government contends that a relator's duties "are limited in time and scope rather than continuing from officeholder to officeholder over time." U.S. Br. 20. But that fails to advance its cause: Courts have long recognized independent counsel are Article II "Officers" "even though the position terminates when the counsel 'has completed … any investigations or prosecutions undertaken pursuant to'" their appointment. *See, e.g.*, *United States v. Donziger*, 38 F.4th 290, 296 (2d Cir. 2022) (quoting *Morrison v. Olson*, 487 U.S. 654, 664 (1988)). In *Morrison*, for example, it was "clear" that a special counsel was an "Officer," even though she was authorized to investigate and prosecute only a single case. *See* 487 U.S. at 671-72 & n.12. After *Morrison*, other courts have consistently held that special counsel are "officers," even though their positions are "temporary." *United States ex rel. Montcrief v. Peripheral Vascular Assocs., P.A.*, 133 F.4th 395, 412 n.2 (5th Cir. 2025) (Duncan, J, concurring) (listing cases); *see also, e.g.*, *Donziger*, 38 F.4th at 297 (special prosecutor); *In re Grand Jury Investigation*, 916 F.3d 1047, 1052-53 (D.C. Cir. 2019) (similar).

Nor does the Government cite any authority to support its contention that, for the position of "relator" to be "continuing," the "duty of litigating a *particular* qui tam action" must be "transferable from relator to relator." U.S. Br. 23. But that argument ignores the many circumstances in which a particular *qui tam* action is "transferrable." As the Government acknowledges (at 23), a relator's estate may

pursue the relator's FCA claims if the relator dies, *see United States v. NEC Corp.*, 11 F.3d 136, 139 (11th Cir. 1993), or becomes bankrupt, *see United States ex rel. Spicer v. Westbrook*, 751 F.3d 354 (5th Cir. 2014). And if a relator's complaint is dismissed on procedural grounds, another relator may raise the same claims. *Kellogg Brown & Root Servs., Inc. v. United States ex rel. Carter*, 575 U.S. 650, 662-64 (2015). Underscoring the significant authority relators possess, although a *qui tam* action may be transferrable, the *United States* can never choose to replace one relator with another.

The Government's attempts to diminish *Zafirov* (at 19, 21-23) fail to persuade. The Government claims (at 19) that "numerous courts have criticized it as unpersuasive," but the Government cites only unpublished district court orders in support, some of which were constrained by circuit precedent, *see United States ex rel. Adams v. Chattanooga Hamilton Cnty. Hosp. Auth.*, 2024 WL 4784372, at *2-3 (E.D. Tenn. Nov. 7, 2024) ("The Sixth Circuit has rejected this argument and unambiguously held that the FCA is constitutional.").

B. The *Qui Tam* Provisions Violate the Vesting and Take Care Clauses.

The Government's arguments that the FCA's *qui tam* device does not violate the Vesting and Take Care Clauses fare no better. The Government urges that "litigation by the Executive" is not "the *exclusive* means of protecting the government's interests," and rely on the *qui tam* device's historical roots. U.S. Br.

27-34 (internal quotation marks omitted); *see also* Relators Br. 57-58. But repeated violations of the Constitution, no matter how longstanding, cannot justify ignoring the Constitution today.

The Government cites several civil rights and antitrust statutes, attempting to show that Congress has authorized private enforcement of federal statutes. U.S. Br. 27. But under these statutes, private litigants bring suit on their own behalf to redress their personal injuries—not "for" or "in the name of the Government." 31 U.S.C. § 3730(b)(1). Nor do cases brought under these statutes bind the Government upon entry of final judgment, unlike the FCA. *See United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 936 (2009).

History does not ameliorate *qui tam*'s constitutional infirmities. The Government and Relators rely primarily on *Stevens* to argue that *qui tam*'s historical roots are "conclusive" of its constitutionality. U.S. Br. 30; Relators Br. 57. But in *Stevens*, the Supreme Court "express[ed] no view" on "whether *qui tam* suits violate Article II." 529 U.S. at 788 n.8. And in any event, "historical patterns"—no matter how longstanding—"cannot justify contemporary violations of constitutional guarantees." *Polansky*, 599 U.S. at 450 (Thomas, J., dissenting) (quoting *Marsh v. Chambers*, 463 U.S. 783, 790 (1983)); *see also Montcrief*, 133 F.4th at 412 n.3 (Duncan, J, concurring).

* * *

In this case, the constitutional problems with the FCA's *qui tam* provisions are especially stark. Relators and the Government are in open disagreement about how to interpret the statute that they both purport to enforce. Relators obtained a $1.6 billion judgment on a theory that allegedly off-label marketing is sufficient to demonstrate falsity under the FCA, yet the Government has "repeatedly articulated"—and asserts directly to this Court—that "[a] finding that a company has marketed its drugs for off-label uses is not, without more, sufficient to find that subsequent claims for the marketed drugs are false within the meaning of the False Claims Act." U.S. Br. 37. And that sky-high award stems from prescription drug reimbursements that the Government never stopped paying and expresses no intention now to cease or clawback. The Constitution is designed to ensure that unaccountable private plaintiffs who are under no obligation to pursue the public interest do not set the Executive's law enforcement priorities. *See, e.g.*, *TransUnion LLC v. Ramirez*, 594 U.S. 413, 429 (2021). If this Court does not reverse the judgment on statutory grounds, it should direct the district court to dismiss this *qui tam* suit on constitutional grounds.

IV. Relators and the Government Fail to Show That the Ten-Figure Civil Penalties Award Was Not Unconstitutionally Excessive.

The district court's civil penalties award of more than $1.2 billion—more than ten times the compensatory damages award—was grossly disproportional and thus violated the Excessive Fines and Due Process Clauses. Janssen Br. 52-57. Unable

to defend that unprecedented award on its merits, Relators and the Government advance arguments that would render those constitutional protections all but meaningless in FCA cases.

Relators and the Government first suggest that civil penalties within the FCA's per-claim range are always constitutional. *See* Relators Br. 58; U.S. Br. 43-44. That is wrong twice over. *First*, statutorily authorized penalties are entitled to a "presumption of constitutionality," but that presumption may be "rebutted." *Yates v. Pinellas Hematology & Oncology, P.A.*, 21 F.4th 1288, 1314 (11th Cir. 2021). Were that not the case, Congress could gut the Excessive Fines and Due Process Clauses by authorizing penalties of billions of dollars per claim. *Cf. FCC v. Consumers' Research*, 145 S. Ct. 2482, 2501 (2025) (explaining that Congress could not constitutionally enact law permitting agency to impose fees of up to $5 trillion).

Second, even staying within statutory limits, a court may nonetheless impose an excessive penalty if it errs in identifying the *number* of false-claim-causing acts. The district court did just that here, assessing an $8,000 penalty per *prescription*. Appx266-67. The number of prescriptions, which was controlled by the physicians who chose to prescribe the drugs to their patients, bears no relationship to the gravity of *Janssen*'s conduct. *See United States v. Bornstein*, 423 U.S. 303, 312 (1976) (the FCA "penalizes a person for his own acts, not for the acts of someone else"); Janssen Br. 54-55. On this point, Relators and the Government are silent.

Relators and the Government are equally mistaken in insisting that the ratio between a civil penalties award and the compensatory damages award is irrelevant under the Excessive Fines Clause. Relators Br. 60-61; U.S. Br. 46-49. To begin, "[i]t's hard to see why the Court's approach to punitive damages under the Fifth Amendment would differ dramatically from analysis under the Excessive Fines Clause." *United States v. Rogan*, 517 F.3d 449, 454 (7th Cir. 2008) (Easterbrook, J.). And in Fifth Amendment cases, the Supreme Court has considered ratios to compensatory damages not because of the need to provide defendants with "fair notice," as the Government claims (at 49), but because such ratios, when excessive, indicate that an award is not "reasonable and proportionate to the amount of harm." *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 426 (2003); *see also, e.g.*, *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 580-83 (1996).[5]

"The touchstone of the constitutional inquiry under the Excessive Fines Clause," in turn, "is the principle of proportionality: The amount of the forfeiture must bear some relationship to the gravity of the offense that it is designed to punish." *United States v. Bajakajian*, 524 U.S. 321, 334 (1998). The ratio of

[5] The Supreme Court invoked "fair notice" in *State Farm* and *BMW* to bolster its conclusion that the Due Process Clause imposes substantive limits on awards in the first place—not in explaining why ratios were relevant to determining whether a particular award transgresses those limits. *See State Farm*, 538 U.S. at 417; *BMW*, 517 U.S. at 574.

penalties to compensatory damages is no less informative to that proportionality inquiry than the Fifth Amendment one, and courts have accordingly considered ratios in assessing compliance with the Excessive Fines Clause (including in False Claims Act cases). *See, e.g.*, *United States ex rel. Grant v. Zorn*, 107 F.4th 782, 798 (8th Cir. 2024); *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 389-90 (4th Cir. 2015).[6]

Here, the ratio of civil penalties (more than $1.2 billion) to compensatory damages (about $120 million) exceeds 10-to-1 and thus strongly suggests an award grossly disproportionate to the gravity of Janssen's conduct. *See* Janssen Br. 55-57. That is especially so given that the compensatory damages award is already "substantial," such that a ratio closer to one-to-one is likely at or near the "outermost limit" of constitutionality. *State Farm*, 538 U.S. at 425; *see* Janssen Br. 55.

That this case arises under the FCA cannot justify the astronomical ratio. The Government argues (at 49-50) that fraud actionable under the FCA can cause non-economic harms not captured by a ratio. But that is no justification for ignoring ratios in FCA cases; non-economic harms are already considered in assessing the reprehensibility (or lack thereof) of the defendant's conduct. *See* Janssen Br. 54;

[6] It is thus irrelevant whether only the Excessive Fines Clause (and not the Due Process Clause) limits FCA civil penalties. *See* U.S. Br. 48-49; *but see Drakeford*, 792 F.3d at 387-90 (assessing FCA civil penalties under both provisions).

Bajakajian, 524 U.S. at 339. And in identifying "particularly reprehensible" conduct, the Supreme Court has distinguished between conduct resulting in purely economic harms and conduct reflecting "reckless disregard for the health and safety of others." *BMW*, 517 U.S. at 576. Relators concede (at 60) a "lack of individualized evidence of patient harm." *See also supra* p. 15. And neither they nor the Government dispute the unrebutted evidence demonstrating that patients would have been prescribed different HIV drugs at the same cost if not prescribed Prezista or Intelence. Janssen Br. 54. A $1.2 billion civil penalty is grossly disproportional by any measure when it exceeds compensatory damages more than tenfold, there is no evidence of patient harm, and there is no reduction in the public fisc because the Government paid for HIV drugs for HIV patients at no greater cost than it would have otherwise.

CONCLUSION

This Court should reverse the judgment, or at a minimum vacate and remand for a new trial.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This Brief complies with the Court's Order on October 23, 2025 granting Janssen's request for additional words, Dkt. No. 73, because it contains 9,496 words, excluding the parts of the Brief exempted by Federal Rule of Appellate Procedure 32(f).

2. This Brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point, Times New Roman font.

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October 29, 2025 /s/ *Mark W. Mosier*

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I certify that on October 29, 2025, I electronically filed the foregoing document with the Clerk of the Court of the United States Court of Appeals for the Third Circuit by using the appellate CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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