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

BRIEF FOR DEFENDANT-APPELLANT JANSSEN PRODUCTS, LP

Mark W. Mosier
Matthew F. Dunn
Krysten Rosen Moller
Daniel G. Randolph
Kendall T. Burchard
Alexander J. Cave
Mishi Jain
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street NW
Washington, DC 20001-4956
(202) 662-6000

Counsel for Defendant-Appellant Janssen Products, LP

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Defendant-Appellant Janssen Products, LP, hereby files this Corporate Disclosure Statement to notify this Court that the following parent corporation owns 10% or more of Janssen Products, LP's stock:

- Johnson & Johnson, JNJ

STATEMENT CONCERNING ORAL ARGUMENT

This complex and significant appeal follows a lengthy jury trial that resulted in a $1.64 billion judgment—the largest in False Claims Act ("FCA") history. This case accordingly involves important questions regarding the proper scope of liability under the FCA, 31 U.S.C. §§ 3729-3733. It also presents significant constitutional questions, including whether the FCA's *qui tam* provisions violate Article II and whether the penalties the district court imposed violate the Excessive Fines and Due Process Clauses. Appellant Janssen Products, LP ("Janssen"), therefore respectfully submits that oral argument would assist the Court in its resolution of these substantial and consequential issues.

TABLE OF CONTENTS

CORPORATE DISCLOSURE STATEMENT i

STATEMENT CONCERNING ORAL ARGUMENT ii

TABLE OF AUTHORITIES vi

INTRODUCTION 1

STATEMENT OF JURISDICTION 5

STATEMENT OF ISSUES 5

STATEMENT OF RELATED CASES AND PROCEEDINGS 6

STATEMENT OF THE CASE 6

A. Prezista and Intelence Are FDA-Approved for Treatment of HIV and Included in HHS's HIV Treatment Guidelines. 6

B. Relators File Suit Alleging Off-Label Marketing and Improper Payments to Speakers. 9

C. The Jury Finds for Relators on the "Off-Label" Claims and for Janssen on the Anti-Kickback Claims 10

D. The District Court Sets Aside the Verdict in Part and Upholds the Rest. 12

SUMMARY OF ARGUMENT 13

STANDARD OF REVIEW 17

ARGUMENT 18

I. Janssen Is Entitled to Judgment as a Matter of Law Because Relators Failed to Prove Materiality. 18

A. Reimbursement Claims Contain No Representations Regarding "Off-Label" Marketing. 19

B. Any Certification Regarding "Off-Label" Marketing Was Not Material to the Government's Payment Decisions. 23

1. The Government's Continued Payment of Claims Precludes a Finding of Materiality. 23

2. The District Court Erred in Finding Sufficient Evidence of Materiality. 27

II. Janssen Is Entitled to Judgment as a Matter of Law or, at Minimum, a New Trial on the Remaining Elements of Relators' Claims. 29

A. The Jury's Finding of Falsity Was Unsupported by the Evidence and the Result of Instructional Error. 30

1. There Is No Evidence that the Government Payors Imposed the Asserted Conditions of Payment. 30

2. There Is No Evidence that Claims Falsely Certified Compliance with Any Conditions of Payment. 33

3. The Relevant Jury Instruction Misstated the Law. 37

B. The Jury's Finding of Causation Was Unsupported by the Evidence and the Result of Instructional Error. 39

1. The FCA Requires Proof of But-For Causation. 39

2. There Was No Evidence of But-For Causation. 41

C. A New Trial Is Warranted on Scienter. 44

D. A Partial Failure of Proof Would Require a New Trial. 45

III. This Case Should Be Dismissed Because the FCA's *Qui Tam* Provisions Are Unconstitutional. 47

IV. The Penalties Award Violated the Excessive Fines Clause and the Due Process Clause. 52

CONCLUSION 58

CERTIFICATE OF COMPLIANCE 59

CERTIFICATE OF BAR MEMBERSHIP 60

CERTIFICATE OF SERVICE 61

STATUTORY & REGULATORY ADDENDUM

TABLE OF AUTHORITIES

Page(s)

Cases

Avaya Inc., RP v. Telecom Labs, Inc.,
838 F.3d 354 (3d Cir. 2016) 17

BMW of N. Am., Inc. v. Gore,
517 U.S. 559 (1996).....55, 57

Brokerage Concepts v. U.S. Healthcare, Inc.,
140 F.3d 494 (3d Cir. 1998) 46

CGB Occupational Therapy, Inc. v. RHA Health Servs., Inc.,
499 F.3d 184 (3d Cir. 2007) 53, 54, 55

Com. of Pa., Dep't of Pub. Welfare v. U.S. Dep't of Health & Hum. Servs.,
80 F.3d 796 (3d Cir. 1996) 48

Curley v. Klem,
499 F.3d 199 (3d Cir. 2007) 17

D'Agostino v. ev3, Inc.,
845 F.3d 1 (1st Cir. 2016).....52

Delaware County, Pa. v. Fed. Hous. Finance Agency,
747 F.3d 215 (3d Cir. 2014) 18

DiFiore v. CSL Behring, LLC,
879 F.3d 71 (3d Cir. 2018) 40

United States ex rel. Drakeford v. Tuomey,
792 F.3d 364 (4th Cir. 2015) 52, 53, 54, 57

United States ex rel. Druding v. Care Alternatives,
81 F.4th 361 (3d Cir. 2023) 28

United States ex rel. Eisenstein v. City of New York,
556 U.S. 928 (2009).....50

Elcock v. Kmart Corp.,
233 F.3d 734 (3d Cir. 2000) 43

Free Enter. Fund v. PCAOB,
561 U.S. 477 (2010).....49

United States ex rel. Grant v. Zorn,
107 F.4th 782 (8th Cir. 2024) 53, 54, 56

United States ex rel. Greenfield v. Medco Health Sols., Inc.,
880 F.3d 89 (3d Cir. 2018) 36

Harvey v. Plains Tp. Police Dep't,
635 F.3d 606 (3d Cir. 2011) 18

Jurinko v. Med. Protective Co.,
305 F. App'x 13 (3d Cir. 2008) 56

United States ex rel. Krahling v. Merck & Co.,
No. 23-2553, 2024 WL 3664648 (3d Cir. Aug. 6, 2024) 24, 28

Lightning Lube, Inc. v. Witco Corp.,
4 F.3d 1153 (3d Cir. 1993) 17

Lucia v. SEC,
585 U.S. 237 (2018).....49, 50

Malley-Duff & Assoc., Inc. v. Crown Life Ins. Co.,
734 F.2d 133 (3d Cir. 1984) 45

United States ex rel. Montcrief v. Peripheral Vascular Assocs., P.A.,
133 F.4th 395 (5th Cir. 2025) 51

United States ex rel. Petratos v. Genentech Inc.,
855 F.3d 481 (3d Cir. 2017) .....*passim*

United States ex rel. Polansky v. Exec. Health Res., Inc.,
599 U.S. 419 (2023) 48

United States ex rel. Polansky v. Pfizer, Inc.,
822 F.3d 613 (2d Cir. 2016) 20

United States ex rel. Polansky v. Pfizer, Inc.,
914 F. Supp. 2d 259 (E.D.N.Y. 2012) 34

United States ex rel. Schmidt v. Zimmer, Inc.,
386 F.3d 235 (3d Cir. 2004) 39

Sec'y, United States Dep't of Lab. v. E. Penn Mfg. Co., Inc.,
123 F.4th 643 (3d Cir. 2024) 17

Seila Law LLC v. CFPB,
591 U.S. 197 (2020).....49

United States ex rel. Spay v. CVS Caremark Corp.,
875 F.3d 746 (3d Cir. 2017) 24, 32

State Farm Mut. Auto. Ins. Co. v. Campbell,
538 U.S. 408 (2003).....53, 55, 56, 57

U.S. ex rel. Tyson v. Amerigroup Illinois, Inc.,
488 F. Supp. 2d 719 (N.D. Ill. 2007).....57

United States v. Bajakajian,
524 U.S. 321 (1998).....53

United States v. Caronia,
703 F.3d 149 (2d Cir. 2012) 20

United States v. Hibbs,
568 F.2d 347 (3d Cir. 1977) 39

United States v. Texas,
599 U.S. 670 (2023).....49

United States v. Valencia,
600 F.3d 389 (5th Cir. 2010) 43

United States v. Waalee,
133 F. App'x 819 (3d Cir. 2005) 40

Universal Health Servs. v. United States,
579 U.S. 176 (2016).....*passim*

Vermont Agency of Nat'l Res. v. United States ex rel. Stevens,
529 U.S. 765 (2000).....50

Wilburn v. Maritrans GP Inc.,
139 F.3d 350 (3d Cir. 1998) 46

Wisconsin Bell, Inc. v. United States ex rel. Health,
145 S. Ct. 498 (2025).....48

United States ex rel. Zafirov v. Fla. Med. Assocs., LLC,
751 F. Supp. 3d 1293 (M.D. Fla. 2024).....50, 51

In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.,
858 F.3d 787 (3d Cir. 2017) 43

Constitutional Provisions

U.S. Const. amend. 8.....52

U.S. Const. art. II, § 1 49

U.S. Const. art. II, § 2, cl.2 49

U.S. Const. art. II, § 3 .....16, 49

Statutes

21 U.S.C. § 352(f).....20

False Claims Act, 31 U.S.C. § 3729 *et seq.*

§ 3729(a) 39, 50

§ 3729(b).....44

§ 3730(b).....50

§ 3730(d).....50

42 U.S.C.

§ 300ff-21.....8

§ 300ff-26(b).....31

§ 1395w-101 8

§ 1395w-102(e) 32, 38

§ 1395w-112 32

§ 1395y(a) 32

§ 1396d(b) 8

§ 1396r-8(d) 31

§ 1396r-8(k) 38

§ 1396-1 8

Regulations

42 C.F.R. § 440.230(d) 32

Pt. D Final Rule, 70 Fed. Reg. 4194 (Jan. 28, 2005) 21, 32

Rules

Fed. R. Evid. 702(c) 43

Fed. R. Evid. 702(d) 43

Treatises

Second Restatement of Torts § 432(1) 39, 40

Second Restatement of Torts § 432(2) 39

Other Authorities

Br. of the United States as Amicus Curiae, *Petratos v. Genentech Inc.*, 855 F.3d 481 (3d Cir. 2017), 2016 WL 3012033 22

Br. of the United States as Amicus Curiae, *United States ex rel. Solis v. Millennium Pharms., Inc., et al.*, 885 F.3d 623 (9th Cir. 2018), 2016 WL 6833796 22

CMS's Medicare Prescription Drug Manual (rev. 2020) 8, 26, 33, 34

HHS, *ADAP Manual* (2012), https://tinyurl.com/2bcceurp.....9, 31, 33

Opportunities to Improve HIV Prevention and Care Delivery to Medicaid and CHIP Beneficiaries (Dec. 1, 2016), https://tinyurl.com/2s3jndnm.....8

INTRODUCTION

The district court entered a judgment against Janssen of $1.64 billion, the largest ever in a False Claims Act ("FCA") case. That judgment rested on the jury's finding that federal healthcare programs paid claims seeking reimbursement for Janssen's HIV medications, Prezista and Intelence, that were not eligible for reimbursement. But every claim at issue sought reimbursement for those HIV medications for HIV patients who needed them. The district court nonetheless imposed this unprecedented judgment based solely on the theory that Prezista and Intelence were marketed for purported "off-label" uses.

A relator cannot establish an FCA violation simply by convincing a jury that a defendant engaged in "off-label" marketing. That is because the term "off-label" pertains to the *marketing* of a drug, not to its eligibility for *reimbursement*. Indeed, federal healthcare programs are expressly required to reimburse for some uses of a drug that the Food & Drug Administration ("FDA") has not approved, even though marketing the drug for that use would be deemed "off-label." FDA itself does not proscribe physicians from prescribing "off-label," deferring instead to physicians' medical judgment as learned intermediaries. Before this case, no court had ever held that a reimbursement claim was necessarily false under the FCA whenever the prescribing physician was exposed to "off-label" marketing. But through an

erroneous jury instruction and an equally flawed post-trial ruling, the district court permitted that result. That judgment should be reversed.

The FCA imposes liability when, among other things, a claim falsely certifies that it is eligible for payment, and that false certification is material to the government's payment decision. *See, e.g.*, *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481 (3d Cir. 2017). The jury was instructed that the claims here were eligible for reimbursement if the underlying prescriptions were written for a "medically accepted indication." But when defining "medically accepted indication" for the jury, the district court inserted an "on the label" requirement found nowhere in the statute. In so doing, the court conflated the laws regulating pharmaceutical marketing—which distinguish between "on-label" and "off-label"—with the laws regulating eligibility for government reimbursement, which do not.

Thereafter, in upholding the jury's verdict, the district court drew an even more direct connection between "off-label" marketing and FCA liability. The court held that "off-label" marketing alone is sufficient to prove that a claim is "false" because such "marketing violate[s] an express condition of payment for reimbursement[.]" Appx244. The court did not identify the source of this "express condition." None exists. No statute or regulation imposes that condition, and there is no evidence that any government payor has ever attempted to impose it.

Likewise, the district court mistakenly upheld the jury's finding of "materiality" based on purported "off-label" marketing. That ruling cannot be reconciled with *Petratos*. There, this Court affirmed the dismissal of an FCA action at the pleading stage on materiality grounds where the government continued to pay reimbursement claims after the alleged fraud was revealed. *See* 855 F.3d at 490. The same is true here. The government continues to pay claims for Prezista and Intelence despite knowing of the alleged "off-label" marketing for over a decade.

The impact of these errors cannot be overstated. Consider, for example, Relators' allegations regarding prescriptions for HIV patients with lipid conditions, which make up the vast majority of claims at issue. Because FDA did not limit Prezista's approval to HIV patients with particular lipid levels, there is no dispute that the prescriptions were written for accepted indications. So how did the district court conclude that such prescriptions were "false"? It began by accepting Relators' expansive definition of "off-label" marketing as any promotional message that departed from any portion of Prezista's label in any way. Under that view, Janssen's marketing was "off-label" because it used phrases like "lipid neutral" or "lipid friendly" in marketing Prezista to physicians even though the drug's label—in a section that listed dozens of adverse reactions—mentioned elevated lipid conditions as a possible side effect. The court then concluded that this purported "off-label"

marketing transformed lifesaving prescriptions into a billion-dollar fraud on the government.

If the Court does not reverse the judgment on these grounds, it must confront the constitutionality of the FCA's *qui tam* provisions. As several Supreme Court Justices have suggested and one federal court has held, the FCA's *qui tam* device violates Article II because it delegates executive power to private individuals. This case is the paradigmatic example of why the Constitution forbids self-appointed, financially motivated, politically unaccountable private relators from bringing suit on behalf of the United States. Congress has sought to make HIV medications widely available to HIV patients, and Janssen is a crucial part of protecting the health of patients living with HIV. But unless fixed by this Court, Plaintiffs-Appellees Jessica Penelow and Christine Brancaccio ("Relators") stand to reap millions and millions of dollars personally on the theory that the government should not have paid for HIV medications for thousands of HIV patients based on marketing considerations that are outside of the patient's control and irrelevant to their need for the medication.

For these reasons, as well as others discussed below, the district court's judgment should be reversed. Janssen is entitled to judgment as a matter of law or, at a minimum, a new trial.

STATEMENT OF JURISDICTION

The district court had jurisdiction under 28 U.S.C. § 1331 and 31 U.S.C. § 3732, and entered final judgment on March 28, 2025. Appx270-71. Janssen filed a timely notice of appeal on April 25, 2025. Appx272-73. This Court has jurisdiction pursuant to 28 U.S.C. § 1291.

STATEMENT OF ISSUES

1. Whether Relators' evidence of "off-label" marketing was insufficient as a matter of law to prove materiality for claims that do not require any certification regarding marketing, and where the government continues to pay the claims despite knowledge of the purported "off-label" marketing.[1]

2. Whether Janssen is entitled to judgment as a matter of law, or a new trial, on the elements of falsity, causation, and scienter.[2]

3. Whether this FCA *qui tam* suit violates Article II of the U.S. Constitution.[3]

---

[1] Janssen raised these issues. *See, e.g.*, Appx2259-65. The district court rejected Janssen's arguments. Appx241-43.

[2] Janssen raised these issues. *See, e.g.*, Appx574-75; Appx2025; Appx2129-34; Appx2139-41; Appx2250-57; Appx2265-79. The district court rejected Janssen's arguments. Appx238-41; Appx243-44; Appx2134; Appx2139-41.

[3] Janssen raised this issue. Appx2296-97. The district court rejected Janssen's arguments. Appx256.

4. Whether the civil penalties award of more than ten times the compensatory damages award violated the Excessive Fines Clause of the Eighth Amendment or the Due Process Clause of the Fifth Amendment to the U.S. Constitution.[4]

STATEMENT OF RELATED CASES AND PROCEEDINGS

Janssen is not aware of any related cases or proceedings.

STATEMENT OF THE CASE

A. Prezista and Intelence Are FDA-Approved for Treatment of HIV and Included in HHS's HIV Treatment Guidelines.

Janssen has developed two antiretroviral medications—Prezista and Intelence—that stop the HIV virus from replicating, thus enabling HIV patients to live long and healthy lives. FDA approved Prezista in June 2006 for the treatment of HIV in treatment-experienced patients (*i.e.*, for patients who had previously taken antiretroviral medications), and in October 2008 for treatment-naïve patients. *See* Appx3200; Appx3954. FDA approved Intelence in January 2008 for the treatment of HIV in treatment-experienced patients. Appx3913; 3937.

Prescribing HIV medications is a highly individualized, patient-specific decision. Appx1935-36; Appx1940-48. Physicians typically prescribe a "cocktail" of medications from different antiretroviral classes. Appx1130-31; Appx1932-34.

[4] Janssen raised this issue. Dkt. No. 479 at 29-40. The district court rejected Janssen's argument. Appx266.

When choosing a combination of antiretrovirals, physicians consider many factors, including blood test results, patient medical history and characteristics, discussions with HIV experts, scientific literature, results from ongoing clinical trials, and personal clinical experience. Appx1940-48.

Physicians also consult consensus-based treatment guidelines, including the Department of Health and Human Services ("HHS") HIV treatment guidelines. Those guidelines are updated regularly and reflect the federal government's position on the standard of care for the use of HIV medications, based on an "expert panel of physicians highly experienced in the treatment of HIV infection." Appx1154-55; Appx4290. During the relevant period, HHS treatment guidelines included Prezista and Intelence and referenced data supporting Prezista and Intelence use in each of the four ways that Relators claimed to be unlawful here. *See, e.g.*, Appx3948-49 (listing Prezista with ritonavir as "preferred" treatment in part because of its favorable lipid profile); Appx3951 (including study suggesting Intelence "once-daily" as an option for treatment-naïve patients); Appx3946 (excerpting clinical trial data supporting Prezista for treatment-naïve patient population).

The federal government has adopted liberal reimbursement policies for HIV treatment to help ensure that all HIV patients—no matter their background or income level—can live long and healthy lives. For Medicare Part D, which provides prescription drug coverage for the elderly and for people with certain disabilities,

see 42 U.S.C. § 1395w-101, the Centers for Medicare & Medicaid Services ("CMS") has implemented this policy by designating antiretroviral medications as a "protected class of drugs." *See* CMS's Medicare Prescription Drug Benefit Manual ch. 6, § 30.2.5 (rev. 2010) ("Part D Manual"). As a result, Part D plan sponsors—private insurance companies with which CMS contracts—must cover "all or substantially all" FDA-approved antiretrovirals "to mitigate the risks and complications associated with an interruption of therapy for … vulnerable populations" and are discouraged from using utilization management tools, such as prior authorizations. *Id.*

For Medicaid, which provides healthcare coverage for low-income people through joint funding by the federal government and States, *see* 42 U.S.C. §§ 1396-1, 1396d(b), CMS directs States to "align their Medicaid policies and practices with the [HHS guidelines]," in order to "ensure both the individual and public health benefits of [antiretroviral therapy] are realized among their Medicaid … beneficiaries and in their communities," *Opportunities to Improve HIV Prevention and Care Delivery to Medicaid and CHIP Beneficiaries*, at 12 (Dec. 1, 2016), https://tinyurl.com/2s3jndnm.

The AIDS Drug Assistance Program ("ADAP") is a federal program that provides grants to States "to improve the quality, availability and organization of health care and support services for individuals and families with HIV/AIDS." 42

U.S.C. § 300ff-21. ADAPs are "payer[s] of last resort," covering HIV medications not covered by Medicare, Medicaid, or other sources. HHS, *ADAP Manual*, at 37 (2012) ("ADAP Manual"), https://tinyurl.com/2bcceurp.

B. Relators File Suit Alleging Off-Label Marketing and Improper Payments to Speakers.

In 2012, Relators brought this action under the federal FCA and numerous state false claims acts. The United States declined to intervene.

In addition to allegations that Janssen violated the Anti-Kickback Statute, Relators alleged that Janssen promoted Prezista and Intelence "off-label," which caused the submission of false claims to various government payors. Relators alleged that Janssen improperly promoted its HIV medications in four ways: (1) describing Prezista's impact on lipids in misleading ways; (2) promoting Prezista for treatment-naïve patients before it was FDA-approved for that patient population; (3) promoting Intelence for once-daily dosing, when it was FDA-approved for twice-daily dosing; and (4) promoting Intelence for treatment-naïve patients, when it was not FDA-approved for that patient population. Appx501. In Relators' view, these messages were "off-label" because they were inconsistent with some aspect—no matter how marginal—of the FDA-approved labels for Prezista and Intelence. Appx632-39.

C. The Jury Finds for Relators on the "Off-Label" Claims and for Janssen on the Anti-Kickback Claims.

After years of litigation, the case proceeded to trial in May 2024. The jury found for Relators on the "off-label" claims and for Janssen on the anti-kickback claims. Appx2228-29.

For their "off-label" claims, Relators alleged that Janssen promoted "off-label" to physicians, the physicians wrote prescriptions for Prezista and Intelence for HIV patients, and pharmacies filled those prescriptions and submitted claims for reimbursement to Medicare Part D sponsors (who submitted the claims to CMS) or to Medicaid or ADAP programs. Despite their burden of proving that the government ultimately paid claims that were "false," Relators did not call any witness from CMS or any other federal or state agency. They also did not call any witnesses from Part D plan sponsors. Nor did they introduce evidence to identify a single actual claim that the government paid that they alleged was "false." Relators instead sought to prove their "off-label" claims by focusing on Janssen's marketing.

Falsity. Relators sought to prove falsity by showing that the government paid for prescriptions that were not written for a "medically accepted indication" and were not "reasonable and necessary" to treat the individual patient's condition. Appx2202. Even though the relevant statute makes no reference to a drug's "label," the district court instructed the jury that "medically accepted indication" refers to "any FDA-approved use on the label." *Id.* Relators principally relied on the

testimony of Dr. Glatt, but he admitted that "[p]rescribing Prezista for someone with a lipid condition is not off the FDA label" and that whether to prescribe Prezista for such a patient is a matter of medical judgment. *See* Appx1243-44; Appx1249-50; Appx1252. Dr. Glatt made similar concessions regarding Relators' treatment-naïve and dosage claims. *See* Appx1242-44; Appx1257.

Materiality. Relators attempted to prove materiality by showing that, in other circumstances, the government has taken actions to address certain types of "off-label" marketing. *See, e.g.*, Appx241-42. But the undisputed evidence established that the government has continued to pay claims for Prezista and Intelence despite knowing of Relators' allegations and evidence for more than a decade. *See*, *e.g.*, Appx704; Appx708; Appx714-18; Appx1105-06; Appx1469-70; Appx1473-74; Appx1518-19; Appx4633-34; Appx4643-44; Appx4258; Appx4630.

Causation. Refusing to instruct the jury that it needed to find but-for causation, the district court instead instructed that causation was proven if Janssen's "conduct was a substantial factor in inducing providers to submit claims for reimbursement[.]" Appx2212. Relators attempted to satisfy this relaxed causation standard through their expert Dr. Shaked, whose testimony was undermined by trial evidence demonstrating its unreliability. Appx1837-38.

Scienter. The district court instructed the jury that "there is no statute or regulation that says that the FDA's silence means that it has approved a promotional

advertising submission." Appx2218. Undisputed testimony from Janssen witness Dr. Patel established, however, that it was industry practice to conclude that materials are effectively approved for use if FDA raises no objection in response to proposed marketing materials. Appx1679-81.

The jury determined that Janssen caused the submission of 159,574 false claims in violation of the federal FCA, resulting in $120,004,736 in damages for those claims. Appx2228; *see also* Appx2152. The jury also found violations of the state FCAs and awarded the States as a group $30,001,184 in damages for the state share of the Medicaid claims. Appx2230-31; *see also* Appx2152. The verdict form—designed by Relators—did not ask the jury to identify how many false claims, or what portion of the damages, were based on submissions to each of the three government payors.

D. The District Court Sets Aside the Verdict in Part and Upholds the Rest.

Following trial, Janssen moved for judgment as a matter of law or for a new trial. *See* Appx2235-98; Dkt. No. 474. The district court granted judgment as a matter of law for Janssen on the state FCA claims and vacated the damages award on those claims. *See* Appx245-49.

The court otherwise denied the motions, determining that Relators presented sufficient evidence of falsity because they "introduced evidence that demonstrated Janssen's marketing of Prezista and Intelence were [off-label], and that this [off-

label] marketing violated an express condition of payment for reimbursement under Medicare, Medicaid, or ADAP." Appx244. Although it was undisputed that the government continues to pay claims for Prezista and Intelence despite knowledge of "off-label" marketing allegations, the court declined to "weigh the evidence" regarding materiality. Appx243. And in finding sufficient evidence of causation, the district court declined to apply a but-for causation requirement. *See* Appx238-41.

The district court trebled the jury's damages award and imposed a fine of $8,000 for each false claim found by the jury, yielding a total civil penalty of more than $1.2 billion. Appx262-67. That penalty dwarfed the jury's compensatory damages award by a ratio of more than ten to one and led to a $1.64 billion judgment.

SUMMARY OF ARGUMENT

I. Relators failed to prove materiality as a matter of law. Contrary to the district court's ruling, the jury could not find materiality based on the evidence that "off-label" marketing violations were material to the government's payment decisions.

A. Materiality could not be established based on certifications regarding "off-label" marketing because reimbursement claims do not certify anything regarding marketing. The district court held that Janssen's alleged "off-label" marketing

violated an "express condition of payment" for reimbursement, but there was no evidence that any government payor imposed this purported condition of payment.

B. Even if reimbursement claims included a certification regarding off-label marketing, those certifications were not material to the government's payment decisions as a matter of law. In *Petratos*, this Court held that a relator failed to show materiality when the government continued to pay claims despite knowledge of the alleged fraud. *See* 855 F.3d at 490. That case controls here: The government continues to reimburse claims for Prezista and Intelence despite learning of Relators' allegations and evidence more than a decade ago.

II. Janssen is also entitled to judgment as a matter of law or a new trial on the remaining elements of Relators' claims.

A. Relators failed to prove falsity. The jury was instructed to find falsity if a reimbursement claim falsely certified that it was for a "medically accepted indication" and was "reasonable and necessary." The evidence did not permit a finding of falsity based on those purported certifications for two independent reasons: (1) Relators failed to prove that government payors imposed those conditions of payment; and (2) Relators failed to prove that any claims violated those conditions. In any event, at a minimum, a new trial is required on falsity based on legal error in the jury instructions. Among other errors, the district court inserted

the phrase "on the label" into the definition of "medically accepted indication," thus conflating restrictions on marketing with conditions for reimbursement.

B. Relators likewise failed to prove causation. The FCA incorporates ordinary causation principles from negligence law, under which but-for causation is required. Relators thus needed to prove that the Prezista and Intelence prescriptions would not have been written absent Janssen's marketing, and the district court erred in not applying this test for causation. Nor did Relators present sufficient evidence for the jury to find but-for causation. Their anecdotal evidence is plainly insufficient, leaving only Dr. Shaked's testimony to establish causation. But that testimony, which rested on multiple flawed assumptions contradicted by the trial evidence, was unreliable and should not have been admitted.

C. Janssen is entitled to a new trial on scienter. Relators failed to show that Janssen knew that its marketing was unlawful. Dr. Patel's undisputed testimony regarding FDA's evaluation of marketing materials refuted any suggestion that Janssen knew its promotional messages were "off label." Yet the jury instructions effectively directed the jury to disregard his testimony.

D. A new trial would be required if Relators proved some, but not all, of their theories of liability. Relators sought to prove that Janssen was liable for false claims submitted to three different government payors on behalf of four different groups of patients. Yet the verdict form allowed the jury to state only one aggregated

number of federal FCA claims and one aggregated amount for federal FCA damages. If Relators failed to prove any theory of liability—for example, that claims for HIV patients with elevated lipids were false—a new trial would be the only way to disaggregate the jury's general verdict and the district court's civil penalties award.

III. The judgment should be vacated because the FCA's *qui tam* provisions violate Article II of the U.S. Constitution. Article II "vest[s]" all executive power in the President and commands the President to "take Care that the Laws be faithfully executed." U.S. Const. art. II, § 3. The Constitution also empowers the President to appoint "Officers of the United States" who may wield executive power subject to the President's oversight and control. But the FCA's *qui tam* device allows relators to exercise executive power by bringing and directing lawsuits on behalf of the United States, even though they are neither appointed pursuant to the Appointments Clause nor subject to the Executive Branch's supervision and control. This case presents a particularly egregious example of how the FCA's *qui tam* device offends Article II because Relators collected a billion-dollar judgment based on a theory the government has rejected, frustrating Congress's goal of providing life-saving HIV medications to vulnerable patient populations in the process.

IV. The district court's judgment offends the Constitution in an additional way: The civil penalties award violates the Excessive Fines and Due Process Clauses. Each relevant guidepost confirms that the district court's $1.2 billion

penalties award exceeds constitutional limits. Relators' claims involve prescriptions for HIV drugs written for HIV patients who undisputedly needed them, and there is no evidence that any patient was ineffectively treated or harmed by Prezista or Intelence. And the disparity between any harm and the award was severe: The penalty award is more than 10 times greater than the compensatory damages award, far exceeding permissible ratios.

STANDARD OF REVIEW

This Court reviews *de novo* an order denying a motion for judgment as a matter of law. *See Avaya Inc., RP v. Telecom Labs, Inc.*, 838 F.3d 354, 373 (3d Cir. 2016). Such a motion should be granted if "viewing the evidence in the light most favorable to the nonmovant," "there is insufficient evidence from which a jury reasonably could find liability," but a "scintilla of evidence is not enough to sustain a verdict of liability," and this Court must reverse if "it is apparent that the verdict is not supported by legally sufficient evidence." *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993).

This Court reviews the denial of a new trial motion for abuse of discretion, unless the denial is "based on application of a legal precept, in which case … review is plenary." *Curley v. Klem*, 499 F.3d 199, 206 (3d Cir. 2007). This Court reviews *de novo* whether a jury instruction misstated the law. *Sec'y, United States Dep't of Lab. v. E. Penn Mfg. Co., Inc.*, 123 F.4th 643, 647 (3d Cir. 2024). "When a jury

instruction is erroneous, a new trial is warranted unless such error is harmless." *Harvey v. Plains Tp. Police Dep't*, 635 F.3d 606, 612 (3d Cir. 2011).

This Court applies "a plenary standard of review … to questions regarding a statute's constitutionality." *Delaware County, Pa. v. Fed. Hous. Finance Agency*, 747 F.3d 215, 220-21 (3d Cir. 2014) (cleaned up).

ARGUMENT

I. Janssen Is Entitled to Judgment as a Matter of Law Because Relators Failed to Prove Materiality.

A relator seeking to recover under the FCA must establish that the misrepresentation rendering a claim false was "material" to the government's payment decision. *See Petratos*, 855 F.3d at 487. Here, Relators alleged that the claims at issue were legally false, which means the claimant falsely certified that it complied "with a statute or regulation the compliance with which is a condition for Government payment." *Id.* at 486 & n.1 (cleaned up). But even when a claim is legally false, liability will lie only if the "misrepresentation about compliance with a statutory, regulatory, or contractual requirement [is] material to the Government's payment decision." *Universal Health Servs. v. United States*, 579 U.S. 176, 192 (2016).

In denying Janssen's motion for judgment as a matter of law, the district court held that the trial evidence supported a finding that every reimbursement claim was false because the pharmacies submitting the claims misrepresented Janssen's

compliance with laws prohibiting "off-label" marketing. Appx243. And the evidence supported a finding of materiality, in the district court's view, because "a reasonable juror could find that Janssen's [off-label] marketing violations were material to the Government's reimbursement decisions." *Id.*

The district court erred at both steps of its analysis. There was no evidence that any pharmacy made any representation regarding Janssen's compliance with laws prohibiting "off-label" marketing. And even if a pharmacy did, the evidence foreclosed a finding that the misrepresentations were material because the government continued to pay the claims after learning of the alleged "off-label" marketing.

A. Reimbursement Claims Contain No Representations Regarding "Off-Label" Marketing.

To establish materiality, a relator must prove that a misrepresentation made to the government was material to the government's decision to pay the claim. *See Petratos*, 855 F.3d at 487. The district court held that Janssen's purported "off-label" marketing violations were material to the government's payment decisions, but such marketing violations could be material only if a pharmacy—the entity that submitted the claims—actually made representations regarding Janssen's compliance with laws regulating marketing of prescription medications. Because pharmacies make no such representations, the district court's materiality analysis necessarily fails.

The district court held—without any analysis—that Janssen's alleged "[off-label] marketing violated an express condition of payment for reimbursement under Medicare, Medicaid, or ADAP." Appx244. But there is no "condition of payment"—let alone an "express" condition of payment—for any of those government programs that depends on whether a prescription was written by a physician who was exposed to "off-label" marketing. *Id.* Indeed, no statutory or regulatory condition of payment for these programs uses the term "on-label" or "off-label" at all.

That government payors do not impose conditions of payment related to marketing is understandable. Medicare, Medicaid, and ADAP do not regulate the marketing of pharmaceutical products. FDA does. And as FDA has interpreted the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 352(f), "pharmaceutical manufacturers are generally prohibited from promoting off-label uses of their products if the off-label marketing is false or misleading, or if it evidences that a drug is intended for such off-label use and is therefore 'misbranded,'" *United States ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 615 (2d Cir. 2016).[5]

[5] Due to First Amendment concerns, courts have construed these provisions not to prohibit off-label promotion where the relevant off-label use is not prohibited and where the promotional speech is not false or misleading. *See, e.g.*, *United States v. Caronia*, 703 F.3d 149, 160, 165 & n. 10, 168-69 (2d Cir. 2012).

Rather than imposing conditions of payment related to marketing, government payors make reimbursement decisions based on considerations such as the patient's medical condition. Medicare Part D, for example, reimburses claims for prescriptions written for a "medically accepted indication." *See infra* Part II.A. But CMS has recognized that a claim may satisfy this condition of payment—and thus be eligible for reimbursement—even if FDA would consider marketing for the prescribed use to be "off-label." *See* Pt. D Final Rule, 70 Fed. Reg. 4194, 4261 (Jan. 28, 2005) (Part D does not "preclude ... prescribers from prescribing drugs for off label indications, provided the drug is prescribed for a 'medically accepted indication.'"). Indeed, CMS has specifically acknowledged that "off-label use is critically important and may be the mainstay of medical practice for successfully managing certain conditions, such as … HIV/AIDS." *Id.* at 4260.

Relators' "lipid" claims—the vast majority of claims at issue—highlight both the differences between these regulatory schemes and the error in the district court's analysis. Prezista prescriptions for HIV patients with lipid conditions are for a "medically accepted indication"; FDA's approval of Prezista does not limit its usage to patients with certain lipid profiles. Yet, in Relators' view, any promotional message that departed from any aspect of the drug label—including language about minor "potential consequences and side effects"—was "off-label." Appx630-31; *see also* Appx1084 (testimony of Relator Brancaccio) ("If it's not in the package

insert, if it's not in the label, it can't go into the marketing material."). Marketing Prezista as "lipid friendly" or "lipid neutral" was thus "off-label" because the Prezista label—in a section that listed dozens of adverse reactions, including dry mouth, nausea, headaches, and hiccups—mentioned elevated lipid conditions as possible side effects. *See* Appx3220 (2006 Prezista label).

The Department of Justice ("DOJ") has correctly recognized that "off-label" marketing does not automatically render reimbursement claims false. It previously informed this Court that "[p]ayment under government health programs is not generally conditioned on a manufacturer's compliance with various FDA procedures, or its compliance with the [FDCA]." Br. of the United States as Amicus Curiae at 26, *Petratos v. Genentech Inc.*, 855 F.3d 481 (3d Cir. 2017), 2016 WL 3012033 ("*Petratos* Br."). DOJ has stated that it "does not support" the theory "that a drug company's violation of the misbranding provisions of the [FDCA] on its own and as a matter of law, makes subsequent claims for reimbursement for that misbranded drug false under the FCA." Br. of the United States as Amici Curiae at 12 n.4, *United States ex rel. Solis v. Millennium Pharms., Inc., et al.*, 885 F.3d 623 (9th Cir. 2018), 2016 WL 6833796; *see also Petratos* Br. at 26 ("merely demonstrating lack of compliance with" the FDCA "is insufficient to establish FCA liability").

The district court erred in rejecting DOJ's view and holding that every claim included an express certification regarding "off-label" marketing. *See* Appx244. Without a certification regarding "off-label" marketing, such a certification could not have been material to the government's payment decision.

B. Any Certification Regarding "Off-Label" Marketing Was Not Material to the Government's Payment Decisions.

Even if every reimbursement claim included an "off-label" marketing certification, Relators still failed to prove that those purported false certifications were material to the government's payment decisions. The district court failed to grapple with the reality that the government—with full knowledge of Relators' allegations regarding Janssen's marketing—continues to pay for lifesaving Prezista and Intelence prescriptions for patients living with HIV. Under this Court's decision in *Petratos*, that fact is fatal to Relators' suit.

1. The Government's Continued Payment of Claims Precludes a Finding of Materiality.

The Supreme Court and this Court have emphasized that the materiality standard is "demanding" and "rigorous." *Universal Health Servs.*, 579 U.S. at 194 & n.6 (cleaned up); *see also Petratos*, 855 F.3d at 487 (same). Because the FCA "is not … a vehicle for punishing garden-variety … regulatory violations," not every instance of "noncompliance" renders a claim for payment false. *Universal Health Servs.*, 579 U.S. at 194 (citation omitted). Instead, for a misrepresentation to be

"material," it must go "to the very essence of the bargain," as materiality "cannot be found where noncompliance is minor or insubstantial." *Id.* (cleaned up).

The Supreme Court has explained that "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated," that provides "very strong evidence" that those requirements were not material to the government. *Id.* at 195. Applying that rule, this Court in *Petratos* affirmed the dismissal of an FCA action at the pleading stage. 855 F.3d at 489. There, the relator alleged that a pharmaceutical company concealed data about side effects associated with a cancer drug, which caused doctors to falsely certify that the drug was "reasonable and necessary" for certain patients. *Id.* at 485. This Court held that the relator failed to establish materiality because, among other things, the relator had disclosed "material, non-public evidence of [the alleged] campaign of misinformation to the FDA and Department of Justice," with no response from the government to either cease reimbursement or bring an enforcement action. *Id.* at 490 (cleaned up).[6]

[6] *See also United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 764 (3d Cir. 2017) (finding lack of materiality in light of government's continued payment of claims despite knowledge that claims were submitted by pharmacies using "dummy numbers" in place of physician identifiers); *United States ex rel. Krahling v. Merck & Co.*, No. 23-2553, 2024 WL 3664648, at *8 (3d Cir. Aug. 6, 2024) (holding that "no reasonable jury could conclude that the Government lacked knowledge of facts relevant to materiality").

Relators' failure to establish materiality here necessarily follows from *Petratos*. The government has been aware of Relators' allegations and evidence for over a decade. *See, e.g.*, Appx1105-06 (Brancaccio provided evidence to the government); Appx1469-70, 1473-74 (Penelow participated in an interview with, and gave materials to, the government); Appx4633-34 (December 2013 email discussing Relators' claims); Appx4643-44 (March 2014 email noting the government's request for evidence); Appx4258 (Brancaccio admission that all evidence was provided to government); Appx4630 (same for Penelow). Underscoring its awareness, the government filed three statements of interest in this case. *See* Appx350-59; Appx2299-2306; Dkt. No. 484.

Despite knowing of Relators' allegations, no government agency or official has ever taken action to address this purported problem. Government payors continue paying claims for Prezista and Intelence without interruption or limitation. Appx1518-19 (testimony from Virginia Evans, Relators' expert on government payment, that she has "not seen any evidence that [CMS] halted reimbursement for these products," "that Janssen was subject to stipulated penalties" for any noncompliance with the corporate integrity agreements, or that "Janssen was excluded from Medicare or Medicaid programs"). FDA has not instituted any adverse proceedings against Janssen for its promotion of Prezista or Intelence, nor has it limited the medically accepted indications for those drugs. *See* Appx1519-20;

see also Petratos, 855 F.3d at 490 (noting FDA did not initiate any proceedings against company). And in the more than twelve years this case has been pending, the government has declined to intervene. *See id.* (weighing that during six-year life of suit, DOJ "has taken no action … and [has] declined to intervene"). Just as in *Petratos*, the government's actions (and non-actions) confirm that any alleged noncompliance was immaterial to the government's payment decisions. *See id.* (no materiality where government "reimburse[d] these claims even with full knowledge of the alleged reporting deficiencies").

Underscoring the lack of materiality, Prezista and Intelence are designated as part of a "protected class": Part D plan sponsors generally must include the drugs in their formularies, must employ an expedited claims review process, and must not use utilization management tools (*e.g.*, prior authorizations) that could curb reimbursements. *See* Part D Manual, ch. 6 § 30.2.5. Those measures are specifically designed to "mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations." *Id.* Rather than constraining prescribers as Relators would, the federal government has adopted a strong policy in favor of paying claims for these medications. That policy, combined with the undisputed fact that the government was aware of the alleged noncompliance in this case and continued to pay claims for Intelence and Prezista without interruption, forecloses any attempt by Relators to show materiality.

2. The District Court Erred in Finding Sufficient Evidence of Materiality.

Flouting controlling precedent from the Supreme Court and this Court, the district court held that "Relators presented sufficient evidence from which a reasonable juror could find that Janssen's [off-label] marketing violations were material to the Government's reimbursement decisions." Appx243. That conclusory statement misses the mark on all levels.

In the face of "very strong evidence" that marketing statements were not material to the government given continued reimbursement, *Universal Health Servs.*, 579 U.S. at 195, Relators' evidence falls flat. First, Relators presented irrelevant corporate integrity agreements and settlement agreements between Janssen and the government that stemmed from alleged promotion of drugs not at issue here for uses that were not approved by FDA. *See, e.g.*, Appx3115-85; Appx2970-3070. And, second, Relators presented evidence suggesting Janssen's awareness that the government may seek to recover payments when it discovers "off-label" marketing. Appx1351, 1354 (testimony from Janssen's President Glen Mattes); Appx1494-95, 1502 (testimony that the government does not reimburse prescriptions provided in violation of the FCA); Appx894 (similar). But that evidence was aimed at far too high a level. The critical question is whether the government would not have reimbursed *these* claims had it known of the conduct alleged *in this case*. *See Petratos*, 855 F.3d at 489-90.

On that narrower and controlling issue, Relators offered no evidence. Specifically, Relators offered no evidence rebutting the government's knowledge, demonstrating that CMS has halted or limited reimbursements for Prezista and Intelence, or even suggesting that that the government took action to address any noncompliance. Indeed, Relators did not even call a government witness to address materiality (or any other issue). And as to the Intelence once-daily claims in particular, the evidence established that whether physicians instructed their patients to take Intelence once or twice a day, the dosage (*i.e.*, the number of pills) remained the same, *see* Appx943, and that CMS's Medicare and Medicaid claims data did not even include information on dosing instructions, *see* Appx1744. Just as in *Petratos*, therefore, Relators failed to prove materiality as a matter of law.[7]

Nor can any other theory of materiality rescue the district court's holding. The district court upheld the verdict solely because, in its view, "[off-label] marketing violations were material to the Government's payment decision." Appx243; *see also* Appx2214 (Jury Instruction 19.4: Relators must prove that "Janssen's alleged … off-label marketing violations were material to the Government's payment

[7] Because there is no dispute that the government has had access to Relators' evidence in this case for over a decade, this is not a case where the scope of the government's knowledge was disputed, like the cases Relators relied on below. *See United States ex rel. Druding v. Care Alternatives*, 81 F.4th 361 (3d Cir. 2023); *Krahling*, 2024 WL 3664648, at *8 n.37 (explaining that *Druding* involved an "open dispute over the Government's actual knowledge").

decision."). But had Relators sought to rely on noncompliance with other asserted conditions of payments—*e.g.*, Medicare Part D's "medically accepted indication" condition, *see infra* Part II.A—Relators' evidence would still have been insufficient for the jury to find materiality. Relators presented no testimony or other evidence that the "essence" of the government's "bargain," *Universal Health Servs.*, 579 U.S. at 194, turned on anything other than reimbursing HIV prescriptions for HIV patients, as reflected by the government's continued reimbursement despite knowledge of the allegations and evidence in this case.

To hold otherwise requires embracing a counterfactual world in which the government would *refuse* to cover Prezista for use by HIV patients based on an HIV patient's lipid profile, or because the patient's prescriber feared that twice-daily dosing would interfere with treatment adherence. But these decisions are left to the medical judgment of the prescribing physician; they are not dictated by government bureaucrats. Relators thus failed as a matter of a law to prove materiality under either the theory presented to the jury or under any theory they could have presented.

II. Janssen Is Entitled to Judgment as a Matter of Law or, at Minimum, a New Trial on the Remaining Elements of Relators' Claims.

The jury verdict also cannot be upheld on the other elements of Relators' FCA claims: falsity, causation, and scienter. The evidence was insufficient as a matter of law for falsity and causation. And for all elements, a new trial is warranted based on errors in the jury instructions.

A. The Jury's Finding of Falsity Was Unsupported by the Evidence and the Result of Instructional Error.

The district court upheld the jury verdict on the theory that every claim falsely certified compliance with an "express condition of payment" regarding "off-label" marketing. Appx243-44. That theory of falsity fails as a matter of law because there is no such condition of payment. *See supra* Part I.A. The jury was instructed on two other potential theories of falsity, but neither supports the verdict.

The jury was instructed to find falsity if a reimbursement claim falsely certified that it was for a "medically accepted indication" and was "reasonable and necessary[.]" Appx2202. But Relators failed to prove that the government payors imposed these conditions of payment or that any claims violated them. The jury's contrary finding stemmed from legal errors in the jury instruction, including the insertion of the phrase "on the label" into the definition of "medically accepted indication," thus conflating marketing restrictions with conditions of payment.

1. There Is No Evidence that the Government Payors Imposed the Asserted Conditions of Payment.

Relators could not prove falsity based on purported false certifications regarding "medically accepted indication" or "reasonable and necessary" because there was no evidence that the government payors imposed these conditions of payment.

First, Relators failed to prove that the challenged Medicaid and ADAP claims certified they were for a "medically accepted indication." This condition of payment may apply to Medicare claims, *see Petratos*, 855 F.3d at 487, but Relators introduced no evidence that state Medicaid or ADAP programs also imposed it.

The Medicaid statute provides that state Medicaid agencies "*may* exclude or otherwise restrict coverage of a covered outpatient drug if … the prescribed use is not for a medically accepted indication," 42 U.S.C. § 1396r-8(d)(1)(B)(i) (emphasis added), and expressly labels this a "[p]ermissible," rather than mandatory, "restriction," *id.* § 1396r-8(d)(1). Far from establishing that all Medicaid agencies impose this condition of payment, Relators' witness testified that "each individual state has different requirements for what they allow to be paid under Medicaid." Appx955.

ADAP programs are also administered on a state-by-state basis, impose varying coverage criteria, and are not required to apply a "medically accepted indication" requirement. *See* 42 U.S.C. § 300ff-26(b). These programs "vary significantly in their administrative structures and the mechanisms they use to make HIV/AIDS medications available to eligible individuals living with HIV," ADAP Manual at Preface, but the statute requires only that individuals eligible for ADAP "have a medical diagnosis of HIV/AIDS" and are "a low-income individual as defined by the State." 42 U.S.C. § 300ff-26(b)(1)-(2). Relators presented no

evidence that any ADAP plan imposes a "medically accepted indication" requirement for reimbursement.

Second, Relators failed to establish that any of the government payors imposed a "reasonable and necessary" condition of payment. Under Medicare Parts A and B, "no payment may be made" for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness." 42 U.S.C. § 1395y(a). But there is no comparable mandate requiring Medicare Part D sponsors, state Medicaid agencies, or ADAP programs to impose that condition of payment.

CMS administers coverage under Medicare Part D through contracts with private insurance companies, referred to as Part D plan sponsors. *See* 42 U.S.C. § 1395w-112; *see also Spay*, 875 F.3d at 764. Each Part D plan sponsor makes its own determination regarding conditions under which it reimburses patients for their prescriptions. Both the Medicare statute and CMS guidance provide that plan sponsors "may exclude from qualified prescription drug coverage any covered Part D drug" that is not "reasonable and necessary," but they are not required to do so. 42 U.S.C. § 1395w-102(e)(3)(A); Pt. D Final Rule, 70 Fed. Reg. at 4230 (similar).

The same is true for Medicaid and ADAP. State Medicaid "agenc[ies] may place appropriate limits on a service based on such criteria as medical necessity," but they are not required to do so. 42 C.F.R. § 440.230(d). And ADAPs vary from

state to state and are given discretion to establish payment eligibility requirements. *See* ADAP Manual at 20-21.

In short, Relators had the burden of proof on falsity. They did not carry that burden given their failure to introduce any evidence that (1) any state Medicaid or ADAP imposes a "medically accepted indication" condition of payment, or (2) any relevant government payor imposes a "reasonable and necessary" condition of payment.

2. There Is No Evidence that Claims Falsely Certified Compliance with Any Conditions of Payment.

Even if "medically accepted indication" and "reasonable and necessary" were conditions of payment, no evidence supported a finding that claims for Prezista and Intelence violated those conditions.

First, CMS has stated that the term "medically accepted indication" means "the *diagnosis or condition* for which a drug is being prescribed." Part D Manual, ch. 6, § 10.6 (emphasis added). CMS has expressly acknowledged that the term is sufficiently broad to include certain "off-label" uses of medications. *See supra* p. 21. As this Court has described it, the term refers to a drug that "has been deemed appropriate for the *particular treated condition*." *Petratos*, 855 F.3d at 487 (emphasis added). All of the claims at issue satisfy that definition.

Lipid claims. Most of the allegedly false claims concern the use of Prezista in patients with elevated lipids. Appx1820-22. But as Relators' witness Dr. Glatt

admitted, "[p]rescribing Prezista for someone with a lipid condition is not off the FDA label" because the label "doesn't state that you cannot use [Prezista]" "in a person with a lipid condition[.]" Appx1244. Indeed, Relators deny ever asserting that "use of Prezista in patients with a lipid condition 'was not a medically accepted indication.'" Appx2352 n.26. It is beyond dispute therefore that claims for HIV patients with elevated lipids accurately certified they were for a "medically accepted indication."

Dosing claims. Relators also failed to prove that prescriptions for once-daily dosing of Intelence were not for a "medically accepted indication." CMS has expressly recognized that "medically accepted indication" does *not* refer to "the dose being prescribed." Part D Manual ch. 6, § 10.6. Accordingly, any certification regarding dosing is not false as a matter of law.

Treatment-naïve claims. Relators failed to prove that prescriptions for treatment-naïve patients included a false certification. Those prescriptions were for a "medically accepted indication" because HIV was "the particular treated condition" for these claims. *Petratos*, 855 F.3d at 487. Insofar as the Prezista and Intelence labels specify use in a particular population, that specification does not alter the medical condition or diagnosis for which the medicines were approved: HIV. *See United States ex rel. Polansky v. Pfizer, Inc.*, 914 F. Supp. 2d 259, 266 (E.D.N.Y. 2012) (noting important distinction between drugs prescribed "to achieve

a treatment not contemplated by the label … and marketing to a patient population not specifically mandated by the label"), *aff'd*, 822 F.3d 613 (2d Cir. 2016). Moreover, read in context, the labels merely state that physicians should "consider[] when initiating therapy" that the risks and benefits of Prezista and Intelence have not been established in treatment-naïve patients, but the labels do not prohibit physicians from prescribing to treatment-naïve patients. Appx3200; Appx3914. Treatment status is instead another consideration for physicians in determining an appropriate treatment for individual patients.

Second, Relators failed to prove that any pharmacy—the entity submitting the claims—falsely certified that any prescription was "reasonable and necessary." Whether a prescription is "reasonable and necessary" is a "multi-step interpretation" involving FDA, CMS, and the prescribing physician. *See Petratos*, 855 F.3d at 487-89. "CMS and the FDA are best positioned to make high-level policy decisions such as issuing national coverage determinations and drug approvals," and "doctors are best suited to evaluate each patient and determine whether a treatment is reasonable and necessary for that individual patient." *Id.* at 489 (cleaned up).

CMS has not issued a national coverage determination limiting reimbursement for Prezista and Intelence in any way, much less one that excluded coverage for the claims here. Nor did Relators offer evidence of any specific prescription for any individual patient that was not "reasonable and necessary." *Id.*

at 488. For example, Relators did not offer any evidence—based on a review of an individual patient's medical records—that prescribing Prezista or Intelence was not "reasonable and necessary" for that patient.

Instead, Relators sought to rely on testimony from Dr. Glatt that *every* prescription at issue violated the "reasonable and necessary" standard. That approach was insufficient as a matter of law, because it did not consider "the medical circumstances of [any] individual case." *Id.* (cleaned up); *see also United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 99 (3d Cir. 2018) (Relators "must provide evidence of at least one false claim").

Moreover, Dr. Glatt conceded that at least some Prezista and Intelence prescriptions for the four relevant uses were "reasonable and necessary":

- In his "medical judgment" there are circumstances where he would prescribe Prezista and Intelence for what he deemed "off-label" uses. *See, e.g.*, Appx1243-44 (Prezista); Appx1176 (Intelence).
- "Under the right circumstances, … it would be medically appropriate for a physician to prescribe Prezista to a patient with a known lipid condition[.]" Appx1249.
- In certain circumstances "it would have been medically appropriate for [a doctor] to prescribe Prezista to a naïve patient even before it got into the label," as well as Intelence. *See, e.g.*, Appx1242-44 (Prezista); Appx1177 (Intelence).
- As to the dosing claims, Dr. Glatt stated only that he "would have used an alternative agent *most* of the time." Appx1257 (emphasis added). And he recognized that other doctors had determined that Intelence once-daily was appropriate. Appx1256-58.

Consistent with those admissions, other physicians testified that there were legitimate reasons to prescribe Prezista and Intelence for the four uses at issue. *See, e.g.*, Appx1704 (Dr. Hsu); Appx1925 (Dr. Frank); Appx1929 (Dr. McMeeking); Appx2099 (Dr. Mills). For example, in determining an appropriate medical treatment, physicians consider a variety of factors including whether a patient will adhere to the prescribed treatment, as a complicated dosing regimen may mean that patients do not take their medications. *See* Appx1134-36 (Glatt); Appx1947 (Dr. Rosenberg). It may therefore be "reasonable and necessary" to prescribe Intelence for once-daily dosing at the same total dosage, to ensure compliance with the treatment regimen. Relators' evidence thus failed as a matter of law to show that the claims here violated that condition.

3. The Relevant Jury Instruction Misstated the Law.

At a minimum, Janssen is entitled to a new trial on falsity. Instruction 17, which informed the jury how to "determin[e] whether a claim is eligible for reimbursement," Appx2202, contained several misstatements of law that merit a new trial.

First, the instruction defined "medically accepted indication" as "any FDA-approved use on the label." *Id.* The court inserted the term "on the label" even though the statutory definition does not use that term. *Id.* Instruction 17 thus suggested that, if a use was even arguably inconsistent with any part of the label or

not explicitly permitted "on the label," it was "off-label"—even if the prescription was for an FDA-approved indication. That error was particularly harmful because it conflated the laws regulating pharmaceutical marketing—which turn on the "on-label/off-label" distinction—with the laws governing reimbursement, which do not depend on that distinction. *See supra* Part I.A.

Second, the court's instruction also ignored the disjunctive language in the statutory definition. An indication is "medically accepted" if (1) "it has been approved by the FDA for a particular use," *or* (2) its use is "supported by" any of the several congressionally identified "compendia." 42 U.S.C. §§ 1395w-102(e)(4)(A)(ii), 1396r-8(k)(6). Rather than tracking that statutory language, Instruction 17 stated that an indication must be *both* an "FDA-approved use on the label" *and* a use "supported by one or more citations in certain drug compendia." Appx2202. That was clear error. *See Petratos*, 855 F.3d at 487 (reading "medically accepted indication" definition in the disjunctive). Instruction 17's misconception of "medically accepted indication" was harmful because it incorrectly required a compendium citation for an indication to be a medically accepted.

Third, Instruction 17 erroneously stated that Part D sponsors, Medicaid agencies, and ADAP programs reimburse claims only if they are for a "medically accepted indication" and are "reasonable and necessary." Appx2202. But Relators did not establish that these conditions of payment actually apply here. *See supra*

section II.A.1. Instruction 17 was thus a prejudicial gap-filler: It instructed the jury on coverage criteria that lacked statutory or evidentiary support.

B. The Jury's Finding of Causation Was Unsupported by the Evidence and the Result of Instructional Error.

Relators also failed to prove that Janssen—through its marketing to physicians—caused pharmacies to submit false claims for reimbursement. 31 U.S.C. § 3729(a)(1)(A). In holding otherwise, the district court doubled down on a jury instruction infected with legal error that invited the jury to ignore problems with unreliable expert testimony that the district court erred in admitting.

1. The FCA Requires Proof of But-For Causation.

The FCA incorporates "ordinary causation principles from negligence law." *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244 (3d Cir. 2004); *see also Universal Health Servs.*, 579 U.S. at 187-88 (same). Those principles require a plaintiff to prove but-for causation. *See, e.g.*, Second Restatement of Torts, § 432(1) & cmt. A (causation generally not established "if the harm would have been sustained even if the actor had not been negligent"); *see also* Second Restatement of Torts § 432(2) & cmt. D (describing exception, inapplicable here, where "two forces" are independently "sufficient to bring about harm").

This Court has long treated but-for causation as necessary, but not sufficient, under the FCA. *See Petratos*, 855 F.3d at 491 ("the causation element cannot be met merely by showing 'but for' causation"); *see also United States v. Hibbs*, 568

F.2d 347, 349, 351 (3d Cir. 1977) (rejecting government's position that causation element was satisfied just because absent defendant's alleged conduct, the government would not have made payments).

Rather than instruct the jury on but-for causation, the district court told the jury it need only find that Janssen's conduct was a "substantial factor in inducing providers to submit claims for reimbursement[.]" Appx2212 (Instruction 19.2). Because the instruction omitted any mention of but-for causation as part of the substantial-factor analysis, *see* Second Restatement of Torts § 432(1), it failed to "state a proper legal standard," *DiFiore v. CSL Behring, LLC*, 879 F.3d 71, 75 (3d Cir. 2018), and was "misleading," *id.* at 76. The term "substantial factor" does not "involve[] plain language within the common understanding of a juror," such that no elaboration was required. *United States v. Waalee*, 133 F. App'x 819, 823 (3d Cir. 2005). By failing to further define "substantial factor," the district court permitted the jury to impose liability even if *every* challenged Prezista and Intelence prescription would have been written absent Janssen's marketing.

In ruling on Janssen's post-trial motions, the district court again stated that Relators need only show that "it was 'reasonably foreseeable or anticipated as a natural consequence' that false claims would result from [Janssen's] conduct." Appx239. The district court justified its approach based on its erroneous view that Janssen "concede[d]" that the "substantial factor" test applies. *Id.* But Janssen

repeatedly advanced its position that but-for causation is required, Appx2025, and proposed an instruction that would have required the jury to find but-for causation, Appx574-75. And in its motion for judgment as a matter of law, Janssen argued—on the same page containing Janssen's supposed concession—that "Relators had to prove that Janssen's alleged conduct was a 'substantial factor' in causing the submission of false claims" and "thus had the burden of proving … but-for cause[.]" Appx2250.

2. There Was No Evidence of But-For Causation.

Under the correct legal standard, the jury could not have found causation based on the trial evidence, including the testimony of their expert, whose error-riddled correlation analysis relied on unsupported assumptions.

Relators' evidence established that doctors unreached by Janssen's marketing routinely prescribed Prezista and Intelence to similar patients. *See, e.g.*, Appx1783; Appx1832-33; Appx1997. That is unsurprising, given the inherently individualized nature of HIV prescribing decisions. *See supra* pp. 6-7. Relators failed to unearth a single physician who would testify to prescribing Prezista or Intelence because of Janssen's marketing. And Relators' anecdotal evidence—including indviduals' statements and a marketing study purporting to identify increases in sales after delivery of marketing from Janssen—is plainly insufficient. *See, e.g.*, Appx1085-86; Appx1440-41; Appx1802-11. That evidence does not speak to whether

prescriptions for specific patients, or even specific categories of patients, would not have been written absent Janssen's marketing.

This leaves only Dr. Shaked, who claimed to demonstrate that the portion of Prezista and Intelence prescriptions that were "off-label" was greater among doctors exposed to Janssen's marketing. But Dr. Shaked's analysis rests on assumptions contradicted by the trial evidence and so is, by his own admission, "unreliable." Appx1837-38.

Contrary to considerable trial evidence demonstrating that HIV-prescribing decisions are individualized, Dr. Shaked assumed that if a doctor received any Janssen marketing and subsequently wrote an "off-label" Prezista or Intelence prescription, *every* prescription written for that patient by that doctor—or even *other doctors* in the future—was attributable to the marketing. *See* Appx1771-72; *see also* Appx1237-38. And Dr. Shaked compounded the error by failing to treat "on-label" prescriptions similarly, *see* Appx2003-04, an inconsistency that accounts for *all* of the asserted correlation, *see* Appx1997-2005. Nor was that all. He further assumed that Janssen delivered "off-label" messages *every time* it contacted a doctor, Appx1838; Appx1842-43, directly contradicting Relators' own testimony, *see* Appx1112-14'; Appx1458-61; Appx1463-64.

Moreover, on its own terms, Dr. Shaked's testimony indicated at most *correlation*, not but-for causation. Evidence of correlation "is often spurious and

misleading when masqueraded as causal evidence, because it does not adequately account for other contributory variables." *United States v. Valencia*, 600 F.3d 389, 425 (5th Cir. 2010). Janssen's expert, Dr. Jena, explained why Dr. Shaked's evidence was misleading: when using a proper pool of doctors with similar HIV-treatment experience, the gap in "off-label" prescribing disappears, indicating that "being contacted is just a proxy for something else[,]" namely "being an HIV doctor[,]" "seeing lots of HIV patients[,]" and "prescribing more HIV drugs." Appx2014; *see also* Appx2009-15. Dr. Shaked failed to account for these confounding variables.

Dr. Shaked's expert testimony was thus unreliable, and the district court abused its discretion in admitting it. *See* Appx74-80; Appx223-32; Appx2111. Rule 702 requires that expert testimony be based on "reliable principles and methods" and "reliable application of the principles and methods to the facts of the case." Fed. R. Evid. 702(c)-(d); *see also In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 792 (3d Cir. 2017). And courts must strike expert testimony lacking foundation in the trial record. *See, e.g., Elcock v. Kmart Corp.*, 233 F.3d 734, 755-56 (3d Cir. 2000). Dr. Shaked's testimony fell short on each count and should not have been admitted.

C. A New Trial Is Warranted on Scienter.

To establish liability, Relators must also prove that Janssen acted with actual knowledge, deliberate indifference, or reckless disregard. 31 U.S.C. § 3729(b)(1)(A). A new trial is warranted because the district court effectively instructed the jury to disregard the testimony of Dr. Patel, a Janssen witness who testified about how FDA evaluates marketing materials. He testified that Janssen submitted its marketing materials to FDA, which stated the drugs had "[l]ow impact on lipids," Appx4092, and received no response, *see* Appx1685-87; *see also* Appx4055-185, Appx4193-213, undermining any scienter on the part of Janssen.

Dr. Patel testified that, once a company submits marketing materials, FDA's review elicits one of two reactions: silence or an enforcement letter. Appx1679-81. If a company "get[s] nothing back in writing," the company assumes it can use the marketing material because FDA will "[n]ever send[] [an] approval letter saying your promotional material is approved." Appx1679. That undisputed testimony established that it was common industry understanding that submitted promotional materials are effectively approved for use if FDA does not raise an objection, as was the case here. Appx1679-81; *see also* Appx1687.

Rather than let the jury consider Dr. Patel's evidence, the court instructed the jury that "there is no statute or regulation that says that the FDA's silence means that it has approved a promotional advertising submission." Appx2218. Although

Janssen proposed adding the phrase "or disapproved" to the instruction to clarify that FDA would not reach out to the parties unless it intended to pursue an enforcement action, Appx2139, the court rejected that proposal, *id.*

By refusing to insert curative language, the district court gave the jury permission to disregard Dr. Patel's undisputed testimony. That error was not harmless; Instruction 22 gave the jury a "misleading impression or inadequate understanding" of FDA's marketing review process, undermining critical evidence of scienter. *Malley-Duff & Assoc., Inc. v. Crown Life Ins. Co.*, 734 F.2d 133, 147 (3d Cir. 1984). Indeed, the jury's confusion is clear from the record: the jury's first substantive question—which the district court addressed only by referring the jury back to the instruction, Appx2168—was whether "the FDA ever write[s] back approving final marketing material in writing and/or [i]s there an FDA approval process for final marketing material that comes in writing[.]" Appx2171. Because this confusion tainted the jury's understanding of FDA's review process and what, if any, inference Janssen could draw from the silence, Instruction 22 merits a new trial.

D. A Partial Failure of Proof Would Require a New Trial.

Where a jury has returned a general verdict and one theory of liability is not sustained by the evidence or legally sound, the verdict cannot stand because the court cannot determine whether the jury based its verdict on an improper ground."

Wilburn v. Maritrans GP Inc., 139 F.3d 350, 361 (3d Cir. 1998). In that situation, "the proper course is … 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). That course would be required here if any one of Relators' theories of liability fails for any reason.

Relators effectively submitted twelve different theories of liability to the jury. They challenged four groups of prescriptions, *see supra* p. 9, and challenged reimbursement of those prescriptions by three different payors. A new trial is necessary if any of the theories fails as a matter of law—for example, claims submitted for patients with elevated lipids or for once-daily dosing, or all claims submitted to ADAP. The Court could not uphold the verdict because the verdict form (which Relators themselves designed) does not identify how many of the false claims or how much of the federal FCA damages were attributable to which theory of liability. Instead, the form allowed the jury to state just one, aggregated figure for federal FCA damages and one aggregated number of false claims. *See* Appx2226-34.

It is not possible to reverse-engineer from those aggregated findings which of Relators' theories the jury accepted. Dr. Shaked testified that the number of false claims was 481,265, yielding $361.9 million in damages, Appx1813-27, but the jury did not accept those figures. Dr. Shaked referred to the damages and claims numbers

associated with particular theories of liability, *see* Appx1820-22; *see also* Appx2079-84, but the jury's damages and claims numbers did not align with any apparent combination of those figures. At most, Dr. Shaked's damages breakdown permits the conclusion that the jury necessarily found *at least some* false claims tied to Prezista prescriptions for patients with lipid conditions.[8] But that insight does nothing to disaggregate among the three government payors, and it is unclear what *portion* of the jury's award is tied to the lipids-based claims versus any other promotional theories the jury may have relied upon.

The same logic dooms the district court's civil penalties award. To calculate that award, the district court multiplied $8,000 by the 159,574 false claims the jury identified, arriving at a civil penalty award of $1,276,592,000. Appx266-67. But again, it is impossible to determine how many false claims are based on which theories of liability, so a new trial is required if any theory fails.

III. This Case Should Be Dismissed Because the FCA's *Qui Tam* Provisions Are Unconstitutional.

The district court's judgment should be vacated for the independent reason that the FCA's *qui tam* provisions violate Article II of the U.S. Constitution. The district court refused to engage with Janssen's constitutional argument and instead

[8] That is because under Dr. Shaked's limited damages breakdowns, Appx1820-22, the lipids-based claims accounted for the vast majority of the asserted damages, and the asserted damages associated with the other three groups of claims do not approach the $120 million in damages the jury awarded.

rested on the observation that, to date, "every federal circuit court of appeals that has addressed this issue" has held that the *qui tam* provisions are constitutional. Appx256.

This Court has yet to decide the issue. *See Com. of Pa., Dep't of Pub. Welfare v. U.S. Dep't of Health & Hum. Servs.*, 80 F.3d 796, 806 (3d Cir. 1996) (assuming, without deciding, that the FCA's *qui tam* provisions are constitutional). Yet three Justices of the Supreme Court have recently observed that "there are substantial arguments that the *qui tam* device is inconsistent with Article II and that private relators may not represent the interests of the United States in litigation." *See, e.g.*, *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 442 (2023) (Kavanaugh, J., concurring, joined by Barrett, J.); *id.* at 451 (Thomas, J., dissenting) ("[T]here is good reason to suspect that Article II does not permit private relators to represent the United States' interests in FCA suits."); *see also Wisconsin Bell, Inc. v. United States ex rel. Health*, 145 S. Ct. 498, 515 (2025) (Kavanaugh, J., concurring, joined by Thomas, J.) ("The Act's *qui tam* provisions raise substantial constitutional questions under Article II."). Those Justices have acknowledged that the constitutionality of FCA *qui tam* suits should be resolved in an appropriate case. *See Polansky*, 599 U.S. at 442 (Kavanaugh, J., concurring); *id.* at 452 (Thomas, J., dissenting).

Article II dictates that all executive power be "vested" in the President. U.S. Const. art. II, § 1. And with that power, Article II directs the President to "take Care that the Laws be faithfully executed." *Id.* § 3. Together, these provisions give the President the "authority to enforce federal law" and bring legal actions on behalf of the United States. *United States v. Texas*, 599 U.S. 670, 678 (2023).

In discharging these duties, the Framers "expected that the President would rely on subordinate officers for assistance." *Seila Law LLC v. CFPB*, 591 U.S. 197, 203-04 (2020). Anyone who "exercise[s] significant authority pursuant to the laws of the United States" and who occupies a "continuing position established by law" qualifies as an "officer." *Lucia v. SEC*, 585 U.S. 237, 245 (2018) (cleaned up). The Constitution requires that the power to appoint such officers be vested by Congress in "the President alone, in the Courts of Law, or in the Heads of Departments." U.S. Const. art. II, § 2, cl.2. To ensure accountability in the Executive Branch, such officers must remain "subject to" the President's "ongoing supervision and control" and removable by the President. *Seila Law*, 591 U.S. at 203-04. Were the rule otherwise, "the President could not be held fully accountable" for failing to execute the laws, in contravention of the Constitution's structure and command. *See Free Enter. Fund v. PCAOB*, 561 U.S. 477, 514 (2010).

When FCA relators litigate *qui tam* suits, they function as "officers" because they both "exercise significant authority pursuant to the laws of the United States"

and occupy a "continuing position established by law." *Lucia*, 585 U.S. at 245. Relators "exercise significant authority" by developing, investigating, and bringing cases "in the name of the Government." 31 U.S.C. § 3730(b)(1). Such lawsuits seek to redress injuries allegedly suffered by the United States, *id.* §§ 3729(a)(1), 3730(b)(1), and attempt to recover "damages that are essentially punitive in nature," *Vermont Agency of Nat'l Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784 (2000), including treble damages, civil penalties, and the relator's attorney's fees, 31 U.S.C. §§ 3729(a)(1), (3), 3730(d)(1)-(2). If the government declines to intervene, the relator alone controls the litigation, even though their decisions will generally bind the government upon entry of final judgment. *See United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 936 (2009). Relators also occupy a "continuing position established by law" because the FCA defines relators' statutory duties, powers, and emoluments in a "continuing and permanent" fashion, rather than for an "occasional" or "temporary" use. *Lucia*, 585 U.S. at 245.

Despite functioning as "officers" when they litigate *qui tam* suits, Relators are neither appointed by nor accountable to the President. This cannot be squared with Article II, as a federal district court recently recognized. Applying *Lucia*, that court held that FCA relators are improperly appointed "officers" under Article II. *See United States ex rel. Zafirov v. Fla. Med. Assocs., LLC*, 751 F. Supp. 3d 1293, 1322 (M.D. Fla. 2024), *appeal docketed*, No. 24-13581 (11th Cir. Oct. 30, 2024); *see also*

United States ex rel. Montcrief v. Peripheral Vascular Assocs., P.A., 133 F.4th 395, 410-12 (5th Cir. 2025) (Duncan, J., concurring) (explaining that the *qui tam* provisions are unconstitutional). The *Zafirov* court emphasized that relators exercise "significant authority" because, absent government intervention, the FCA "allows a relator not only to direct litigation, but also to bind the federal government without direct accountability to anyone in the Executive Branch," giving relators "greater independence than a Senate-confirmed United States Attorney or Assistant Attorney General." 751 F. Supp. 3d at 1301-02. Additionally, the court reasoned that relators occupy a "continuing position established by law" because "the office of relator persists by operation of the FCA" alone. *Id.* at 1300, 1314 (citation omitted).

This case presents a particularly egregious example of how the FCA's *qui tam* device offends Article II. To help ensure that HIV patients live long and healthy lives, the federal government adopted a liberal reimbursement policy for HIV treatment and instituted special reimbursement programs to ensure coverage. *See supra* pp. 7-9. And there is no dispute that Janssen provided effective, life-saving medications to thousands of patients. But because the government declined to intervene, Relators pursued litigation that undermines the government's approach to HIV treatment—and collected a judgment exceeding a billion dollars in doing so. Vesting relators with such sweeping and unchecked executive authority threatens to unsettle the government's reimbursement regime and frustrate patient care,

undermining Congress's and CMS's objectives in the process. *See, e.g.*, *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 8 (1st Cir. 2016) ("The FCA exists to protect the government from paying fraudulent claims, not to second-guess agencies' judgments[.]").

By declining to intervene, the government has allowed self-appointed, financially motivated Relators to wield significant executive power. To make matters worse, Relators prevailed on a legal theory with which DOJ disagrees: that off-label marketing automatically renders reimbursement claims false. *See supra* Part I.A. This Court should conclude the FCA's qui tam device violates Article II, vacate the judgment, and dismiss the case.

IV. The Penalties Award Violated the Excessive Fines Clause and the Due Process Clause.

The district court's civil penalty award of more than $1.2 billion amounted to more than ten times the compensatory damages award. In a case lacking any evidence of patient harm, and where the allegations involve HIV patients receiving life-saving HIV medications, that award is grossly excessive and violated the Excessive Fines and Due Process Clauses.

The Eighth Amendment provides that "[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." U.S. Const. amend. 8. That prohibition on excessive fines extends to civil penalties imposed under the FCA, as the district court acknowledged, *see* Appx266, because such penalties are "completely punitive" in nature, *United States ex rel. Drakeford*

v. Tuomey, 792 F.3d 364, 388 (4th Cir. 2015). Likewise, the Due Process Clause's prohibition on "grossly excessive" punitive damages awards also applies to civil penalties under the FCA. *Id.* at 387-88.

Whether analyzed under the Fifth or Eighth Amendment, a civil penalty is unconstitutional "if it is grossly disproportional to the gravity of a defendant's offense." *United States v. Bajakajian*, 524 U.S. 321, 334 (1998). In assessing whether a penalty is grossly excessive, "courts must 'consider three guideposts: (1) the degree of reprehensibility of the defendant's misconduct; (2) the disparity between the actual or potential harm suffered by the plaintiff and the punitive damages award; and (3) the difference between the punitive damages awarded by the jury and the civil penalties authorized or imposed in comparable cases.'" *CGB Occupational Therapy, Inc. v. RHA Health Servs., Inc.*, 499 F.3d 184, 188-89 (3d Cir. 2007) (quoting *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 418 (2003)); *see also United States ex rel. Grant v. Zorn*, 107 F.4th 782, 798-800 (8th Cir. 2024) (applying same guideposts in finding Excessive Fines Clause violation in FCA case).

The district court did not analyze the "guideposts," relying instead on a corporate integrity agreement related to different conduct and a misguided belief that exercising the right to appeal indicated a failure to accept responsibility. *See*

Appx265. But the guideposts confirm that the district court's civil penalty award was unconstitutionally excessive.

Degree of reprehensibility. The most important guidepost is "the degree of reprehensibility" of the defendant's actions. *CGB*, 499 F.3d at 189 (cleaned up). This factor counsels in favor of a lower award here.

This is not a case involving, for instance, "tortious conduct that evinced an indifference to the health or safety of others," *Grant*, 107 F.4th at 799, or a "massive course of fraudulent conduct," *Drakeford*, 792 F.3d at 389. Instead, the prescriptions on which Relators' claims are based were prescriptions for HIV drugs written for HIV patients. There is no dispute that these patients needed HIV drugs and that Medicare Part D, Medicaid, and ADAP would have reimbursed claims for HIV drugs for these patients. Relators' contention is that because of Janssen's marketing, these patients were prescribed Prezista and Intelence rather than alternatives. But there is no evidence that Prezista or Intelence were less effective for these patients than alternatives or that any patients were harmed because they were prescribed Prezista or Intelence. *See* Appx266. In addition, the evidence shows that the cost of Prezista and Intelence was similar to the amount that government payors would have paid for alternative HIV drugs. *See* Appx1384-86.

Nor is the number of false claims on which the district court based its award indicative of the reprehensibility of Janssen's conduct. The district court assessed

an $8,000 civil penalty for each *prescription* leading to an allegedly false claim—a calculation influenced by Dr. Shaked's flawed assumption that Janssen's marketing caused all allegedly "off-label" prescribing that followed, even prescriptions written by doctors with whom Janssen never met. *See supra* Part II.B.2. Physicians wrote those prescriptions, not Janssen. The reprehensibility of Janssen's conduct instead depends on what *Janssen* did—spend millions of dollars developing lifesaving HIV drugs, go through the arduous process of securing FDA approval, submit marketing materials for FDA review, and promote HIV drugs for use by HIV patients who indisputably need treatment. Indeed, the jury rejected the vast majority of the false claims Relators asserted and the damages they sought. *See supra* p. 12. And it rejected Relators' anti-kickback claims, which were the only claims that required willfulness. *See* Appx2203, 2207. This record hardly supports a finding of reprehensibility sufficient to justify a ten-figure civil penalties award.

Disparity between harm and award. The second guidepost is "the disparity between the harm or potential harm" caused and the award. *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 575 (1996). Courts have generally held punitive damages awards unconstitutional when they exceed a few multiples of compensatory damages. *See, e.g.*, *State Farm*, 538 U.S. at 425 (four-to-one ratio "might be close to the line of constitutional impropriety"); *CGB*, 499 F.3d at 190-95 (seven-to-one ratio at "constitutional upper limit" even where defendant's "tortious conduct

involved 'repeated stalling and dishonesty'" and defendant had resorted to "abusive and dilatory litigation tactics"). The Supreme Court has cautioned that "a lesser ratio, perhaps only equal to compensatory damages, can reach the outermost limit" of constitutionality where "compensatory damages are substantial." *State Farm*, 538 U.S. at 425; *see also Jurinko v. Med. Protective Co.*, 305 F. App'x 13, 28 (3d Cir. 2008) (roughly three-to-one ratio violated due process where "compensatory damages [were] substantial" and the only harm was economic).

Here, the compensatory damages award—about $120 million—is "substantial" by any measure. Yet the district court nonetheless imposed a civil penalty award of more than $1.2 billion, a ratio of more than 10 to 1. Indeed, that civil penalty award exceeded even the full *trebled* damage award—including the "punitive portion," which constitutes the bulk of the multiplied damages and should be removed from the analysis, *Grant*, 107 F.4th at 798-99, as it is itself subject to constitutional limits—by a ratio of more than 3.5 to 1. Those multipliers are grossly disproportionate to the gravity of Janssen's conduct. And coupled with the jury's significant compensatory damages award, they yield an award that is nothing short of astronomical.

The district court did not consider the ratio it was imposing, observing only that penalties "falling below the maximum statutory fines for a given offense" are presumed constitutional. Appx266 (cleaned up). But a presumption is just that: a

presumption. It cannot override the outer boundaries of constitutionality the Supreme Court has identified and that the district court blew past in this case.

Comparable cases. Finally, "the difference between this remedy and the civil penalties authorized or imposed in comparable cases" is striking. *BMW*, 517 U.S. at 575. It is doubtful that there *are* any truly comparable cases. The district court's penalty award accounts for most of the largest FCA judgment ever, and yet the ratio of penalties to compensatory damages awarded exceeds the ratios in FCA cases involving more egregious conduct. *See, e.g.*, *Drakeford*, 792 F.3d at 384, 387-90 ($120 million in penalties, totaling 3.04 times compensatory damages award, in case involving "massive course of fraudulent" submission of claims); *U.S. ex rel. Tyson v. Amerigroup Illinois, Inc.*, 488 F. Supp. 2d 719, 742-48 (N.D. Ill. 2007) ($190 million in penalties, totaling 3.97 times compensatory damages award, in case involving insurance company's fraudulent representations that it would not discriminate against unhealthy patients). Moreover, the penalties award in this case exceeds the "outermost limit[s]" of what the Supreme Court has declared permissible *regardless* of factual circumstances. *State Farm*, 538 U.S. at 425. The penalty award was thus unconstitutionally excessive under any possible measurement.

CONCLUSION

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

July 14, 2025

Respectfully submitted,

/s/ *Mark W. Mosier*

Mark W. Mosier
Matthew F. Dunn
Krysten Rosen Moller
Daniel G. Randolph
Kendall T. Burchard
Alexander J. Cave
Mishi Jain
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street NW
Washington, DC 20001-4956
(202) 662-6000

Counsel for Defendant-Appellant Janssen Products, LP

CERTIFICATE OF COMPLIANCE

1. This Brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(b) because it contains 12,933 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.

3. Pursuant to Third Circuit Local Appellate Rule 31.1(c), the text of the electronic brief is identical to the text in the paper copies.

4. Pursuant to Third Circuit Local Appellate Rule 31.1(c), virus detection programs—Anti-Malware Solution CrowdStrike Falcon Agent v. 7.25.19706.0 and Palo Alto's Continuously Integrated Continuous Delivery (CI/CD) anti-virus platform Wildfire—have been run on the electronic file and no virus was detected.

July 14, 2025 */s/ Mark W. Mosier*

CERTIFICATE OF BAR MEMBERSHIP

Pursuant to Third Circuit Local Appellate Rule 28.3(d), I certify that the following attorneys whose names appear on the brief are members of the bar of this Court:

Mark W. Mosier

Matthew F. Dunn

Krysten Rosen Moller

Daniel G. Randolph

Kendall T. Burchard

Alexander J. Cave

Mishi Jain

July 14, 2025 */s/ Mark W. Mosier*

CERTIFICATE OF SERVICE

I certify that on July 14, 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.

/s/ Mark W. Mosier

STATUTORY & REGULATORY ADDENDUM

ADDENDUM TABLE OF CONTENTS

Page

Excerpts of 31 U.S.C. § 3729 .....ADD-1

Excerpts of 31 U.S.C. § 3730 .....ADD-4

Excerpts of 42 U.S.C § 300ff-26 .....ADD-8

Excerpts of 42 U.S.C. § 1395y(a) ADD-9

Excerpts of 42 U.S.C. § 1395w-102 .....ADD-10

Excerpts of 42 U.S.C. § 1396r-8 .....ADD-11

Excerpts of 42 C.F.R. § 440.230 .....ADD-12

Excerpts of 31 U.S.C. § 3729

§ 3729 − False claims

(a) Liability for Certain Acts. —

(1) In general. — Subject to paragraph (2), any person who —

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

(D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;

(E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104–410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

(2) Reduced damages. — If the court finds that —

(A) the person committing the violation of this subsection furnished officials of the United States responsible for investigating false claims violations

with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information;

(B) such person fully cooperated with any Government investigation of such violation; and

(C) at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation,

the court may assess not less than 2 times the amount of damages which the Government sustains because of the act of that person.

(3) Costs of civil actions. —

A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.

(b) Definitions. — For purposes of this section —

(1) the terms "knowing" and "knowingly" —

(A) mean that a person, with respect to information —

(i) has actual knowledge of the information;

(ii) acts in deliberate ignorance of the truth or falsity of the information; or

(iii) acts in reckless disregard of the truth or falsity of the information; and

(B) require no proof of specific intent to defraud;

(2) the term "claim" —

(A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that —

(i) is presented to an officer, employee, or agent of the United States; or

(ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance

a Government program or interest, and if the United States Government —

(I) provides or has provided any portion of the money or property requested or demanded; or

(II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and

(B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual's use of the money or property;

(3) the term "obligation" means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment; and

(4) the term "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

….

Excerpts of 31 U.S.C. § 3730

§ 3730 - Civil actions for false claims

(a) Responsibilities of the Attorney General. —

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

(b) Actions by Private Persons. —

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

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

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

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

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

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

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

(c) Rights of the Parties to Qui Tam Actions. —

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

(2)

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

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

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

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

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

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

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

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

(3) If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action. If the Government so requests, it shall be served with copies of all pleadings filed in the action and shall be supplied with copies of all deposition transcripts (at the Government's expense). When a person proceeds with the action, the court, without limiting the

status and rights of the person initiating the action, may nevertheless permit the Government to intervene at a later date upon a showing of good cause.

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

(5) Notwithstanding subsection (b), the Government may elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty. If any such alternate remedy is pursued in another proceeding, the person initiating the action shall have the same rights in such proceeding as such person would have had if the action had continued under this section. Any finding of fact or conclusion of law made in such other proceeding that has become final shall be conclusive on all parties to an action under this section. For purposes of the preceding sentence, a finding or conclusion is final if it has been finally determined on appeal to the appropriate court of the United States, if all time for filing such an appeal with respect to the finding or conclusion has expired, or if the finding or conclusion is not subject to judicial review.

(d) Award to Qui Tam Plaintiff. —

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

under the first or second sentence of this paragraph shall be made from the proceeds. Any such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

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

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

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

….

Excerpts of 42 U.S.C § 300ff-26

§ 300ff-26 - Provision of treatments

(a) In general

A State shall use a portion of the amounts provided under a grant awarded under section 300ff–21 of this title to establish a program under section 300ff–22(b)(3)(B) of this title to provide therapeutics to treat HIV/AIDS or prevent the serious deterioration of health arising from HIV/AIDS in eligible individuals, including measures for the prevention and treatment of opportunistic infections.

(b) Eligible individual

To be eligible to receive assistance from a State under this section an individual shall —

(1) have a medical diagnosis of HIV/AIDS; and

(2) be a low-income individual, as defined by the State.

(c) State duties

In carrying out this section the State shall —

(1) ensure that the therapeutics included on the list of classes of core antiretroviral therapeutics established by the Secretary under subsection (e) are, at a minimum, the treatments provided by the State pursuant to this section;

(2) provide assistance for the purchase of treatments determined to be eligible under paragraph (1), and the provision of such ancillary devices that are essential to administer such treatments;

(3) provide outreach to individuals with HIV/AIDS, and as appropriate to the families of such individuals;

(4) facilitate access to treatments for such individuals;

(5) document the progress made in making therapeutics described in subsection (a) available to individuals eligible for assistance under this section; and

(6) encourage, support, and enhance adherence to and compliance with treatment regimens, including related medical monitoring.

….

Excerpts of 42 U.S.C. § 1395y(a)

§ 1395y(a) - Exclusions from coverage and medicare as secondary payer

(a) Items or services specifically excluded

Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B for any expenses incurred for items or services —

(1)

(A) which, except for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1395x(ddd)(1) of this title), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,

(B) in the case of items and services described in section 1395x(s)(10) of this title, which are not reasonable and necessary for the prevention of illness,

….

Excerpts of 42 U.S.C. § 1395w-102

§ 1395w-102 – Prescription drug benefits

….

(e) Covered part D drug defined

….

(3) Application of general exclusion provisions

A prescription drug plan or an MA–PD plan may exclude from qualified prescription drug coverage any covered part D drug —

(A) for which payment would not be made if section 1395y(a) of this title applied to this part; or

(B) which is not prescribed in accordance with the plan or this part.

Such exclusions are determinations subject to reconsideration and appeal pursuant to subsections (g) and (h), respectively, of section 1395w–104 of this title.

(4) Medically accepted indication defined

(A) In general

For purposes of paragraph (1), the term "medically accepted indication" has the meaning given that term —

(i) in the case of a covered part D drug used in an anticancer chemotherapeutic regimen, in section 1395x(t)(2)(B) of this title, except that in applying such section —

(I) "prescription drug plan or MA–PD plan" shall be substituted for "carrier" each place it appears; and

(II) subject to subparagraph (B), the compendia described in section 1396r–8(g)(1)(B)(i)(III) of this title shall be included in the list of compendia described in clause (ii)(I) section 1395x(t)(2)(B) of this title; and

(ii) in the case of any other covered part D drug, in section 1396r–8(k)(6) of this title.

….

Excerpts of 42 U.S.C. § 1396r-8

§ 1396r-8 – Payment for covered outpatient drugs

……

(d) Limitations on coverage of drugs

(1) Permissible restrictions

(A) A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).

(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if —

(i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6));

(ii) the drug is contained in the list referred to in paragraph (2);

(iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) or in effect pursuant to subsection (a)(4); or

(iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).

….

§ 1396r-8(k) Definitions

In this section —

….

(6) Medically accepted indication

The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i).

….

Excerpts of 42 C.F.R. § 440.230

§ 440.230 – Sufficiency of amount, duration, and scope.

(a) The plan must specify the amount, duration, and scope of each service that it provides for—

(1) The categorically needy; and

(2) Each covered group of medically needy.

(b) Each service must be sufficient in amount, duration, and scope to reasonably achieve its purpose.

(c) The Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a required service under §§ 440.210 and 440.220 to an otherwise eligible beneficiary solely because of the diagnosis, type of illness, or condition.

(d) The agency may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures.

….