

No. 25-1818

**IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT**

UNITED STATES ex rel. JESSICA PENELOW, et al.,

Plaintiffs-Appellees, and

UNITED STATES OF AMERICA,

Intervenor-Appellee,

v.

JANSSEN PRODUCTS, L.P.,

Defendant-Appellant.

On Appeal from the United States District Court
for the District of New Jersey

**BRIEF FOR THE UNITED STATES AS INTERVENOR
AND AMICUS IN SUPPORT OF NEITHER PARTY**

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INTEREST OF THE UNITED STATES

This is a qui tam action under the False Claims Act, brought by relators and pursued by them after the government decided not to take over the litigation under 31 U.S.C. § 3730.¹ After a jury trial, the district court entered judgment against defendant Janssen Products, L.P. Janssen appeals on numerous grounds, some of which implicate the constitutionality of the False Claims Act. The government therefore intervened in this Court, under 28 U.S.C. § 2403(a), for the limited purpose of defending the Act’s constitutionality. The government is a party only as to the constitutional issues in the appeal, not as to the non-constitutional issues. *See United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 932-934 (2009) (government is not a party to qui tam actions that it has not taken over under 31 U.S.C. § 3730).

The government addresses one of the non-constitutional issues—the falsity element of liability under the False Claims Act—as amicus curiae in support of neither party. Because the government is a “‘real party in interest’” in all qui tam cases under the Act, *Eisenstein*, 556 U.S. at 934, which are brought “for” it and “in [its] name,” 31 U.S.C. § 3730(b)(1), it has a strong

¹ References to “the government” in this brief are to the United States. Various States are also real parties in interest.

interest in ensuring that courts correctly interpret the Act in cases pursued by relators. The government routinely participates as amicus curiae in such cases. Here, the government participates as amicus to apprise the Court of its view that the district court appears, both in its jury instructions and in its post-trial order, to have misapprehended the relationship between the approval of a drug by the Food and Drug Administration (FDA) and the reimbursability by federal healthcare programs of a claim for that drug.

STATEMENT OF ISSUES

We address two issues as intervenor in support of appellees:

1. Whether the qui tam provisions of the False Claims Act, as applied where the government has declined to take over an action brought by a relator, are consistent with Article II of the Constitution.

2. Whether the amount of civil penalties imposed in this case, within the range permitted by the False Claims Act, is consistent with the Excessive Fines Clause of the Eighth Amendment.

We address one issue as amicus curiae:

Whether the district court erred, in its jury instructions and post-trial opinion, by misstating the relationship between FDA approval of a drug and the reimbursability by federal healthcare programs of a claim for that drug.

STATEMENT OF RELATED CASES AND PROCEEDINGS

This case has not previously been before this Court, and the government is unaware of related cases.

STATEMENT OF THE CASE

1. The False Claims Act, 31 U.S.C. § 3729 *et seq.*, imposes civil liability for a variety of deceptive practices involving government funds and property. The Act renders liable, for example, any person who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,” *id.* § 3729(a)(1)(A), and any person who “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim,” *id.* § 3729(a)(1)(B). The Act defines a “‘claim’” to include “any request or demand ... for money or property [that] ... is presented to an officer, employee, or agent of the United States.” *Id.* § 3729(b)(2)(A)(i).

When Congress enacted the statute in 1863, it followed a “long tradition ... in England and the American Colonies,” *Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 768, 772-774 (2000), by incorporating qui tam provisions authorizing private persons to bring suit to redress frauds against the United States. Act of Mar. 2, 1863, ch. 67, §§ 4, 6, 12 Stat.

696, 698. The current version of the Act retains the basic structure of the qui tam mechanism. The Attorney General may bring a civil action to recover treble damages and civil penalties for a violation of the Act. *See* 31 U.S.C. § 3730(a). Alternatively, a private person known as a relator may bring suit, “for the person and for the United States Government,” “in the name of the Government.” *Id.* § 3730(b)(1). The relator’s complaint must be filed under seal and served on the United States. *Id.* § 3730(b)(2). The government then has 60 days, subject to extension, to decide whether to intervene and take over the suit. *Id.* § 3730(b)(2), (3).

If the government intervenes – either before the complaint is unsealed or “at a later date upon a showing of good cause,” 31 U.S.C. § 3730(c)(3) – then “the action shall be conducted by the Government,” *id.* § 3730(b)(4)(A); *see id.* § 3730(c)(1) (government “shall have the primary responsibility for prosecuting the action”). The government may file its own complaint or may amend the relator’s complaint to add or alter claims. *Id.* § 3731(c).

If the government declines to intervene, then “the person bringing the action shall have the right to conduct the action.” 31 U.S.C. § 3730(b)(4)(B). But the government retains considerable control over such actions. For example, the government is entitled to receive “copies of all pleadings filed in

the action and ... all deposition transcripts.” *Id.* § 3730(c)(3). It may stay discovery to avoid “interfere[nce]” with a related governmental investigation or prosecution. *Id.* § 3730(c)(4). It may “elect to pursue its claim through any alternate remedy available to [it], including any administrative proceeding to determine a civil money penalty.” *Id.* § 3730(c)(5). It may veto a relator’s proposed dismissal or settlement of the action. *Id.* § 3730(b)(1). And on a showing of good cause, it may intervene in the action even after having previously chosen not to do so, including for the purpose of seeking to dismiss the action over the relator’s objection. *Id.* § 3730(c)(2)(A), (B); see *United States ex rel. Polansky v. Executive Health Res., Inc.*, 599 U.S. 419 (2023).

The Act specifies that “any person who” commits a violation “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, plus 3 times the amount of damages which the Government sustains because of the act of that person.” 31 U.S.C. § 3729(a)(1) (footnote and citation omitted). Those penalties are “per claim.” *Stevens*, 529 U.S. at 769. For violations on or before November 2, 2015, the inflation-adjusted minimum penalty is \$5,500 per claim, and the inflation-adjusted maximum is \$11,000 per claim. 28 C.F.R. § 85.3(a)(9). If a qui tam

action results in any monetary recovery, an eligible relator is entitled to a share of the recovery. 31 U.S.C. § 3730(d).

2. In 2012, relators Jessica Penelow and Christine Brancaccio brought this qui tam action against Janssen under the False Claims Act as well as numerous state false claims acts. The government declined to intervene and take over the action under 31 U.S.C. § 3730.

Relators asserted two counts of liability under the federal False Claims Act. One count, not relevant here, asserted that Janssen had violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), by providing doctors with remuneration (through speaker programs) to induce them to prescribe two antiretroviral drugs, known as Prezista and Intelence, and thus caused the submission of claims rendered false by those kickbacks. Appx433-434. The other count, at issue in this appeal, asserted that Janssen had falsely and misleadingly marketed the drugs and thus caused healthcare providers to submit false claims for the drugs. Appx432-433. In particular, relators alleged that Janssen promoted the drugs for unapproved uses, *see* Appx403-408, and falsely represented the safety profile of the drugs when used for approved uses, *see* Appx390-402. The claims in question were submitted to three federal healthcare programs: Medicare, which funds medical care for elderly

people and people with disabilities; Medicaid, a cooperative federal-state program that funds medical care for low-income people; and the AIDS Drug Assistance Program (ADAP), a federal-state program that provides medications to low-income people with HIV, *see* Health Res. & Servs. Admin., *Part B: AIDS Drug Assistance Program (ADAP)*, <https://perma.cc/G5PH-6S5J>.

The legal framework for drug approvals and marketing is relevant background for this count. Under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, a new drug may not be introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application based on the determination that the drug is safe and effective for use under the conditions prescribed, recommended, or suggested in the drug's labeling. *Id.* § 355. For prescription drugs, FDA must also approve the drug's labeling, which specifies, among other things, the FDA-approved uses and adequate directions for those uses. *Id.*; *id.* § 352(f)(1); *see* 21 C.F.R. §§ 201.5, 201.55-201.57, 201.100. Because a drug that is safe and effective for one use may be neither safe nor effective for others, FDA approval extends only to the uses specified in a drug's approved application and labeling. 21 U.S.C. § 355(d).

A new drug that is introduced or delivered for introduction into interstate commerce for an intended use not approved by FDA is “misbranded” because it does not have FDA-approved labeling with adequate directions for that unapproved use. 21 U.S.C. § 352(f)(1). The FDCA prohibits the introduction or the delivery for introduction into interstate commerce of misbranded drugs. 21 U.S.C. § 331. A drug’s “intended uses” are determined by the objective intent of the drug manufacturer, which may be demonstrated by the drug’s “advertising” and by other “oral or written statements” by the manufacturer or its representatives. 21 C.F.R. § 201.128. A manufacturer’s promotion of a drug for unapproved uses thus may constitute evidence that the manufacturer has violated the FDCA’s misbranding provisions by distributing a drug for an intended use not approved by FDA without adequate directions for use.

FDA does not, however, attempt to regulate the practice of medicine. Once a drug is approved for one use at one dosage, doctors are free to prescribe it for unapproved uses or at other dosages—a practice sometimes called “off-label” prescribing. *See, e.g., Washington Legal Found. v. Henney*, 202 F.3d 331, 332-333 (D.C. Cir. 2000).

Prescriptions for unapproved uses are sometimes, but not always, eligible for reimbursement under federal healthcare programs. To be eligible for reimbursement by Medicare Part D (the Medicare program that would cover the drugs at issue here), a drug generally must be prescribed for an FDA-approved use or for another “medically accepted indication” listed in one of several statutorily specified compendia. 42 U.S.C. § 1395w-102(e)(1), (4); *see id.* § 1396r-8(g)(1)(B)(i) (identifying compendia). More generally, it must be “reasonable and necessary.” *Id.* § 1395y(a)(1)(A); *see id.* § 1395w-102(e)(3)(A). Off-label prescription of a drug can sometimes be both medically accepted and reasonable and necessary for a given patient. *See, e.g.*, 70 Fed. Reg. 4,194, 4,261 (Jan. 28, 2005) (Part D implementing rule, explaining that the program does “not preclude physicians and other prescribers from prescribing drugs for off label indications”). Conversely, on-label prescriptions are not reimbursable if the use of the drug is not reasonable and necessary for the “individual patient” — a determination made in the first instance by the prescribing physician, and “with reference to accepted standards of medical practice and the medical circumstances of the individual case.” Ctrs. for Medicare & Medicaid Servs., *Medicare Benefit Policy Manual* ch. 15, § 50.4.3 (rev. 13051; issued Jan. 16, 2025), <https://perma.cc/GG99-QF67>.

State Medicaid programs and ADAP programs may have somewhat different eligibility criteria. *See, e.g.*, 42 U.S.C. § 1396r-8(d)(1)(B)(i) (Medicaid programs “*may* exclude ... coverage of a covered outpatient drug if ... the prescribed use is not for a medically accepted indication” (emphasis added)); *id.* § 300ff-26 (ADAP requirements).

3. After the district court largely denied a motion to dismiss, *United States ex rel. Penelow v. Johnson & Johnson*, 2017 WL 2367050 (D.N.J. May 31, 2017), and denied summary judgment, *United States ex rel. Penelow v. Janssen Prods., LP*, 2021 WL 6052425 (D.N.J. Dec. 21, 2021), the case proceeded to a six-week trial in 2024.

The jury instructions stated in relevant part that a “claim is false if it is ineligible for reimbursement under a federal health care program.” Appx2202. The instructions then identified two grounds on which a claim could be ineligible for reimbursement. First, the instruction stated that “federal health care programs, including Medicare Part D, Medicaid, and ADAP, will cover and pay for a drug that is used for a ‘medically accepted indication,’ which means any FDA-approved use on the label that is supported by one or more citations in certain drug compendia.” Appx2202. Second, the instruction stated that “[c]overage for drugs may also be excluded if they are

not reasonable and necessary for the diagnosis or treatment of illness or injury.” Appx2202.

The jury found in Janssen’s favor on the kickback claim, but it found against Janssen on the claim that it had caused the submission of false claims by engaging in false and misleading marketing of its drugs. Appx2228-2229. The jury found that Janssen had caused the submission of 159,574 false claims and that the United States sustained \$120,004,736 in damages. Appx2228. The jury also found that Janssen had violated all the state false claims acts at issue, by virtue of the same conduct, and that the States had suffered \$30,001,184 in damages. Appx2230-2231.

4. Relators moved for entry of judgment on the verdict, requesting treble damages and a civil penalty of \$9,000 per false claim. Defendants objected that the proposed judgment would be unconstitutionally excessive. Defendants also moved for judgment as a matter of law, including on the grounds that the evidence was insufficient to establish falsity and that the qui tam provisions of the False Claims Act are inconsistent with Article II.

The district court granted Janssen’s motion for judgment as a matter of law on the state-law claims, but denied it as to the federal False Claims Act, and entered judgment with civil penalties of \$8,000 per claim. Appx233-271.

As to the Article II challenge to the qui tam provisions, the district court “decline[d] to follow,” Appx256, what was then the only decision holding the qui tam provisions unconstitutional: *United States ex rel. Zafirov v. Florida Med. Assocs., LLC*, 751 F. Supp. 3d 1293 (M.D. Fla. 2024). The district court “instead follow[ed] every federal circuit court of appeals that has addressed this issue” by upholding the constitutionality of the qui tam provisions. Appx256.

As to the falsity issue, the district court observed that relators had introduced evidence “that while Janssen promoted Prezista for treatment-naïve patients, Prezista’s label was not indicated for treatment-naïve patients from 2006–2008, nor did recognized compendia support the use of Prezista in treatment-naïve patients,” and “that while Janssen promoted Intelence for once-a-day dosing and for treatment-naïve patients, Intelence’s label was only indicated for twice-a-day and for a ‘very specific group of experienced patients.’” Appx243-244. The court stated that Janssen’s off-label “marketing violated an express condition ... for reimbursement under Medicare, Medicaid, or ADAP.” Appx244.

Finally, as to the Excessive Fines Clause challenge, the district court was “mindful of its role to grant ‘substantial deference to the broad authority

that legislatures necessarily possess in determining the types and limits of punishments for crimes,’ and” accordingly “decline[d] to impose a penalty below the minimum statutory range.” Appx265. The court determined that several factors “support[ed] a civil penalty near the middle of the statutory range of \$5,500 and \$11,000” —namely that “Janssen engaged in a deliberate and calculated scheme that spanned several years and involved the unlawful marketing of its products”; that it “was aware of the seriousness of its conduct, and entered into at least three agreements with the Government in the past to resolve allegations related to [off-label] marketing of other drugs”; and that, “despite the jury’s verdict, Janssen refuses to accept responsibility for its conduct.” Appx265. But the court found that “the lack of evidence regarding patient harm and general fairness principles” —as well as the constitutional “duty to impose a fine that is not ‘grossly disproportionat[e] to the gravity of [the] defendant’s offense’” —“counsel[ed] against ... imposing the maximum penalty.” Appx266.

The district court accordingly imposed a per-claim penalty of \$8,000, which—multiplied by the number of false claims found by the jury—produced an overall penalty of \$1,276,592,000. Appx266-267. The court noted

that its civil-penalty award “would amount to over ten times the actual damages suffered by the Government,” and it concluded that such a ratio would “adequately serve[] Relators’ interests and reflect[] the seriousness of the offense without being unfair to Janssen.” Appx266. The court also awarded treble damages of \$360,014,208, Appx263, for a total judgment of more than \$1.6 billion.

SUMMARY OF ARGUMENT

I. The False Claims Act’s qui tam provisions are consistent with Article II, as every court of appeals to have addressed the issue has held.

A. Qui tam relators need not be appointed in the manner prescribed by the Appointments Clause because they have none of the indicia of officeholders within the meaning of the Appointments Clause. They do not occupy continuing positions; rather, their roles are limited in time and scope, confined to a particular case, and fundamentally personal in nature. And Congress did not vest them with uniquely governmental authority.

B. Nor do the qui tam provisions violate the Vesting and Take Care Clauses. Congress has the power to authorize private parties who have suffered Article III injury to sue to enforce federal statutes. Qui tam suits under the False Claims Act do differ in some significant respects from private suits

under other statutes, and if Congress's use of the qui tam mechanism were a new development, these features of qui tam suits would give rise to substantial questions about whether they are consistent with the Vesting and Take Care Clauses. But any such doubts are resolved by the extensive body of evidence that qui tam provisions have, since the Founding, been understood as established features of American law.

II. The district court correctly stated that a "claim is false if it is ineligible for reimbursement under a federal health care program." Appx2202. The court erred, however, by misapprehending the relationship between FDA approval of a drug and the reimbursability by federal healthcare programs of a claim for that drug. In its jury instructions, the court incorrectly suggested that FDA approval of a drug for a given indication is necessary for a claim for the drug to be reimbursable. And in its post-trial opinion, the court incorrectly suggested that a violation of the FDCA's misbranding provisions is itself a basis for treating claims for the misbranded drugs as false for purposes of the False Claims Act. The FDCA's misbranding provisions govern how drugs may be marketed; they do not govern whether federal healthcare programs will reimburse for the drugs.

Janssen appears to have forfeited the challenge it now raises to the jury instruction, so the district court's instructional error would not be a basis for a new trial unless it satisfies the highly demanding plain-error standard. Assuming the Court concludes that a new trial is unnecessary, it should vacate the judgment and remand for the district court to reassess its post-trial ruling under a correct view of the law.

III. If the Court does not vacate the judgment, and therefore must address the constitutionality of the amount of civil penalties the district court imposed, it should uphold the penalty amount.

A monetary penalty violates the Excessive Fines Clause only if it bears no relationship to the gravity of the misconduct it punishes. Under that deferential standard, the federal courts of appeals have almost uniformly upheld the constitutionality of civil penalties within the statutorily authorized range in False Claims Act cases. And there is no proper basis here to conclude that the statutorily specified penalty range for the submission of the claims the jury found to have been false, or the district court's determination of a penalty, violates the constitutional standard.

Janssen’s contrary argument focuses on the sort of ratio-based analysis that the Supreme Court has articulated for determining whether jury punitive-damages awards are consistent with the Due Process Clause. But the due-process standard does not apply to the review of statutorily prescribed penalties under the Excessive Fines Clause, and it is particularly inapposite to penalties for fraud.

STANDARD OF REVIEW

Most of the issues addressed by this brief are legal issues reviewed *de novo*. See *Addie v. Kjaer*, 737 F.3d 854, 861 (3d Cir. 2013) (this Court “‘review[s] the denial of judgment as a matter of law *de novo*, viewing the evidence in the light most favorable to ... the prevailing party’”); *United States v. Weatherly*, 525 F.3d 265, 273 (3d Cir. 2008) (“This Court reviews challenges to the constitutionality of a statute under a *de novo* standard of review.”); *Grashoff v. Adams*, 65 F.4th 910, 916 (7th Cir. 2023) (reviewing *de novo* a determination that a penalty does not violate the Excessive Fines Clause); *cf.* *Washington v. Gilmore*, 124 F.4th 178, 184 (3d Cir. 2024) (this Court reviews *de novo* “a district court’s ‘decision upholding the constitutionality’ of a punitive damages award”). A forfeited challenge to a jury instruction is reviewed for plain error, and the Court “will reverse only where the error is

‘fundamental and highly prejudicial.’” *Robinson v. First State Cmty. Action Agency*, 920 F.3d 182, 187 (3d Cir. 2019).

ARGUMENT

I. The False Claims Act’s Qui Tam Provisions Are Consistent With Article II

Every court of appeals to have addressed the question has held that the False Claims Act’s qui tam provisions are consistent with Article II. *United States ex rel. Stone v. Rockwell Int’l Corp.*, 282 F.3d 787, 804-807 (10th Cir. 2002); *Riley v. St. Luke’s Episcopal Hosp.*, 252 F.3d 749, 753-758 (5th Cir. 2001) (en banc); *United States ex rel. Taxpayers Against Fraud v. General Elec. Co.*, 41 F.3d 1032, 1040-1042 (6th Cir. 1994); *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 749-759 (9th Cir. 1993); see also *United States ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1155 (2d Cir. 1993) (explaining, in rejecting an Article III challenge, that the qui tam “provisions do not usurp the executive branch’s litigating function”).

So has nearly every district court that has addressed the question, with the exception of a single court that has held the qui tam provisions invalid within the past year. *United States ex rel. Zafirov v. Florida Med. Assocs., LLC*, 751 F. Supp. 3d 1293 (M.D. Fla. 2024); see *United States ex rel. Gose v. Native*

Am. Servs. Corp., 2025 WL 1531137 (M.D. Fla. May 29, 2025) (same judge, relying on *Zafirov*). The *Zafirov* decision is on appeal before the Eleventh Circuit (Nos. 24-13581, -13583), and numerous courts have criticized it as unpersuasive. *United States ex rel. Adler v. Sporn Co.*, 2025 WL 1371272, at *17 (D. Vt. May 12, 2025); *Kenley Emergency Med. v. Schumacher Grp. of La. Inc.*, 2025 WL 1359065, at *5 (N.D. Cal. May 9, 2025); *United States ex rel. Adams v. Chattanooga Hamilton Cnty. Hosp. Auth.*, 2024 WL 4784372, at *3 (E.D. Tenn. Nov. 7, 2024); see also *United States ex rel. Permenter v. eClinicalWorks, LLC*, 2025 WL 1762264, at *11 (M.D. Ga. June 25, 2025) (declining to follow *Zafirov*); *Kane v. Select Med. Corp.*, 2025 WL 1726253, at *1 n.1 (M.D. Fla. June 20, 2025) (same); *United States ex rel. Gonite v. UnitedHealthcare of Ga., Inc.*, 2025 WL 1184109, at *3-4 (M.D. Ga. Apr. 23, 2025) (same).

This Court should align itself with nearly every prior decision on this issue and hold that the False Claims Act's qui tam provisions are consistent with Article II.

A. Relators Need Not Be Appointed In The Manner Prescribed By The Appointments Clause

Janssen and its amici contend that the qui tam provisions are inconsistent with the Appointments Clause, which specifies the permissible

means of appointing “Officers of the United States” to public offices “established by Law.” U.S. Const. art. II, § 2, cl. 2. But relators possess none of the indicia of officeholders within the meaning of the Appointments Clause: Their roles are limited in time and scope, confined to a particular case, and fundamentally personal in nature.

1. Relators do not occupy continuing positions

To be an “Officer of the United States” subject to the Appointments Clause, a person “must occupy a ‘continuing’ position established by law.” *Lucia v. SEC*, 585 U.S. 237, 245 (2018). This requirement derives from the Supreme Court’s decision in *United States v. Germaine*, 99 U.S. 508 (1879), which “held that ‘civil surgeons’ (doctors hired to perform various physical exams) were mere employees,” as opposed to officers, “because their duties were ‘occasional or temporary’ rather than ‘continuing and permanent.’” *Lucia*, 585 U.S. at 245 (quoting *Germaine*, 99 U.S. at 508, 512). A hallmark of an office is that its “duties continue, though the person” occupying it “be changed.” *United States v. Maurice*, 26 F. Cas. 1211, 1214 (C.C.D. Va. 1823) (No. 15,747) (Marshall, C.J.). Relators’ roles, in contrast, are limited in time and scope rather than continuing from officeholder to officeholder over time.

The *Zafirov* decision likened relators to independent counsels, 751 F. Supp. 3d at 1308, 1314-1315, or bank receivers, *id.* at 1315, who have been held to be officers even though their roles were temporary. See, e.g., *Morrison v. Olson*, 487 U.S. 654, 671 n.12 (1988) (independent counsel); *United States v. Weitzel*, 246 U.S. 533, 541 (1918) (bank receiver); *United States v. Donziger*, 38 F.4th 290, 296-299 (2d Cir. 2022) (special prosecutor). But those roles, unlike relators' roles, were not specific to the individuals appointed to perform them. They were continuing in the crucial sense that their "duties" would "continue" even "though the person" performing them "be changed." *Maurice*, 26 F. Cas. at 1214. As the Supreme Court explained, Alexia Morrison was not even the first person to hold her independent counsel office: The court that appointed her had initially appointed James McKay, who had resigned and been replaced by her. *Morrison*, 487 U.S. at 667. Her role was thus clearly "continuing" even though it was not permanent. The duties of a bank receiver were likewise not limited to performance by a single individual. See *Officers of the United States Within the Meaning of the Appointments Clause*, 31 Op. O.L.C. 73, 111 (2007). If a given person appointed to act as a receiver became unable to perform his duties, that would not negate the need for a receivership; it would simply require the appointment of another

receiver in place of the first. In *Stanton v. Wilkeson*, 22 F. Cas. 1074 (S.D.N.Y. 1876), another bank-receiver case, the court made this point clear when explaining that “[v]acation of office by the comptroller” of the currency, who delegated authority to the receiver, would not “vacate the receivership.” *Id.* at 1074-1075. And in *Donziger*, the Second Circuit – citing *Maurice* – specifically based its conclusion that a special prosecutor was an officer on the premise that “the individuals appointed as special prosecutors could be replaced without the duties of the positions terminating.” 38 F.4th at 297.

The role of a relator is nothing like that. If a particular relator who has blown the whistle on a fraud by filing a qui tam action decides she is no longer interested in pursuing the action, another person cannot simply take her place as relator. The False Claims Act states expressly that “[w]hen a person brings an action under” the qui tam provisions, “no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.” 31 U.S.C. § 3730(b)(5).

The *Zafirov* decision suggested that the role of relator is continuing because any person can be a relator if she satisfies the statutory prerequisites. 751 F. Supp. 3d at 1314. But whether multiple people can hold the so-called office of “relator” at any given time has no bearing on whether that role is

continuing. What matters is whether the duty—here, the duty of litigating a *particular* qui tam action—can continue from inhabitant to inhabitant of that office, and it clearly cannot. A relator’s pursuit of a qui tam action is personal to that relator and not transferable from relator to relator. The fact that an individual can serve as a relator in a particular qui tam case for years is likewise irrelevant to whether a role is continuing in the relevant sense—*i.e.*, whether the duties of the role can be passed from one person who occupies the role to the next.

It is true that a relator’s qui tam action survives her death and may be pursued by her estate’s personal representative, just as the estates of deceased plaintiffs routinely maintain other types of actions personal to the deceased plaintiff. *United States v. NEC Corp.*, 11 F.3d 136, 139 (11th Cir. 1993); *see also United States ex rel. Spicer v. Westbrook*, 751 F.3d 354 (5th Cir. 2014) (bankruptcy trustee, as opposed to new relator, can assert False Claims Act claims belonging to relator’s bankruptcy estate). But that does not mean a relator’s role is continuing in the relevant sense; rather, it underscores that a relator’s role is personal and unlike that of an actual office. The duties of an actual office—that of the Attorney General, for example—are not personal and thus are not inherited by the official’s estate if she dies.

2. Congress did not vest relators with uniquely governmental authority

Relators are also not officeholders subject to the Appointments Clause because Congress envisioned their roles as fundamentally personal rather than governmental in nature. In *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765 (2000), the Supreme Court expressly rejected the idea that relators have Article III standing to pursue suits under the False Claims Act because they serve as agents of the United States. *Id.* at 772. Rather, the Court held that relators have standing on the ground that the Act “can reasonably be regarded as effecting a partial assignment of the Government’s damages claim” by entitling the relator to a share of any ultimate recovery. *Id.* at 773; see *United States ex rel. Polansky v. Executive Health Res., Inc.*, 599 U.S. 419, 425 (2023) (similar). And in another part of the opinion holding that relators cannot pursue qui tam actions against States, the Court emphasized that such actions are “private suit[s]” brought by “private parties.” *Stevens*, 529 U.S. at 780 n.9, 786 n.17.

Stevens thus recognized that when Congress authorized relators to bring qui tam suits under the False Claims Act, it did not intend to create a governmental office subject to the Appointments Clause. Rather, Congress

was authorizing relators to pursue a personal monetary recovery – employing “the theory, based on experience as old as modern civilization, that one of the least expensive and most effective means of preventing frauds on the treasury is to make the perpetrators of them liable to actions by private persons acting ... under ... the hope of gain.” *United States v. Griswold*, 24 F. 361, 366 (D. Or. 1885), *quoted in United States ex rel. Marcus v. Hess*, 317 U.S. 537, 541 n.5 (1943), and *Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939, 949 (1997).

That a relator brings a qui tam suit “in the name of the Government,” 31 U.S.C. § 3730(b)(1), does not alter the nature of the relator’s interest in the suit. The Supreme Court explained in *Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 587 U.S. 262 (2019), that the statutory provision for qui tam actions to be brought “‘for the [relator] and for the ... Government,’” and “‘in the name of the Government,’ ... does not make the relator anything other than a private person” as opposed to an “‘official of the United States.’” *Id.* at 272; *see also, e.g., Taxpayers Against Fraud*, 41 F.3d at 1041 (“Although a relator may sue in the government’s name, the relator is not vested with governmental power.”).

The fact that relators decide whether to commence litigation by filing a qui tam complaint likewise does not make them governmental officeholders. A qui tam action cannot proceed — indeed, it cannot even be unsealed — until after the government has had an opportunity to determine whether to “intervene and proceed with the action,” intervene and move to dismiss it, or allow the relator “to conduct the action” subject to ongoing government oversight. 31 U.S.C. § 3730(b)(2)-(4). This upfront review by the government makes clear that relators are not acting as government officials when they bring suit. It is the government that determines whether the action should go forward and, if so, who should litigate it.

* * *

Relators do not act on a continuing basis, and they do not perform a function that only the government can constitutionally perform. To the contrary, Congress routinely chooses “to rely ... on private enforcement to implement public policy.” *Alyeska Pipeline Serv. Co. v. Wilderness Soc’y*, 421 U.S. 240, 263 (1975). And as explained below, there is abundant evidence that Congress and the courts have historically viewed private qui tam suits as a constitutionally permissible means of redressing and deterring violations of

federal law. For all these reasons, relators need not be appointed in a manner consistent with the Appointments Clause.

B. The Qui Tam Provisions Do Not Violate The Vesting And Take Care Clauses

The qui tam provisions are likewise consistent with the Vesting and Take Care Clauses of Article II, which state that “[t]he executive Power shall be vested in a President of the United States,” U.S. Const. art. II, § 1, cl. 1, and that the President “shall take Care that the Laws be faithfully executed,” *id.* § 3.

Article II “does not require Congress to prescribe litigation by the Executive as the *exclusive* means of” protecting the government’s interests. *Riley*, 252 F.3d at 753. Rather, Congress unquestionably has the power to authorize private parties who have suffered Article III injury to sue to enforce federal statutes, like Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e-5(f), or the antitrust laws, 15 U.S.C. § 15. Private suits under such provisions generally do not raise Article II concerns even if Congress has created a private right of action for the purpose of supplementing government enforcement actions. The Supreme Court has routinely described pri-

vate suits as a means of enforcing federal statutes for the benefit of the public, not just as a means of redressing private injuries. *See, e.g., Cummings v. Premier Rehab Keller, PLLC*, 596 U.S. 212, 218 (2022) (“‘[P]rivate individuals may sue to enforce’ ... antidiscrimination statutes[.]”); *Fortner Enters., Inc. v. U.S. Steel Corp.*, 394 U.S. 495, 502 (1969) (“Congress has encouraged private antitrust litigation not merely to compensate those who have been directly injured but also to vindicate the important public interest in free competition.”).

Qui tam suits under the False Claims Act do differ in some significant respects from private suits under other statutes. Relators are authorized to pursue False Claims Act suits solely on the basis of the government’s partial assignment of a share of its right to a monetary recovery, *see Stevens*, 529 U.S. at 773, whereas private plaintiffs under other statutes must establish a personal injury as a basis for standing. A judgment on the merits in a qui tam action under the False Claims Act can have claim-preclusive effect against the United States, *see United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 936 (2009), whereas judgments in private suits under other statutes do not. And the United States receives a share (indeed, the majority) of a monetary judgment in a qui tam action under the False Claims Act, *see* 31

U.S.C. § 3730(d)(1), (2), whereas judgments in private suits under other statutes are payable solely to the plaintiffs. If Congress's use of the qui tam mechanism were a new development, these features of qui tam actions under the False Claims Act would give rise to substantial questions about whether such actions are consistent with the Vesting and Take Care Clauses.

Those questions are resolved, however, by the extensive body of evidence that qui tam provisions have, since the Founding, been understood as established features of American law. “Statutes providing for actions by a common informer, who himself had no interest whatever in the controversy other than that given by statute, have been in existence for hundreds of years in England, and in this country ever since the foundation of our Government[.]” *Hess*, 317 U.S. at 541 n.4 (quoting *Marvin v. Trout*, 199 U.S. 212, 225 (1905)). And in *Stevens*, the Supreme Court reviewed this “long tradition of *qui tam* actions in England and the American Colonies,” as well as the “considerable number” of qui tam provisions passed by the First Congress, in holding the qui tam provisions to be consistent with Article III. 529 U.S. at 774-777. For example, one early statute allowed “informer[s] to sue for, and receive half of [the] fine for, [a] failure to file [a] census return.” *Id.* at 777 n.6

(citing Act of Mar. 1, 1790, ch. 2, § 3, 1 Stat. 101, 102). Another allowed “private individual[s] to sue for, and receive half of [the] fine for, carriage of seamen without contract or illegal harboring of runaway seamen.” *Id.* (citing Act of July 20, 1790, ch. 29, §§ 1, 4, 1 Stat. 131, 131, 133). And a third allowed “private individual[s] to sue for, and receive half of [the] goods forfeited for, unlicensed trading with Indian tribes.” *Id.* (citing Act of July 22, 1790, ch. 33, § 3, 1 Stat. 137, 137-138).

The Supreme Court found this body of history “well nigh conclusive” as to the qui tam provisions’ consistency with Article III. *Stevens*, 529 U.S. at 777. Justice Stevens’s separate opinion in *Stevens* — which was a dissent as to the statutory question whether relators could sue States, but which agreed with the majority on the predicate issue of Article III standing — observed that history was just as “sufficient to resolve” any question whether the qui tam provisions were consistent with Article II. *Id.* at 801 (Stevens, J., joined by Souter, J., dissenting). And the en banc Fifth Circuit expressed the same view, finding it “logically inescapable that the same history that was conclusive on the Article III question in *Stevens* ... is similarly conclusive with respect to the Article II question.” *Riley*, 252 F.3d at 752.

That is for good reason. Legislation “‘passed by the first Congress assembled under the Constitution, many of whose members had taken part in framing that instrument, ... is contemporaneous and weighty evidence of its true meaning.’” *Marsh v. Chambers*, 463 U.S. 783, 790 (1983); see *Bowsher v. Synar*, 478 U.S. 714, 723-724 (1986) (giving weight to the First Congress’s conclusion that the Legislative Branch should have no role in the removal of Executive officers); *Mistretta v. United States*, 488 U.S. 361, 401 (1989) (explaining that “‘traditional ways of conducting government ... give meaning’ to the Constitution” (quoting *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 610 (1952) (Frankfurter, J., concurring))).

The Executive Branch likewise accepted qui tam provisions as an established feature of early American law. In 1795, for example, Attorney General Bradford submitted to Congress a draft bill proposing fees to be awarded by the federal courts; the bill included the sort of cost-shifting provision for qui tam suits that Congress had previously enacted in 1792. See *Fees of Courts, Communicated to the House of Representatives, January 12, 1795, in 1 American State Papers: Class X, Miscellaneous* 117, 121 (William S. Hein & Co. 1998) (provision for cost-shifting in suits brought by “any informer or plaintiff, on a penal statute, to whose benefit the penalty, or any part thereof,

if recovered, is directed by law to accrue”), <https://perma.cc/JGR5-8AQA>. The inclusion of that provision in the Attorney General’s proposal strongly suggests the early Executive Branch perceived no constitutional problem with *qui tam* suits.

That is equally true of the Supreme Court. In *Marvin*, for example, the Court upheld the constitutionality of a state statute allowing a person to sue to recover an amount of money lost by another person in illegal gambling, if the person who had lost the money did not bring suit within six months. To hold that such a statute was unconstitutional, the Court explained, “would be in effect to hold invalid all legislation providing for proceedings in the nature of *qui tam* actions,” even though such statutes had “been in existence for hundreds of years in England, and in this country ever since the foundation of our Government.” 199 U.S. at 225. And in *Hess*, the Supreme Court held that the court of appeals had been wrong to construe the False Claims Act narrowly “on the premise that *qui tam* or informer actions ‘have always been regarded with disfavor.’” 317 U.S. at 540-541. To the contrary, the Court observed that “[q]ui tam suits have been frequently permitted by legislative action” and that “Congress has power to choose this method to protect the government from burdens fraudulently imposed upon it.” *Id.* at 541-

542. The historical record thus suggests that all three branches of the early American government accepted qui tam statutes as an established feature of the legal system.

Moreover, the modern False Claims Act's qui tam provisions provide greater means for the Executive Branch to control qui tam suits than the early qui tam statutes did. As explained above, the government must review a qui tam action, and determine whether to take it over or allow the relator to litigate it, before it can proceed or even be unsealed. 31 U.S.C. § 3730(b)(2)-(4). Even if the government initially declines to intervene, it may still intervene at a later time for good cause. *Id.* § 3730(c)(2)(D)(3). And the government may move to dismiss a False Claims Act action over a relator's objection, subject to highly deferential review under Federal Rule of Civil Procedure 41(a). *Id.* § 3730(c)(2)(A). The Supreme Court emphasized that district courts must grant dismissal "in all but the most exceptional cases ... even if the relator presents a credible assessment to the contrary." *Polansky*, 599 U.S. at 437-438. The government may also settle a pending suit over the objections of the relator, *see* 31 U.S.C. § 3730(c)(2)(B); and veto a relator's proposed settlement or voluntary dismissal of his action, *id.* § 3730(b)(1). If early qui

tam statutes (which lacked such controls) were understood to pose no Article II problem, then that is true a fortiori of the False Claims Act's qui tam provisions cannot be understood to pose any Article II problem either.

* * *

For all these reasons, the district court was correct to reject Janssen's constitutional challenge to the False Claims Act's qui tam provisions.

II. The District Court Erred By Suggesting That An FDCA Violation, Without More, Can Render Claims False

The district court appears to have erred, however, in its understanding of the circumstances under which false or misleading marketing of FDA-approved drugs can render subsequent claims for those drugs false for purposes of the False Claims Act.

1. If use of a medical item or service is not covered under the terms of the public health insurance programs, then a claim for payment for that item or service is not reimbursable by the government. *See, e.g.*, 42 U.S.C. § 1395y(a). And a claim for payment "is legally false when it does not comply 'with a statute or regulation the compliance with which is a condition for Government payment.'" *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 486 (3d Cir. 2017). For that reason, the drug reimbursement claims at issue here were false if the drugs in question were not reimbursable by the

program from which reimbursement was sought. For Medicare claims, that would be true if the drugs were not prescribed “for a ‘medically accepted indication,’” or if their use was not “‘reasonable and necessary’” for a particular patient. *Id.* at 487-488 (discussing the statutory and regulatory framework for a different part of Medicare); *see supra* p. 9.

Part of the district court’s jury instructions and post-trial ruling are consistent with that understanding of falsity. The court correctly instructed the jury that a “claim is false if it is ineligible for reimbursement under a federal health care program.” Appx2202. It repeated that statement in its post-trial opinion. Appx243. And much of the evidence the court discussed in the relevant paragraph of that opinion, Appx243-244, was relevant to the issue of falsity (at least for Medicare). That is true, for example, of what the court described as evidence “that while Janssen promoted Prezista for treatment-naïve patients, Prezista’s label was not indicated for treatment-naïve patients from 2006–2008, nor did recognized compendia support the use of Prezista in treatment-naïve patients.” Appx243-244.

2.a. Other language in the post-trial ruling, however, seems to suggest that a violation of the FDCA’s misbranding provisions is itself a basis for treating claims for the misbranded drugs as false for purposes of the False

Claims Act. Most notably, the district court stated that relators had “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. “Taken together” with other evidence, the court determined, this evidence would have allowed “a reasonable jury” to find “that claims for Prezista and Intelence submitted to Medicare, Medicaid, or ADAP were [off-label] and ineligible for reimbursement.” Appx244.

That language appears to reflect an incorrect understanding of the law. As discussed above, the FDCA’s misbranding provisions govern how drugs may be marketed; they do not govern whether federal healthcare programs will reimburse for the drugs, as prescribed for particular patients. Medicare Part D, for example, may reimburse a claim for a drug if it is prescribed for a medically accepted indication and is reasonable and necessary for a particular patient, even if the drug is not FDA-approved for that indication. *See supra* p. 9. Conversely, Medicare Part D may *not* reimburse a claim for a drug, even one prescribed for an FDA-approved indication, if the use of that drug is not reasonable and necessary for the patient. *Id.* In other words, compliance with the FDCA is not a condition of Medicare reimbursement.

And it is likewise not a condition of reimbursement for state Medicaid and ADAP programs. *See supra* p. 10.

The district court was therefore incorrect to the extent its post-trial opinion suggested that off-label marketing by Janssen, in and of itself, “violated an express condition of payment for reimbursement under Medicare, Medicaid, or ADAP,” Appx244. A finding that a company has marketed its drugs for off-label uses is not, without more, sufficient to find that subsequent claims for the marketed drugs are false within the meaning of the False Claims Act. The government has repeatedly articulated this understanding of the law. *See* U.S. Amicus Br., *United States ex rel. Solis v. Millennium Pharms., Inc.*, Nos. 15-16953, 15-17055, 15-17057, 2016 WL 6833796, at *12 n.4 (9th Cir. Nov. 17, 2016); *see also* U.S. Amicus Br., *Petratos v. Genentech Inc.*, No. 15-3805, 2016 WL 3012033, at *26 (3d Cir. May 23, 2016).²

To be sure, false marketing of a drug can *cause* a doctor to submit a false claim for that drug. For example, if a drug company misleads doctors

² Janssen’s brief frames the district court’s error as bearing on materiality, but the Supreme Court has rejected the notion that “a contractual, statutory, or regulatory provision” must be “designated as a condition of payment” for its violation to be material. *Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 190 (2016).

about the safety profile of a drug, that representation may lead a doctor to prescribe the drug for a patient for whom it is not actually reasonable and necessary. In that scenario, the company's representation could cause the submission of a false claim for the drug—that is, the submission of a claim that is not reimbursable because the drug is not reasonable and necessary for the individual patient. But what makes the claim false would be its non-reimbursability, not the falsity of the representations that led the doctor to prescribe the drug.

b. The district court also erred when it instructed the jury that federal healthcare programs “will cover and pay for a drug that is used for a ‘medically accepted indication,’ which means any FDA-approved use on the label that is supported by one or more citations in certain drug compendia,” Appx2202. An indication for the use of a drug is medically accepted if the drug is FDA-approved for that indication *or* if the use of that drug for that indication is supported by drug compendia. *See supra* p. 9. The district court may well have intended to convey that point, and had it included the words “or one” after “FDA-approved use on the label,” its instruction would have been correct. But the omission of those words suggested incorrectly that

FDA approval of a drug for a particular indication is necessary for the drug to be medically accepted for that indication.

Janssen appears to have forfeited its current challenge to that instruction, however, by not raising it during the charge conference. *See* Fed. R. Civ. P. 51(c), (d)(1)(A). During the portions of the charge conference that Janssen cites as sufficient to preserve the issue, *see* Br. 5 n.2 (citing Appx2129-2134, Appx2139-2141), Janssen's objection to the instruction was as follows:

MR. WYATT: The next issue is with respect to medically accepted indication where it says, "which means any FDA-approved use on the label that is supported by one or more citations in certain drug compendia." We would propose that instead we define medically accepted indication, because I'm not sure where this language comes from, but it doesn't track the statute or the policy manual.

What the policy manual says is, "Medically accepted indication refers to the diagnosis or condition for which a drug is being prescribed, not the dose being prescribed for such indication." We think that's how the language there should read.

THE COURT: Where would that language go?

MR. WYATT: Instead of "which means any FDA-approved use on the label" through the end of that sentence, it should say, "use for medically accepted indication," ... "[w]hich means the diagnosis or condition for which a drug is being prescribed, not the dose being prescribed for such indication."

Appx2131-2132. That objection did propose to remove the "FDA-approved" language from the instruction, but it did not explain why the inclusion of

that language was problematic — because, as Janssen now explains (Br. 38), it “conflated the laws regulating pharmaceutical marketing ... with the laws governing reimbursement.” The objection simply suggested that the instruction was inaccurate in its definition of a medically accepted indication. It therefore appears to have fallen short of the requirement for an objection to be “specific to the alleged error,” *Lesende v. Borrero*, 752 F.3d 324, 335 (3d Cir. 2014); *see id.* at 336, “bring[ing] into focus the precise nature of the alleged error,” *Palmer v. Hoffman*, 318 U.S. 109, 119 (1943), as well as the requirement for an objection to ““specify the authority upon which it [is] based,”” *Lesende*, 752 F.3d at 336. And although Janssen also cites its proposed jury instructions as a basis for preservation, *see* Br. 5 (citing Appx574-575), it does not cite the proposed falsity instruction, Appx582-584 — and even if it did, “[m]erely proposing a jury instruction that differs from the charge given is insufficient to preserve an objection,” *Franklin Prescriptions, Inc. v. New York Times Co.*, 424 F.3d 336, 339 (3d Cir. 2005).

Given Janssen’s forfeiture of the objection it now raises, the district court’s error in the jury instruction would be a basis for a new trial only if it is plain — that is, if it “is ‘fundamental and highly prejudicial, such that’” de-

clining to remedy the error “‘would result in a miscarriage of justice.’” *Robinson v. First State Cmty. Action Agency*, 920 F.3d 182, 187 (3d Cir. 2019). “Plain error review is discretionary,” and this Court has explained that “it ‘should be exercised sparingly’ and ‘should only be invoked with extreme caution in the civil context.’” *Franklin Prescriptions*, 424 F.3d at 341. The government leaves for the parties to address whether the error here rises to the level of plain error and thus warrants a new trial. If not, the Court should simply vacate the judgment and remand for the district court to reassess its post-trial ruling under a correct view of the law.³

III. The Penalty Imposed Here Is Not Unconstitutionally Excessive

If the Court vacates the judgment and remands in the manner suggested above, then it need not address the constitutionality of the amount of civil penalties the district court imposed on Janssen. To the extent the Court addresses the issue, however, it should reject Janssen’s challenge to the penalties. Assuming the Eighth Amendment’s Excessive Fines Clause applies

³ The government takes no position on whether the evidence was legally sufficient to support the judgment under a correct understanding of the law. For that reason, the government does not urge the Court to avoid the Article II question as Janssen has done, because the Court would need to address that question if it were to vacate and remand for further proceedings on the merits, rather than reversing the judgment as Janssen suggests.

in a qui tam action that the government has not taken over, the amount of civil penalties that the district court imposed, within the range permitted by statute, is consistent with the Excessive Fines Clause.⁴

1. A monetary penalty violates the Excessive Fines Clause only “if it is grossly disproportional to the gravity of a defendant’s offense.” *United States v. Bajakajian*, 524 U.S. 321, 334 (1998). That is the same “standard of gross disproportionality articulated in” the Supreme Court’s “Cruel and Unusual Punishments Clause precedents.” *Id.* at 336. Under that highly deferential standard, a penalty need only “bear *some relationship* to the gravity of the offense that it is designed to punish.” *Id.* at 334 (emphasis added).

In *Bajakajian* itself, the Supreme Court held that it was unconstitutional to require the forfeiture of the full amount of cash (more than \$300,000) carried by a person who had failed to disclose it to a customs inspector, reasoning that the amount of the forfeiture had literally nothing to do with the

⁴ The Supreme Court has twice reserved the question whether the Excessive Fines Clause applies in qui tam suits in which the government has not intervened. See *Austin v. United States*, 509 U.S. 602, 607 n.3 (1993); *Browning-Ferris Indus. of Vt., Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 275 n.21 (1989). For present purposes, the government does not dispute the applicability of the Excessive Fines Clause. The Court can assume, without deciding, that it applies.

gravity of the offense—the failure to report. 524 U.S. at 337-340. But *Bajakajian* did not involve a statutorily specified penalty for a particular offense, and nothing in its reasoning suggests that, where Congress has specified what it regards as an appropriate penalty for a particular act, a court may hold that provision unconstitutional because it disagrees with Congress’s judgment about what penalty is proportionate to the offense. To the contrary, *Bajakajian*—like other decisions of the Supreme Court—emphasizes “that judgments about the appropriate punishment for an offense belong in the first instance to the legislature.” *Id.* at 336; *see, e.g., Solem v. Helm*, 463 U.S. 277, 290 (1983) (“Reviewing courts ... should grant substantial deference to the broad authority that legislatures necessarily possess in determining the types and limits of punishments for crimes[.]”); *Gore v. United States*, 357 U.S. 386, 393 (1958) (similar).

Applying *Bajakajian*, the federal courts of appeals have almost uniformly upheld the constitutionality of civil penalties within the statutorily authorized range in False Claims Act cases. *See Stop Ill. Health Care Fraud, LLC v. Sayeed*, 100 F.4th 899, 906-908 (7th Cir. 2024), *reh’g denied*, 2024 WL 2785312 (7th Cir. May 30, 2024); *Yates v. Pinellas Hematology & Oncology, P.A.*, 21 F.4th 1288, 1314-1316 (11th Cir. 2021); *United States ex rel. Drakeford v.*

Tuomey, 792 F.3d 364, 387-390 (4th Cir. 2015); *United States v. Aleff*, 772 F.3d 508, 512-513 (8th Cir. 2014); *United States ex rel. Bunk v. Gosselin World Wide Moving, N.V.*, 741 F.3d 390, 405-410 (4th Cir. 2013); *United States v. Bourseau*, 531 F.3d 1159, 1173-1174 (9th Cir. 2008); *United States v. Rogan*, 517 F.3d 449, 454 (7th Cir. 2008). Like the Supreme Court, the courts of appeals have emphasized that it is for Congress rather than the courts to determine what penalty is appropriate for a false claim. They have accordingly recognized “‘a strong presumption of constitutionality where the value of a’” penalty “‘falls within the ... range prescribed by Congress.’” *Stop Ill. Health Care Fraud*, 100 F.4th at 907; *see Yates*, 21 F.4th at 1314 (“‘[Penalties] falling below the maximum statutory fines for a given offense ... receive a strong presumption of constitutionality.’”).

2. Under the gross-disproportionality standard, there is no proper basis to conclude that the statutorily prescribed penalty for the submission of a false claim – a penalty within a range from \$5,500 to \$11,000, *see* 31 U.S.C. § 3729(a)(1); 28 C.F.R. § 85.3(a)(9) – violates the Constitution. Unlike the forfeiture in *Bajakajian*, which bore no relationship to the gravity of the offense at issue, a penalty of between \$5,500 and \$11,000 plainly “bear[s] some relationship to the gravity of the offense that it is designed to punish,” 524 U.S.

at 334: the offense of knowingly submitting, or causing the submission of, a false claim seeking payment from the federal government. No one could reasonably argue—and Janssen does not try to argue—that that penalty is somehow wholly unmoored from the gravity of the offense. A penalty that Congress determines to be appropriate for a given offense will virtually always “bear” at least “some relationship to the gravity of the offense that it is designed to punish,” *id.*, and that is clearly true of Congress’s determination that knowingly submitting or causing the submission of a false claim warrants a penalty within the range prescribed here.

Nor is there a proper basis to conclude that the district court somehow abused its discretion, in a constitutionally relevant way, in selecting an appropriate per-claim penalty within the statutorily prescribed range. As noted above, the district court determined the penalty by assessing the seriousness of Janssen’s misconduct, in light of what the district court characterized as evidence that “Janssen engaged in a deliberate and calculated scheme that spanned several years and involved the unlawful marketing of its products”; that it “was aware of the seriousness of its conduct, and entered into at least three agreements with the Government in the past to resolve allegations related to [off-label] marketing of other drugs”; that, “despite the jury’s

verdict, Janssen refuses to accept responsibility for its conduct”; and that (on the other side of the balance) there was no “evidence regarding patient harm.” Appx265-266. That is exactly the sort of assessment that district courts routinely conduct in fixing penalties, most commonly criminal fines or incarceration, within statutorily prescribed ranges. It is doubtful that that sort of exercise of discretion, within statutory bounds, could ever be so erroneous as to cause the ultimate penalty to bear no “relationship to the gravity of the offense that it is designed to punish,” *Bajakajian*, 524 U.S. at 334, and there is certainly no basis for that conclusion here. Indeed, the penalty here was in the lower half of the statutorily prescribed range.

3. Unsurprisingly, then, Janssen’s constitutional argument focuses on the sort of ratio-based analysis that the Supreme Court has articulated for determining whether jury punitive-damages awards are consistent with the Due Process Clause. But the due-process standard does not apply to the review of statutorily prescribed penalties under the Excessive Fines Clause, and it is particularly inapposite to penalties for fraud, where the harm to the government transcends economic losses.

a. In *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), the Supreme Court held that the Due Process Clause did not permit a \$2 million

punitive-damages award against BMW for having failed to advise dealers or customers of certain predelivery repairs to new cars. The Court's reasoning rested on the premise that BMW had not received "fair notice ... of the severity of the penalty that" it could face for its conduct. *Id.* at 574. The Court considered the ratio between the punitive-damages award and the actual "harm or potential harm" caused by BMW's conduct, but only as one of "[t]hree guideposts ... indicat[ing]," in its view, that BMW had not "receive[d] adequate notice." *Id.* at 574-575.

The Supreme Court's reasoning in *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), was similar. In invalidating a \$145 million punitive-damages award, in a case with \$1 million in actual damages, the Court again emphasized the need for "'fair notice.'" *Id.* at 417. It expressed concern about "the imprecise manner in which punitive damages systems are administered," leaving juries "'with wide discretion in choosing amounts'" and "'pos[ing] an acute danger of arbitrar[iness].'" *Id.* As in *Gore*, the Court looked to the ratio between the punitive and actual damages as a "guidepost," *id.* at 418—but as in *Gore*, the Court's analysis of the ratio was tied to the fair-notice and arbitrariness concerns arising from the ad hoc determination of punitive damages by juries, *see id.* at 424-428.

And in *CGB Occupational Therapy, Inc. v. RHA Health Services, Inc.*, 499 F.3d 184 (3d Cir. 2007), on which Janssen heavily relies, the Court applied the “guideposts” set forth in *Gore* and *State Farm* to hold that a \$2 million jury award of punitive damages had to be reduced to \$750,000, including because it exceeded a “single-digit” multiple of the compensatory damages award. *Id.* at 193; *see id.* at 188-193.

b. For several reasons, the analysis set forth in *Gore* and *State Farm* and applied in *CGB* cannot properly be understood to mean that it is unconstitutional for Congress to specify a monetary penalty for a given offense that exceeds, by more than “a single-digit ratio,” *State Farm*, 538 U.S. at 425, the actual harm caused by the offense.

First, the Supreme Court has explained that “if a constitutional claim is covered by a specific constitutional provision, such as the Fourth or Eighth Amendment, the claim must be analyzed under the standard appropriate to that specific provision, not under the rubric of substantive due process.” *United States v. Lanier*, 520 U.S. 259, 272 n.7 (1997) (citing *Graham v. Connor*, 490 U.S. 386, 394 (1989)). The Due Process Clause can properly apply to punitive damages because the “Excessive Fines Clause does not apply to awards of punitive damages in cases between private parties,” *Browning-*

Ferris Indus. of Vt., Inc. v. Kelco Disposal, Inc., 492 U.S. 257, 260 (1989). But it cannot properly apply to civil penalties more specifically governed by the Excessive Fines Clause.

Second, even if it were otherwise applicable, the due-process analysis articulated in *Gore* and *State Farm* does not suggest a constitutional problem here. Where Congress has specified the penalty for violating a given prohibition, potential violators have fair notice of that sanction, and it is neither arbitrary nor unfair for a court to impose the sanction. In other contexts, the Supreme Court has explained that the Due Process Clause protects those rights that are “‘deeply rooted in this Nation’s history and tradition’ and ‘implicit in the concept of ordered liberty.’” *Dobbs v. Jackson Women’s Health Org.*, 597 U.S. 215, 231 (2022). There is no basis to believe that “history and tradition” or “the concept of ordered liberty” require capping civil penalties at a single-digit multiplier of the actual harm caused by an offense.

Finally, even if a ratio-based analysis could ever play a proper role in the review of statutorily prescribed penalties under the Excessive Fines Clause, it is particularly inapposite for fraud offenses. That is because “[f]raud harms the United States in ways untethered to the value of any ultimate payment,” such as by diminishing “‘the public’s confidence in the

government’” and by requiring the government to devote resources to detecting and pursuing fraudsters. *Yates*, 21 F.4th at 1316. For that reason, “the concept of harm” in the Eighth Amendment analysis “need not be confined strictly to the economic realm” where the harm arises from fraud. *Bunk*, 741 F.3d at 409. Indeed, economic harm is not even an element of a False Claims Act violation: The Act can be violated by the submission of false or fraudulent claims, and civil penalties for that conduct can be imposed, even when the government has suffered no economic loss at all. *See, e.g., id.* at 404 (“[T]he [Act] ‘provides for penalties even if (indeed, *especially* if) actual loss is hard to quantify.’”); *United States v. Hughes*, 585 F.2d 284, 286 n.1 (7th Cir. 1978) (“A false claim is actionable under the Act even though the United States has suffered no measurable damages[.]”).

c. For those reasons, the only appellate decision to have held a statutorily prescribed False Claims Act penalty to be unconstitutional—the Eighth Circuit’s decision in *Grant v. Zorn*, 107 F.4th 782 (8th Cir. 2024), *cert. denied*, 2025 WL 1727379 (U.S. June 23, 2025), *and* 2025 WL 1727394 (U.S. June 23, 2025)—was erroneous. In that case, where the United States did not participate as an intervenor or amicus curiae until the rehearing stage, neither

party disputed “that cases analyzing punitive damages under the Due Process Clause are instructive in analyzing punitive sanctions under the Excessive Fines Clause,” *id.* at 798, and the inadequacy of the parties’ briefing led the court to an incorrect result.⁵

The Eighth Circuit’s decision in *Grant* relied heavily on the fact that, in a handful of cases, courts have identified a low ratio between civil penalties and actual damages as one reason for upholding the constitutionality of a penalty award under the False Claims Act. But none of those decisions suggested that a low ratio was *necessary* to uphold a penalty within the statutory range. In *Aleff*, the Eighth Circuit discussed the ratio between the penalty and the actual damages only in a sentence concluding with the point that the penalty was “within the FCA’s statutory limits,” and immediately after that sentence, the Court cited one of its precedents for the proposition that “a penalty less than [the] statutory maximum was not excessive.” 772 F.3d at 513. In *Rogan*, the Seventh Circuit pointed to the single-digit magnitude of

⁵ For that reason among others, the government declined to seek certiorari. See Letter from Sarah M. Harris, Acting Solic. Gen., to the Hon. Mike Johnson, Speaker, U.S. House of Representatives (Feb. 24, 2025), <https://perma.cc/BU34-UGUC>.

the ratio in explaining that a penalty would pass muster even if it were evaluated under the Due Process Clause—but it went on to explain that “[i]f there is to be a difference” between the due-process and excessive-fines standards, “one would think that a fine expressly authorized by statute could be higher than a penalty selected *ad hoc* by a jury.” 517 F.3d at 454. And in *Drakeford*, where the Fourth Circuit likewise noted the single-digit magnitude of the ratio between the penalty and the economic harm of a fraud offense, it likewise cited that ratio as just one among several factors in upholding the penalty’s constitutionality. 792 F.3d at 389-390.

In other cases, moreover, courts of appeals (including the courts that decided *Rogan* and *Drakeford*) have upheld civil penalties within the statutory range that would be invalid under Janssen’s reasoning. In *Stop Illinois Health Care Fraud*, the Seventh Circuit affirmed a False Claims Act judgment over an Excessive Fines Clause challenge without commenting on the ratio between the statutorily prescribed civil penalties and the actual damages, *see* 100 F.4th at 906-908, even though the defendants had argued that the penalty for one of the defendants was “more than *forty times* the actual damages” caused by that defendant, Defs.’ Reply Br., *Stop Ill. Health Care Fraud, LLC v. Sayeed*, Nos. 22-3295, 23-1943, 2023 WL 6729509, at *23 (7th Cir. Oct. 5, 2023).

In *Bunk*, the Fourth Circuit upheld the constitutionality of a \$24 million civil penalty under the False Claims Act where the district court had found “insufficient evidence of any” economic harm to the government. 741 F.3d at 409. And in *Yates*, the Eleventh Circuit rejected an Excessive Fines Clause challenge to a False Claims Act “judgment of \$1.179 million based on \$755.54 in actual damages.” 21 F.4th at 1314. The court recognized that the ratio between the penalty amount and the actual damages might “raise an eyebrow,” but it explained that any “optic[al]” concern was “negated” by the fact that the penalty amount was “the result of [the defendant’s] repeated (214) instances of fraud against the United States.” *Id.*

Janssen is therefore incorrect to contend that the district court erred by not considering the “more than 10 to 1” ratio (Br. 56) between the civil penalty award here and the amount of the government’s loss. To the contrary, it would have been error for the district court to rely on that sort of ratio-based analysis as a reason for *not* imposing a civil penalty within the range specified by Congress.

CONCLUSION

The district court’s judgment should be vacated, and this case remanded, because of the court’s errors with respect to the falsity element of

False Claims Act liability. The Court should not, however, accept Janssen's constitutional arguments.

Respectfully submitted,

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COMBINED CERTIFICATIONS

1. Government counsel are not required to be members of the bar of this Court.

2. This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 11,611 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in 14-point Book Antiqua, a proportionally spaced typeface.

3. I electronically filed this brief with the U.S. Court of Appeals for the Third Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

4. The text of the electronic version of this document is identical to the text of the hard copies that will be provided.

5. This document was scanned for viruses using CrowdStrike Falcon Sensor, Version 7.27.19907.0, and no virus was detected.

/s/ Daniel Winik

DANIEL WINIK

ADDENDUM

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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; [or]

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

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 104-4101), plus 3 times the amount of damages which the Government sustains because of the act of that person.

...

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 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.

(e) Certain Actions Barred. —

(1) No court shall have jurisdiction over an action brought by a former or present member of the armed forces under subsection (b) of this section against a member of the armed forces arising out of such person's service in the armed forces.

(2) (A) No court shall have jurisdiction over an action brought under subsection (b) against a Member of Congress, a member of the judiciary, or

a senior executive branch official if the action is based on evidence or information known to the Government when the action was brought.

(B) For purposes of this paragraph, “senior executive branch official” means any officer or employee listed in paragraphs (1) through (8) of section 13103(f) of title 5.

(3) In no event may a person bring an action under subsection (b) which is based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party.

(4) (A) The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed —

(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;

(ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or

(iii) from the news media,

unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

(B) For purposes of this paragraph, “original source” means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2)3 who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

(f) Government not liable for certain expenses. — The Government is not liable for expenses which a person incurs in bringing an action under this section.

...

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...

(c) If the Government elects to intervene and proceed with an action brought under [section] 3730(b), the Government may file its own complaint or amend the complaint of a person who has brought an action under section 3730(b) to clarify or add detail to the claims in which the Government is intervening and to add any additional claims with respect to which the Government contends it is entitled to relief. For statute of limitations purposes, any such Government pleading shall relate back to the filing date of the complaint of the person who originally brought the action, to the extent that the claim of the Government arises out of the conduct, transactions, or occurrences set forth, or attempted to be set forth, in the prior complaint of that person.

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