IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA *ex rel.* PETER HUESEMAN *Plaintiff*	§	
-vs-	§	SA-14-CV-00212-XR
PROFESSIONAL COMPOUNDING CENTERS OF AMERICA, INC., *Defendant*	§	

ORDER DENYING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AS TO ITS STATUTE-OF-LIMITATIONS DEFENSE

On this date, the Court considered Defendant Professional Compounding Centers of America, Inc.'s motion for summary judgment as to its statute-of-limitations defense (ECF No. 154), the Government's response (ECF No. 165), Defendant's reply (ECF No. 167), and the parties arguments at the hearing held on January 30, 2024. After careful consideration, the motion (ECF No. 154) is **GRANTED IN PART** and **DENIED IN PART**.

BACKGROUND

Defendant Professional Compounding Centers of America ("PCCA") sells chemical ingredients to compounding pharmacies. Compounding is a practice in which a licensed pharmacist combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. PCCA's pharmacy customers ("members") use these ingredients to prepare and dispense compound medications for patients. The United States of America (the "Government") alleges that, from 2012 to 2015, PCCA and its members reported fraudulently inflated prices for its ingredients for reimbursement purposes and thereby enriched themselves at the expense of the federal TRICARE program, which provides health care coverage for active-duty military personnel, military retirees, and military dependents. *See* ECF No. 66.

On March 10, 2014, Relator Peter Hueseman, a licensed pharmacist who previously worked for Pharmacy Solutions, Inc., d/b/a Bellevue Pharmacy ("Bellevue"), filed a *qui tam* complaint under seal against PCCA and eleven other named defendants, alleging violations of the False Claims Act ("FCA"), 31 U.S.C. § 3729(a), and the Anti-Kickback Statute ("AKS"), 42 U.S.C. §§ 1320a–7b(b). ECF No. 1. The other defendants included (1) another supplier of compounding ingredients—Freedom Pharmaceuticals, Inc. ("Freedom" and, together with PCCA, the "Supplier Defendants"), *see id.* ¶¶ 52–53, 55–58; (2) Bellevue and several of its principals and affiliated retail pharmacies (the "Bellevue Defendants"), *see id.* ¶¶ 14–51; and (3) a licensed physician alleged to have a kickback arrangement with the Bellevue Defendants, *see id.* ¶¶ 59–60.

The Relator alleged that, during and after his tenure with Bellevue between 2010 and 2013, the pharmacy purchased products and services from PCCA and Freedom. *Id.* ¶¶ 12, 13. He summarized his allegations against PCCA as follows:

> [PCCA] knowingly reported fraudulent, grossly inflated ingredient prices which it knew government programs relied upon to set the reimbursement rates the programs paid to compounding pharmacies on prescription compound drug claims. The fraudulently reported ingredient prices were far more than the actual prices at which the Defendants sold ingredients to compounding pharmacies frequently 1000%, or more, higher. The "spreads" created between compounding pharmacy reimbursements and costs, through the Defendant's manipulation of its fraudulently overstated reported prices and actual sales prices, caused its customers to submit claims for and receive inflated reimbursement and profits from government programs and were used by the Defendant as a kickback to induce customers to purchase its products over competitor products.

Id. ¶ 8a; *see also id.* ¶ 8b (alleging that Freedom engaged in the same unlawful conduct as PCCA).

More specifically, the Relator accused PCCA of fraudulently reporting grossly inflated Average Wholesale Prices ("AWPs") for its ingredients to pricing compendia used in payment decisions by federal health care programs ("FHPs"), including TRICARE. *Id.* ¶ 66. The Relator alleged that, to guard against overpayment for drugs, FHPs reimbursed compound claims at the

lesser of multiple approximations of ingredient costs. *See id.* ¶ 73. These often include AWP plus a dispensing fee, based on the supplier's reported pricing, and the Usual and Customary ("U&C") price, which is intended to reflect the amount the pharmacy would charge a cash-paying customer, including discounts. [1] *Id.* ¶¶ 67, 73; *see also id.* ¶ 98 (alleging that TRICARE paid the lesser of an AWP-based cost and U&C). The Relator asserted that, by reporting inflated AWPs and U&C charges, the Bellevue Defendants fraudulently obtained higher reimbursement from FHPs than they were lawfully entitled to receive. *Id.* ¶ 67. "The 'spreads' created between compounding pharmacy reimbursements and costs, through [PCCA's] manipulation of its fraudulently overstated reported prices and actual sales prices, caused its customers to submit claims for and received inflated reimbursement and profits from [FHPs]," in violation of the FCA. *Id.* ¶¶ 8a, 98–102. The Relator further alleged that PCCA "'marketed the spread' between its reported AWP and its actual prices to customers to induce the purchase of its products," *id.* ¶ 119, and that its "use of the spread" constituted a kickback in violation of the AKS, *id.* ¶ 145. Along with its ingredients, PCCA also allegedly provided pharmacies with proprietary formulas, pharmacy software, third-party billing support, laboratory equipment, training and educating, and consulting services and technical support. Id ¶ 5c. Under the umbrella of its "consulting services," PCCA also provided pharmacies with materials about the benefits of compound drugs in order to market their medications. ¶¶ 197–8.

After several extensions of its deadline to intervene, the Government reached settlements with the Bellevue Defendants and Freedom, who were dismissed from the case. The Government filed a notice of partial intervention against PCCA in August 2021, ECF No. 64, and filed its complaint-in-intervention November 2021, ECF No. 66.

[1] *See also* ECF No. 1 ¶ 73 (noting that reimbursement methodology may also consider a metric called "Wholesale Acquisition Cost.").

In its complaint, the Government alleges that "PCCA established and reported fraudulently inflated" AWPs "for many of its ingredients relative to the actual prices at which it sold those ingredients . . . to its compound pharmacy customers." *Id*. ¶ 1. The Government asserts that PCCA's conduct in inflating and marketing its AWPs caused TRICARE to pay more for compound drugs than it would have otherwise. *Id.* ¶¶ 1, 164, 179. The Government limited its FCA and AKS claims to violations involving payments by TRICARE between March 2012 and May 2015. *See id.* It also added claims under federal common law for payment by mistake, unjust enrichment, and fraud arising out of the same conduct. *See id.* ¶¶ 190–201.

The Government alleged that TRICARE generally reimbursed compound drug claims based on the lowest of:

(1) the sum total of the AWPs (minus a contracted discount) for all ingredients in the compound drug, plus a dispensing fee and level of effort fee;

(2) the sum total of the costs submitted by the pharmacy for all ingredients in the compound drug, plus a dispensing fee and level of effort fee; or

(3) the pharmacy's usual and customary ("U&C") charge for the medication.

Id. ¶ 45. The Government limited its claims paid by TRICARE on the basis of PCCA's AWPs.

The complaint identifies thirteen PCCA products with AWPs marked up between 1,323% to 56,461% over PCCA's selling prices. *Id.* ¶ 61. It details how PCCA used inflated AWPs and marketed the spreads to induce sales of its products, alleging that the "lucrative AWP spreads" functioned as kickbacks intended "to induce pharmacies to purchase ingredients from PCCA" in violation of the FCA and AKS. *Id.* ¶¶ 64, 73–111, 182. The Government alleged that PCCA urged customers never to disclose their actual acquisition costs to auditors because disclosure will "create huge problems for you" and is "a disaster waiting to happen." *Id.* ¶ 156. Instead, if an auditor requested an invoice from a PCCA customer, PCCA allegedly recommended that customers call

PCCA and, in response, PCCA would generate a report for the auditor that would exclude the actual selling prices of PCCA's ingredients from the report. *Id.* ¶ 157.

Along with supplying pharmacies with chemical ingredients, the Government alleged that PCCA also provided members with services and information intended to increase their reimbursement rates. Knowing that its members submitted claims to TRICARE for compound drugs containing its ingredients, PCCA actively monitored TRICARE's compound drug reimbursement policies and shared updates on TRICARE coverage with customers. *Id.* ¶ 118. PCCA allegedly taught members how to bill compound claims to get the "widest spread possible," offering access to specialized billing software and a database of over 8,000 suggested formulas for compound drugs. *See id*. ¶¶ 51, 112–17. The billing software allowed customers to submit claims to FHPs, including TRICARE, that would allow the pharmacy to manipulate this "lesser of" methodology by automatically reporting its U&C price as equal to the AWP-based price. *Id.* ¶ 117. The Government also asserted that PCCA also rewarded its most loyal customers with all-expenses paid trips to destinations, such as a trip to Cancun, Mexico for "Diamond" customers who made at least $300,000 in annual purchases from PCCA. *See id.* ¶¶ 141–49. PCCA used these trips as a "negotiating tool" and an incentive to buy more ingredients. *See id.*

In March 2022, PCCA moved to dismiss this case for failure to state a claim under Rule 12(b)(6). ECF No. 84. The Court denied the motion in all respects. *United States ex rel. Hueseman v. Pro. Compounding Centers of Am., Inc.*, 664 F. Supp. 3d 722 (W.D. Tex. 2023) [hereinafter "*PCCA*"].

In October 2023, the Court permitted PCCA to add a statute-of-limitations defense based on the Fifth Circuit's recent ruling in *United States ex. Rel. Aldridge v. Corp. Mgmt., Inc.*, 78 F.4th

727 (5th Cir. Aug. 21, 2023) [hereinafter, "*Aldridge*"].[2] *See* ECF No. 156, Oct. 30, 2023 Hr'g Tr. at 37:19–38:13. PCCA now moves for summary judgment based on its statute-of-limitations defense, asserting that the Government's complaint-in-intervention does not relate back to the Intervenor's complaint.

DISCUSSION

I. Legal Standard

The Court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. FED. R. CIV. P. 56. To prevail on an affirmative defense, "the moving party 'must establish beyond peradventure all of the essential elements of the claim or defense to warrant judgment in his favor.'" *Smith v. Ochsner Health Sys.*, 956 F.3d 681, 683 (5th Cir. 2020) (citation omitted).

II. Analysis

Whether the statute of limitations has run is a "question of law."[3] *United States ex rel. Aldridge v. Corp. Mgmt., Inc.*, 78 F.4th 727, 742 (5th Cir. 2023) (quoting *Newby v. Enron Corp.*, 542 F.3d 463, 468 (5th Cir. 2008)). PCCA, "as the party asserting the statute-of-limitations defense, bear[s] the burden of proving limitations barred the Government's claims." *Id.* (quotation marks omitted) (quoting *United States ex rel. Vavra v. Kellogg Brown & Root, Inc.*, 848 F.3d 366, 383 (5th Cir. 2017)).

[2] In doing so, the Court warned that PCCA was unlikely to succeed on the merits of its limitations defense but nonetheless decided to reserve the question for summary judgment based on the "fine line between futility and whether or not [PCCA] arguably had matter for which an amended answer should have been allowed to be filed." *See* ECF No. 156, Oct. 30, 2023 Hr'g Tr. at 37:19–38:13.

[3] PCCA acknowledges that relation-back is a "pure 'question of law'" for which "there is no necessity for the types of 'undisputed material facts' that usually accompany other types of summary judgment motions." ECF No. 154 at 6. PCCA submits a "Background Statement of Uncontested Facts" as to the separate issue of "tolling." *See id.* at 6–13. Because the Government has not argued tolling but instead that its complaint relates back to the Relator's original complaint, the Court need not address the tolling issue or consider PCCA's statement of facts at this time.

The statute of limitations for FCA cases (including those predicated on an AKS violation) is either:

(1) six years from the date of violation, or

(2) three years from the date that the Government knew, or reasonably should have known of the violation,

"but in no event more than 10 years after the date on which the violation is committed." 31 U.S.C. § 3731(b). In a "qui tam" case like this one, "relation back" to the Relator's filing date is permitted "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." *Id.* § 3731(c).

To relate back to the Relator's complaint, a new FCA claim or pleading must be tied to a common core of operative facts. *United States ex rel. Aldridge v. Corp. Mgmt., Inc.*, 78 F.4th 727 (5th Cir. 2023) (citing *United States ex rel. Vavra v. Kellogg Brown & Root, Inc.*, 848 F.3d 366, 383–84 (5th Cir. 2017)). By contrast, relation back is generally improper when, though a new pleading shares some elements in common with the original pleading, it faults the defendant for different conduct than that alleged in the original complaint. *Id.* (citing *United States ex rel. Miller v. Bill Harbert Int'l Constr., Inc.*, 608 F.3d 871, 881 (D.C. Cir. 2010) (concluding that allegations about one contract did not fairly encompass two other contracts "because each contract is unique and no two involved the same 'conduct, transaction, or occurrence.'"). Or, as the Fifth Circuit recently put it in *Aldridge*, "a new [FCA] claim or pleading will not relate back when it asserts a new ground for relief supported by *facts that differ in both time and type* from those the original pleading set forth." *Aldridge*, 78 F.4th at 742 (emphasis added).

Aldridge involved an appeal of a verdict of over $10M after a 9-week jury trial in an FCA case in which the Government intervened, alleging that the defendants—a corporate management

company, company owner, corporate executives, and a hospital—defrauded Medicare out of millions over the span of twelve years by overbilling for the owner's and his wife's compensation despite little or no reimbursable work. *Id.* at 741. On appeal, a divided panel narrowed the scope of the Government's recovery for claims accruing before September 2009—six years before the Government elected to intervene—because they did not relate back to the relator's original complaint.

According to the *Aldridge* majority, the "crux" of the Government's intervening complaint was "[excessive] salaries or luxury cars." *Id.* The relator's complaint, on the other hand, alleged that the defendants "falsified their claims by engaging in a number of practices including fraudulent cost reporting, inflating supply costs, manipulating the swing bed status of the hospitals controlled by [CMI] . . ., and improperly waiving co-payments and deductibles." *Id.* at 743. Neither of Aldridge's complaints nor the Government's notice letter to the defendants mentioned excessive salaries or luxury vehicles. By contrast, the Government's intervening complaint, though generally premised on fraudulent cost reporting, primarily alleged that the defendants "abused the special Medicare rules for Critical Access Hospitals by improperly claiming expenses for the Cains' excessive and unwarranted compensation for work not performed and for Ted Cain's personal luxury automobiles[.]" *Id.* Thus, according to the Fifth Circuit, the upshot of the Government's complaint was "to fault [the defendants] for conduct different from that" alleged by Aldridge. *Id.*

Relying on *Aldridge*, PCCA argues that (A) the Government's complaint cannot relate back because the Relator's complaint failed to state a claim under Rule 12(b)(6), and (B) the Relator's allegations are sufficiently different from the Government's that the claims in the Government's complaint-in-intervention do not relate back to the Relator's complaint. The Court disagrees on both counts.

A. The sufficiency of the Relator's pleading is not at issue here.

PCCA argues that the Government's complaint cannot relate back because the Relator's complaint failed to state a claim under Rule 12(b)(6). This argument fails for at least two reasons.

1. PCCA grossly mischaracterizes the Relator's factual allegations

First, it appears to rely on a reading of the Relator's complaint that is at best misleading. For example, an exhibit attached to the motion purports to list all the paragraphs in the Relator's complaint that mention PCCA by name, presumably to summarize his allegations against PCCA. *See* ECF No. 154-2. In preparing this list, however, PCCA selectively excluded several paragraphs describing conduct by "Supplier Defendants," which is specifically defined in the Relator's complaint to *include* PCCA. *See generally id.*; *see also* ECF No. 1 ¶ 52 ("Defendants Professional Compounding Centers of America, Inc. and Freedom Pharmaceuticals, Inc. are collectively referred to as the 'Supplier Defendants.'"). These allegations, by definition, apply to PCCA—excluding them from the "list" of allegations against PCCA defies not only the Rule 12(b)(6) requirement that the allegations be construed in the light most favorable to the plaintiff but also basic principles of reading comprehension.

For example, the following allegations involving PCCA in the Relator's complaint have been omitted from PCCA's list:[4]

> ¶ 8(h) Bellevue Defendants regularly compounded medications that were copies of considerably less expensive, FDA approved, commercially available products, and conspired with **[S]upplier Defendants** to manipulate AWPs and U&Cs.
>
> ¶ 53 Each of the chemical **Supplier Defendants** supplies compounding pharmacies and pharmacists with the active and non-active chemical ingredients for compounding, and also offers compounding proprietary formulas, pharmacy

[4] The Relator's complaint also includes a number of ingredient-specific examples of false claims and overpayments resulting from the Supplier Defendants and Bellevue Defendants manipulation and misrepresentation of AWP and U&C. Because the relation-back analysis requires the Court to consider the nature of PCCA's conduct—rather than the details of any particular violation—the Court does not recite those paragraphs here.

software, third-party billing support, laboratory equipment, training and education, and consulting services and technical support.

¶ 66 Each of the **Supplier Defendants** fraudulently report to nationally recognized pricing sources at grossly inflated rates the compound ingredient Average Wholesale Prices relied on by FHPs to set compound pharmacy reimbursement rates, causing FHPs to overpay its pharmacy customer's claims, including Bellevue Defendant claims, based on the false pricing. . . . By reporting inflated prices that greatly exceed the actual prices at which they sell their products to pharmacies, **Supplier Defendants** cause its pharmacy customers to submit false claims for payment to FHPs and FHPs to pay flagrantly overstated claims.

¶ 72 Manufacturers and distributors such as the **Supplier Defendants**, . . . serve as the primary, if not sole, source of the industry-defined current prices published by nationally recognized references, and they know that FHPs rely on the truthful reporting of the published prices to determine reimbursement on prescription drug claims and they have a legal duty to accurately determine and report their prices based on the industry-defined standards.

¶ 83 In the context of this action, each **Supplier Defendant** reports to nationally recognized pricing sources its AWP for each ingredient by the ingredient's unique 11-digit, 3 segment National Drug Code (NDC); . . . . FHPs and private plans rely on and use the pricing information reported on the claim by the Bellevue Defendants, including the ingredient cost calculated on the basis of the published AWP prices and their U&C determined on the basis of the specific definition and actual sales transactions.

¶ 119 Each of the **Supplier Defendants** knowingly manipulated and misrepresented its reported compound ingredient AWPs, in order to increase the reimbursement its pharmacy customers received from third party payers, including FHPs, and in turn, increase its business and market share. In particular, each **Supplier Defendant** knew that third party payers base their reimbursement for its products on the AWPs it reports. To gain a competitive advantage over other suppliers and maintain and develop old and new business, each **Supplier Defendant** reported inflated AWPs far in excess of the actual prices for which it sold its products to pharmacy customers. It then "marketed the spread" between its reported AWP and its actual prices to customers to induce the purchase of its products. Customers, fully aware of the actual costs they paid for compound ingredients and the extent to which the AWPs reported by **Supplier Defendants** were inflated, purchased the products from **Supplier Defendants** to reap the unreasonably high profits made possible by the fabricated spread, knowing the excessive profits came at the expense of third party payers. In effect, FHPs and other third party payers have subsidized each **Supplier Defendant's** marketing and sales.

¶ 120 At the same time, Bellevue Defendants knowingly submitted inflated AWPs and manipulated and misrepresented the U&C prices it reported on claims to third party payers, including FHPs, in order to receive uncommonly high, excessive reimbursements. In particular, Bellevue Defendants knew that third party payers reimbursed compound claims at the lesser of U&C or the AWP-based ingredient cost amount. They also knew that the compound ingredient AWPs reported by the **Supplier Defendants** were far higher than the prices at which they purchased compound ingredients from the suppliers or sold compounds medications to cash-paying customers. Yet, in order to receive extraordinary, excessive and unlawful, profits on third party claims Bellevue Defendants knowingly failed to report the true U&C prices at which it sold compound drugs to cash-paying customers. Instead, they submitted inflated U&C prices on claims, along with inflated ingredient costs based on AWPs they knew were fraudulent exaggerated.

¶ 142 The **Supplier Defendants'** spreads between their reported AWPs and actual prices to customers as a rule are materially higher than the pricing spreads of other suppliers, and for this reason, to ensure maximum revenues the Bellevue Defendants instruct its pharmacists to avoid using products in formulas which cannot be purchased through the **Supplier Defendants.**

¶ 145 Each **Supplier Defendant's** use of the "spread" it fraudulently created between its reported AWPs and its actual prices to induce pharmacy customers, including the Bellevue Defendants, to purchase its products, constituted the offer of illegal remuneration in violation of the AKS.

¶ 146 The Bellevue Defendants reciprocal purchase of products from each **Supplier Defendant** for which it submitted claims and received reimbursement from FHPs, based on the inflated AWPs which they reported and knew far exceeded their actual purchase prices, constituted the receipt of illegal remuneration in violation of the AKS.

¶ 147 All claims caused to be submitted by **Supplier Defendants** and submitted by Bellevue Defendants and tainted by the AKS violations are fully recoverable.

¶ 172 Bellevue Defendants regularly compounded medications that were copies of considerably less expensive, FDA approved, commercially available products, and conspired with **Supplier Defendants** to manipulate AWPs and U&Cs.

¶ 197 Bellevue Defendants rely on the advice of the **Supplier Defendants** and others to provide recommendations for items to use in their compounding formulas, ingredient amounts to be utilized in their compounding formulas, and the benefits to assert in their marketing materials.

¶ 197 Bellevue Defendants market their compounded medications with numerous brochures, drug ingredient lists and other advertising materials that set forth

> claims about the effectiveness of their compounded medications. . . . These marketing materials are provided to Bellevue Defendants as part of the consulting services provided by the **Supplier Defendants**.

By this measure the list leaves out more of the allegations against PCCA than it includes.[5]

Based on its mischaracterization of the Relator's allegations, PCCA insists that this complaint is "a classic example 'naked assertions' that are not plausible under *Iqbal* and *Twombly*." ECF No. 167 at 2; *see also* ECF No. 154 at 10 ("Exhibit B fails to allege a 'plausible' basis for asserting Texas common law claims or either an FCA or KSA claim.");[6] *id.* at 11 (noting that "[t]here are *a couple* of formulaic allegations against both 'supplier defendants'" and insisting that ¶ 66 and ¶ 119 contain "nothing that would survive a *Twiqbal* challenge," without addressing any other allegations against the Supplier Defendants) (emphasis added).

Acknowledging that the Government's complaint survived a motion to dismiss, PCCA contends that, for statute of limitations purposes, the Government's pleadings cannot "retroactively render the Relator's conclusory statements plausible, and thus an appropriate pleading to which the Government's pleading can relate back to." ECF No. 167 at 2.[7] Setting aside PCCA's mischaracterization of the Relator's complaint, as discussed below, this argument overlooks the explicit text of the FCA.

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[5] The list also omits at least one paragraph that mentions PCCA by name. *See* ECF No. 154-2 (omitting ¶ 15).

[6] The Government's complaint asserts claims under federal common law, not Texas common law. *See* ECF No. 66 at 44–46.

[7] Despite this "acknowledgment" of the Court's order denying PCCA's motion to dismiss, PCCA's arguments about the plausibility of the Relator's allegations are themselves premised on legal theories that the Court rejected over a year ago. For example, PCCA asserts that the Relator's complaint failed to allege that compound prescriptions were "reimbursable" under the AKS. *See* ECF No. 154 at 11; PCCA, 664 F. Supp. 3d at 744 n.7 ("[N]either the FCA nor the AKS is limited to fraudulent or kickback schemes for items that are "covered" or "reimbursable.").

2. The FCA expressly permits relation-back to cure pleading deficiencies

Third, and most importantly, even assuming that the Relator's complaint somehow failed to satisfy the pleading requirements, the text of the statute clearly contemplates relation back to deficient pleadings. *See* 31 U.S.C. § 3731(c). Section 3731(c) permits relation back "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." *Id.* (emphasis added).

Ignoring the statutory text, PCCA looks instead to dicta in a D.C. Circuit case cited in *Aldridge*, *United States ex rel. Miller v. Bill Harbert International Construction, Inc.*, 608 F.3d 871 (D.C. Cir. 2010). *Miller* held that the Government's allegations concerning a contract that was not identified in the relator's complaint did not relate back simply because the relator's complaint used the plural form "contracts" in some of its allegations. Aside from the fact that the new contracts did not involve the same "conduct, transaction, or occurrence" in the relator's pleading, the panel "note[d]" that permitting relation back based on the mere reference to "contracts" would "circumvent the recent teachings of *Iqbal* and *Twombly* by allowing amendments to relate back to allegations that were themselves nothing more than 'naked assertions.'" *Miller*, 608 F.3d at 882.[8]

Neither *Aldridge* nor *Miller* adopted the standard that a relator's complaint must satisfy the pleading requirements to allow the Government's complaint to relate back. Instead, they confirm the common-sense proposition that the relator's complaint must provide enough detail to permit the court to determine whether the government's complaint refer to the same "conduct, transaction, or occurrence." A properly pled complaint is sufficient—but not necessary—to allow a court to conduct such an analysis. After all, there are an infinite number of ways to run afoul of the pleading standard that have nothing to do with the common core of operative facts. Failure to allege

[8] This *dicta* is best understood as applying the then-new plausibility standard set forth in *Twombly* and *Iqbal* to illustrate the need for allegations to be sufficiently detailed to support relation back.

damages in connection with a breach-of-contract claim, for example, would be dispositive on a 12(b)(6) motion but would not necessarily cast doubt on the nature of the underlying contract or the parties' performance thereunder—the relevant considerations in a relation-back analysis.

The Government's common-sense understanding comports with the rationale for permitting relation-back in the first place: "once litigation involving a particular transaction has been instituted, the parties should not be protected [by the statute of limitations] from later asserted claims that arose out of the same conduct set forth in the original pleadings." *Quantlab Techs. Ltd. (BGI) v. Godlevsky*, No. CIV.A. H-9-4039, 2012 WL 1596710, at *4 (S.D. Tex. May 4, 2012) (quoting *Flores v. Cameron County*, 92 F.3d 258, 272 (5th Cir. 1996)) (addressing relation-back under Federal Rule of Civil Procedure 15).[9] The Fifth Circuit has explained that it regards as "'critical' whether the opposing party was put on notice regarding the claim raised therein." *Holmes v. Greyhound Lines, Inc.*, 757 F.2d 1563, 1566 (5th Cir. 1985) (same).

In both *Miller* and *Aldridge*, the relator's pleading failed to even mention the conduct or transactions raised in the Government's complaint. By failing to mention the new contracts, the relator in *Miller* both "failed to state a claim" for breach of those contracts under 12(b)(6) and failed to notify the defendant about claims arising under those contracts. Likewise, by failing to mention excessive salaries or luxury vehicles, the relator in *Aldridge* failed to state a claim arising out of the improper expenses and failed to put the defendants on notice about such a claim. But these tautologies do nothing to advance PCCA's position that relation-back is impermissible where there is any deficiency in the original pleading.

[9] Courts have noted that the standards for "relation back" under section 3731(c) and Rule 15 are "substantially the same," *Miller*, 608 F. 3d at 883, and have used cases interpreting Rule 15 in their section 3731(c) analysis. *Id.* at 880–83; *see also Aldridge*, 78 F.4th at 742.

B. The Government's complaint relates back to the Relator's complaint

A government FCA complaint against a particular defendant relates back where it is tied to the same "common core of operative facts" as the original complaint against the same defendant. *Aldridge*, 78 F.4th at 742 (cleaned up). The analysis requires the Court only to compare the two complaints. *See id.* at 743 (comparing relator complaint and government complaint).

Despite acknowledging that the relation-back analysis is determined by a comparison between the factual allegations in the underlying complaints, PCCA suggests that the Court should look to outside evidence—including civil investigative demand and deposition transcripts and a PowerPoint presentation—to interpret the Relator's and the Government's complaints. *See* ECF No. 154 at 4, 6. But this outside evidence is entirely irrelevant to the question at hand.

Meanwhile, in a misguided effort to compare the thrust of the complaints' allegations against PCCA, PCCA points to a "'Comparison Report' generated by Adobe Reader software," showing "48 'insertions'" in the Government's complaint not found in the Relator's complaint. *Id.* at 4. Nowhere in its motion does PCCA address any of the "insertions" in the Government's complaint, let alone how the Government's complaint faults PCCA for "different conduct" than that alleged in the Relator's complaint. *Miller*, 608 F.3d at 881. The mere fact that some differences in wording exist between the documents is irrelevant because the FCA permits the government to "clarify or add detail to" a relator's complaint and file its own complaint. 31 U.S.C. § 3731(c). Here, the Government's complaint provides additional detail and clarification to the same fraudulent scheme alleged in the Relator's complaint.

Arguing that the conduct alleged in the Government's complaint is different from the conduct in the Relator's complaint, PCCA first asserts that the "crux" of the Relator's complaint were its allegations against the Bellevue Defendants, who settled with the Government during the

course of the DOJ investigation. *See* ECF No. 154 at 8–10.[10] But in determining whether the claims against PCCA in the Government's complaint-in-intervention relate back, the Court must examine the allegations against *PCCA* in the Relator's complaint, *not* the allegations against the Bellevue pharmacies. Of course, the conduct is related because PCCA and the Bellevue Defendants allegedly participated in the same fraudulent scheme, but the Court cannot look to the allegations against the Bellevue Defendants alone to determine the thrust of the Relator's case against PCCA.

The Government's claims against PCCA based on AWP-inflation very clearly relate back to the allegations against PCCA in the Relator's complaint by providing more detail in support of those allegations. Both complaints allege the same claims (violations of the FCA and AKS) against the same defendant (PCCA) over the same period of time (2012–2015), based on the same conduct (AWP manipulation) causing the same harm (overpayment) to the same government payor (TRICARE). In its response to PCCA's motion, the Government provided a chart illustrating that its claims arise out of the same "conduct, transactions, or occurrences" set forth, or attempted to be set forth, in the [Relator's] complaint." 31 U.S.C. § 3731(c); *see* ECF No. 165 at 5–7. The Court reproduces the chart in part below.

[10] The basis for this argument is genuinely unclear to the Court. As best the Court can tell, it seems to be based on a comparison of the sheer number of allegations involving the Bellevue Defendants to the number of allegations against PCCA. Even setting aside PCCA's omission of references to "Supplier Defendants" from its analysis, this approach to determining the "crux" of the allegations is specious. To illustrate PCCA's logical fallacy, consider a personal injury claim in which a pedestrian struck by a vehicle sues the driver (for running a red light) and sues the car manufacturer for products liability (for a faulty break system). Due to the nature of the claims, the complaint would likely devote more paragraphs to explaining the defects in the design or manufacturing of the break system than to describing the driver's negligence. Under PCCA's reading of *Aldridge*, an amended complaint adding an allegation that the other driver was intoxicated would not relate back to the original complaint because the "thrust" of the allegations in the complaint were against the manufacturer.

Allegations	Relator's Complaint	Government's Complaint
Same Conduct	"Defendant Professional Compounding Centers of America, Inc., a supplier of chemical ingredients to compounding pharmacies, knowingly reported fraudulent, grossly inflated ingredient prices which it knew government programs relied upon to set the reimbursement rates the programs paid to compounding pharmacies on Prescription compound drug claims." ECF No. 1 ¶ 8a. "Professional Compounding Centers of America, Inc. . . . reported inflated ingredient prices to manipulate third party reimbursement for compound drugs and create extraordinary 'spreads' between compounding pharmacy reimbursements and costs." *Id.* ¶ 8d.; *see also id.* ¶¶ 66, 119.	"PCCA's scheme was plain and direct: generate mega-spreads to increase pharmacies' potential profits from using PCCA's ingredients. PCCA implemented its scheme by reporting AWPs that bore no rational relationship to the actual selling prices for its ingredients, and which were often marked up by thousands of percent. PCCA used the inflated AWPs and resulting spreads to induce pharmacies to purchase its ingredients." ECF No. 66 ¶ 8.
Same Means	"The fraudulently reported ingredient prices were far more than the actual prices at which the Defendants sold ingredients to compounding pharmacies frequently 1000%, or more, higher." ECF No. 1 ¶ 8a. "To gain a competitive advantage over other suppliers and maintain and develop old and new business, [PCCA] reported inflated AWPs far in excess of the actual prices for which it sold its products to pharmacy customers. It then 'marketed the spread' between its reported AWP and its actual prices to customers to induce the purchase of its products." *Id.* ¶ 119.	Several PCCA "ingredients had AWPs that ranged from 1,323% to 56,461% of PCCA's selling prices for these ingredients to its top customers . . . far in excess of PCCA's 2014 catalog prices for these ingredients[.]" ECF No. 66 ¶¶ 61–63. "PCCA's AWP increases were an important part of its overall pricing and promotional strategy for selling its ingredients. PCCA typically charged more than its competitors for its ingredients, which enabled PCCA to earn greater revenues. But that meant that, unless PCCA's products offered the possibility of higher reimbursement rates from insurers, customers that were price-sensitive would opt for competitors' products." *Id.* ¶ 75.

Same Kickbacks	"The 'spreads' created between compounding pharmacy reimbursements and costs, through [PCCA's] manipulation of its fraudulently overstated reported prices and actual sales prices . . . were used by [PCCA] as a kickback to induce customers to purchase its products over competitor products." ECF No. 1 ¶ 8a. "[PCCA]'s use of the 'spread' it fraudulently created between its reported AWPs and its actual prices to induce pharmacy customers . . . to purchase its products, constituted the offer of illegal remuneration in violation of the AKS." *Id.* ¶ 145.	"PCCA knowingly caused to be presented false or fraudulent TRICARE claims that were the result of Anti-Kickback Statute violations in the form of lucrative 'AWP spreads' . . . that were intended to induce pharmacies to purchase ingredients from PCCA." ECF No. 66 ¶ 182.
Same Time Period	"Beginning in early 2012, TRICARE compound claims were submitted, adjudicated, and reimbursed using the [multiple ingredient compound] method NCPDP version D.0 format." ECF No. 1 ¶ 104; *see also id.* ¶ 97. Detailing claims involving PCCA products from 2012 onward, *see, e.g.*, *id.* ¶¶ 131–33, and stating that the harm "continues" as of filing in 2014, *id.* ¶¶ 202, 206, 210.	"From at least March 2012 through May 2015, PCCA established and reported fraudulently inflated [AWPs] for many of its ingredients relative to the actual prices at which it sold those ingredients[] to its compound pharmacy customers[.]" ECF No. 66 ¶¶ 1; *see also id.* ¶ 170 ("On May 1, 2015, an enhanced screening procedure and prior authorization process for compound prescription claims was implemented by TRICARE.").
Same Claims	Violations of the FCA and AKS. ECF No. 1 ¶¶ 199–210.	Violations of the FCA and AKS along with common law claims based on the same the conduct, transactions, or occurrences. ECF No. 66 ¶¶ 180–201.

Many of PCCA's arguments about the differences between the allegations in the relevant pleadings betray a profound confusion about the difference between the "spread" marketed to PCCA's customers—the difference between the customer's acquisition costs for an ingredient and PCCA's AWP—and the measure of the Government's damages in this case—the difference between what TRICARE paid in reimbursements based on PCCA's AWPs and what it should have

paid had the AWPs not been fraudulently inflated. *See* ECF No. 154 at 11 (incorrectly asserting that the Relator's allegation "has absolutely nothing to do with the "spread" subsequently alleged by the Government").

This confusion appears to arise out PCCA's misunderstanding of the allegations in the Government's complaint concerning TRICARE's approach to claim adjudication. PCCA argues that Government's complaint does not relate back to the Relator's complaint insofar as it alleges that TRICARE paid the lesser "TWO – not THREE – amounts." ECF No. 154 at 12. Of course, two of the metrics—AWP-based costs and U&C charges—appear in both complaints. *See* ECF No. 1 ¶ 198; ECF No. 66 ¶ 45. PCCA seems to believe that the additional metric identified in the Government's complaint—the sum total of the costs submitted by the pharmacy for all ingredients in the compound drug, plus a dispensing fee and level of effort fee—must be based on the pharmacy's *actual acquisition costs* and must also represent the "spread" referenced throughout the Government's complaint. *See* ECF No. 154 at 18 (arguing that the Relator's complaint "negates" the "spread" because pharmacies' acquisition costs were "not even submitted to ESI or TRICARE").

But the Government does not allege that PCCA's customers either submitted or were required to submit their "acquisition costs" in their compound claims. The "sum total of costs submitted by the pharmacy" obviously does not apply to claims for which pharmacies did not report such costs and, in any event, the "costs submitted by pharmacies" does not reflect a requirement that pharmacies disclose their "actual acquisition costs." All of TRICARE's reimbursement methods contemplate some "spread" in the form of a reasonable markup between the cost of an ingredient to the pharmacy and the cost to the Government. *See* ECF No. 66 ¶ 47 (noting that Express Scripts Manuals prohibit pharmacies from submitting compound claims with

inflated AWPs or for amounts in excess of the pharmacy's acquisition costs, "*taking into account a reasonable markup*") (emphasis added). The Government's theory is that the "spreads" based on PCCA's inflated AWPs—and PCCA's marketing of its inflated spread—violated the FCA and AKS. It does not suggest that all "spreads" are *per se* illegal. In short, nothing in the Government's allegations suggests that TRICARE's claims adjudication policies requires pharmacies to disclose their actual acquisition costs on their claims forms.[11] Rather, the Government alleges that PCCA urged its pharmacy customers not to disclose PCCA's selling prices or the pharmacy's acquisition costs to auditors because this would have revealed the magnitude of PCCA's fraudulent AWP inflation. *See* ECF No. 66 ¶¶ 153–57; ECF No. 109 at 10. Finally, the Court observes that PCCA's arguments on this point are entirely academic because the Government has limited its claims to those in which PCCA's AWPs were *actually* the basis for TRICARE reimbursement.

Many of PCCA's other arguments misconstrue the relevance of the allegations added in the Government's complaint. For example, the Government does not suggest that PCCA's efforts to conceal its actual prices are a basis for independent liability under the FCA; they are merely "additional details" supporting scienter. Likewise, PCCA's billing software is not the basis for an independent claim under the FCA.[12] Rather, the existence and features of the software bear on the elements of scienter and causation insofar as they reflect that PCCA *knew* that customers used its inflated AWPs in the submission of claims for reimbursement for compound drugs to TRICARE and in fact *assisted* in the submission of those claims. *See Aldridge*, 78 F.4th at 741 (noting that

[11] This is obvious in light of the Government's allegations that PCCA urged its customers to maintain the secrecy of their acquisition prices. *See* ECF No. 66 ¶ 157 (alleging that, if an auditor requested an invoice from a PCCA customer, PCCA would generate a report for the auditor that would exclude the actual selling prices of PCCA's ingredients from the report). If pharmacies were required to submit their actual acquisition costs on claims forms, auditors would have no need to solicit that information from the pharmacies themselves (rather than Express Scripts or TRICARE), and PCCA's sanitized invoice would do nothing to help the pharmacies escape the auditor's scrutiny.

[12] Even the feature permitting a pharmacy to automatically populate the U&C price with the AWP-based price would not violate the FCA if (a) the AWP-based price was not fraudulently inflated (b) the pharmacy actually charged cash customers the AWP-based price.

proof of causation "merely demands more than mere passive acquiescence in the presentation of the claim and some sort of affirmative act that causes or assists the presentation of a false claim'").

The Court agrees with PCCA, however, that nothing in the Relator's complaint would have put PCCA on notice about FCA and AKS claims premised on the all-inclusive trips offered through its rewards program. Because the Government's allegations as to those trips "faults [PCCA] for different conduct that that alleged in the [Relator's] complaint," independent claims premised on those trips do not relate back to the Relator's complaint and are thus barred by the statute of limitations. *Id.*at 743. PCCA's motion is otherwise denied in all respects.

In sum, despite PCCA's beliefs to the contrary, *Aldridge* does not represent a sea change in FCA or relation-back jurisprudence. As Judge Ho noted in his dissent to the majority opinion in *Aldridge*, the Fifth Circuit has recognized that "'determining when an amendment will relate back' can be 'difficult.'" *Aldridge*, 78 F.4th at 753 (Ho, J., dissenting) (quoting *FDIC v. Conner*, 20 F.3d 1376, 1386 (5th Cir. 1994)). Although he would have permitted the Government's complaint in *Aldridge* to relate back to the relator's, he agreed that it was a "close question." *Id.* With respect to the Government's allegations of AWP manipulation, the question here is not close: Relator's allegations against PCCA are identical to the fraudulent AWP pricing and marketing scheme alleged by the United States in its complaint in partial intervention. The Government's complaint plainly relates back to the Relator's complaint.

CONCLUSION

For the foregoing reasons, Professional Compounding Centers of America, Inc.'s motion for summary judgment based on its statute-of-limitations defense (ECF No. 154) is **GRANTED IN PART** and **DENIED IN PART**.

Defendant's motion is granted to the extent that the Government's claims are premised on PCCA's provision of all-inclusive trips to its pharmacy customers, they are barred by the statute of limitations. PCCA's motion is otherwise denied in all respects.

It is so **ORDERED**.

SIGNED this 30th day of April, 2024.

XAVIER RODRIGUEZ
UNITED STATES DISTRICT JUDGE