IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES, *et al., ex rel.* DEBORAH SHELDON *Plaintiffs* v. FOREST LABORATORIES, LLC, *et al.*, *Defendants.*	Civil Action No. ELH-14-2535

MEMORANDUM OPINION

This *qui tam* action concerns an allegedly fraudulent reporting scheme under the Medicaid Drug Rebate Program (the "Rebate Program"). Pursuant to the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq.*, and analogous state statutes, the late Troy Sheldon, as Relator, filed suit against his employer, Forest Laboratories, LLC, f/k/a Tango Merger Sub 2 LLC, f/k/a Forest Laboratories, Inc., and Forest Pharmaceuticals, Inc., as well as Allergan, PLC, f/k/a Actavis, PLC, "as acquirer" of Forest (collectively, "Forest").[1] *See* ECF 16 (the "Amended Complaint").[2] Suit was filed on behalf of the United States of America, the District of Columbia ("D.C."), and numerous states.[3]

[1] In addition to ordinary federal question jurisdiction, *see* 28 U.S.C. § 1331, the FCA contains a specific grant of subject matter jurisdiction. *See* 31 U.S.C. § 3732(a). And, a district court with jurisdiction under the Federal FCA also has jurisdiction as to state-law qui tam claims "aris[ing] from the same transaction or occurrence." *Id.* § 3732(b).

[2] According to defendants, as of January 1, 2018, Forest Laboratories, LLC and Forest Pharmaceuticals, Inc. merged into Allergan Sales, LLC ("Allergan") and "no longer exist." ECF 72-1 at 11 n.1.

[3] The *qui tam* states are California; Colorado; Connecticut; Delaware; Florida; Georgia; Hawaii; Illinois; Indiana; Iowa; Louisiana; Maryland; the Commonwealth of Massachusetts; Michigan; Minnesota; Montana; Nevada; New Hampshire; New Jersey; New Mexico; New York; North Carolina; Oklahoma; Rhode Island; Tennessee; Texas; Vermont; the

Mr. Sheldon died on November 10, 2017. His wife, Deborah Sheldon, as Executrix of the Estate of Troy Sheldon, was substituted as the plaintiff on March 19, 2018. ECF 29 (Motion to Substitute Party); ECF 31 (Order Granting Motion to Substitute Party). And, based on the Joint Stipulation of the Parties (ECF 71), the Court entered an Order substituting Allergan as the successor in interest to Forest. ECF 75.

Mr. Sheldon, the Relator, filed his initial Complaint (ECF 1) on August 11, 2014, and the Amended Complaint (ECF 16) was filed on August 30, 2016.[4] It is 184 pages in length. In the suit, Sheldon alleged that Forest engaged in a fraud scheme by which it provided false price reports to the government and, in turn, this caused the government to overpay for Forest's drugs under the Rebate Program. ECF 72-1 at 11; ECF 16 at 6-7. Among other things, Sheldon claimed that Forest was required to aggregate the rebates it paid to its customers for purposes of calculating and reporting the "Best Price" for the drug, but failed to do so. *Id.*

The FCA and related state statutes permit a private party, a whistleblower known as a relator, to sue on behalf of the government to recover damages from a defendant who has caused the submission of fraudulent claims for payment injuring the public fisc. As an incentive to bring such suits, a successful relator is entitled to share in the government's recovery. *See United States ex rel. Bunk & Ammons v. Gov't Logistics N.V.*, 842 F.3d 261, 265 n.3 (4th Cir. 2016); *see also Schindler Elevator Corp. v. United States ex rel. Kirk*, 563 U.S. 401, 404 (2011); *ACLU v. Holder*, 673 F.3d 245, 246-51 (4th Cir. 2011) (describing history and current provisions of FCA).

Commonwealth of Virginia; Washington; and Wisconsin. The District of Columbia is also a qui tam plaintiff.

I shall refer to D.C. and the states collectively as the "*Qui Tam* States."

[4] Unless otherwise noted, the terms "Relator" and "Sheldon" shall refer to Troy Sheldon.

Pursuant to the initial sealing provisions of the FCA, suit was filed under seal in order to provide time to the United States and the *Qui Tam* States to decide whether they wished to intervene. *See* 31 U.S.C. § 3730(b)(2).[5] The government undertook a lengthy investigation. *See* ECF 17; ECF 21; ECF 23; ECF 24; ECF 26; ECF 30; ECF 33; ECF 35; ECF 37; ECF 39. Eventually, on September 17, 2019, the United States and the *Qui Tam* States declined to intervene. ECF 41. The suit was unsealed on October 16, 2019. ECF 42. Thereafter, on December 9, 2019, defendant waived service of process. ECF 47; ECF 48.

Defendant subsequently moved to dismiss, pursuant to Fed. R. Civ. P. 12(b)(6) and 9(b). ECF 72. The motion is supported by a memorandum of law (ECF 72-1) (collectively, the "Motion") and one exhibit. ECF 72-2. The Relator opposes the Motion (ECF 79), supported by five exhibits. ECF 79-1 to ECF 79-5. And, defendant has replied (ECF 82), supported by five exhibits. ECF 82-1 to ECF 82-5. In addition, defendant has submitted a Notice of Supplemental Authority (ECF 84), and plaintiff has replied. ECF 85.

No hearing is necessary to resolve the Motion. *See* Local Rule 105.6. For the reasons that follow, I shall grant the Motion.

I. Factual Background[6]

Forest was a Delaware limited liability company with its principal place of business in New Jersey. ECF 16, ¶ 9. It manufactured, sold, and distributed prescription drug products in

[5] The analogous state *qui tam* statutes also provide for initial filing of a *qui tam* complaint under seal, in order to permit the state to investigate the claim and determine whether it wishes to intervene.

[6] As discussed, *infra*, in the posture of this case, I must assume the truth of the facts as alleged by the Relator. And, I may consider exhibits appended to the suit and take judicial notice of public records, without converting the Motion to one for summary judgment.

the United States. *Id.* ¶ 10. Forest also participated in the Rebate Program. *Id.* ¶ 12. In January 2018, Forest merged into Allergan. ECF 72-1 at 11 n.1.

Sheldon worked for Forest from the 1990s until he was terminated in 2014. ECF 16, ¶ 55. He served "in managerial roles and had responsibilities over billions in revenues streams, overseeing many sales representatives, and overseeing Pharmacy Provider and GPO account managers." *Id.* Moreover, Sheldon was "directly involved in the launch, marketing and sale of Forest" drugs, which included negotiating discounts, rebates, and other incentives to drug purchasers. *Id.* Relator claimed that he "ha[d] direct, personal knowledge of the drug rebates and other discounts given to Forest customers that impact the reported Best Price for each drug." *Id.* ¶¶ 55, 62.

A. Medicaid Drug Rebate Program

Medicaid is a joint federal-state program that pays for health care services, including prescription drug coverage, for low-income individuals. *Id.* ¶ 13. State Medicaid programs reimburse providers for prescription drugs. *Id.* ¶ 15. "Most states contract with private companies" to evaluate and process "claims submitted by providers for reimbursement under the Medicaid program." *Id.* In general, a provider submits claims electronically to a private company for reimbursement, and the company then processes and pays the claim on behalf of the state or provides the state with the information needed for the state to pay the claim. *Id.* On a quarterly basis, each state submits a claim to the Department of Health and Human Services ("HHS") "for payment of the federal share of the state's Medicaid spending, including prescription drug reimbursements." *Id.*

Drug manufacturers, like Forest, usually do not submit claims for reimbursement directly to Medicaid. *Id.* ¶ 18. Rather, "Forest markets its drug products to its customers, who then

purchase the products either directly or through wholesalers, based on a price the customers negotiated with Forest." *Id.* Customers might also purchase products through Group Purchasing Organizations ("GPOs"), which negotiate prices on behalf of Forest's customers. *Id.* After dispensing or administering the drugs purchased from Forest, the customers submit claims for the drugs to Medicaid. *Id.* ¶ 19.

The drugs at issue in this case include Celexa, Lexapro, Armour Thyroid, Levothroid, Namenda, and many others. *Id.* ¶¶ 17, 56. The Food and Drug Administration ("FDA") assigns each drug product "a unique 11-digit, 3-segment number, known as the National Drug Code ('NDC')." *Id.* ¶ 17.[7]

Medicaid drug reimbursement formulas vary by state. ECF 16, ¶ 22. But, state Medicaid programs generally reimburse based upon the lower of the estimated acquisition cost ("EAC") as determined by the state, the maximum allowable cost ("MAC") set by the state, or the provider's usual and customary charge. *Id.*[8]

Congress established the Rebate Program in 1991 to create a rebate mechanism that gives "'Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser.'" *Id.* ¶ 26 (quoting H.R. Rep. No. 101-881, at 96 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108). According to Relator, "the overarching purpose of the Best Price rebate mechanism is to reduce total Medicaid expenditures by giving the government the benefit of purchasing a drug at the lowest price per unit that a manufacturer has actually realized (*i.e.*, received) in selling that drug on the open market." ECF 16, ¶ 26.

[7] Under the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, pharmaceutical drug companies must submit to the FDA a listing of every drug product in commercial distribution. 21 U.S.C. § 355.

[8] Under 42 C.F.R. § 447.301, EAC is defined in relevant part as "the agency's best estimate of the price generally and currently paid by providers for a drug[.]" ECF 16, ¶ 21.

When originally enacted, the Medicaid Rebate Statute ("Rebate Statute") defined the Best Price as follows, 42 U.S.C. § 1396r-8(c)(1)(C) (1991); ECF 16, ¶ 27:

> [T]he lowest price available from the manufacturer to any wholesaler, retailer, nonprofit entity, or governmental entity within the United States (excluding depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government). The best price shall be inclusive of cash discounts, free goods, volume discounts, and rebates….

The Center for Medicaid and Medicare Service ("CMS"), a federal agency within HHS, promulgated a regulation in 1991 with the requisite language for the Rebate Agreement. ECF 16, ¶¶ 6, 29. The Rebate Statute was amended in 1993. *Id.* ¶ 27. It added "providers" to the list of exemplar entities included for purposes of calculating Best Price. *Id.* (citing 42 U.S.C. § 1396r-8(c)(1)(C) (1993)).

Under the terms of the Rebate Statute, a "drug manufacturer must enter into a Rebate Agreement with the Secretary of HHS in order for its covered outpatient drugs" to qualify for federal payment under Medicaid. ECF 16, ¶ 29 (citing 42 U.S.C. § 1396r-8(a)(1)). Pursuant to the Rebate Statute and the Rebate Agreement, a manufacturer has "two primary obligations." ECF 16, ¶ 29. First, the manufacturer must send a quarterly report to the Secretary of HHS with the "Average Manufacturer Price" ("AMP") and "Best Price" for its covered drugs. *Id.* ¶ 30; 42 U.S.C. § 1396r-8(b)(3)(A). In general, AMP is defined as the average price that a wholesaler or retailer pays directly to the manufacturer for a product, on a per unit basis. ECF 16, ¶ 30; 42 U.S.C. § 1396r-8(k)(1)(A).

The Rebate Agreement confirms and expands on the Rebate Statute's definition of Best Price, ECF 72-2 (72 Fed. Reg. 7049 (1991)) at 3; ECF 16, ¶ 30 (emphasis omitted):

> (d) "Best Price" means, with respect to Single Source and Innovator Multiple Source Drugs, the lowest price at which the manufacturer sells the Covered Outpatient Drug to any purchaser in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is

> computed. Best price includes prices to wholesalers, retailers, nonprofit entities, or governmental entities within the States (excluding Depot Prices and Single Award Contract Prices of any agency of the Federal Government). Federal Supply Schedule prices are included in the calculation of the best price.
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> The best prices shall be inclusive of cash discounts, free goods, volume discounts, and rebates, (other than rebates under section 1927 of the Act).
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> It shall be determined on a unit basis without regard to special packaging, labeling or identifiers on the dosage form or product or package, and shall not take into account prices that are Nominal in amount. For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The best price for a quarter shall be adjusted by the Manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized.

According to Relator, the Rebate Agreement "makes clear that the 'best price' manufacturers are required to report and the government is entitled to receive the final lowest price a manufacturer receives for a single drug unit (*e.g.*, per pill) after taking into account any and all pricing arrangements with any and all entities." ECF 16, ¶ 31.

In addition, under the Rebate Statute and Rebate Agreement, the manufacturer is obligated to pay each state a quarterly rebate equal to the total number of drug units purchased by the state Medicaid program "times the greater of (1) the statutory minimum rebate percentage, or (2) the difference between the AMP and the Best Price." *Id.* ¶ 33 (citing 42 U.S.C. § 1396r-8(c)(1)(A)). For the rebate period from December 31, 1995 until January 1, 2010, the statutory minimum rebate percentage was 15.1%. ECF 16, ¶ 33. For the rebate period after December 31, 2009, the statutory minimum rebate percentage is 23.1%, with exceptions not pertinent here. *Id.* (citing 42 U.S.C. § 1396r-8(c)(1)(B)(i),(iii)).

Based on a manufacturer's reported AMP and Best Price, the Secretary of HHS, through CMS, calculates the quarterly Unit Rebate Amount ("URA") used by each state Medicaid program "to invoice the manufacturer for the rebate based on each state's utilization of the drug."

ECF 16, ¶ 34. The "rebate amount paid by a manufacturer to a state reduces the amount spent by the state" and thus "reduces the amount of Medicaid spending that the federal government provides to the state." *Id.* ¶ 35 (citing 42 U.S.C. § 1396r-8(b)(1)(B)).

In 1991 and 1994, CMS issued program releases confirming and clarifying the requirements of the Rebate Statute and Rebate Agreement for calculation of the Best Price. ECF 16, ¶ 36. In the release from August 1991, CMS stated, ECF 82-1 (Medicaid Drug Rebate Program Release No. 2) at 2; ECF 16, ¶ 36 (emphasis omitted):

> The Average Manufacturer Price (AMP) is calculated as a weighted average based on sales, whereas the Best Price (BP) is the lowest price for a drug product in any package size for any quantity sold. It is not weighted but represents the single best price (that is not nominal) at which any package size of the product was sold in the quarter.

And, with respect to discounts and other price arrangements, CMS explained: "As stated in paragraphs I(a) and I(d) of the rebate agreement, you must revise AMPs and/or BPs to reflect the impact of cumulative discounts or other arrangements on the prices actually realized in any quarter." ECF 82-1 at 3; ECF 16, ¶ 36.

Moreover, in the December 1994 release, CMS stated, in part, ECF 82-2 (Medicaid Drug Rebate Program Release No. 14) at 2; ECF 16, ¶ 37:

> [I]n accordance with sections I(a) and I(d) of the rebate agreement, AMP and best price data "…must be adjusted by the Manufacturer if …other arrangements subsequently adjust the prices actually realized." Thus, we consider any price adjustment which ultimately affects the price actually realized by the manufacturer as "other arrangements" and, as required by the rebate agreement, included in the calculations of AMP and best price.

According to Relator, the CMS releases reiterate that "the clear requirement of 'best price' under the Rebate Statute and Rebate Agreement is to calculate the final lowest price *actually realized* by a manufacturer for a single drug unit after taking into account any and all pricing arrangements." ECF 16, ¶ 37 (emphasis in original).

In 2005, the Government Accountability Office ("GAO") issued a report to Congress noting differences in the way drug manufacturers calculated Best Price and AMP "in a situation involving two different rebates to two different entities (a prompt pay discount given by a manufacturer to a wholesaler, and a second discount given by the manufacturer to the end purchaser through a chargeback relationship). . . ." *Id.* ¶ 38. The Report explained that some manufacturers "correctly combined both of these rebates which involved *two separate entities* in order to properly arrive at the lowest 'net price realized' by the manufacturer[,]" but others did not. *Id.* (emphasis in original). According to Relator, "Forest has taken the same erroneous position as the manufacturers in the 2005 GAO report." *Id.* ¶ 39.

In addition to the program releases from the 1990s, in 2006 and 2007, CMS provided guidance on reporting requirements in the form of comments and proposed and final regulations. On December 22, 2006, CMS issued a proposed rule relating to Best Price and sought public comment. *Id.* ¶ 41. The proposed rule stated, ECF 79-5 (71 Fed. Reg. 77174, 77181-77182 (Dec. 22, 2006)) at 14; ECF 16, ¶ 41 (emphasis omitted):

> Consistent with these [Medicaid Rebate Statute] provisions and the national rebate agreement, it has been our policy that in order to reflect market transactions, the best price for a rebate period should be adjusted by the manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.
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> Because best price represents the lowest price available from the manufacturer to any entity with respect to a single source drug or innovator multiple source drug of a manufacturer, including an authorized generic, any price concession associated with that sale should be netted out of the price received by the manufacturer in calculating best price and best price should be adjusted by the manufacturer if other arrangements subsequently adjust the prices actually realized.

And, the final rule issued by CMS expressly provides, ECF 79-3 (42 C.F.R. § 447.505(a), (e) (2007)) at 172-74; ECF 16, ¶ 42 (emphasis omitted):

> (a) Best price means, … the lowest price available from the manufacturer during the rebate period to any entity in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. Best price shall be calculated to include all sales and associated rebates, discounts and other price concessions provided by the manufacturer to any entity unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation from the rebate calculation.
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> ***
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> (e) Further clarification of best price.
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> (1) Best price shall be net of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, customary prompt pay discounts, chargebacks, returns, incentives, promotional fees, administrative fees, service fees (except bona fide service fees), distribution fees, and any other discounts or price reductions and rebates, other than rebates under section 1927 of the Act, which reduce the price available from the manufacturer.
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> (3) The manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices available from the manufacturer.

In addition to the final regulations, CMS published guidance and responses to comments from manufacturers and others who responded to the proposed regulations. ECF 16, ¶ 43. According to Relator, "CMS's published guidance and comments accompanying the regulations leave no doubt that all rebates and price concessions among all entities must be aggregated to arrive at the price 'actually realized' by the drug manufacturer for a single drug unit." *Id.*

During the rulemaking, CMS specifically addressed in comments two situations involving discounts to multiple entities. *Id.* ¶ 44. In a scenario involving both a prompt pay discount and a chargeback, which Relator avers is "directly analogous to Forest's situation," CMS "explicitly refuted the argument that such rebates did not need to be aggregated." *Id.* ¶ 45. ECF 79-3 at 97; ECF 16, ¶ 45 (emphasis omitted):

> *Comment:* One commenter requested that when best price is determined, customary prompt pay discounts extended to wholesalers should not be

> aggregated with price concessions available to an end-customer under a contract administered through a wholesaler chargeback arrangement, regardless of whether the manufacturer negotiated the contract directly with the end-customer or with a third party.
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> *Response:* We do not agree. As we have previously stated, there is no basis to exclude these discounts. Both the customary prompt pay discounts and other price concessions available to the end-customer are to be included in the determination of best price.

And, with respect to a scenario involving "multiple entities in the context of [Pharmacy Benefit Managers ("PBMs")]," CMS said, ECF 79-3 at 96; ECF 16, ¶ 46 (emphasis omitted):

> *Comment*: Several commenters stated that some industry analysts appeared to misread the proposed rule to suggest that manufacturers may be obligated to add concessions paid to PBMs to the concessions paid to customers of the PBMs in calculating best price. This would effectively call for the combining of two separate prices, one offered to a PBM and the other to a customer of a PBM. The commenter stated that the statute is quite clear in defining best price as the lowest price to "any wholesaler, retailer, provider, health maintenance organization, non–profit entity, or government entity…." The commenters argued that if Congress had intended anything other than a customer-by-customer analysis of separate prices, the statute would have combined each customer with the word "and" instead of the disjunctive "or." The commenters requested that CMS reaffirm that best price is the lowest price available from the manufacturers reflecting concessions provided by the manufacturers.
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> *Response*: We do not agree with the commenters. Although we have deleted the requirement that manufacturers include PBM rebates and discounts and other price concessions in best price.… Best price is designed to reflect the lowest price available from the manufacturer to any purchaser, inclusive of rebates, discounts, or price concessions that adjust the price realized. Where PBM rebates, discounts, or price concessions do not operate to adjust prices, they should not be included in the best price calculation.

Based on these examples, Relator posits: "Just as the Rebate Statute, Rebate Agreement, and Regulations require that two rebates to two different entities in two separate transactions be combined in the prompt pay/chargeback scenario (and in the context of PBMs), so too must Forest combine two rebates to two different entities for the same drug for purposes of reporting Best Price." ECF 16, ¶ 47.

Counsel for Forest submitted a letter to CMS on February 20, 2007, in response to the request for comments to the proposed regulations. ECF 16, ¶ 48; ECF 79-2 (Letter from Forest to CMS). In the letter, counsel noted that the statutory definition of Best Price, which the proposed rule adopts, "has always been interpreted to mean the single lowest price to a particular customer unless the customer or transaction is exempt." ECF 79-2 at 14. The letter also stated, *id.*:

> [L]anguage in the preamble to the proposed rule suggests that CMS views best price as the net amount realized by the manufacturer on a sale rather than the lowest price to a particular customer. It is critical that the final rule clarify that only discounts and price concessions to the same entity to which a drug is sold should be included in the computation of best price to that entity…. In sum, prices to unrelated entities in the chain of distribution should not be aggregated in determining the single lowest price to an entity, even if they concern the same unit of a drug.

Other drug manufacturers in the industry also submitted public comments. For example, Reed Smith, "counsel for an anonymous leading pharmaceutical company," stated that "CMS should clarify that the reference to 'all sales and discounts' and 'to any entity' are not intended to require a manufacturer to aggregate discounts offered to <u>different</u> entities when determining BP." ECF 82-3 (Letter from Smith to CMS) at 10 (emphasis in original); *see* ECF 16, ¶ 52. The letter also posited, ECF 82-3 at 10: "Unlike AMP, which clearly contemplates that prices be aggregated to determine an 'average' amount, the [Best Price] is the single lowest price at which the manufacturer sells the product to a single customer. Thus, it is inappropriate to require a manufacturer to 'stack' discounts offered at one level of the pharmaceutical delivery system (e.g., to a wholesaler) on top of discounts offered at a completely different level of that system (e.g., to a retailer or health plan)."

Moreover, Covington & Burling, "counsel for a variety of pharmaceutical clients," noted that the "ambiguity [in language about cumulative discounts] leaves room for considerable

manipulation of best price." ECF 82-4 (Letter from Covington & Burling to CMS) at 7; ECF 16, ¶ 52. Based on the Rebate Statute's definition of Best Price, Covington concluded that "it is not appropriate to consider discounts other than the discounts offered to one customer when determining best price, for those other discounts are never available to that customer." ECF 82-4 at 7. Therefore, Covington requested "that CMS clarify that discounts to a single entity should be cumulated, but discounts to different purchasers should not be cumulated, when determining best price." *Id.*; *see* ECF 16, ¶ 52.

B. Forest's Rebate Program

Relator avers that Forest engaged in a practice that fraudulently reduced the Best Price it reported to the Secretary of HHS, in violation of fulfilling its reporting obligation under the Rebate Statute and Rebate Agreement. ECF 16 at 6. According to Relator, in the course of his employment, he "discovered that Forest was knowingly, with deliberate ignorance, or with reckless disregard failing to account for the double-rebates being provided by Forest to two separate customers on the same dispensed drug units to the same patient in Forest's Pharmacy Provider/GPO Market." *Id.* ¶ 56. He maintains that this practice resulted in "the false and fraudulent reporting of Best Price to the Secretary [of HHS] for Forest's pharmaceutical drug products in such markets." *Id.*

In the commercial market, "Forest negotiates with private insurance companies to have its drugs placed on the private insurance company's drug formulary." *Id.* ¶ 57.[9] Relator asserts that, "[i]n exchange for placing Forest's drugs not only on its formulary, but also at a preferred tier" on its formulary, Forest pays private insurance companies a "negotiated rebate" on each

[9] A drug formulary is a private insurance company's "list of preferred prescription drugs, both generic and brand name," usually organized into different tiers with different co-payment amounts. ECF 16, ¶ 57.

drug "based upon the number of dispensed drug units" for which the insurer pays. *Id.* ¶ 58. Forest accounts for this rebate in calculating Best Price and uses this price "to set the overall Best Price for its drugs." *Id.*

Forest also negotiates with Pharmacy Providers and GPOs for its drugs to be "disbursed by long term care, rehabilitation/transitional, short term stay and group home facilities, as well as through home delivery." *Id.* ¶ 59. These sales comprise a significant amount of Forest's business. "For example, in FY2008, combined sales to Pharmacy Provider Facilities for Lexapro, Namenda and Bystolic alone totaled over $526 million, which was about 14.5% of the $3.6 billion in total sales Forest received for those drugs." *Id.* The same year, Forest paid Pharmacy Providers over $35 million in rebates, which constituted about 10% of the total rebates paid by Forest in 2008. *Id.*

Usually, Pharmacy Providers and GPOs purchase Forest drugs indirectly through a third-party wholesaler pursuant to a purchasing agreement between Forest and the Pharmacy Provider or GPO. *Id.* ¶ 60. As part of those agreements, the third-party wholesaler sells the drugs to the Pharmacy Provider or GPO at a discount, "which it then charges back to Forest." *Id.* The Pharmacy Providers and GPOs "are also paid a negotiated rebate by Forest on each drug. . . ." *Id.* Before 2009, this rebate amount was based on the number of drug units purchased by a Pharmacy Provider or GPO. *Id.* However, the rebate amount is now based on "the number of dispensed drug units to patients made inside each respective Pharmacy Provider Facility." *Id.* According to Relator, in calculating Best Price, Forest is required to aggregate the discounts and rebates provided to all participants in the chain of distribution, including the Pharmacy Providers, GPOs, and insurance companies. ECF 16 at 8.

Relator alleges that Forest "does not account for such double rebates and other discounts in determining a drug's Best Price if the drug is dispensed at a Pharmacy Provider Facility." *Id.* ¶ 66. Instead, Forest reports Best Price to HHS based only on the rebate or discount given to the private insurance company. *Id.* As a result, argues Relator, Forest falsely reports to the government a "higher Best Price" for drugs dispensed in a Pharmacy Provider Facility, and consequently Forest pays less in Medicaid drug rebates to the state Medicaid programs than it should, which "results in the federal government paying more in Medicaid spending . . . and states are similarly damaged because they are not receiving their proper rebates." *Id.*

In 2008, top level managers at Forest "held meetings and prepared reports focusing on the fact that two rebates were occasionally claimed or paid on the same drug being dispensed to a single patient." *Id.* ¶ 69. The managers were concerned that a patient might have both primary and secondary private medical insurance that would each pay a portion of the patient's drug treatment and then each seek a rebate on the same drug disbursements, creating a double rebate on the same dispersed drug. *Id.* In response, Forest implemented a data audit process for all rebate claims submitted to Forest by private insurance companies in the commercial market and contracted with Data Niche & Associates ("DNA") to develop a data scrubbing process. *Id.* The process identifies outliers in a customer's rebate submissions, including double rebate claims for the same dispensed drug units to the same patient, so that Forest does not pay for both claims. *Id.* Relator asserts that Forest initiated this audit because it was "[a]ware of the potential Best Price violation based upon double rebate claims from its customers." *Id.*

According to Relator, "Forest deliberately chose not to institute the DNA process on the Pharmacy Provider/GPO side to avoid negatively impacting its relationships with major Pharmacy Provider/GPO drug purchasers and preserve shareholder profits." *Id.* ¶ 71. Therefore,

it has continued paying double rebates without accounting for them in its Best Price calculations. *Id.*

Further, Relator alleges that Forest's failure to account for these "double rebates" has resulted in significant overpayments by Medicaid since 2005. *Id.* ¶ 72. Relator estimates the overpayments amount to approximately $686.64 million, "plus significant additional reimbursement owed from FY2014 to the present." *Id.* ¶ 119. He reached this estimate by applying a similar formula to calculate the additional amount that Forest should have paid in Medicaid rebates for each relevant drug for each fiscal year between 2005 and 2014. *Id.* ¶¶ 72-119. The drugs at issue include Celexa, Lexapro, Namenda, Namenda XR, Bystolic, Savella, Viibryd, Fetzima, Tudorza, Daliresp, Saphris, Linzess, Campral, Armour Thyroid, Levothroid, Thyrolar, Tiazac, and Combunox. *Id.* ¶¶ 17, 56.

To calculate the amount that Forest should have paid in rebates for each drug, Relator first alleges, "[u]pon information and belief," the amount of Forest's net sales for that drug in a fiscal year. *See, e.g., id.* ¶ 72. Next, he avers that, "[u]pon information and belief," Forest's highest reported Best Price rebate percentage for that drug was either "the statutory rebate percentage" for some drugs, *see, e.g., id.*, or based on the Best Price set by the maximum rebate given by Forest on the commercial side of its business. *See, e.g., id.* ¶ 73. And, Medicaid received a reimbursement based on this amount. *Id.* Further, he posits, "[u]pon information and belief," that the drug was dispensed to a certain percentage of patients in Pharmacy Provider Facilities with private insurance, and the Pharmacy Providers and GPOs received the maximum possible discount from Forest. *Id.* The commercial insurance companies also received their designated rebate on the same dispersed drug. *Id.* He then calculates the additional rebate that Medicaid should have received by adding together the commercial rebate and the Pharmacy

Provider/GPO rebate and subtracting the reported Best Price, and determines the additional amount that Forest should have paid in Medicaid rebates for that drug in that year. *Id.*

For example, plaintiff alleges, *id.* ¶ 72:

> Upon information and belief, in FY2005, Forest's net sales for Celexa were about $653 Million, at least 20% of which were Medicaid sales - $130.6. Upon information and belief, Forest's highest reported Best Price rebate percentage for Celexa in FY2005 was the statutory rebate percentage of 15.1% based upon the maximum rebate of 15% given by Forest on the Commercial side of its business. Accordingly, Medicaid received a reimbursement from Forest of about $19.72 Million (0.151 * $130.6 Million). However, upon information and belief, Celexa was dispersed to patients in Pharmacy Provider Facilities with private insurance, with Pharmacy Providers/GPOs receiving a maximum discount/rebate of 12% and commercial insurance companies, again, receiving up to a 15% rebate on the same dispersed drug. However, Forest knowingly, with deliberate ignorance, or with reckless disregard ignored such double rebates, while also purposefully or with reckless disregard failing to implement the DNA process in the Pharmacy Provider/GPO market to identify such double rebates, despite knowing, or it should have known, upon information and belief, that at least 15% of Pharmacy Provider patients receiving Celexa had private insurance. Therefore, taking into account such double rebates, Medicaid should have received an additional 11.9% rebate (15% Commercial rebate + 12% Pharmacy Provider/GPO rebate – 15.1% reported Best Price rebate = 11.9% under-rebate), resulting in Forest owing Medicaid an additional reimbursement of about $15.54 Million (0.119 * $130.6 Million) for Celexa in FY2005.

II. Standards of Review

A. Rule 12(b)(6)

A defendant may test the legal sufficiency of a complaint by way of a motion to dismiss under Fed. R. Civ. P. 12(b)(6). *Fessler v. Int'l Bus. Machs. Corp.*, 959 F.3d 146, 152 (4th Cir. 2020); *Paradise Wire & Cable Defined Benefit Pension Plan v. Weil*, 918 F.3d 312, 317 (4th Cir. 2019); *In re Birmingham*, 846 F.3d 88, 92 (4th Cir. 2017); *Goines v. Valley Cmty. Servs. Bd.*, 822 F.3d 159, 165-66 (4th Cir. 2016); *McBurney v. Cuccinelli*, 616 F.3d 393, 408 (4th Cir. 2010), *aff'd sub nom.*, *McBurney v. Young*, 569 U.S. 221 (2013); *Edwards v. City of Goldsboro*, 178 F.3d 231, 243 (4th Cir. 1999). A Rule 12(b)(6) motion constitutes an assertion by a

defendant that, even if the facts alleged by a plaintiff are true, the complaint fails as a matter of law "to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6).

Whether a complaint states a claim for relief is assessed by reference to the pleading requirements of Fed. R. Civ. P. 8(a)(2). That rule provides that a complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." The purpose of the rule is to provide the defendants with "fair notice" of the claims and the "grounds" for entitlement to relief. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555-56 (2007).

To survive a motion under Fed. R. Civ. P. 12(b)(6), a complaint must contain facts sufficient to "state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570; *see Ashcroft v. Iqbal*, 556 U.S. 662, 684 (2009) ("Our decision in *Twombly* expounded the pleading standard for 'all civil actions' . . . ." (citation omitted)); *see also Fauconier v. Clarke*, 996 F.3d 265, 276 (4th Cir. 2020); *Paradise Wire & Cable*, 918 F.3d at 317; *Willner v. Dimon*, 849 F.3d 93, 112 (4th Cir. 2017). To be sure, a plaintiff need not include "detailed factual allegations" in order to satisfy Rule 8(a)(2). *Twombly*, 550 U.S. at 555. Moreover, federal pleading rules "do not countenance dismissal of a complaint for imperfect statement of the legal theory supporting the claim asserted." *Johnson v. City of Shelby, Miss.*, 574 U.S. 10, 10 (2014) (per curiam). But, mere "'naked assertions' of wrongdoing" are generally insufficient to state a claim for relief. *Francis v. Giacomelli*, 588 F.3d 186, 193 (4th Cir. 2009) (citation omitted).

In other words, the rule demands more than bald accusations or mere speculation. *Twombly*, 550 U.S. at 555; *see Painter's Mill Grille, LLC v. Brown*, 716 F.3d 342, 350 (4th Cir. 2013). If a complaint provides no more than "labels and conclusions" or "a formulaic recitation of the elements of a cause of action," it is insufficient. *Twombly*, 550 U.S. at 555. "[A]n unadorned, the-defendant-unlawfully-harmed-me accusation" does not state a plausible claim of

relief. *Iqbal*, 556 U.S. at 678. Rather, to satisfy the minimal requirements of Rule 8(a)(2), the complaint must set forth "enough factual matter (taken as true) to suggest" a cognizable cause of action, "even if . . . [the] actual proof of those facts is improbable and . . . recovery is very remote and unlikely." *Twombly*, 550 U.S. at 556 (internal quotation marks omitted).

In reviewing a Rule 12(b)(6) motion, "a court 'must accept as true all of the factual allegations contained in the complaint,' and must 'draw all reasonable inferences [from those facts] in favor of the plaintiff.'" *Retfalvi v. United States*, 930 F.3d 600, 605 (4th Cir. 2019) (alteration in *Retfalvi*) (quoting *E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc.*, 637 F.3d 435, 440 (4th Cir. 2011)); *see Semenova v. Md. Transit Admin.*, 845 F.3d 564, 567 (4th Cir. 2017); *Houck v. Substitute Tr. Servs., Inc.*, 791 F.3d 473, 484 (4th Cir. 2015). However, "a court is not required to accept legal conclusions drawn from the facts." *Retfalvi*, 930 F.3d at 605 (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)); *see Glassman v. Arlington Cty.*, 628 F.3d 140, 146 (4th Cir. 2010). "A court decides whether [the pleading] standard is met by separating the legal conclusions from the factual allegations, assuming the truth of only the factual allegations, and then determining whether those allegations allow the court to reasonably infer" that the plaintiff is entitled to the legal remedy sought. *A Society Without a Name v. Virginia*, 655 F.3d 342, 346 (4th. Cir. 2011), *cert. denied*, 566 U.S. 937 (2012).

Courts ordinarily do not "'resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses.'" *King v. Rubenstein*, 825 F.3d 206, 214 (4th Cir. 2016) (quoting *Edwards*, 178 F.3d at 243); *see Bing v. Brio Sys., LLC*, 959 F.3d 605, 616 (4th Cir. 2020) (citation omitted). But, "in the relatively rare circumstances where facts sufficient to rule on an affirmative defense are alleged in the complaint, the defense may be reached by a motion to dismiss filed under Rule 12(b)(6)." *Goodman v. Praxair, Inc.*, 494 F.3d 458, 464 (4th Cir.

2007) (en banc); *accord Pressley v. Tupperware Long Term Disability Plan*, 553 F.3d 334, 336 (4th Cir. 2009). Because Rule 12(b)(6) "is intended [only] to test the legal adequacy of the complaint," *Richmond, Fredericksburg & Potomac R.R. Co. v. Forst*, 4 F.3d 244, 250 (4th Cir. 1993), "[t]his principle only applies . . . if all facts necessary to the affirmative defense 'clearly appear[ ] *on the face of the complaint.*'" *Goodman*, 494 F.3d at 464 (emphasis in *Goodman*) (quoting *Forst*, 4 F.3d at 250).

"Generally, when a defendant moves to dismiss a complaint under Rule 12(b)(6), courts are limited to considering the sufficiency of allegations set forth in the complaint and the 'documents attached or incorporated into the complaint.'" *Zak v. Chelsea Therapeutics Int'l, Ltd.*, 780 F.3d 597, 606 (4th Cir. 2015) (quoting *E.I. du Pont de Nemours & Co.*, 637 F.3d at 448). Ordinarily, the court "may not consider any documents that are outside of the complaint, or not expressly incorporated therein . . . ." *Clatterbuck v. City of Charlottesville*, 708 F.3d 549, 557 (4th Cir. 2013); *see Bosiger v. U.S. Airways, Inc.*, 510 F.3d 442, 450 (4th Cir. 2007).

But, under limited circumstances, when resolving a Rule 12(b)(6) motion, a court may consider documents beyond the complaint without converting the motion to dismiss to one for summary judgment. *Goldfarb v. Mayor & City Council of Balt.*, 791 F.3d 500, 508 (4th Cir. 2015). In particular, a court may properly consider documents that are "explicitly incorporated into the complaint by reference and those attached to the complaint as exhibits." *Goines*, 822 F.3d at 166 (citation omitted); *see also Six v. Generations Fed. Credit Union*, 891 F.3d 508, 512 (4th Cir. 2018); *Anand v. Ocwen Loan Servicing, LLC*, 754 F.3d 195, 198 (4th Cir. 2014); *U.S. ex rel. Oberg v. Pa. Higher Educ. Assistance Agency*, 745 F.3d 131, 136 (4th Cir. 2014); *Am. Chiropractic Ass'n v. Trigon Healthcare, Inc.*, 367 F.3d 212, 234 (4th Cir. 2004), *cert. denied*, 543 U.S. 979 (2004); *Phillips v. LCI Int'l Inc.*, 190 F.3d 609, 618 (4th Cir. 1999).

However, "before treating the contents of an attached or incorporated document as true, the district court should consider the nature of the document and why the plaintiff attached it." *Goines*, 822 F.3d at 167 (citing *N. Ind. Gun & Outdoor Shows, Inc. v. City of S. Bend*, 163 F.3d 449, 455 (7th Cir. 1998)). Of import here, "[w]hen the plaintiff attaches or incorporates a document upon which his claim is based, or when the complaint otherwise shows that the plaintiff has adopted the contents of the document, crediting the document over conflicting allegations in the complaint is proper." *Goines*, 822 F.3d at 167. Conversely, "where the plaintiff attaches or incorporates a document for purposes other than the truthfulness of the document, it is inappropriate to treat the contents of that document as true." *Id.*

A court may also "consider a document submitted by the movant that [is] not attached to or expressly incorporated in a complaint, so long as the document was integral to the complaint and there is no dispute about the document's authenticity." *Goines*, 822 F.3d at 166 (citations omitted); *see also Woods v. City of Greensboro*, 855 F.3d 639, 642 (4th Cir. 2017), *cert. denied*, __ U.S. __, 138 S. Ct. 558 (2017); *Oberg*, 745 F.3d at 136; *Kensington Volunteer Fire Dep't. v. Montgomery Cty.*, 684 F.3d 462, 467 (4th Cir. 2012). To be "integral," a document must be one "that by its 'very existence, *and not the mere information it contains*, gives rise to the legal rights asserted.'" *Chesapeake Bay Found., Inc. v. Severstal Sparrows Point, LLC*, 794 F. Supp. 2d 602, 611 (D. Md. 2011) (citation omitted) (emphasis in original). *See also* Fed. R. Civ. P. 10(c) ("A copy of a written instrument that is an exhibit to a pleading is a part of the pleading for all purposes.").

In addition, "a court may properly take judicial notice of 'matters of public record' and other information that, under Federal Rule of Evidence 201, constitute 'adjudicative facts.'" *Goldfarb*, 791 F.3d at 508; *see also Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308,

322 (2007); *Katyle v. Penn Nat'l Gaming, Inc.,* 637 F.3d 462, 466 (4th Cir. 2011), *cert. denied*, 565 U.S. 825 (2011); *Philips v. Pitt Cty. Mem. Hosp.*, 572 F.3d 176, 180 (4th Cir. 2009). However, under Fed. R. Evid. 201, a court may take judicial notice of adjudicative facts only if they are "not subject to reasonable dispute," in that they are "(1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned."

As indicated, the Motion is supported by one exhibit: the Rebate Agreement (ECF 72-2). The Opposition is supported by five exhibits, which include the Rebate Agreement (ECF 79-1); a letter from defendant to CMS dated Feb. 20, 2007, regarding the 2006 proposed rule (ECF 79-2); the final regulations issued by CMS, 42 C.F.R. §447.505 (2007) (ECF 79-3); a document listing the amendments to 42 U.S.C. § 1396r-8 (ECF 79-4); and CMS's proposed rule, 72 Fed. Reg. 39,142-01 (2006) (ECF 79-5). As noted, Relator also submitted the Rebate Agreement. ECF 79-1. It is central to Relator's claim and referenced in the Amended Complaint. Accordingly, I may consider the Rebate Agreement without converting the Motion to one for summary judgment. The letter (ECF 79-2), amendments to the statute (ECF 79-4), and proposed and final rules (ECF 79-3; ECF 79-5) are publicly available. Accordingly, I may take judicial notice of them.

The Reply contains five exhibits, which include the CMS Program Release No. 2, dated Aug. 9, 1991 (ECF 82-1); CMS Program Release No. 14, dated Dec. 21, 1994 (ECF 82-2); a letter from Reed Smith to CMS, dated Feb. 20, 2007 (ECF 82-3); a letter from Covington & Burling to CMS, dated Feb. 20, 2007 (ECF 82-4); and a letter from PhRMA to CMS, dated Feb. 20, 2017 (ECF 82-5). All of these documents are publicly available and their authenticity is not contested. Therefore, I may consider them in resolving the Motion.

B. Rule 9(b)

Rule 9(b) states: "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Suits brought under the False Claims Act sound in fraud, and thus are "subject to" Fed. R. Civ. P. 9(b). *See Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 783-84 (4th Cir. 1999). In addition, "Rule 9(b)'s heightened pleading standard applies to state law fraud claims asserted in federal court." *N. Am. Catholic Educ. Programming Found., Inc. v. Cardinale*, 567 F.3d 8, 13 (1st Cir. 2009). Therefore, Rule 9(b) governs the adequacy of Relator's state law *qui tam* claims as well as his claims under the FCA.

Under Rule 9(b), a claim that sounds in fraud "'must, at a minimum, describe the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby.'" *United States ex rel. Nathan v. Takeda Pharms. N.A., Inc.*, 707 F.3d 451, 455 (4th Cir. 2013) (citation omitted); *see United States ex rel. Owens v. First Kuwaiti Gen'l Trading & Contracting Co.*, 612 F.3d 724, 731 (4th Cir. 2010). In other words, Rule 9(b) requires the plaintiff to plead "the who, what, when, where, and how of the alleged fraud" before the parties can proceed to discovery. *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 379 (4th Cir. 2008) (internal quotation marks and citation omitted).

Rule 9(b) serves several salutary purposes:

> "First, the rule ensures that the defendant has sufficient information to formulate a defense by putting it on notice of the conduct complained of. . . . Second, Rule 9(b) exists to protect defendants from frivolous suits. A third reason for the rule is to eliminate fraud actions in which all the facts are learned after discovery. Finally, Rule 9(b) protects defendants from harm to their goodwill and reputation."

Harrison, 176 F.3d at 784 (citation omitted).

The "'clear intent of Rule 9(b) is to eliminate fraud actions in which all the facts are learned through discovery after the complaint is filed.'" *Id.* at 789 (citation omitted); *see Wilson*, 525 F.3d at 380 ("[I]f allowed to go forward, Relators' FCA claim would have to rest primarily on facts learned through the costly process of discovery. This is precisely what Rule 9(b) seeks to prevent.").

However, by its plain text, Rule 9(b) permits general averment of aspects of fraud that relate to a defendant's state of mind. "A court should hesitate to dismiss a complaint under Rule 9(b) if the court is satisfied (1) that the defendant has been made aware of the particular circumstances for which she will have to prepare a defense at trial, and (2) that plaintiff has substantial prediscovery evidence of those facts." *Id.* Moreover, Rule 9(b) is "less strictly applied with respect to claims of fraud by concealment" or omission of material facts, as opposed to affirmative misrepresentations, because "an omission 'cannot be described in terms of place, contents of the misrepresentation or the identity of the person making the misrepresentation." *Shaw v. Brown & Williamson Tobacco Corp*., 973 F. Supp. 539, 552 (D. Md. 1997) (quoting *Flynn v. Everything Yogurt*, HAR-92-3421, 1993 WL 454355, at *9 (D. Md. Sept. 14, 1993)).

III. Discussion

Defendant has moved to dismiss the Relator's FCA claims on four grounds. First, defendant urges dismissal of the Amended Complaint pursuant to Fed. R. Civ. P. 12(b)(6), "because Relator has not plausibly alleged that Forest made a false statement or that it acted with the requisite scienter," as required by the federal and state FCA statutes. ECF 72-1 at 18-33. Second, defendant maintains that Relator's suit warrants dismissal under Fed. R. Civ. P. 9(b) because Relator failed to plead fraud with sufficient particularity. *Id.* at 34-36. Further, defendant argues that Relator's FCA conspiracy claim (Count III) fails because Relator did not

allege an agreement to violate the FCA and the alleged coconspirators are both Forest entities. *Id.* at 37. Finally, defendant contends that Relator's FCA claims are foreclosed by the FCA's public disclosure bar. *Id.* at 38-44.

Relator concedes that the federal conspiracy claim (Count III) and claims under New Hampshire's FCA are subject to dismissal. ECF 79 at 43 n.16. But, Relator contends that defendant's remaining arguments are unavailing. *See* ECF 79.

The question concerning the public disclosure bar is a threshold matter. Therefore, I first consider defendant's last contention.

A. Public Disclosure Bar

Defendant contends that the Relator's claims are foreclosed by the FCA's public disclosure bar. ECF 72-1 at 38-44.

As noted, the FCA protects the government fisc by "impos[ing] civil liability on persons who knowingly submit false claims for goods and services to the United States." *United States ex rel. Beauchamp v. Academi Training Ctr.*, 816 F.3d 37, 39 (4th Cir. 2016); *see United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 700 (4th Cir. 2014), *cert. denied*, 574 U.S. 819 (2014). In order to prevent fraud that might otherwise evade detection and to supplement government enforcement, the FCA permits a private individual, *i.e.*, a relator, to file a civil lawsuit on behalf of the government against those who defraud the federal government. *Id.* To encourage such suits, the statute allows the relator to collect a portion of the recovery as a reward. *See* 31 U.S.C. § 3730(b).

But, a *qui tam* suit is of no help to the government if the alleged fraud has already been uncovered. *Graham Cty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 294-95 (2010). Thus, since enacting the FCA in 1863, Congress has repeatedly

amended the statute in an effort "to strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits' in which a relator, instead of plowing new ground, attempts to free-ride by merely reiterating previously disclosed fraudulent acts.'" *Beauchamp*, 816 F.3d at 39 (quoting *Graham Cty. Soil & Water*, 559 U.S. at 295).

One such mechanism is the FCA's public disclosure bar. *See* 31 U.S.C. § 3730(e)(4)(A) (1986), amended by Patient Protection & Affordable Care Act, Pub. L. No. 111-148, § 10104(j)(2), 124 Stat. 119, 901-02 (2010); *see also State Farm Fire & Cas. Co. v. United States ex rel. Rigsby*, ___ U.S. ___, 137 S. Ct. 436, 440 (2016) (describing the public disclosure bar as a threshold that a relator must clear in order to proceed on a *qui tam* suit). The provision "disqualifies private suits based on fraud already disclosed in particular settings—such as hearings, government reports, or news reports—unless the relator meets the definition of an 'original source' under the FCA." *Beauchamp*, 816 F.3d at 39 (quoting 31 U.S.C. § 3730(e)(4)); *see United States ex rel. Siller v. Becton Dickenson & Co.*, 21 F.3d 1339, 1347 (4th Cir. 1994).

This case implicates two versions of the public disclosure bar, which Congress amended in 2010. Notably, the FCA does not have retroactive force and therefore may not be applied to cases arising before the effective date of the amendments. *Graham Cty. Soil & Water*, 559 U.S. at 283 n.1; *United States ex rel. May v. Purdue Pharma L.P.*, 737 F.3d 908, 918 (4th Cir. 2013).

Prior to 2010, the statute provided, 31 U.S.C. § 3730(e)(4)(A) (1986):

> No court shall have jurisdiction over an action under this section based upon the public disclosure of 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, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

Notably, the pre-2010 version of the statute "operated as a jurisdictional limitation—the public-disclosure bar, if applicable, divested the district court of subject-matter jurisdiction over the action." *May*, 737 F.3d at 916; *see Beauchamp*, 816 F.3d at 39.

In 2010, Congress amended the public disclosure bar as part of the Patient Protection and Affordable Care Act. *See* Pub. L. No. 111-148, § 10104(j)(2), 124 Stat. 119, 901-02 (2010). Effective March 23, 2010, the operative public disclosure provision states, 31 U.S.C. § 3730(e)(4)(A) (2010):

> 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.

The "original source" definition was also amended. Under § 3730(e)(4)(B), it includes 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) 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.

These amendments "significantly changed the scope of the public-disclosure bar." *May*, 737 F.3d at 917. Notably, unlike the pre-2010 public disclosure bar, the current provision is not jurisdictional. Instead, it operates, in effect, as "an affirmative defense." *Beauchamp*, 816 F.3d at 40; *see May*, 737 F.3d at 916. The amendment also "changed the required connection between

the [relator's] claims and the public disclosure." *Beauchamp*, 816 F.3d at 40. Whereas the public disclosure bar previously foreclosed claims only when the relator's suit was based on the public disclosure, the current provision "'no longer requires actual knowledge of the public disclosure, but instead applies if substantially the same allegations or transactions were publicly disclosed.'" *Beauchamp*, 816 F.3d at 40 (quoting *May*, 737 F.3d at 917).

Despite these differences, both versions of the statute require the Court to ask three questions: (1) is there a qualifying public disclosure? (2) if yes, is the disclosed information the basis of the relator's suit? (3) and, if so, is the relator the original source of that information? *United States ex rel. Wilson v. Graham Cty. Soil & Water Conservation Dist.*, 528 F.3d 292, 308 (4th Cir. 2008), *rev'd on other grounds*, 559 U.S. 280 (2010); *see United States ex rel. Moore v. Cardinal Fin. Co., L.P.*, CCB-12-1824, 2017 WL 1165952, at *10 (D. Md. Mar. 28, 2017); *United States ex rel. Davis v. Prince*, 753 F. Supp. 2d 569, 579 (E.D. Va. 2011).

Forest asserts that Relator's claims are barred under either version of the statute, because the factual allegations underlying his suit are based on publicly available sources and he is not the original source of those disclosures. ECF 72-1 at 39-44. Specifically, defendant contends that Relator's claims were inferred from publicly disclosed federal regulations, administrative reports, and sales data. *Id.* at 39-41.

In response, Relator argues that there has not been a qualifying public disclosure of his allegations within the meaning of § 3730(e)(4)(A). ECF 79 at 37-39. Further, Relator posits that his allegations were not "based upon" or "substantially the same" as any public disclosure, *id.* at 40-41, and he qualifies as the original source of the information. *Id.* at 42-43.

As a threshold matter, the bar does not apply unless the fraud alleged by the Relator was disclosed to the public in a source enumerated in the statute. *See United States v. Meridian*

Senior Living, LLC, 5:16-CV-410-BO, 2018 WL 1463347, at *8 (E.D.N.C. Mar. 23, 2018); *Davis*, 753 F. Supp. 2d at 579. The disclosure "must be a disclosure of fraudulent 'allegations or transactions' and not merely a disclosure of information." *See A1 Procurement, LLC v. Thermcor, Inc.*, No. 2:15-00015, 2017 WL 9478501, at *8 (E.D. Va. Apr. 4, 2017) (*citing United States ex rel. Saunders v. Unisys Corp.*, No. 1:12-00379, 2014 WL 1165869, at *1, *6 (E.D. Va. Mar. 21, 2014)).

The D.C. Circuit's analysis of whether a disclosure is an allegation or a transaction provides useful guidance with respect to distinguishing a fraudulent allegation or transaction from mere information. *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 654 (D.C. Cir. 1994) (emphasis in original):

> [I]f X + Y = Z, Z represents the *allegation* of fraud and X and Y represent its essential elements. In order to disclose the fraudulent *transaction* publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, *i.e.*, the conclusion that fraud has been committed. The language employed in § 3730(e)(4)(A) suggests that Congress sought to prohibit *qui tam* actions *only* when either the allegation of fraud or the critical elements of the fraudulent transaction themselves were in the public domain.

See also United States ex rel. Digital Healthcare, Inc. v. Affiliated Computer Services, Inc., 778 F. Supp. 2d 37, 46 (D.D.C. 2011); *United States ex rel. Ven-A-Care v. Actavis Mid Atlantic LLC*, 659 F. Supp. 2d 262, 267 (D. Mass. 2009).

Although the sources that Relator cites reveal important background information, the information does not rise to the level of "allegations or transactions" as contemplated by § 3730(e)(4)(A). *See Digital Healthcare*, 778 F. Supp. 2d at 49 (finding claims not barred by public disclosure requirement where GAO reports on which plaintiff relied were devoid of any allegations of fraud or wrongdoing by anyone). The Relator cites a GAO report, CMS regulations and guidance documents, publicly submitted letters from the CMS rulemaking

process, and sales data. ECF 16, ¶¶ 13-53. These documents lack any suggestion of fraudulent activity by Forest or anyone else. Most of these documents merely note the various reporting requirements or the confusion about certain requirements.

Based on Relator's allegations, the 2005 GAO report and CMS rulemaking comments, at most, note that some drug manufacturers differed in how they were calculating Best Price. *See* ECF 16 at 27-35. But, they stop short of making an allegation of fraud or improper conduct. *See Digital Healthcare*, 778 F. Supp. 2d at 50 (finding GAO report expressing dissatisfaction with entities in defendant's industry does not reveal any allegations against defendant); *see also Davis*, 753 F. Supp. 2d at 586 ("To be sure, the audit report clearly expresses dissatisfaction with the fact that Blackwater does not require its employees to fill out time sheets in which they certify the number of hours worked each day, but there is no allegation of fraud or wrongdoing by anyone."); *Ven-A-Care*, 659 F. Supp. 2d at 267 (finding that even though government reports establish that Medicaid was paying too much for drugs, the reports did not "broadcast" an allegation of fraud because there was no discussion of the reasons for the overcharge or any suggestion of wrongdoing by the defendants).

Further, although the public sales data, containing rebate percentages and price points, may have disclosed the "allegedly false set of facts," they do not identify the allegedly true set of facts that Relator alleges Forest should have reported to the government. *Ven-A-Care*, 659 F. Supp. 2d at 267. Most important, both the sales data and government documents fail to disclose the central issue in this case, *i.e.*, whether Forest's Best Price violated the requirements of the Rebate Statute.

Therefore, the public disclosure bar does not apply to Relator's Amended Complaint because the claims are not based on, or substantially similar to, any allegations or transactions

that were publicly disclosed. Having made this determination, the Court need not consider whether the Relator was the "original source" of the information. *See Springfield*, 14 F.3d at 651.

Accordingly, the public disclosure bar does not warrant dismissal of the suit.

B. Rule 12(b)(6)

Relator alleges that Forest willfully failed to report rebates properly, as required by the Medicaid Drug Rebate Statute, and seeks damages and civil penalties under four Subsections of two versions of the FCA: 31 U.S.C. §§ 3729(a)(1), (a)(2), (a)(3), (a)(7) from the 1990 version and 31 U.S.C. §§ 3729(a)(1)(A), (a)(1)(B), (a)(1)(C), and (a)(1)(G) from the 2009 version,[10] as well as the related state statutes.

To state a claim under all of the statutory provisions of the FCA under which Sheldon alleges liability, he must allege sufficient facts by which the Court could plausibly infer that (1) defendant made false statements or engaged in a fraudulent course of conduct; (2) with the requisite knowledge; (3) the statements or conduct were material; and (4) caused the government to pay out money or to forfeit monies due on a "claim." *See Omnicare, Inc.*, 745 F.3d at 700 (quoting *Harrison*, 176 F.3d at 788). The parties dispute the first two elements of his claim.

"To satisfy the first element of an FCA claim, the statement of conduct alleged must represent an objective falsehood." *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376-77 (4th Cir. 2008) (citations omitted); *see United States ex rel. Hixson v.*

[10] On May 20, 2009, Congress amended the FCA by passing the Fraud Enforcement and Recovery Act of 2009 ("FERA"), PL 111–21, 123 Stat 1617. FERA changed the numbering of 31 U.S.C. § 3729(a) and also changed the language of the statute to include an express materiality requirement for the false record provisions in § 3729(a)(2) and to change the definition of "obligation" in § 3729(a)(7). Relator brings his claims under both versions of the Statute.

Health Mgmt. Sys., Inc., 613 F.3d 1186, 1191 (8th Cir. 2010) ("As we have said, to prevail here the relators must show that there is no reasonable interpretation of the law that would make the allegedly false statement true."). Notably, "'imprecise statements or differences in interpretation growing out of a disputed legal question are [ ] not false under the FCA.'" *Wilson*, 525 F.3d at 377 (quoting *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999)); *see also Wilson*, 525 F.3d at 378 ("An FCA relator cannot base a fraud claim on nothing more than his own interpretation of an imprecise contractual provision.").

Under the second element, the FCA imposes liability only when a person "knowingly" makes a false claim to the government. 31 U.S.C. § 3279(a)(1)(A). "Knowing" and "knowingly" mean that the person (1) has actual knowledge of the falsity of information; (2) acts in deliberate ignorance of the truth or falsity of the information provided; or (3) acts in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b); *see United States ex rel. Complin v. North Carolina Baptist Hospital*, 818 F. App'x 179, 182 (4th Cir. 2020). The scienter requirement is "'rigorous'" and constitutes a "key element of an FCA claim," even at the motion to dismiss stage. *Complin*, 818 F. App'x at 183 (quoting *Universal Health Servs., Inc., v. United States*, __ U.S. __, 136 S. Ct. 1989, 2002 (2016)); *see also Complin*, 818 F. App'x at 183 n.5 (noting scienter may be resolved on a motion to dismiss).

Of relevance here, "'honest mistakes or incorrect claims submitted through mere negligence' are not enough" to satisfy the scienter requirement. *Complin*, 818 F. App'x at 184 (quoting *United States ex rel. Owens v. First Kuwaiti Gen. Trading & Contracting Co.*, 612 F.3d 724, 728 (4th Cir. 2010)). "Consistent with the need for a knowing violation, the FCA does not reach an innocent, good-faith mistake about the meaning of an applicable rule or regulation. Nor does it reach those claims based on reasonable but erroneous interpretations of a defendant's

legal obligations." *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 287-88 (D.C. Cir. 2015) (recognizing the defense of reasonable but erroneous interpretation of ambiguous statute) (citing *Oliver*, 195 F. 3d at 463-64).

"[E]stablishing 'even the loosest standard of knowledge, i.e., acting in reckless disregard of the truth or falsity of the information'" is difficult when falsity turns on a disputed interpretive question. *Purcell*, 807 F.3d at 288 (quoting *United States ex rel. Siewick v. Jamieson Sci. & Eng'g, Inc.*, 214 F.3d 1372, 1378 (D.C. Cir. 2000) (quoting 31 U.S.C. § 3279(b)(3))). Therefore, "'[w]here there are legitimate grounds for disagreement over the scope of a … regulatory provision, and the claimant's actions are in good faith, the claimant cannot be said to have knowingly presented a false claim.'" *United States ex rel. Kirk v. Schindler Elevator Corp.*, 130 F. Supp. 3d 866, 877 (S.D.N.Y. 2015) (quoting *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 684 (5th Cir. 2003) (en banc) (Jones, J., concurring)).

Moreover, even if a court determines that a defendant's interpretation of the statute or contract at issue is erroneous, it should consider "(1) whether the relevant statute was ambiguous; (2) whether a defendant's interpretation of that ambiguity was objectively unreasonable; and (3) whether a defendant was 'warned away' from that interpretation by available administrative and judicial guidance." *United States v. Allergan, Inc.*, 746 F. App'x 101, 106 (3rd Cir. 2018) (quoting *Purcell*, 807 F.3d at 288).

The first two elements of an FCA claim may be considered together because "it is impossible to meaningfully discuss falsity without implicating the knowledge requirement." *Lamers*, 168 F.3d at 1018; *see also United States v. Savannah River Nuclear Solutions, LLC*, No. 16-00825, 2016 WL 7104823, at *13 (D. S.C. Dec. 6, 2016) (noting that assessing whether there is an objective falsehood is "better assessed under the scienter requirement"). And, whether

there was a "false statement or fraudulent course of conduct," and whether it was "made or carried out with the requisite scienter," depends on the interpretation of the Rebate Statute, which implicates principles of statutory construction.

In general, the task of interpreting a statute starts with the text. *Murphy v. Smith*, __ U.S. ___, 138 S. Ct. 784, 787 (2018) ("As always, we start with the specific statutory language in dispute."); *see also Hixson*, 613 F.3d at 1190-91 (affirming dismissal of FCA claim because "plain language" of statute and legislative intent confirmed that "the defendant's interpretation of the applicable law is a reasonable interpretation"). To ascertain a statute's meaning, "'the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.'" *Gundy v. United States*, ___ U.S. ___, 139 S. Ct. 2116, 2126 (2019) (quoting *Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 666 (2007)). Terms that are not defined are "'interpreted as taking their ordinary, contemporary, common meaning.'" *Sandifer v. U.S. Steel Corp.*, 571 U.S. 220, 227 (2014) (citation omitted); *accord United States v. George*, 946 F.3d 643, 645 (4th Cir. 2020).

Of relevance here, courts may consult dictionaries to discern a term's "'plain or common meaning.'" *In re Construction Supervision Services, Inc.*, 753 F.3d 124, 128 (4th Cir. 2014) (quoting *Blakely v. Wards*, 738 F.3d 607, 611 (4th Cir. 2013) (internal citations omitted)). Courts may also consider a statute's history and purpose to give effect to its language. *See Gundy*, 139 S. Ct. at 2126. However, courts may "not resort to legislative history to cloud a statutory text that is clear." *Ratzlaf v. United States*, 510 U.S. 135, 147-48 (1994); *see Raplee v. United States*, 842 F.3d 328, 332 (4th Cir. 2016) ("If the meaning of the text is plain . . . that meaning controls.").

Defendant argues that the Court should dismiss the Amended Complaint under Fed. R. Civ. P. 12(b)(6) because Relator fails plausibly to allege that Forest made a false statement or that it acted with the requisite scienter. ECF 72-1 at 11, 18-33. Forest insists that, under the Rebate Statute, it was not legally required to "aggregate rebates provided to different unrelated customers in calculating Best Price" and therefore Forest's failure to aggregate such prices could not, "as a matter of law, have rendered its government pricing submissions false." *Id.* at 11. Further, defendant contends that, "even if the Court were to conclude that Forest misinterpreted the Medicaid statute and regulations, Relator cannot plausibly plead falsity or scienter because Forest's interpretation was objectively reasonable." *Id.* at 12. In contrast, Relator avers that the Rebate Statute unambiguously requires manufacturers like Forest to aggregate all rebates paid to all entities along the distribution chain to "arrive at the net lowest 'best price' that is actually realized." ECF 16 at 7-8.

"Best Price" is defined in the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8(c)(1)(C)(i) (emphasis added):

> [T]he lowest price *available from* the manufacturer during the rebate period to *any wholesaler, retailer, provider, health maintenance organization, nonprofit entity,* or governmental entity within the United States, excluding [certain governmental entities not applicable to this case.].

Further, the Rebate Statute provides that Best Price "shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates" that reduce the manufacturer's price to a Best Price eligible entity. 42 U.S.C. § 1396r-8(c)(1)(C)(ii).

Using the tools of statutory construction, I conclude that the Rebate Statute may be susceptible to multiple interpretations, including Relator's construction. But, defendant also alleges a plausible and objectively reasonable interpretation. Accordingly, the Relator failed

adequately to plead that Forest made claims that can be deemed "false" within the meaning of the FCA.

Looking at the statutory text, the plain and natural reading of the provision is that Best Price means the lowest price made available by the manufacturer, including all price concessions, to any one of the listed entities, but not to multiple entities. This reading is reinforced when contrasted with the definition of Average Manufacturer Price ("AMP"). The AMP is defined as "the average price *paid to* the manufacturer for the drug in the United States." 42 U.S.C. § 1396r-8(k)(1)(A) (emphasis added). And, based on that definition, the AMP is generally understood as requiring manufacturers to "'stack' price concessions provided to any single best price-eligible entity on a single unit of a product." 81 Fed. Reg. 5170-01, 5252 (Feb. 1, 2016). Therefore, Congress's choice to use "available from the manufacturer" in the Best Price definition, as opposed to "paid to the manufacturer," as used in the AMP definition, bears some significance. *See Barnhart v. Sigmon Coal Co., Inc.*, 534 U.S. 438, 452-53 (2002) (observing the "general principal of statutory construction that when Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion") (internal quotation marks and citations omitted).

The linguistic difference between the definition of AMP and Best Price indicates that Congress knew what language to use to indicate a requirement for manufacturers to aggregate discounts from multiple transactions. Yet, it chose not to use that language in the definition of Best Price. *Soliman v. Gonzalez*, 419 F.3d 276, 283 (4th Cir. 2005) (citing *United States v. Nordic Village*, 503 U.S. 30, 36 (1992)) ("Where Congress has utilized distinct terms within the

same statute, the applicable cannons of statutory construction require that [courts] endeavor to give different meanings to those different terms.").

However, the language of the Rebate Statute is not so precise that it is not susceptible to other interpretations, particularly with respect to its use of "any," as used in "any wholesaler, retailer, nonprofit entity, or governmental entity…." Therefore, the Court cannot end its inquiry here.

Relator urges the Court to give an "expansive meaning" to the word "any." ECF 79 at 15-16. According to Relator, both the Supreme Court and the Fourth Circuit have interpreted the word "any" to mean "all." *Id.* at 16 (citing *SAS Inst., Inc., v. Iancu*, __ U.S. __, 138 S. Ct. 1348 (2018); *Ali v. Federal Bureau of Prisons*, 552 U.S. 214, 218-19 (2008); *United States v. Maxwell*, 285 F.3d 336 (4th Cir. 2002); *Mapoy v. Carroll*, 185 F.3d 224, 229 (4th Cir. 1999); *Alexander S. v. Boyd*, 113 F.3d 1373, 1383 (4th Cir. 1997)). Therefore, he concludes that the word "any" in the context it is used here means the aggregation of *all* entities along the distribution chain. ECF 79 at 17.

To be sure, the term "any" can carry "an expansive meaning." *SAS*, 138 S. Ct. at 1354 (internal citation omitted). But, as defendant points out, the modifier "any" can also mean "different things depending upon the setting." ECF 82 at 9 (citing *Nixon v. Missouri Municipal League*, 541 U.S. 125, 126 (2004)); *see United States v. Dunford*, 148 F.3d 385, 389 (4th Cir. 1998) (noting that the word "any" may mean a single item if "used in [the] context of [a] singular noun"). And, the dictionary definition does not provide more clarity as to its meaning; the Oxford English Dictionary defines "any" as being "used to refer to an unspecified member of a particular class." *Oxford English Dictionary*, OED.COM, https://www.oed.com/view/Entry/8973?redirectedFrom=any#eid (last visited September 8,

2020). Therefore, although Relator's reading of the term "any" is not definitive, as he avers, it is also not implausible.

Looking beyond the text, the regulatory language interpreting the Rebate Statute and related CMS releases can be read to support the viewpoints of both Relator and defendant. For instance, in the Rebate Agreement, CMS states: "The best price for a quarter shall be adjusted by the Manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized." ECF 72-2 at 3; ECF 16, ¶ 30. Moreover, the CMS release from 1991 states, for example, that the Best Price should "reflect the impact of cumulative discounts or other arrangements on the prices actually realized in any quarter." ECF 16, ¶ 36; ECF 82-1 at 3. And, the 1994 release states that "AMP and best price data… 'must be adjusted by the Manufacturer if … other arrangements subsequently adjust the prices actually realized.'" ECF 82-2 at 2; ECF 16, ¶ 37.

Relator focuses on CMS's use of the phrase "actually realized" in each of those texts and alleges that the language "makes clear" that the Best Price "is the final lowest price a manufacturer receives for a single drug unit (*e.g.*, per pill) after taking into account any and all pricing arrangements with any and all entities." ECF 16, ¶ 31; ECF 79 at 11. In contrast, defendant argues that "price actually realized" means the price "the manufacturer realizes on a sale to an individual customer, after accounting for all price concessions provided to that customer, whether realized at the time of sale or at a later date." ECF 82 at 11. Both interpretations seem plausible.

However, the final rule issued by CMS in 2007 complicates Relator's position. The rule states: "The manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the *prices available from the manufacturer*."

42 C.F.R. § 447.505 (2007) (emphasis added); ECF 82 at 13. Notably, CMS used the phrase "prices available from the manufacturer," *id.*, instead of the "price actually realized by the manufacturer," as used in the Rebate Agreement. ECF 72-2 at 3. The fact that CMS seems to use these two phrases interchangeably weakens Relator's argument because he relies on CMS's use of "price actually realized" to support his interpretation calling for an aggregation of multiple price concessions.

The absence of clear or consistent language in the relevant texts gives me pause; I cannot conclude that the Best Price provision unambiguously refers to cumulative rebates from all entities. Moreover, the other sources on which Relator relies to support his interpretation of the Rebate Statute—legislative history, CMS and manufacturer comments from the rulemaking, and a 2005 GAO report[11]—merely demonstrate some ambiguities and some specific technical requirements, but do not unequivocally support Relator's reading.

First, the legislative history clarifies that Medicaid "should have the benefit of the same discounts on single source drugs that other large public and private consumers enjoy." H.R. Rep. No. 101-881 (1990), *as reprinted in* 1990 U.S.C.C.A.N. 2017, 2108. And, it confirms that the purpose of the Rebate Statute is to "give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser." *Id.* If anything, this supports defendant's reading that the Best Price is the lowest price that a manufacturer makes available to any particular purchaser in order to put Medicaid on the same footing as a manufacturer's lowest paying customer, not a combination of its customers. *See* ECF 72-1 at 22.

[11] Relator also refers to CMS's guidance and comments from 2016 in the Amended Complaint. *See* ECF 16, ¶ 53. Because Relator's allegations concern Forest's price reporting between 2005 and 2014, the 2016 commentary is not relevant with respect to Forest's alleged obligations. Accordingly, I have not considered it in my analysis.

Second, the examples Relator provides in the Amended Complaint from the 2006 rulemaking process suffer from being cherry-picked and are not entirely comparable to Forest's alleged situation. In the example that is most analogous, the "commenter requested that when best price is determined, customary prompt pay discounts extended to wholesalers should not be aggregated with price concessions available to an end-customer under a contract administered through a wholesaler chargeback arrangement." ECF 79-3 at 97; ECF 16, ¶ 45. And, CMS responded by explaining: "Both the customary prompt pay discounts and other price concessions available to the end-customer are to be included in the determination of best price." *Id.*

However, the situation described in this example is not directly analogous to Forest's situation. Rather, it is specific to a situation involving a wholesaler chargeback arrangement. In a wholesaler chargeback arrangement, "the wholesaler delivers the product to the favored purchaser at the discounted price and then 'charges back' the manufacturer for the difference between the price paid by the wholesaler and the lower price at which it was delivered." *In re Brand Name Prescription Drugs Antitrust Litig.*, No. 94-cv-897, 1996 WL 167350, at *2 (N.D. Ill. Apr. 4, 1996). In that arrangement, the different price concessions to the end-customer both actually function as price concessions to the single entity–the wholesaler. Therefore, CMS's instruction did not actually clarify whether there is a requirement to aggregate concessions from multiple entities in separate arrangements.

Relator's other examples are similarly unconvincing. Indeed, Relator has not pointed to a single example where CMS explicitly states that manufacturers must aggregate discounts to different customers along the supply chain in a given sale.

Finally, the letters from Forest and other drug manufacturers during the CMS rulemaking process suggest that there was some confusion over the language in the proposed rule concerning

Best Price. But, the letters also indicate widespread agreement among the manufacturers over how to calculate Best Price based on the guidance they had received up to that point. In particular, the letters reflect a shared industry understanding that the Best Price "has always been interpreted to mean the single lowest price to a particular customer…." ECF 79-2 at 21; ECF 82 at 19. And, notably, none of the letters acknowledges a requirement, either from the previous guidance or the new proposed rule, to aggregate discounts to multiple entities. *See* ECF 79-2 at 14; ECF 82-3 at 10; ECF 82-4 at 7.

In sum, Relator's interpretation, along with some of the relevant guidance and commentary, indicates that there is some ambiguity in the Best Price provision of the Rebate Statute. However, Relator's interpretation of the Rebate Statute is not the only plausible reading of the text, and the allegations do not suggest that defendant's interpretation is objectively unreasonable. It follows that claims based on Forest's interpretation cannot qualify as objective falsehoods or constitute false statements under the FCA. *See Hixson,* 613 F.3d at 1190-91 (where FCA relators "based their allegation that the statements and the claims made to the government were false on a legal conclusion that federal law [required certain conduct by defendants, and] there is a reasonable interpretation of the law that does not obligate [that conduct],…the [relators] have not stated a claim under the FCA"); *United States ex rel. Raynor v. Nat'l Rural Utilities Co-op Finance Corp.,* No. 8:08-48, 2011 WL 976482, at *9 (D. Neb. Mar. 15, 2011) (finding relator failed to plead objective falsity because his "allegations are devoid of any indication that [his] characterization of [the rules] were the only acceptable method under the circumstances"); *see also Wilson,* 525 F.3d at 377.

Additionally, because Forest's interpretation is objectively reasonable, Relator cannot plausibly allege that Forest acted with the requisite scienter unless he can demonstrate that

defendant had been warned about its interpretation. And, because there is no judicial authority directly on point, the only question is whether Relator plausibly alleges that CMS regulations and guidance warned Forest away from the view it took. Although some of the guidance could be read to support Relator's interpretation, such as the CMS releases during the 1990s, the guidance was not so clear as to warn Forest away from its interpretation. *See Complin*, 818 F. App'x at 184 (affirming dismissal for failure to plead scienter because defendants adopted reasonable interpretation of Medicare regulations and were not warned away from it); *Purcell*, 807 F.3d at 288 (FCA does not reach "claims made based on [a defendant's] reasonable but erroneous interpretations of a defendant's legal obligations"); *Allergan, Inc.*, 746 F. App'x at 106 (affirming dismissal because administrative guidance did not warn defendants away from their interpretation and defendants' "reasonable interpretation of an ambiguous statute was inconsistent with the reckless disregard [relator] was required to allege at this stage in the litigation"); *see also United States ex rel. Johnson v. Golden Gate Nat'l Senior Care, L.L.C.*, 223 F. Supp. 3d 882, 891 (D. Minn. 2016) ("In short, if a regulation is ambiguous, a defendant may escape liability if its interpretation of the regulation was reasonable in light of available official guidance—even if the interpretation was 'opportunistic.'").

Moreover, instead of warning Forest away from its interpretation, CMS has accounted for the complexity of the Rebate Statute and price reporting requirements, and encourages manufacturers to make "reasonable assumptions" in calculating Best Price. ECF 72-1 at 14; ECF 72-2 at 7. *See Complin*, 818 F. App'x at 184 n.6 (affirming dismissal because the "complex and highly technical regulatory regime at issue" resulted in a "lack of clarity" as to the application of the rule and the non-precedential judicial decision was not enough to warn defendant away from an otherwise reasonable interpretation of the regulation) (internal

quotations omitted); *see also Allergan*, 746 F. App'x at 110 (in light of confusion regarding calculation of AMP, defendant was not warned away from its interpretation even if it was not the best interpretation of the statute).

Therefore, for the same reasons that Relator has failed to plead the existence of a false statement, he cannot plausibly allege that Forest acted with the requisite scienter when submitting Best Price reports to the government. And, because the states construe their FCA statutes in accordance with the federal FCA standards, Relator's state-based FCA claims fail for the same reasons that his federal FCA claim fails.

Accordingly, I shall grant the Motion as to all counts.

C. Rule 9(b)

As an alternative ground for dismissal, defendant argues that the Court should dismiss Relator's complaint for failure to adequately plead as required under Fed. R. Civ. P 9(b). ECF 72-1 at 34-36. In particular, defendant posits that Relator "pleads no facts related to Forest's actual prices to particular customers." *Id.* at 2.

As noted, fraud-based claims arising under the FCA must satisfy Rule 9(b)'s heightened pleading standard. *United States ex rel. Nathan v. Takeda Pharmaceuticals of North America, Inc.*, 707 F.3d 451, 455-56 (4th Cir. 2013). However, because I conclude that Relator failed to plead the existence of a false statement and the scienter required for an FCA claim, I do not address Forest's alternative argument that Relator did not allege a false claim with the requisite particularity under Rule 9(b). *Omnicare, Inc.*, 745 F.3d at 703 n.8 (noting that the court did not need to address defendant's alternative argument that relator did not allege a claim under Rule 9(b) because court conclude relator failed to plead the existence of a false statement and the scienter requirement required for an FCA claim); *Allergan*, 746 F. App'x at 110 (same).

IV. Conclusion

For the foregoing reasons, I shall grant the Motion (ECF 72). An Order follows, consistent with this Memorandum Opinion.

Date: November 5, 2020

_____/s/_____
Ellen L. Hollander
United States District Judge