PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 24-1793

UNITED STATES EX REL. DEBORAH SHELDON, Executrix of the Estate of Troy Sheldon, United States of America, ex rel.,

Plaintiff - Appellant,

v.

ALLERGAN SALES, LLC,

Defendant - Appellee.

THE ANTI-FRAUD COALITION,

Amicus Supporting Appellant.

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA; CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA,

Amici Supporting Appellee.

Appeal from the United States District Court for the District of Maryland, at Baltimore. Ellen Lipton Hollander, Senior District Judge. (1:14-cv-02535-ELH)

Argued: September 10, 2025 Decided: March 13, 2026

Before BENJAMIN and BERNER, Circuit Judges, and KEENAN, Senior Circuit Judge.

Reversed and remanded by published opinion. Judge Berner wrote the opinion, which Judge Benjamin joined. Judge Keenan wrote a dissenting opinion.

ARGUED: Joseph M. Callow, Jr., CALLOW + UTTER LAW GROUP, Cincinnati, Ohio, for Appellant. John Patrick Elwood, ARNOLD & PORTER KAYE SCHOLER LLP, Washington, D.C., for Appellee. **ON BRIEF:** Gregory M. Utter, CALLOW + UTTER LAW GROUP, Cincinnati, Ohio; Joel D. Hesch, THE HESCH FIRM, LLC, Lynchburg, Virginia, for Appellant. Michael E. Rogoff, Paul R. Ramer, New York, New York, Jeffrey L. Handwerker, Christian D. Sheehan, Elliot S. Rosenwald, ARNOLD & PORTER KAYE SCHOLER LLP, Washington, D.C., for Appellee. Jacklyn DeMar, THE ANTI-FRAUD COALITION, Washington, D.C.; Samuel J. Buffone, Jr., Michael DeJesus, BUFFONE LAW GROUP PLLC, Washington, D.C., for Amicus The Anti-Fraud Coalition. James C. Stansel, Melissa B. Kimmel, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Washington, D.C., for Amicus Pharmaceutical Research and Manufacturers of America. John C. O'Quinn, Caroline S. Milner, KIRKLAND & ELLIS LLP, Washington, D.C., for Amici Pharmaceutical Research and Manufacturers of America and the Chamber of Commerce of the United States of America. Andrew R. Varcoe, Mariel A. Brookins, UNITED STATES CHAMBER LITIGATION CENTER, Washington, D.C., for Amicus the Chamber of Commerce of the United States of America.

BERNER, Circuit Judge:

This case calls upon us to interpret two statutes that serve a common purpose: conserving the public fisc. Though enacted over a century apart, the Medicaid Rebate Statue and the False Claims Act were passed by Congress in response to concerns about misuse and abuse of government funds. The Medicaid Rebate Statute of 1990 was meant to address the rapid rise in drug prices that threatened to bankrupt Medicaid—the joint federal and state program that provides medical care to poor and disabled Americans—by requiring drug manufacturers to report rebates and other discounts they provide to private companies. This reporting requirement was to ensure that Medicaid receives the benefit of the lowest prices that manufacturers charge private companies.

The False Claims Act, passed shortly after the Civil War, was designed to deter and punish fraud in federal government contracting by incentivizing whistleblowers to assist in recovering taxpayer dollars by filing lawsuits—referred to as *qui tam* actions. The False Claims Act serves as a powerful tool for recovering fraudulently obtained government funds.

In response to growing concern that courts were improperly narrowing the scope of conduct prohibited by the False Claims Act, Congress amended the Act in 1986 to strengthen its scienter requirement. Scienter refers to the degree of knowledge an individual must possess in order to be held liable under the Act. The 1986 amendments made clear that liability can found if a defendant acted with one of three states of mind: actual knowledge of, deliberate ignorance to, or reckless disregard of, the truth or falsity of the claim. In a recent decision, the Supreme Court held that this scienter standard is a subjective

one. Accordingly, the False Claims Act prohibits the submission of a false claim to the federal government if the defendant either subjectively believed the claim to be false or was substantially aware of the risk of it being so.

Troy Sheldon brought this *qui tam* action against his former employer, Forest Laboratories, LLC. Sheldon alleges that Forest falsely reported the lowest price it charged private companies for its pharmaceuticals, thereby leading to Forest's overcharging the federal government and state governments for drugs purchased for Medicaid recipients. Sheldon alleges that Forest acted with, at a minimum, reckless disregard for the truth or falsity of its reported lowest prices when it submitted these reports because it had been warned that its interpretation of the Medicaid Rebate Statute was not correct. The district court dismissed Sheldon's complaint, concluding that the facts as pled—even if true—could not satisfy the scienter requirement of the False Claims Act. We conclude that Sheldon's allegations that Forest acted with reckless disregard in reporting its lowest prices under the Medicaid Rebate Statute satisfy the requisite pleading standards. Accordingly, we reverse and remand to the district court for further proceedings.

I. Relevant Statutes

Because this case concerns both the False Claims Act and the Medicaid Rebate Statute, we begin by describing these two statutory frameworks.

A. False Claims Act

Congress enacted the False Claims Act (FCA) in 1863 to provide a mechanism for the government to redress fraud in government procurement during the Civil War. *United*

States ex rel. Wheeler v. Acadia Healthcare Co., Inc., 127 F.4th 472, 479 (4th Cir. 2025). The FCA is the "government's primary litigative tool for the recovery of losses sustained as the result of fraud against the government." *Avco Corp. v. U.S. Dep't of Just.*, 884 F.2d 621, 622 (D.C. Cir. 1989) (citing S. Rep. No. 99-345, 99th Cong., 2d Sess. 2 (1986)). The purpose of the FCA is to incentivize whistleblowers "to come forward when they become aware of fraud against the government, and to protect them from retaliation when they do." *Wheeler*, 127 F.4th at 479. The FCA both "punishes companies that have committed fraud in government contracts and serves an important function in deterring other companies from doing the same." *Id.*

The FCA "imposes liability on those who 'knowingly presen[t] . . . a false or fraudulent claim for payment or approval'" to the government. *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 747 (2023) (quoting 31 U.S.C. § 3729(a)(1)(A)). A claim is defined as "any request or demand" for money or property presented to either an officer, employee, or agent of the United States or, as relevant here, a grantee or other recipient of federal funds if, among other things, the United States government will reimburse the grantee or recipient for the funds requested. 31 U.S.C. § 3729(b)(2). The phrase "false or fraudulent claim" is to be construed broadly. *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 788 (4th Cir. 1999).

As in this case, the FCA is often invoked to seek redress for fraud committed against government healthcare programs, the largest of which is the Medicaid program. In the 2024 fiscal year alone, the Justice Department reported over $2.9 billion recovered through False Claims Act settlements and judgments. U.S. Dep't of Justice, *Press Release: False Claims*

Act Settlements and Judgments Exceed $2.9B in Fiscal Year 2024, https://www.justice.gov/archives/opa/pr/false-claims-act-settlements-and-judgments-exceed-29b-fiscal-year-2024 [https://perma.cc/K2FR-HKRK]. Nearly two thirds of these recovered funds derived from health-care related matters. *Id.*

The FCA requires a relator—a private individual who brings a lawsuit on behalf of the United States—to adequately allege four elements: 1) the defendant made a false statement or engaged in a fraudulent course of conduct; 2) such statement or conduct was carried out with the requisite scienter; 3) the statement or conduct was material; and 4) the statement or conduct caused the government to pay out money or to forfeit money due. *Wheeler*, 127 F.4th at 487; *see* 31 U.S.C. § 3729(a)(1)(A), (B). A defendant can only be held liable under the FCA, therefore, if the defendant possessed the requisite scienter and the claim submitted was objectively false.

The FCA scienter standard requires the defendant to have acted with actual knowledge, deliberate ignorance, or reckless disregard as to the truth or falsity of the claim. 31 U.S.C. § 3279(a)(1)(A). The scienter standard is purposefully broad to combat the "'ostrich-like' conduct which can occur in large corporations [that] poses insurmountable difficulties for civil false claims recoveries." S. Rep. 99-345, at 7. Proof of "specific intent to defraud" is not required. 31 U.S.C. § 3729(b)(1)(B).

In *United States ex rel. Schutte v. SuperValu Inc.*, the Supreme Court held that the FCA scienter standard is subjective. 598 U.S. at 749.[1] The Court explained that what matters is the defendant's "knowledge and subjective beliefs—not what an objectively reasonable person may have known or believed." *Id.* This is the first time our court has had occasion to consider the application of this subjective scienter standard following *Schutte*.

B. Medicaid Rebate Statute

Medicaid provides health care to millions of low-income Americans through a cooperative federal and state program. 42 U.S.C. § 1395 *et seq*. The federal government distributes financial assistance directly to state Medicaid programs which in turn provide healthcare coverage to low-income Americans. *Children's Hosp. of the King's Daughters, Inc. v. Azar*, 896 F.3d 615, 617 (4th Cir. 2018). This assistance includes reimbursing states for the cost of prescription drugs. *See generally Pharms. Rsch. & Mfrs. of Am. v. Walsh,* 538 U.S. 644, 650–51 (2003).

[1] Prior to *Schutte*, several federal circuit courts of appeal, including our own, applied an objective scienter standard in FCA cases. *See, e.g.*, *United States ex rel. Proctor v. Safeway, Inc.*, 30 F.4th 469, 652–53 (7th Cir. 2022). Under this objective scienter standard, a defendant could escape liability if the defendant acted under a reasonable interpretation of the statute. Whether the defendant subjectively believed or was aware of a substantial risk that the claims were false or misleading was irrelevant. The initial district court decision and Fourth Circuit decisions in this case applied this standard. *See United States ex rel. Sheldon v. Forest Laboratories*, 499 F. Supp. 3d 184 (D. Md. 2020), *judgment vacated by United States, ex rel. Sheldon v. Allergan Sales, LLC*, 143 S. Ct. 2686 (2023), and *United States ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 240 (4th Cir. 2022), *vacated on rehearing en banc by United States ex rel. Sheldon v. Allergan Sales, LLC*, 2022 WL 1467710 (4th Cir. May 10, 2022). In *Schutte*, the Supreme Court unanimously rejected the argument that an objective scienter standard applies under the FCA. 598 U.S. at 749.

Prior to 1990, Medicaid saw a significant increase in the cost of prescription drugs in part because Medicaid routinely paid more for these drugs than private entities paid. *See* 136 Cong. Rec. S. 12954 (1990); H.R. Rep. No. 101-881, 96 (1990). In response, in 1990, Congress enacted the Medicaid Rebate Statute which requires drug manufacturers to pay rebates to states on their Medicaid purchases. *See Pharms. Rsch. & Mfrs. Of Am.*, 538 U.S. at 649. These rebates are calculated based on the rebates that drug manufacturers provide to private entities, thereby preventing the manufacturers from charging Medicaid more. *Id.* Congress thus tied the cost of drugs prescribed to Medicaid patients to the lowest price offered by the manufacturers for drugs on the private market.

For a drug manufacturer to be eligible to sell drugs to state Medicaid agencies, the Rebate Statute requires it first to enter into a standardized rebate agreement with the federal government. 42 U.S.C. § 1396r-8(a)(1). *See* Medicaid Program; Drug Rebate Agreement, 56 Fed. Reg. 7049, 7050 (Feb. 21, 1991) (Rebate Agreement). Under the Rebate Agreement, drug manufacturers must provide states with rebates on drugs that the states purchase for Medicaid beneficiaries. *Id.* § 1396r-8(b)(1)(A). The federal government also benefits from these rebates because it correspondingly reduces its payments to states in step with the states' savings from manufacturers' rebates. *Id.* § 1396r-8(a)(1)–(c). This rebate process is designed to give Medicaid the "benefit of the best price" for prescription drugs. H.R. Rep. No. 101-881, at 96 (1990).

The Rebate Statute sets forth a two-step process through which these rebates are calculated. At the first step, the manufacturer is required to report the "Average Manufacturer Price" and the "Best Price" for its covered drugs to the Centers for Medicare

and Medicaid (CMS). 42 U.S.C. § 1396r-8(a)(1), (b)(3)(A). At the second step, CMS then calculates the rebate that the manufacturer is required to pay to the states for each drug. *Id.* § 1396r-8(c)(1). The required rebate is the greater of either 1) the statutory minimum rebate percentage or 2) the difference between the Average Manufacturer Price and the Best Price. *Id.*

The Rebate Statute defines the Best Price as the "lowest price available from any manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity." *Id.* § 1396r-8(c)(1)(C)(i). The Best Price includes "cash discounts, free goods that are contingent on any purchase requirements, volume discounts, and rebates." *Id.* §1396r-8(c)(1)(C)(ii)(I). The Rebate Agreement between the drug manufacturer and Medicaid further requires the manufacturer to adjust the Best Price "if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized." 56 Fed. Reg. at 7050. In recognition of the complexity of these calculations, the Rebate Agreement provides that "[i]n the absence of specific guidance," manufacturers can "make reasonable assumptions in [their] calculations of . . . Best Price, consistent with the intent of [the Rebate Statute], Federal regulations, and the terms of this agreement." *Id.* at 7052.

II. Sheldon's Allegations

Because this is an appeal from an order granting a motion to dismiss, we accept as true the factual allegations in the complaint and draw all reasonable inferences in favor of the plaintiff. *Shook v. NCG Acquisition, LLC*, 114 F.4th 242, 248 (4th Cir. 2024). Troy

Sheldon, acting as a relator, filed this *qui tam* action under the FCA against his former employer, Forest, in 2014, on behalf of the United States as well as numerous states[2] and the District of Columbia. Sheldon amended his complaint in 2016, and it is from this amended complaint that we recite the facts.[3]

During the relevant period, Forest was one of the nation's leading pharmaceutical drug manufacturers. It sold a number of commonly prescribed drugs.[4] Dating back to the time period of the allegations in the complaint, 2005-2014, Forest's net sales for these drugs totaled billions of dollars annually. Medicaid sales constituted at least 20% of Forest's annual sales for each drug.

Troy Sheldon worked in managerial roles at Forest starting in the 1990s until he was fired in 2014. In these roles, Sheldon was directly involved in the sale of drugs, including the negotiation of discounts, rebates, and other incentives. Through this work, Sheldon had

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[2] The relevant states include California; Colorado; Connecticut; Florida; Georgia; Hawaii; Illinois; Indiana; Iowa; Louisiana; 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 Commonwealth of Virginia; Washington; and Wisconsin.

[3] Troy Sheldon passed away after he filed this action. Sheldon's widow and the executor of his estate, Deborah Sheldon, has been substituted as the plaintiff. Forest Laboratories was acquired by Actavis, PC (which subsequently changed its name to Allergan Sales, LLC), in 2014. Actavis, PC has been substituted as the defendant. For clarity, we continue to refer to Troy Sheldon rather than Deborah and to Forest rather than Actavis, PC/Allergan, as those are the parties named in the amended complaint.

[4] The Forest drugs relevant to this appeal include Celexa, Lexapro, Namenda, Namenda XR, Bystolic, Savella, Viibryd, Fetzima, Tudorza, Daliresp, Saphris, Linzess, Campral, Armour Thyroid, Levothyroid, Thyrolar, Tiazac, and Combunox. Namenda, Forest's top selling drug, netted over $1.5 billion in the 2014 fiscal year, the year Sheldon filed his original complaint.

"direct, personal knowledge of the drug rebates and other discounts given to Forest customers that impact[ed] the reported Best Price for each drug" that Forest reported to Medicaid. Parties' Joint Appendix (J.A.) 64.

Sheldon's 2016 amended complaint alleges the following. First, Forest submitted a false claim under the FCA by reporting its Best Prices to CMS without including cumulative discounts it provided to different entities for a single drug. In so doing, Sheldon alleges, Forest's reported Best Prices did not accurately reflect the "price[ ] actually realized" by Forest. 56 Fed. Reg. at 7050. Second, Forest possessed the requisite scienter because it knew, deliberately ignored, or acted with reckless disregard in submitting these false claims. Third, Forest's false claims were material. Fourth, Forest unlawfully avoided paying Medicaid $686.64 million over the course of nearly ten years by basing the rebates it paid to the states on its falsely reported Best Prices.

We begin by describing the alleged false claims before discussing Sheldon's allegations of scienter.

A. Alleged False Claims

In 2004, Sheldon became aware that Forest was paying rebates and discounts to two separate customers on the same dispensed drug that was ultimately provided to the same patient. The rebates and discounts that drug manufacturers provide play a significant role in generating sales. In the commercial market, for example, Forest "negotiates with [a] private insurance compan[y] to have its drugs placed on the private insurance company's drug formulary," a list of the company's preferred drugs. J.A. 65. In exchange, Forest pays the insurance company a rebate or other discount for each drug that the private insurance

company purchases from Forest. Forest is then required to account for these rebates and other discounts in its calculation of the Best Price for each drug.

During the time period of the amended complaint, Forest routinely conducted business with multiple entities on a single drug transaction. For example, Forest often sold drugs indirectly through a third-party wholesaler. The wholesaler would act as a middleman and then sell the drugs to other customers "at a discount, which it then charge[d] back to Forest." J.A. 66. The wholesalers frequently sold drugs manufactured by Forest to entities known as Pharmacy Providers and group purchasing organizations (GPOs), which collectively purchase drugs for a variety of individual facilities.

Forest also negotiated rebates and other discounts directly with Pharmacy Providers and GPOs for the purchase of drugs to be "disbursed by long term care, rehabilitation/transitional, short term stay and group home facilities, as well as through home delivery." J.A. 66. Multiple rebates and discounts, therefore, were often provided for a single drug through these transactions when a Pharmacy Provider or GPO purchased Forest's drugs from a middleman, including for example: 1) the discount that the wholesaler provided and then charged back to Forest; and 2) the negotiated rebate claimed by the Pharmacy Provider or GPO. To encourage both the wholesaler and the Pharmacy Provider or GPO to use its products, Forest provided a rebate or discount to each entity for the same drug.

Sheldon alleges that, through these multiple transactions to different purchasers, Forest essentially "stacked" rebates and other discounts for the same drug. When reporting its Best Price to CMS, however, Forest would report only the highest rebate or other

discount it gave to a single entity for each individual drug, rather than combining the total amount of rebates and discounts provided to all entities on the same drug.

To illustrate how this works, Sheldon offers an example in which a patient with private insurance was staying at a care facility ("Pharmacy Provider Facility"). The Pharmacy Provider Facility determined that the patient needs an antidepressant. To incentivize both the Pharmacy Provider Facility and the patient's private health insurer to prescribe and pay for an antidepressant manufactured by Forest rather than a competitor, Forest provided rebates to both the Pharmacy Provider Facility and to the private insurance company. Forest gave the Pharmacy Provider Facility a 15% rebate for the drug and then paid an additional 18% rebate to a private insurance company for the *same* drug prescribed to the *same* patient. Thus, all told, Forest provided 33% worth of rebates for the same drug. The price "actually realized" by Forest for the individual drug was therefore only 67% of the total market price. In reporting its Best Price for that drug to CMS, however, Forest reported the price after applying only the larger of the two rebates (i.e., the 18% rebate). Because Forest reported its Best Price to Medicaid based on this calculation, Medicaid received only an 18% rebate, not the combined rebate of 33% of the total market price.

Thus, Sheldon alleges that Forest submitted false claims under the FCA by reporting its Best Prices to CMS without stacking rebates and other discounts provided to different entities on the same drug.

B. Alleged Scienter

Sheldon alleges that Forest "knowingly, with deliberate ignorance, or with reckless disregard engaged in a systemic false and fraudulent scheme" through its "willful failure

to report accurate Best Price to state Medicaid programs, resulting in lower Medicaid drug rebates being paid by Forest to each state[.]" J.A. 63. In support of his assertion that Forest acted with the requisite scienter, Sheldon alleges that Forest was subjectively aware that CMS interpreted the statute to require aggregation of all discounts as evidenced by its statements during a 2006–2007 CMS rulemaking regarding the definition of Best Price. He further alleges that, after becoming aware of CMS's interpretation, Forest sought to eliminate most of its double rebates and other discounts following the promulgation of CMS's final rule. He alleges that Forest decided to nonetheless continue paying such rebates and other discounts to certain customers to preserve important business relationships and maximize revenue. Finally, he asserts that, despite being aware of the risk that its own interpretation of the statute was incorrect—or at the very least, that its interpretation differed from CMS's interpretation—Forest continued to report its Best Price calculations without aggregating the rebates and discounts it provided to different customers. Because the sufficiency of Sheldon's allegations regarding Forest's scienter is central to this dispute, we describe them in detail.

i. *Forest's Response to the 2006-2007 CMS Rulemaking*

In 2006 and 2007, CMS undertook rulemaking to further clarify the definition of Best Price. When an agency promulgates a new rule, it must generally first provide public notice of the proposed rule to allow the public to submit comments on the rule before it becomes final. *North Carolina Growers Ass'n, Inc. v. United Farm Workers*, 702 F.3d 755, 765 (4th Cir. 2012). In this case, CMS issued its proposed rule in 2006. Medicaid Program; Prescription Drugs, 71 Fed. Reg. 77,174 (proposed Dec. 22, 2006) (hereinafter 2006

Proposed Rule). It published its final rule in July 2007. 72 Fed. Reg. 39,142 (July 17, 2007) (codified at 42 C.F.R. pt. 447) (hereinafter 2007 Final Rule). It also published guidance accompanying the 2007 Final Rule. 72 Fed. Reg. 39,164 (hereinafter 2007 Guidance). Sheldon alleges that Forest's communication to CMS in response to the 2006 Proposed Rule evidences that Forest "knew exactly what was required" by CMS for the Best Price calculations "when the final regulations were promulgated" in 2007. J.A. 61.

The 2006 Proposed Rule defined Best Price as "the lowest price available from the manufacturer during the rebate period to any entity in the United States in any pricing structure," including "all sales and associated discounts and other price concessions provided by the manufacturer to any entity unless . . . specifically excluded by statute or regulation." 2006 Proposed Rule, at 77,197. It further clarified that Best Price "shall be the [net] of cash discounts . . . and any other discounts or price reductions and rebates . . . which reduce the price available from the manufacturer." *Id.* at 77,198. In its preamble to the proposed rule, CMS noted that "any price adjustment which ultimately affects those prices which are *actually realized* by the manufacturer . . . should be included in the calculation of best price." *Id.* at 77,182 (emphasis added).

Sheldon attached to the amended complaint a copy of a letter that Forest submitted in response to CMS's proposed rule (the "McKenna letter"). In the McKenna letter, Forest expressed its concern that the 2006 Proposed Rule improperly required aggregation of the rebates and other discounts provided to multiple entities. Forest asserted that the "statutory definition of best price has always been interpreted to mean the single lowest price to a particular customer." J.A. 401. Under this view, "prices to unrelated entities in the chain

of distribution should not be aggregated . . . even if they concern the same unit of a drug." *Id.* at 401–02. Forest expressed concern that "language 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." *Id.* at 401. Forest urged CMS to change this language in the final rule to "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." *Id.* "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." *Id.* at 401–02.

When it issued its final rule in 2007, CMS declined to modify the Best Price language that Forest had urged it to change. 2007 Final Rule, at 39,242. Instead, CMS reiterated that the 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 . . . [and] shall be calculated to include all sales and associated rebates, discounts, and other price concessions provided by the manufacturer to any entity" unless specifically excluded. *Id.* at 39,242. It affirmed that "[b]ecause best price represents the lowest price available from the manufacturer to any entity . . . 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 the manufacturer if other arrangements subsequently adjust the price actually realized." *Id.* at 39,150. Sheldon alleges that the fact that "CMS did *not* change the regulation or the requirements of the Rebate Statute and Rebate Agreement by adopting any new qualifying and limiting language like that suggested by Forest, but instead enacted

the regulation as proposed without substantive changes" demonstrates that Forest was aware—when the rule was promulgated—that CMS interpreted the regulation to require aggregation. J.A. 61 (emphasis in original).

In his amended complaint, Sheldon further alleges that "CMS's published guidance and comments accompanying the regulations le[ft] no doubt that all rebates and price concessions among all entities must be aggregated[.]" *Id.* at 57. Sheldon points to two relevant CMS comments. First, CMS responded to one commenter's request that "when best price is determined," discounts provided to wholesalers should *not* be aggregated with discounts provided to the end-customer. 2007 Guidance, at 39,199. In response, CMS stated, "[w]e do not agree." *Id.* Rather, these discounts must be aggregated. *Id.* In the example provided by CMS, however, the wholesaler and end-customer that both received rebates and other discounts were the same entity, not separate entities. *Id.*

In a second comment, CMS addressed the provision of rebates and other discounts to Pharmacy Benefit Managers (PBMs), which serve as intermediaries that commonly receive a rebate in addition to the end customer. Several commenters had raised concerns that the proposed rule suggested that "manufacturers may be obligated to add concessions paid to PBMs to the concessions paid to customers of the PBMs in calculating best price." *Id.* at 39,198. Echoing the concerns raised by Forest in the McKenna letter, the commenters feared that 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." *Id.* The commenters argued that "if Congress had intended anything other than a customer-to-customer analysis of separate prices, the statute would have combined each customer with the word 'and' instead of the

disjunctive 'or.'" *Id.* As Forest urged in the McKenna letter, the commenters "requested that CMS reaffirm that best price is the lowest price available from the manufacturers" to a single customer. *Id.* In response, CMS stated, "we do not agree with the commenters . . . [b]est 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." *Id.* Sheldon alleges that the CMS Guidance "made clear that," contrary to Forest's own interpretation of Best Price, CMS interpreted the Rebate Statute to require "that rebates between multiple entities [ ] be *aggregated* together to the extent that they affect the ultimate price actually realized by the manufacturer[.]" J.A. 59 (emphasis in original).

ii. *Forest's 2008 Data Audit*

Sheldon alleges that, after CMS issued the 2007 Final Rule, "top level managers at Forest held meetings and prepared reports" to address situations in which Forest would grant rebates and other discounts to multiple different entities on the same drug dispensed to a single patient. J.A. 69. According to Sheldon, Forest was "[a]ware of [its] potential Best Price violation based upon double rebate claims from its customers, [and therefore] implemented a data audit process for all rebate claims submitted" by certain customers to identify any such stacked rebate claims. J.A. 70. Forest changed its rebate practices for these customers following its audit. Moving forward, Forest would only provide rebates and other discounts to one entity in each individual drug's distribution chain and report the resulting price as the Best Price.

Sheldon alleges that Forest purposefully excluded Pharmacy Providers and GPOs from this data audit. Forest did so, according to Sheldon, to "avoid negatively impacting its relationships with" these major customers to "preserve shareholder profits." *Id.* at 71. Forest therefore continued paying rebates and other discounts to the Pharmacy Providers and GPOs, as well as others in the same chain of distribution. Yet, Forest also did not aggregate these stacked rebates and discounts in reporting its Best Price to CMS. Sheldon alleges that by excluding these stacked rebates and other discounts, Forest "pa[id] less in Medicaid drug rebates to state Medicaid programs[.]" *Id.* at 68. As a result, the federal government reimbursed more "to the states than it would have had Forest accurately reported Best Price and states are similarly damaged because they [were] not receiving their proper rebates." *Id.*

Sheldon alleges that, through this scheme, Forest either intentionally or with reckless disregard underpaid Medicaid by $686.64 million.

III. Procedural Background

This case has traveled a long and circuitous journey before returning to this court for the fourth time. Sheldon filed this *qui tam* action under seal in 2014 and filed his amended complaint under seal in 2016.[5] When a private party sues under the FCA, the government is given an opportunity to investigate the claims and decide whether it wishes

[5] In his amended complaint, Sheldon alleges violations of the FCA and various state false claims statutes. State false claims statutes generally track, and are thus construed in accordance with, the FCA. *See e.g.*, *New York v. Amgen*, 652 F.3d 103, 109 (1st Cir. 2011).

to intervene. *See* 31 U.S.C. § 3730(b)(2–4). During this period, the case remains under seal. *Id.* In 2019, after a lengthy investigation, the United States and the state governments declined to intervene, and the amended complaint was unsealed. Subsequently, Forest moved to dismiss the action pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6).

In 2020, the district court granted Forest's motion and dismissed Sheldon's amended complaint for failure to state a claim on the ground that Sheldon did not adequately plead scienter and falsity. *United States ex rel. Sheldon v. Forest Lab'ys, LLC*, 499 F. Supp. 3d 184 (D. Md. 2020). The district court applied an objective reasonableness standard for scienter and found that a defendant cannot knowingly make a false statement when the defendant's interpretation of a legal issue is "objectively reasonable." *Id.* at 207–09. The district court determined that Forest could not have acted with the requisite scienter nor could the claims themselves have been false because Forest's interpretation of the Best Price reporting requirement was objectively reasonable. *Id.* at 209–13.

Two years later, on Sheldon's first appeal, a panel of this court affirmed the ruling of the district court. *See United States ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340 (4th Cir. 2022). There, the majority adopted the district court's objective scienter standard. *Id.* at 350–51. The dissent would have applied a subjective standard to scienter and reversed, concluding that Sheldon plausibly alleged scienter under that standard. *Id.* at 375–76. The dissent also maintained that the best reading of the Rebate Statute required the aggregation of stacked rebates and other discounts in the calculation of Best Price—though relying on now disfavored *Chevron* deference. *Id.* at 372–75.

Sheldon petitioned for rehearing *en banc*, which this court granted. This court *en banc* entered a *per curiam* opinion vacating the panel opinion and affirming the district court. *United States ex rel. Sheldon v. Allergan Sales, LLC*, 49 F.4th 873 (4th Cir. 2022). Sheldon then petitioned to the Supreme Court for a writ of *certiorari*. While Sheldon's petition was pending, the Supreme Court decided *United States ex rel. Schutte v. SuperValu Inc.*, unanimously adopting the subjective scienter standard for FCA claims rather than the objective standard that this court had previously applied. 598 U.S. at 749. The Supreme Court granted Sheldon's petition for *certiorari*, vacated the district court's order, and remanded to the Fourth Circuit for further consideration in light of *Schutte*. *See United States ex rel. Sheldon v. Allergan Sales, LLC*, 143 S. Ct. 2686 (2023). This court then remanded to the district court.

On remand, this time applying the Supreme Court's *Schutte* holding, the district court once again dismissed Sheldon's amended complaint. *United States ex rel. Sheldon v. Forest Laby's*, 754 F. Supp. 3d 615 (D. Md. 2024). The district court found that, even under the subjective intent standard, Sheldon failed to plausibly allege scienter. We review the district court's second dismissal on this appeal.

IV. Analysis

We review *de novo* the district court's grant of a motion to dismiss for failure to state a claim, construing factual allegations in the light most favorable to the plaintiff. *United States v. Walgreen Co.*, 78 F.4th 87, 92 (4th Cir. 2023). For dismissals at this early pleading stage, we accept all allegations in the complaint as true and draw all reasonable

inferences in favor of the plaintiff. *Shook*, 114 F.4th at 248. We first clarify the legal standard for scienter under the FCA and its application at the motion to dismiss stage. We then analyze the sufficiency of Sheldon's allegations of scienter under this standard, finding that Sheldon has plausibly alleged scienter. We conclude by clarifying the implications of our opinion on remand.

A. The FCA Scienter Standard

The FCA takes a broad approach to the level of knowledge necessary for liability. A defendant can act with actual knowledge, with deliberate ignorance, or with reckless disregard of the truth or the falsity of the information contained in the claims. 42 U.S.C. § 3729(b)(1)(A). Actual knowledge refers to information of which a defendant is actually aware. *Schutte*, 598 U.S. at 751. Deliberate ignorance "encompasses defendants who are aware of a substantial risk that their statements are false, but intentionally avoid taking steps to confirm the statement's truth or falsity." *Id*. Reckless disregard "captures defendants who are conscious of a substantial and unjustifiable risk that their claims are false, but submit the claims anyway." *Id.* Tracking the common-law scienter requirement, a party acts with reckless disregard when a claim is submitted carelessly with respect to its truth or falsity. *Id.* at 752 (citing the Restatement (Second) of Torts, § 526, Comment *e*).

Under the FCA, the scienter standard is a subjective one that focuses on the defendant's thoughts and beliefs. *Id.* at 749. Ambiguities in the law are therefore not dispositive. Neither is a defendant's objectively reasonable interpretation of the law. Under the subjective standard, "ambiguity" in the language of a statute "does not preclude [a

company] from having learned [the statute's] correct meaning—or, at least, becoming aware of a substantial likelihood of the terms' correct meaning." *Id.* at 753.

In *Schutte*, the Supreme Court offered an example to illustrate this conclusion. A medical doctor must submit payments for only "customary" medical tests. *Id.* at 742–43. Many doctors might be confused by the meaning of "customary," and some might "honestly mistake what that term means[.]" *Id.* at 743. Doctors who make an honest mistake might nonetheless submit a false claim—but may not necessarily violate the FCA. That is because liability under the FCA requires both scienter and falsity. Doctors who lack the requisite scienter therefore cannot be held liable for false statements. Conversely, other doctors "might correctly understand whatever 'customary' meant in this context—and submit claims that were inaccurate anyway." *Id.* These doctors, subjectively aware of the risk that their interpretation of "customary" is contrary to its intended meaning, can be held liable under the FCA.

The complexity of the Medicaid statute is well-recognized. As evidenced by the lengthy procedural history of this case, the requirements for the Best Price calculation are "less than perfectly clear." *Id.* at 752. Companies should not be held liable for making honest mistakes in interpreting ambiguous statutory language. Indeed, the Medicaid Rebate Agreement explicitly recognizes the right of manufacturers to "make reasonable assumptions" in calculating Best Price given this complexity. J.A. 361. *Schutte* counsels, however, that a company cannot exploit such ambiguities by relying on an objectively reasonable interpretation if the company is subjectively aware of the risk that such an interpretation is incorrect. 598 U.S. at 753–54.

The underlying purpose of the FCA supports this reasoning. "Protection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law." *Heckler v. Cmty. Health Servs. of Crawford County, Inc.*, 467 U.S. 51, 63 (1984). Indeed, "those who deal with the Government are expected to know the law" and "to familiarize [themselves] with the legal requirements for cost reimbursement." *Id.* at 63–64. Thus, a defendant who becomes aware that the government's interpretation of what a statute requires differs from its own yet continues to rely on its interpretation in submitting claims may be found to have been subjectively aware of the risk that its interpretation was incorrect.

B. Pleading Requirements for Scienter

To withstand a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the complaint must allege facts sufficient to state a plausible claim for relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A claim is plausible when the facts pled allow "the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* Like most claims arising under the FCA, Sheldon's claims are fraud-based and therefore must also satisfy Federal Rule of Civil Procedure 9(b)'s heightened pleading standard. *Wheeler*, 127 F.4th at 485. Rule 9(b) requires a plaintiff alleging fraud or mistake to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). These circumstances include the "who, what, when, where, and how" of the alleged fraud. *United States ex rel. Taylor v. Boyko*, 39 F.4th 177, 189 (4th Cir. 2022) (internal citation omitted).

Even in these fraud-based claims, scienter may be alleged generally. Fed. R. Civ. P. 9(b) (stating that "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally"). The FCA does not require scienter to be pled with specificity for good reason. As the district court correctly observed, "direct proof of scienter is often unavailable." J.A. 953. This is particularly true at the pleading stage before the parties have had an opportunity to engage in discovery. Courts must not impose a higher bar for pleading scienter.

In the aftermath of *Schutte*, motions to dismiss for failure to plausibly allege scienter under the FCA have overwhelmingly been denied, further demonstrating this low threshold. *See, e.g.*, *United States ex rel. Jacobs v. Pac. Dermatology Inst., Inc.*, 2024 WL 3086586, at *7 (C.D. Cal. May 16, 2024) ("The scienter standard is met where certain facts should have tipped off the defendants and should have suggested that something was amiss." (internal citation and quotation marks omitted)); *United States ex rel. Nunnelly v. Regeneron Pharms., Inc.*, 780 F. Supp. 3d 336, 348 (D. Mass. 2025) (finding that whether "the [statutory provision] is ambiguous and [whether the defendant's] current interpretation is reasonable" are irrelevant considerations under *Schutte*); *United States ex rel. McCullough v. Anthem Ins. Cos., Inc.*, 2025 WL 2782576, at *9 (S.D. Ind. Sept. 30, 2025) (rejecting defendant's arguments that a plaintiff must adequately allege scienter with more than circumstantial evidence because it would mean that "even the most blatant of FCA violations would be stifled at the motion to dismiss stage"). Indeed, a number of courts have reopened cases previously dismissed for failure to adequately plead scienter. *See, e.g.*, *United States ex rel. Ocean State Transit, LLC v. Infante-Green*, 2023 WL 6199183, at *2

(D.R.I. Sept. 22, 2023) (reopening an FCA action previously dismissed for failure to state a claim on the ground that, following *Schutte*, "a dearth of clarity as to the [relevant statutory phrase] is not—at the pleadings stage—itself a reason that an FCA action must fail").

C. Sufficiency of Sheldon's Pleading

The relevant question for purposes of FCA liability, therefore, is whether Forest was subjectively aware of a substantial risk that CMS interpreted the Rebate Statute to require drug manufacturers to aggregate rebates and other discounts provided to multiple entities on the same drug in reporting Best Price. If Forest was aware, then it may have acted with reckless disregard under the FCA scienter requirement in continuing to report its Best Price pursuant to its own interpretation. To survive a motion to dismiss, Sheldon need only have plausibly alleged facts to support an inference that Forest possessed such a scienter. We find that Sheldon has done so.

First, Sheldon alleges that Forest's McKenna letter to CMS shows that Forest understood CMS's proposed rule to require aggregation of discounts to multiple entities in reporting its Best Price.[6] In the McKenna Letter, Forest articulated its legal interpretation that such stacking was not and should not be required by the Rebate Statute. Despite Forest's urging that it was "critical" that CMS change that language to avoid imposing such a requirement, J.A. 401, CMS declined to do so in the final rule. 2007 Final Rule, at 39,150. We may reasonably infer from these facts that Forest's interpretation of the language of

[6] The amended complaint does not contain any allegations that would support an inference that Forest acted with reckless disregard prior to the 2006–2007 rulemaking.

the rule remained the same as it articulated in the McKenna letter—that CMS required aggregation of all rebates and other discounts.

Furthermore, Sheldon alleges that Forest's decision to undertake an audit further demonstrates Forest's subjective awareness that CMS expected it to either 1) report the stacked rebates and other discounts in its Best Price or 2) provide only one customer in the chain with rebates and other discounts. Specifically, Sheldon alleges that Forest conducted the audit with the purpose of eliminating stacked rebates and other discounts for most of its customers in the aftermath of CMS's rulemaking so that only one customer in the chain received a rebate moving forward. Sheldon alleges that Forest continued, however, to pay double rebates to certain preferred customers in order to preserve these relationships. Viewed in the light most favorable to Sheldon, the timing of this audit, the decision to provide only one rebate in most situations, and Sheldon's personal knowledge of these events support a reasonable inference of the requisite scienter. Finally, despite this subjective awareness, Sheldon alleges that Forest continued to report its Best Price for the remainder of the period of the amended complaint without stacking the discounts provided to multiple entities in its Best Price calculations.

Taken together, Sheldon's allegations regarding scienter, including: 1) that Forest's letter to CMS, CMS's decision not to change the offending language, and CMS's response in the guidance demonstrate subjective awareness; 2) that Forest subsequently undertook an audit for the purpose of adopting CMS's approach for most clients, with the exception of a select group of preferred clients; and 3) that Forest continued to report the Best Price

without aggregation after the 2006-2007 rulemaking, suffice to withstand a motion to dismiss.

Forest argues that these allegations are insufficient because CMS failed to respond directly to the McKenna letter and because, according to Forest, CMS's 2007 Guidance was unclear. From this, Forest asserts, it could not have known of a substantial risk that CMS interpreted the Rebate Statute to require aggregation. Forest also asserts that the post-rulemaking audit was conducted for purely business reasons. Forest's arguments to this effect misapprehend the pleading requirement for the subjective scienter element of an FCA claim at this stage. In considering a motion to dismiss, we look only to the allegations in the operative complaint and must accept them as true.[7] The allegations contained in Sheldon's amended complaint ably allege what is required.

[7] Rather than limiting its review to Sheldon's allegations, the district court took judicial notice of and considered as part of its analysis information contained in several voluminous documents beyond the amended complaint including: 1) the Rebate Agreement; 2) Medicaid Drug Rebate Program Release No. 2; 3) Medicaid Drug Rebate Program Release No. 14 ; 4) several letters to CMS; 5) the May 26, 2023 proposed rule (88 Fed. Reg. 34238); 6) the Government's Brief; 7) a Press Release; and 8) the contents of the Federal Register and the Code of Federal Regulations. J.A. 943. The ability of district courts to consider matters outside of pleadings on a motion to dismiss is limited. *Bosiger v. U.S. Airways*, 510 F.3d 442, 450 (4th Cir. 2007). When materials outside the pleadings are considered in ruling on a 12(b)(6) motion, unless the materials are integral to and explicitly relied on in the complaint, the court must generally convert that motion to "one for summary judgment under Rule 56" and provide all parties "a reasonable opportunity to present all material that is pertinent to the motion." Fed. R. Civ. P. 12(d). *See e.g.*, *E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc.*, 637 F.3d 435, 448 (4th Cir. 2011).

D. Statutory Ambiguity and Falsity

In addition to finding that Sheldon failed to adequately plead scienter, the district court also suggested that Forest could not have submitted false claims because the statute is ambiguous. We disagree. The ambiguity of a statute is relevant to both the scienter and falsity analyses, but for different reasons.

Indeed, as we have discussed, *Schutte* expressly rejected the argument that a company cannot be found to have acted with the requisite scienter under the FCA simply because a Medicaid statute is ambiguous. 598 U.S. at 752–54. Certainly, the ambiguity of a statute may be a defense to scienter. It is not generally appropriate to consider such defenses at the motion to dismiss stage, however, unless the plaintiff fails to allege facts beyond the plain text of the statute to support an inference of the requisite scienter. That is not the case here. Sheldon sufficiently alleges, through the McKenna letter and subsequent audit, that Forest was subjectively aware of the risk that it was reporting false claims. These allegations go well beyond the plain text of the statute.

Falsity is a distinct element of an FCA claim. Unlike for purposes of the scienter analysis, ambiguity in a statute is not a defense to the falsity of the claim. *United States ex*

rel. Drakeford v. Tuomey, 792 F.3d 364, 383–84 (4th Cir. 2015); [8] *see also United States v. Elfenbein*, 144 F.4th 551, 566 (4th Cir. 2025) ("[T]he possibility of reasonable disagreement doesn't rule out falsity.") Rather, falsity is an objective inquiry. *Drakeford*, 792 F.3d at 384. Even reasonable interpretations of a regulation can be false as a matter of law for purposes of the FCA. *United States ex rel. Streck v. Eli Lilly & Co.*, 152 F.4th 816, 839–41 (7th Cir. 2025). When considering whether a plaintiff sufficiently alleges the element of falsity, the district court must determine whether the claims were objectively false by interpreting the relevant statute. Because the district court has yet to reach this issue, we remand for consideration in the first instance.[9]

[8] Rather than relying on *Drakeford*'s objective falsity test, Forest urges us instead to take the approach of this court in *Wilson v. Kellog Brown & Root, Inc.*, 525 F.3d 370 (4th Cir. 2008). There, the alleged false claim stemmed from a dispute about whether a party had complied with the requisite maintenance and safety requirements that had been agreed to by contract. *Id.* at 375. The dispute in *Wilson* did not turn on an "either/or proposition" of the objective meaning of a statute, however. It instead turned on the subjective interpretations of contractual duties. *See Drakeford*, 792 F.3d at 384, n.14 (describing and distinguishing *Wilson*). Under such circumstances, the objective falsity test may not be appropriate. In contrast here, like in *Drakeford*, the dispute turns on the objective meaning of a statute and the district court must determine whether reporting Best Price without aggregating all rebates and other discounts was false as a matter of law.

[9] The district court granted Forest's motion to dismiss on the basis that Sheldon failed to adequately plead scienter. It did not reach the issue of objective falsity, nor did it determine whether the Medicaid Rebate Statute obligates a manufacturer to report stacked discounts to multiple entities. We decline to exercise our discretion to reach this issue and leave this question in the district court's able hands for consideration in the first instance.

V. Conclusion

In *Schutte*, the Supreme Court underscored the breadth of conduct addressed by the FCA. The subjective scienter standard prevents wrongdoers from taking advantage of arguable ambiguity in a statute to exploit the public fisc for private gain. Sheldon adequately alleged that his former employer Forest acted with reckless disregard when it reported its Best Prices without aggregating rebates and other discounts after becoming aware that CMS interpreted the Rebate Statute to require such aggregation. These allegations suffice to withstand Forest's motion to dismiss.

The district court's order granting Forest's motion to dismiss is reversed, and we remand for further proceedings consistent with this opinion.

REVERSED AND REMANDED

BARBARA MILANO KEENAN, Senior Circuit Judge, dissenting:

The majority provides a thorough discussion of scienter in a False Claims Act case but fails to address the central issue raised by the parties, namely, whether rebates must be stacked across different entities in a distribution chain when determining "best price" under the Rebate Statute, 42 U.S.C. § 1396r-8. I write separately because, in my view, the unambiguous meaning of the statutory term "best price" does not require such stacking and, thus, resolves this case as a matter of law based on Troy Sheldon's failure to sufficiently allege the element of falsity.

Applying familiar principles of statutory interpretation, I would conclude that "best price" is the single lowest price available from the manufacturer to a single purchaser. Given this interpretation, I would further hold that in determining "best price," Forest Laboratories, LLC (Forest)[1] was not required to combine discounts[2] provided to multiple purchasers and, thus, Forest could not have violated the False Claims Act, 31 U.S.C. § 3729, by failing to do so. For this reason, I would affirm the district court's judgment dismissing Sheldon's complaint.

Medicaid, a joint federal and state program, provides health care coverage for millions of low-income individuals. Seeking to ensure that "Medicaid [has] the benefit of

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[1] Forest has been acquired by another corporate entity. And the plaintiff, Troy Sheldon, as relator, died after filing this action. The executor of his estate, Deborah Sheldon, has been substituted as the named plaintiff. I continue to refer to the parties as originally named in the complaint.

[2] For simplicity, I use the term "discounts" broadly to include all sorts of price concessions, rebates, and price reductions.

the best price for which a manufacturer sells a prescription drug to any public or private purchaser," Congress enacted the Rebate Statute in 1990. H.R. Rep. No. 101-881 (1990).

Under that statute, drug manufacturers are required to enter "rebate agreements" with the Secretary of Health and Human Services in which the manufacturers must provide quarterly rebates to states for their purchases of covered prescription drugs for Medicaid patients. 42 U.S.C. § 1396r-8(a)(1), (b)(1)(A). The Rebate Statute sets forth the formula for establishing the rebate amounts, requiring calculation of "the difference between the 'average manufacturer price' and the 'best price,'"[3] which difference manufacturers must report to the Centers for Medicare and Medicaid Services (CMS). 42 U.S.C. § 1396r-8(a)(1), (b)(3)(A), (c)(1)(A).

Once the rebate amount is calculated by CMS, the manufacturer applies the rebate to the state's Medicaid drug costs and, in turn, the federal government reimburses the states for the discounted cost. So, this reimbursement system necessarily involves the submission of claims to be paid by the federal government, giving rise to a potential violation of the False Claims Act. *See United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 700 (4th Cir. 2014) (setting forth the elements for an FCA claim as (1) making a false statement, (2) with the required scienter, (3) that was material, and (4) caused the federal government to pay money).

[3] There is also a minimum rebate figure that will apply when the difference between the "average manufacturer price" and the "best price" is lower than the stated minimum rebate. 42 U.S.C. § 1396r-8(c)(1)(A)(ii), (c)(1)(B)(i).

The present case involves a narrow question of statutory interpretation and the method by which drug manufacturers account for discounts when calculating the "best price" for use by CMS in determining the rebate amount. The parties agree that the Rebate Statute requires manufacturers to include in their determination of "best price" all discounts afforded to an individual purchaser. But Sheldon submits that the "best price" determination requires an aggregation of discounts provided to multiple entities along the distribution chain, and that Forest failed to do so.

As with any case involving statutory interpretation, I begin with the text of the Rebate Statute. *Copley v. United States*, 959 F.3d 118, 123 (4th Cir. 2020) (citing *Desert Palace, Inc. v. Costa*, 539 U.S. 90, 98 (2003)). When a statute's plain meaning is clear and unambiguous, our job "is to enforce [that language] according to its terms." *Lamie v. U.S. Tr.*, 540 U.S. 526, 534 (2004) (quoting *Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000)). In considering plain 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*, 588 U.S. 128, 141 (2019) (quoting *Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 666 (2007)).

The Rebate Statute defines the "best price" as "the lowest price *available from* the manufacturer . . . to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity," including "cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates." § 1396r-8(c)(1)(C)(i), (c)(1)(C)(ii)(I) (emphasis added). The straightforward reading of this language indicates that "best price" is "the lowest price available," meaning a singular

cost at which the drug can be obtained by a purchaser from a manufacturer.[4] By using the phrase "lowest price available," the statute contemplates an actual, established price paid by an individual purchaser, not a theoretical price that no purchaser pays. Quite simply, a "price" cannot be considered "available" to an entity if the manufacturer must construct that figure by aggregating discounts as the drug moves through the distribution chain to the end user. Thus, "best price," unambiguously, is the lowest price actually offered by the manufacturer to a single purchaser, which could include any one entity among the categories provided: "any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity." 42 U.S.C. § 1396r-8(c)(1)(C)(i).

Sheldon, however, takes issue with this plain meaning of "best price" in the Rebate Statute by contending that it must be read "through the lens" of the rebate agreement between CMS and Forest. According to Sheldon, the language of the Rebate Agreement clarifies that "best price" means "the *price actually realized* by a drug manufacturer for a single drug unit after aggregating *any and all* price concessions to *all* entities." I disagree.[5]

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[4] "Price" means "the cost at which something is obtained." *Merriam-Webster*, https://www.merriam-webster.com/dictionary/price; https://perma.cc/4AHQ-JSZV. "Available" means "accessible, obtainable." *Merriam-Webster*, https://www.merriam-webster.com/dictionary/available; https://perma.cc/325V-3AQD.

[5] I also disagree with Sheldon's assertion that the "average manufacturer price" (AMP) ultimately "*paid to"* the manufacturer, must always be larger than the "best price" "*available from"* the manufacturer. *See* 42 U.S.C. § 1396r-8(k)(1)(A). The Rebate Statute provides that the rebate amount is set at the "greater" between the statutory minimum rebate percentage and the difference between AMP and "best price." *Id.* § 1396r-8(c)(1)(A)(ii). The statute does not require that the difference between AMP and best price be a positive figure.

As an initial matter, I observe that CMS is required to draft rebate agreements that conform with the Rebate Statute, including the determination of rebate amounts. *See* 42 U.S.C. § 1396r-8(b)(1)(A) (referencing subsection (c) of the Rebate Statute); *see Astra USA Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 118 (2011) (explaining that such agreements "serve as the means by which drug manufacturers opt into the statutory scheme" and that the statutory and contractual obligations "are one and the same"). Thus, the language of the rebate agreement cannot transform or override the unambiguous plain meaning of "best price" in the Rebate Statute.[6]

Nonetheless, the language in the rebate agreement reinforces the plain meaning of "best price" in the Rebate Statute. The rebate agreement defines "best price" as "the lowest price at which the manufacturer sells the [drug] to any purchaser *in any pricing structure*. [And b]est price includes prices to wholesalers, retailers, nonprofit entities, or governmental entities." J.A. 357 (emphasis added). The rebate agreement further states that "best price" "shall be adjusted by the manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the *prices actually realized*." J.A. 357 (emphasis added).

[6] When statutory language is unambiguous, courts enforce its plain meaning, and any contrary agency regulation is irrelevant. *See Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 398-99 (2024) (reaffirming that courts independently determine the meaning of unambiguous statutes). For this reason, I do not address Sheldon's arguments relying on CMS's regulations or statements made in rulemaking that "interpret" the Rebate Statute.

The only notable variations in the rebate agreement's language defining "best price" are the phrases "any pricing structure" and "prices actually realized." But "any pricing structure" neatly describes the requirement, agreed upon by the parties, that all discounts applied to an individual purchaser must be aggregated, whether that discount is provided at the time of sale or provided in the form of a lagged price concession. And the phrase "prices actually realized" refers to the final, net amount a seller receives from a purchaser after aggregating all discounts to that purchaser. Nothing in this language suggests a requirement to calculate an aggregated amount that is not actually available to any individual purchaser.

I acknowledge that applying the plain meaning of "best price" may produce results that restrict the amount of the pricing benefit that the government receives under the Rebate Statute. But that perceived severity reflects Congress's choice to structure the Rebate Statute to ensure that the government receives the benefit of the lowest price actually "*available from the manufacturer*" to an individual purchaser in the private or public market. By focusing on the lowest price available to an actual market participant, rather than to a theoretical purchaser, the statute ensures that the government receives the same price benefit obtained by the actual market participant. If Congress had intended that "best price" account for complex, multi-party commercial arrangements, Congress would not have defined "best price" as "the lowest price available" to any entity.

In sum, the allegations of Sheldon's complaint, and his entire False Claim Act theory of recovery, depend on an interpretation of the Rebate Statute that would require Forest to aggregate discounts offered to multiple entities in a distribution chain when computing

"best price." In failing to decide whether Sheldon's interpretation of the Rebate Statute is correct, the majority sends the district court back to the very beginning of the inquiry. Instead, I would conclude as a matter of law that Sheldon misinterprets the plain language of the Rebate Statute, which does not require a manufacturer to aggregate discounts across multiple entities in computing its "best price." So, in my view, Sheldon has failed to sufficiently allege the element of falsity in his complaint against Forest, and I would affirm the district court's dismissal of Sheldon's complaint.