No. 22-

IN THE

Supreme Court of the United States

UNITED STATES OF AMERICA
ex rel. DEBORAH SHELDON,

Petitioner,

v.

ALLERGAN SALES, LLC,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

This case presents a nearly identical question as No. 21-1326, *United States ex rel. Schutte v. SuperValu Inc.* and No. 22-111, *United States ex rel. Proctor v. Safeway, Inc.* In *Schutte*, at the invitation of this Court, the United States, through the Solicitor General, filed a Brief as Amicus Curiae and advocated that the petition for a writ of certiorari in that case should be granted. In that Amicus Brief, the United States explained that this case also "highlights the need for this Court's review." United States *Schutte* Amicus Br. 22. Accordingly, the Court may wish to consider this petition along with the petitions filed in *Schutte* and *Proctor*. Alternatively, Sheldon respectfully requests that the Court hold this petition pending the Court's decisions in *Schutte* and *Proctor* and then dispose of this petition as appropriate.

The FCA protects Government programs from fraud by, *inter alia*, imposing civil liability on anybody who knowingly presents false claims for payment to the Government. 31 U.S.C. § 3729(a). The statute defines "knowingly" to include acting with: (1) actual knowledge; (2) deliberate ignorance; or (3) reckless disregard of the falsity of information. *See id. at* § 3729(b)(1)(A). The question presented is:

Whether and when a defendant's contemporaneous subjective understanding or beliefs about the lawfulness of its conduct are relevant to whether it "knowingly" violated the False Claims Act.

PARTIES TO THE PROCEEDING

Petitioner Deborah Sheldon is Relator for the following Governments under their various False Claims Acts: the United States of America and the States of California, Connecticut, Colorado, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Iowa, Indiana, Louisiana, Massachusetts, Maryland, Michigan, Minnesota, Montana, New Hampshire, New Jersey, Nevada, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, Washington, and Wisconsin.

Respondent is Allergan Sales, LLC.

RELATED PROCEEDINGS

United States ex rel. Sheldon v. Forest Laboratories, LLC, et al., No. 14-2535, U.S. District Court of the District of Maryland. Judgment entered Nov 5, 2020.

United States ex rel. Sheldon v. Allergan Sales, LLC, No. 20-2330, U.S Court of Appeals for the Fourth Circuit. Judgement entered Jan. 25, 2022.

United States ex rel. Sheldon v. Allergan Sales, LLC, No. 20-2330, U.S Court of Appeals for the Fourth Circuit, en banc. Judgement entered Sept. 15, 2022.

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The Fourth Circuit's en banc decision (Pet. App. 1a-2a) is available at 2022 U.S. App. LEXIS 27437. The Fourth Circuit's vacated panel opinion (Pet. App. 3a-81a) is published at 24 F.4th 340. The district court's opinion (Pet. App. 82a-140a) is available at 2020 U.S. Dist. LEXIS 249501.

JURISDICTION

The Fourth Circuit entered its en banc decision on September 23, 2022. Pet. App. 1a-2a. This Court has jurisdiction under 28 U.S.C. § 1254.

STATUTORY PROVISIONS

The relevant statutory provision are 31 U.S.C. §3729(a) (reproduced at Pet. App. 141a-142a) and 31 U.S.C. §3729(b) (reproduced at Pet. App. 143a).

INTRODUCTION

The False Claims Act imposes liability if a defendant "knowingly" presents false claims or makes false statements to the Government. 31 U.S.C. § 3729(a). "Knowingly" means to act with: (1) actual knowledge; (2) deliberate ignorance; or (3) reckless disregard of the falsity of information. 31 U.S.C. § 3729(b)(1)(A).

Since 1986, courts have generally and uniformly recognized that the FCA includes three definitions of the knowledge standard, and that liability may be found for a violation under any of the three standards. "By covering

all three states of mind, Congress cast a net broad enough to reach those who act in bad faith or without an appropriate degree of care, even where claims for payment implicate ambiguous legal conditions." United States *Schutte* Amicus Br. 11. In line with Congress's widely cast net, courts have generally applied commonly understood scienter rules and held that a defendant acts "knowingly" if the defendant subjectively knew or believed—or had reason to know or believe—that its conduct was unlawful. Scienter ultimately turns on whether the defendant understood or should have understood that its conduct was unlawful and is a mixed question of law and fact.

This consistency was interrupted in recent Seventh Circuit opinions, creating a circuit split. In *United States ex rel. Schutte v. SuperValu, Inc.*, 9 F.4th 455 (7th Cir. 2021), the Seventh Circuit applied an FCA scienter standard inspired by this Court's decision in *Safeco Insurance Co. of America v. Burr*, 551 U.S. 47 (2007). *See also United States ex rel. Proctor v. Safeway, Inc.*, 30 F.4th 649, 652 (7th Cir. 2022) (applying *Schutte*'s interpretation of *Safeco* to the FCA). Under these holdings, a relator cannot, as a matter of law, meet any of the three definitions of scienter if the defendant's conduct was consistent with a reasonable interpretation of an ambiguous legal requirement, unless authoritative guidance warned the defendant away from that interpretation.

Despite the United States filing an Amicus Brief in support of the relator in *Schutte*, the Seventh Circuit issued an extreme holding that, no matter the defendant's state of mind, ambiguity precludes a finding of actual knowledge, deliberate ignorance, or reckless disregard absent authoritative guidance. The Seventh Circuit held

that the defendant's subjective intent is "irrelevant" to the scienter inquiry. Thus, under the Seventh Circuit's rule, even if a defendant believes it is presenting false claims, wants to present false claims, and in fact presents false claims, the defendant cannot be found to have "knowingly" presented false claims if the defendant's lawyers can later convince a court in litigation that the defendant's conduct fell within a reasonable interpretation of the law.

Additionally, there is now a further split regarding whether a defendant asserting this defense must have subjectively believed its reasonable interpretation at the time of the alleged misconduct (as *Safeco* put it, "followed" the interpretation, 551 U.S. at 70 n.20) or whether a "threshold test" applies such that the defendant can escape liability merely by identifying an objectively reasonable interpretation of the law post hoc.

This case—in which the United States filed briefs and participated in oral arguments in support of Sheldon at both the panel stage and en banc stage—further exacerbated the conflict and split. A Fourth Circuit panel reviewed the district court's determination that objective reasonableness is part of both falsity and scienter. Over a forceful dissent, the panel majority adopted the threshold objective-reasonableness test laid out by the Seventh Circuit in *Schutte*.

The Fourth Circuit vacated that opinion by granting a petition for en banc rehearing. Fourth Cir. Local Rule 35 (c). After hearing additional oral argument, and even with the United States participating in oral argument in support of Sheldon, the en banc Court deadlocked seven-to-seven on whether to affirm or reverse the district court's

determination that objective reasonableness precludes liability. The Fourth Circuit's split leaves in place an incorrect district court decision that: (a) misapplied the Rule 12 motion to dismiss standard and (b) misapplied statutory construction principles. Indeed, no Fourth Circuit judge expressed support for the district court's analysis.

In its *Schutte* Amicus Brief, the United States explained how this case demonstrates the need for this Court to grant certiorari and resolve the split:

> Finally, the en banc Fourth Circuit recently deadlocked in a case raising the question presented, leaving the governing law there uncertain. In *United States ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340 (2022), the panel majority endorsed the approach adopted by the Seventh Circuit here. *See id.* at 348 (discussing decision below). The full court subsequently granted rehearing en banc and vacated the panel opinion, but the court ultimately affirmed the district court's judgment by an equally divided vote. *See United States ex rel. Sheldon v. Allergan Sales, LLC*, 49 F.4th 873 (4th Cir. 2022) (per curiam). That court's inability to agree upon a governing standard highlights the need for this Court's review.

United States *Schutte* Amicus Br. 22.

As discussed in the *Schutte* and *Proctor* petitions, and as the United States has repeatedly advocated in

this case and others, federal court decisions now evince at least three conflicts that the Court should address. *First*, this Court should address whether *Safeco* applies to the FCA. *Second*, this Court should address whether *Safeco* applies to the falsity or scienter prongs of the FCA. And, *third*, this Court should address whether *Safeco* applies as a threshold test precluding liability, even if the defendant concocted the "objectively reasonable" interpretation post hoc and did not believe or otherwise have that interpretation at the time of its alleged violative conduct.

This Court should grant certiorari and overturn the incorrect precedent that a defendant's identification of an "objectively reasonable" interpretation of a legal requirement, claimed to be ambiguous, insulates its conduct even if: (a) the defendant actually knew its conduct was wrong at the time; (b) the interpretation proffered in litigation differs from the defendant's actual contemporaneous interpretation; or (c) the defendant deliberately avoided determining the correct interpretation when the claim was submitted.

This Court should grant certiorari and reverse.

STATEMENT OF THE CASE

I. Legal Background

The FCA is the Government's primary tool to combat fraud, and the Government long ago recognized it needed "a more effective weapon against Government fraud." S. Rep. No. 99-345, at 3, 1986 U.S.C.C.A.N. 5266, 5266. Every year, between $100 and $360 billion are lost to health care fraud. *See* National Health Care Anti-Fraud Association,

The Challenge of Health Care Fraud, https://www.nhcaa.org/tools-insights/about-health-care-fraud/the-challenge-of-health-care-fraud/ (last visited Dec. 9, 2022).

To establish liability, the FCA requires both falsity and scienter—the latter of which was at the heart of the panel decision vacated by the en banc court in this case. *See* 31 U.S.C. § 3729(a)(1)(A)-(G). Anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim" has violated the FCA. *Id.* § 3729(a)(1)(A), (B) (emphasis added). The FCA explicitly defines the terms "knowing" and "knowingly," providing three possible ways to establish scienter: the person (1) had "actual knowledge of the information"; (2) acted "in deliberate ignorance of the truth or falsity of the information"; or (3) acted "in reckless disregard of the truth or falsity of the information." *Id.* § 3729(b)(1)(A). The definition "require[s] no proof of specific intent to defraud." *Id.* § 3729(b)(1)(B).

Congress added the FCA's constructive knowledge scienter provisions in 1986 to solve the so-called "ostrich" problem, *i.e.*, defendants "who ignore 'red flags' that the information may not be accurate or those persons who deliberately choose to remain ignorant of the process through which their company handles a claim." H.R. Rep. No. 99-660, at 21 (1986). Congress wanted claimants seeking public funds to make reasonable inquiries before doing so. This is one of the reasons that Congress created a standard that "unquestionably focuses on a person's subjective mental state. Congress used the phrase to reach defendants who consciously avoid steps that might reveal the truth." *See* Grassley *Schutte* Amicus Br. 7-8.

The requirement to make reasonable inquiries before seeking public funds is consistent with this Court's holdings. There is a longstanding principle that "[m]en must turn square corners when they deal with the Government." *Rock Island Ark. & La. R.R. v. United States*, 254 U.S. 141, 143 (1920). "This observation has its greatest force when a private party seeks to spend the Government's money. 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 Cnty., Inc.*, 467 U.S. 51, 63 (1984). Those claiming Government funds are "held to the most demanding standards" and subject to "the general rule that those who deal with the Government are expected to know the law." *Id.* This includes a "duty to familiarize [oneself] with the legal requirements for cost reimbursement," including "obtain[ing] an interpretation of the applicable regulations" when confronted with "a doubtful question not clearly covered by existing policy statements." *Id.* at 64.

Further, scienter is measured against an actor's knowledge at the time of conduct; a defendant may not rely on attorney's post hoc rationalization to negate scienter. *See Halo Elecs., Inc. v. Zimmer, Inc.*, 579 U.S. 93, 105 (2016).

II. Factual Background and Procedural History

The FCA claim in this case is that Defendant intentionally violated the Medicaid Rebate Statute ("Rebate Statute"). 42 U.S.C. § 1396r-8(c)(1)(C). The Rebate Statute requires drug manufacturers, to report to the Government their drugs' lowest price (i.e., "Best

Price"), inclusive of all rebates, discounts, and other price concessions given to any entity or entities.

Congress passed the Rebate Statute to ensure that manufacturers did not profit more from selling prescription drugs to the Government than they did from selling the same prescription drugs to private entities. *See* 136 Cong. Rec. S. 12954 (1990). One mechanism by which Congress achieved its goal is the Best Price provision in the Rebate Statute and Agreement. 42 U.S.C. § 1396r-8(c)(1)(C); 56 Fed. Reg. 7049; *see also Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 118 (2011) (The Rebate Statute's obligations and the "contractual obligations, in short, are one and the same."). Congress designed Best Price to ensure that the Government benefits from all rebates, discounts, and other price concessions given to any other entity or entities. Best Price requires manufacturers to report the final lowest price "actually realized" by a manufacturer for a single drug unit. 56 Fed. Reg. 7049. To report the amount the manufacturer "actually realized," the manufacturer must aggregate all "cumulative discounts, rebates, *or other arrangements*" that "subsequently adjust the prices *actually realized*" by the manufacturer for a single drug unit. *Id.* (emphasis added).

CMS repeatedly provided guidance and regulations stating that "Best Price" means the price "actually realized" by a drug manufacturer for a single drug unit after aggregating any price concessions to all entities. CMS's 2007 final regulations and accompanying comments provide that manufacturers must aggregate any price concessions to calculate the net lowest price "actually realized." *See* 72 Fed. Reg. 39142, 39201. CMS published

comments explaining that manufacturers must aggregate rebates on the same drug unit and provided one example of how aggregation works in practice. This guidance informed manufacturers that they must aggregate discounts to distinct entities in the distribution chain when calculating Best Price. *Id.* at 39199. In 2016, CMS reiterated this position regarding the requirements of the Rebate Statute and Agreement—all rebates, discounts, and pricing arrangements that affect the price actually realized by the manufacturer must be combined, even if the price concessions are received by two distinct entities. 81 Fed. Reg. 5170, 5252-53. Despite these mandates, Defendant did not report aggregated discounts.

In her Complaint, Sheldon alleged Defendant, with actual knowledge of its Best Price obligations, failed to abide by the provision's mandates. *See* Sheldon C.A. Br. 10. Sheldon alleged Defendant's unlawful reporting began in 2005 and continued until at least August 2016 and later. *Id.* Sheldon alleged Defendant actually knew, and buried its head in the sand to avoid gaining further knowledge, that the Rebate Statute and Agreement require manufacturers to aggregate discounts when calculating Best Price. *Id.*

Attached to her Complaint, Sheldon provided actual evidence of Defendant's knowledge. *Id.* at 10. In response to CMS's request for comments in advance of the 2007 regulations, Defendant, through counsel, admitted that the proposed regulation "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 10-11. Defendant urged CMS to change the language to read 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" and "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 11 (emphasis added). Not only did CMS decline to make the change Defendant proposed, CMS explicitly rejected Defendant's interpretation. 72 Fed. Reg. 39142, 39150-51, 97-99, 201.

Shortly after CMS issued its guidance, top-level managers at Defendant held meetings and prepared reports focused on the discounts Defendant offered to more than one entity in the distribution chain for a drug unit. *See* Sheldon C.A. Br. 11. Actually aware of its Best Price problem, Defendant implemented a data-audit process for rebate claims submitted by its customers. *Id.* Defendant contracted with Data Niche & Associates to develop a data-scrubbing process in which it identified the occasions Defendant paid rebates to multiple entities for a drug dispensed to a single patient. *Id.* The purpose of this process was to identify multiple-rebate claims and pay a rebate to only one entity. *Id.* Defendant included in its contracts with these entities a clause providing that Defendant would pay only one rebate when more than one entity qualified for a rebate for the same drug unit. *Id.* at 11-12. Sheldon alleged in her Complaint that Defendant initiated this process because it understood the Best Price implications of not conducting such a process. *Id.* at 12. The timing of Defendant's initiation of this audit creates the reasonable inference that the 2007 guidance was the catalyst for Defendant's decision.

But Defendant did not follow this process for all of its customers. *Id.* Instead, Defendant offered multiple concessions to preferred customers but listed only one

concession when reporting Best Price. *Id.* In doing so, Defendant violated the Rebate Statute.

In her Complaint, Sheldon estimated the difference between Defendant's one-discount-only reporting method and proper Best Price reporting: Defendant gained in excess of $680 million for the 2005-14 timeframe alone. *Id.* at 13.

Defendant filed a Motion to Dismiss Sheldon's Complaint. *See* Pet. App. 85a. Defendant argued, among other things, that Best Price does not require manufacturers to aggregate discounts when calculating the amount manufacturers actually realized. *See id. at* 129a. Contrary to the position Defendant took in its letter to CMS, Defendant argued CMS's guidance provides that it needed to report only the largest discount offered to a single entity in the supply chain. *See id.* Defendant further asserted that, even if Best Price does require it to aggregate discounts, the provision is ambiguous, Defendant's interpretation is objectively reasonable, and it was not warned away from that interpretation. *See id. at* 129a-130a.

Despite the fact that the case was at the pleadings stage, the district court avoided issues of law and instead engaged in fact finding—ultimately granting Defendant's Motion to Dismiss. *Id. at* 130a-139a. In so doing, the district court erroneously applied both falsity and scienter precedent.

With regard to falsity, the district court conflated the falsity and scienter standards. The court elected not to interpret Best Price, but accepted as plausible both

Sheldon's and Defendant's interpretation. *Id. at* 130a. Based on that non-decision, the district court determined that an objectively reasonable misinterpretation of a purportedly ambiguous statute cannot result in a false claim. *Id. at* 137a.

With regard to scienter, the district court ignored the three scienter standards and skipped ahead to the warned-away analysis. The district court failed to credit Sheldon's allegations or accept that whether an entity knew its report was false is an issue of fact that cannot be resolved at the pleading stage. *Id. at* 138a. One reason the district court engaged in improper fact-finding is that it understood the warned-away standard to be purely legal. *Id. at* 138a-139a.

On appeal, the Fourth Circuit panel issued a split decision affirming the district court—albeit with different underlying reasoning. *Id. at* 12a-33a. The panel majority adopted a singular "threshold requirement"—which is materially indistinguishable from one of the three statutory scienter prongs, reckless disregard. That threshold requirement precludes courts from analyzing the actual knowledge and deliberate ignorance prongs of FCA scienter (and precludes a relator from conducting any fact discovery on scienter). *Id. at* 16a-17a. This rendered the "warned away" analysis a purely legal issue rather than a mixed issue of fact and law, and narrowed what guidance a court may consider when conducting the warned-away analysis. *Id. at* 26a-27a.

The dissenting judge lamented the "judicial overhaul" of the FCA and explained the majority's opinion would have catastrophic effects for the Government when

fighting fraud. *Id. at* 36a-37a. The dissent highlighted that all of the cases the majority cited were unpublished or easily distinguishable, and all but one either predated or failed to distinguish this Court's decision in *Halo*. *See id. at* 49a-54a ("It's hard to see much daylight between *Halo* and the present case.").

The dissent also identified the devastating effect of the majority's over-reach:

> [T]he majority opinion effectively neuter[s] the False Claims Act—the Government's primary tool for fighting fraud—by eliminating two of its three scienter standards (actual knowledge and deliberate ignorance) and replacing the remaining standard with a test (objective recklessness) that only the dimmest of fraudsters could fail to take advantage of.
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>
> [I]t is not only the "sad truth . . . that [fraud] against the Government often does pay," S. Rep. No. 99-345, at 3, 1986 U.S.C.C.A.N. at 5268, but getting away with it is also getting easier.

Pet. App. 34a, 79a.

Sheldon sought en banc rehearing and the United States joined her in those efforts. *See* Pet. App. 2a. The Fourth Circuit voted to rehear the case, thereby vacating the panel opinion that aligned with the *Schutte* decision. *See id.* After oral argument, with the United States participating in oral argument in support of Sheldon, the

en banc court did not come to a consensus on any issue. *Id.* With an equal number of votes to affirm and reverse the district court's dismissal of the complaint, the en banc court affirmed the district court's decision by default, without opinion, thereby leaving the law unsettled with no governing standard. *Id.*

This petition followed.

REASONS FOR GRANTING THE WRIT

I. The Circuits Are Split Over How To Interpret The False Claims Act's Scienter Requirement

Certiorari should be granted to resolve a circuit split and uncertainty regarding the FCA's scienter requirement and cases involving claims of legal falsity under a "knowingly" analysis. As explained in the United States's *Schutte* Amicus Brief, "[t]he question presented has generated disagreement in the courts of appeals and is important to efforts to fight fraud involving the public fisc." United States *Schutte* Amicus Br. 18-19.

1. Four circuits apply common-place scienter principles when determining whether a defendant "knowingly" violated the FCA. These four circuits look to the defendant's subjective understanding at the time the defendant submitted its claim to determine whether it acted "knowingly." These four circuits also consider a range of evidence—from Government documents to advice of counsel to internal company warnings—as relevant indicia of the defendant's knowledge at the time the claim was made. Although some of these circuits acknowledge that *Safeco Insurance Co. of America v. Burr*, 551 U.S.

47 (2007) is relevant authority, they do not apply a rigid *Safeco* analysis to all three scienter variations of the "knowingly" analysis. A defendant's reasonable-but-wrong interpretation of a potentially ambiguous statute or regulation is evaluated under all three standards.

For example, the Eleventh Circuit has held that "[a]lthough ambiguity may be relevant to the scienter analysis, it does not foreclose a finding of scienter." *United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1155 (11th Cir. 2017). The appropriate inquiry under the False Claims Act is "whether the defendant actually knew or should have known that its conduct violated a regulation in light of any ambiguity at the time of the alleged violation." *Id.* (emphasis added). In making this inquiry, the Eleventh Circuit precedent directly contradicts the Seventh Circuit's ruling in *Schutte* and the now-vacated panel decision in this case; the Eleventh Circuit rejects the position that the defendant can hide behind a "'reasonable' interpretation of an ambiguous regulation manufactured post hoc." *Id.*

The defendants in *Phalp* argued that *Safeco* required a different result. *See* Appellees' Answer Br. at 77, *Phalp*, 2016 U.S. 11th Cir. Briefs LEXIS 2035 ("*Safeco* is instructive on the issue of FCA scienter in a case, like this, where Defendants adopted reasonable interpretations of the Medicare regulations at issue in the absence of contrary authorities"); *id.* at 79 (arguing that *Safeco*'s "definition of 'willfully' and the FCA's definition of 'knowingly' are synonymous," such that the Eleventh Circuit should follow "the Supreme Court's knowledge analysis in *Safeco*"). The Eleventh Circuit rejected that argument, relying on the United States's Amicus Brief that is nearly identical to

the United States's Amicus Briefs filed in this case and in *Schutte*, among others. *See also United States ex rel. Walker v. R&F Properties of Lake County, Inc.*, 433 F.3d 1349 (11th Cir. 2005).

The Ninth Circuit has adopted a similar approach to the "knowingly" analysis. In *United States ex rel. Oliver v. Parsons Co.*, 195 F.3d 457, 461 (9th Cir. 1999), the defendant improperly reported information, thereby causing the Government to overpay under a contract—those are the allegations in the Complaint in this case. Although the defendant argued that its reasonable interpretation of the reporting requirement precluded liability, the Ninth Circuit determined this was not dispositive. *Id.* at 463-64. Instead, the court inquired into the defendant's subjective belief at the time, holding that evidence of the defendant's intent to leave a subcontractor off Government forms—including its directive to "forget about it" when the issue was brought to the defendant's attention by an employee—was enough to "preclud[e] summary judgment on the issue of scienter." *Id.* at 465.

In *United States v. Mackby*, 261 F.3d 821 (9th Cir. 2001), the Ninth Circuit also rejected the argument that "to sustain an FCA action, a claim must be found to be false under any plausible interpretation" of the relevant legal requirements. *Id.* at 827 (quotation marks omitted). Citing this Court's decision in *Heckler*, the Ninth Circuit recognized that "[p]rotection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law," and held that the defendant had "a duty to familiarize [himself] with the legal requirements for payment," and was properly held liable for his failure to conduct a reasonable inquiry before

seeking payment. *Id.* at 828 (quoting *Heckler v. Cmty. Health Servs. of Crawford Cnty., Inc.*, 467 U.S. 51, 63-64 (1984)).

Post-*Safeco*, the Ninth Circuit reached a similar result. In *United States v. Chen*, the Ninth Circuit determined that Medicare "pamphlets and newsletters that collectively explained the requirements" for a regulation were evidence that the defendant's interpretation "was neither correct nor in good faith." 402 F. App'x 185, 187-88 (9th Cir. 2010) (citing *Oliver*, 195 F.3d at 464). The Ninth Circuit explained that "Medicare providers have a duty to familiarize themselves with billing requirements," and that providers that fail to do so and get the law wrong "act[] in reckless disregard or deliberate ignorance." *Id.* at 187 (citing *Heckler*, 467 U.S. at 64); *see also United States ex rel. Ali v. Daniel, Mann, Johnson & Mendenhall*, 355 F.3d 1140, 1150 (9th Cir. 2004) (holding that evidence of defendant's preparation of a document "without investigating the truth of [a] claim" within the document "is sufficient to raise a triable issue of material fact as to whether [defendants] . . . acted knowingly or with reckless disregard for or deliberate ignorance of the truth or falsity of the representations"). District courts in the Ninth Circuit apply the same rule.

The Sixth Circuit reached a similar result in *United States ex rel. Prather v. Brookdale Senior Living Communities*, 892 F.3d 822 (6th Cir. 2018), where the Sixth Circuit focused on the defendant's subjective understanding at the time of the alleged misconduct and held that "defendants deliberately ignored multiple employees' concerns about their compliance with relevant regulations," indicating "that they acted with 'reckless

disregard." *Id.* at 838. The Sixth Circuit continued: "[o]nce the defendants had been informed by the employees explicitly hired to review these claims that there may be compliance issues, they had an obligation to inquire into whether they were actually in compliance with all appropriate regulations." *Id.*; *see also United States ex rel. Williams v. Renal Care Grp., Inc.*, 696 F.3d 518, 531 (6th Cir. 2012) (holding evidence of good faith, including seeking legal counsel on an ambiguous issue and having counsel seek "clarification on the rules from CMS officials," proved "defendants were not in reckless disregard of the truth or falsity of their claims").

Finally, the Tenth Circuit has held that a defendant's understanding of a statute at the time a claim is made is relevant but not dispositive. In *United States v. Boeing Co.*, 825 F.3d 1138, 1145 (10th Cir. 2016), the Tenth Circuit looked to the record for evidence that the defendant subjectively "knew the [aircraft] parts didn't comply with FAA regulations—or, alternatively, was deliberately ignorant of, or acted with reckless disregard to, FAA violations—yet submitted a claim to the Government for payment anyway." *Id.* at 1149. The Tenth Circuit was "struck [t]here by what is not in the record," *i.e.*, the lack of evidence of subjective understanding or intent. *Id.* (quotation marks omitted). It also found the relevant requirements ambiguous, but ambiguity was only one consideration in the court's holistic scienter inquiry. *See id.* at 1149-50; *see also United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 950 (10th Cir. 2008) (finding no scienter because defendants did not "intentionally ignore[]," "appreciate[] the significance of, yet disavow[]," or "purposefully refuse[] to verify" ambiguous legal requirements for Department of Defense grants).

2. In contrast with these circuits that apply commonly understood scienter principles, the Seventh Circuit, and two other circuits, have adopted narrower rules inspired by this Court's decision in *Safeco*. Those three circuits hold that a defendant can use a reasonable-but-wrong interpretation to disprove FCA scienter unless authoritative guidance warned the defendant away from that interpretation.

In *Schutte*, the majority wrongly asserted that its decision to apply a threshold "objective reasonableness" test was consistent with the decisions of other circuits. *Schutte*, 9 F.4th at 465 ("Every other circuit court to discuss the relevance of *Safeco*'s scienter standard to the FCA has arrived at this conclusion"). The *Schutte* majority reached that conclusion after misframing the discussion regarding the split—arguing that there is no split because no circuit court has explicitly rejected the application of *Safeco* to the FCA. This framing is wrong because the circuit-split inquiry does not turn on whether courts have cited particular precedents; it turns on whether different circuits' precedential decisions resolve the same legal question using materially different rules such that a given case will come out differently if filed in a different circuit. *See also Proctor*, 30 F.4th at 652 (applying *Schutte*'s threshold "objective reasonableness" test).

Properly understood, the split is clear because *Schutte* would have been decided differently in other circuits. Under the commonly understood scienter rule, evidence of a defendants' subjective understanding would have precluded summary judgment despite any ambiguity about the statutory scheme.

The Eighth and D.C. Circuits also apply *Safeco* in the FCA context, but are somewhat less clear as to whether a defendant must have actually held the subjective belief that its interpretation was correct at the time of the challenged conduct. For example, the Eighth Circuit holds that "a reasonable interpretation of a statute cannot support a claim under the FCA if there is no authoritative contrary interpretation of that statute." *United States ex rel. Hixson v. Health Mgmt. Sys., Inc.*, 613 F.3d 1186, 1190 (8th Cir. 2010); *see also Olson v. Fairview Health Servs. Of Minn.*, 831 F.3d 1063, 1072 (8th Cir. 2016); *United States ex rel. Ketroser v. Mayo Found.,* 729 F.3d 825, 832 (8th Cir. 2013); *United States ex rel. Donegan v. Anesthesia Associates of Kansas City, PC*, 833 F.3d 874 (8th Cir. 2016); *but see United States ex rel. Miller v. Weston Educ., Inc.*, 840 F.3d 494, 502-03 (8th Cir. 2016) (reversing summary judgment because evidence of defendant's understanding "both before and after" the challenged conduct showed a "dispute of material fact whether, when signing the [agreement, defendant] intended to manipulate its records").

In *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281 (D.C. Cir. 2015), the D.C. Circuit held as a matter of law that a defendant could not be liable under the FCA because (1) its interpretation of an ambiguous term was "reasonable" and (2) there was no "authoritative guidance" from the court of appeals or relevant agency warning the defendant away from that interpretation. *Id.* at 289 (citing *United States ex rel. K&R Ltd. P'ship v. Mass. Hous. Fin. Agency*, 530 F.3d 980, 983 (D.C. Cir. 2008)). The D.C. Circuit precedent, like the Eighth Circuit precedent, is ambiguous as to whether defendants must have contemporaneously held their reasonable interpretation

at the time of the challenged conduct. Compare *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1272 (D.C. Cir. 2010) and *United States ex rel. Morsell v. NortonLifelock, Inc.*, 560 F. Supp. 3d 32, 46 (D.D.C. 2021).

3. In this case, a sharply divided panel of the Fourth Circuit issued an opinion that mirrored *Schutte*'s reasoning. The panel majority held that because a defendant's reading of the relevant statute was "objectively reasonable and because it was not warned away from that reading by authoritative guidance, it did not act 'knowingly' under the False Claims Act." Pet. App. 4a. According to the panel majority, allegations in the Complaint that the Defendant was aware that its reporting conduct violated the reporting requirements were of no matter because, according to the majority, the knowledge inquiry ends once the defendant offered an objectively reasonable interpretation of the reporting requirement that would justify its reporting procedure. Pet. App. 12a-17a. The panel majority's opinion provoked a passionate dissent arguing that the panel majority had committed a "judicial overhaul of the False Claims Act" by applying *Safeco* to the FCA, deepened a split with the Eleventh Circuit, and applied the *Safeco* framework incorrectly. Pet. App. 49a.

The Fourth Circuit, however, did not allow the *Schutte*-mirroring panel decision to stand. The en banc court voted to rehear the case. But the en banc proceedings muddied rather than cleared the waters. The Court issued a single-sentence decision in which it announced that the Court was equally divided. *Id.* at 2a. The Fourth Circuit judges split seven-to-seven after en banc rehearing— which "highlights the need for this Court's review." United States *Schutte* Amicus Br. 22. As a result, the panel

opinion was vacated, and that the district court's decision was affirmed—essentially by default.

II. The Question Presented Is Frequently Recurring And Important

Certiorari should be granted because the question presented is frequently recurring. Indeed, there are currently multiple petitions pending before this Court raising the same question. *See, e.g.*, No. 21-1326, *United States ex rel. Schutte v. SuperValu Inc.* and No. 22-111, and *United States ex rel. Proctor v. Safeway, Inc.* Further, the fact pattern in this case is one that occurs frequently in FCA litigation: a company submitted false claims in violation of a legal requirement under a Government program, but, in litigation, that company identifies an interpretation of the rule that is incorrect but objectively reasonable and would have allowed its conduct. The issue arises mostly in health care, Medicare, and prescription drug cases,[1] but it also arises in an array of FCA cases—

1. *See, e.g.*, *United States v. Allergan, Inc.*, 746 F. App'x 101, 103, 106 (3d Cir. 2018) (affirming motion to dismiss because defendants held a reasonable-but-wrong interpretation of their drugs' "Average Manufacturer Price"); *United States ex rel. Garbe v. Kmart Corp.*, 824 F.3d 632, 645 (7th Cir. 2016) (holding Kmart's generic-drug discount prices were its "usual and customary" prices, not the much-higher prices charged to Medicare Part D); *BCBSM, Inc. v. Walgreen Co.*, 512 F. Supp. 3d 837, 847 n.3 (N.D. Ill. 2021) (describing Walgreen's settlement of FCA claims for submitting "usual and customary" prices higher than those for its cash-discount program); *United States v. Safeway Inc.*, 466 F. Supp. 3d 912, 941 (C.D. Ill. 2020) (granting summary judgment for a reasonable-but-wrong interpretation of "usual and customary prices"), appeal pending, No. 20-3425 (7th Cir. docketed Dec. 15, 2020).

everything from military contracting to education financing to reimbursements for hospitals.[2] Indeed, defenses related to regulatory ambiguity are litigated in myriad FCA cases every year.[3]

The problem is not that the Government is lax about regulating or resolving ambiguities. Instead, the problem is that a certain amount of ambiguity is inevitable in complex Government programs—and so it is unrealistic to expect the Government to anticipate and regulate in response to every potential ambiguity, particularly when, as here, a defendant in bad faith conceals its unlawful conduct. Instead, the Government relies—and indeed must rely—on contractors acting in good faith and attempting to resolve ambiguities relating to payment and reporting requirements instead of exploiting every ambiguity to extract the maximum amount of taxpayer funds.

Certiorari should also be granted because the question presented is important in the qualitative sense. As the United States explained in its *Schutte* Amicus brief, the threshold objective reasonableness test "could significantly

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2. *See, e.g.*, *Oasis Int'l Waters, Inc. v. United States*, 134 Fed. Cl. 405 (2016); *Miller*, 840 F.3d 494; Olson, 831 F.3d 1063.

3. *See, e.g.*, *United States ex rel. Martino-Fleming v. S. Bay Mental Health Ctrs.*, 540 F. Supp. 3d 103 (D. Mass. 2021) (discussing whether regulations for clinical supervision, recordkeeping, and counselor credentialing were ambiguous, based on defendant's "reasonable interpretations" defense); *United States ex rel. Ormsby v. Sutter Health*, 444 F. Supp. 3d 1010, 1071-72 (N.D. Cal. 2020) (finding that defendants' claimed "reasonable interpretation" of an actuarial-equivalence regulation was precluded by authoritative guidance).

disrupt Government programs involving everything from medical insurance to military equipment." United States *Schutte* Amicus Br. 22.[4] Divergent interpretations of the FCA threaten to drastically expand the defense of regulatory ambiguity in a way "that only the dimmest of fraudsters could fail to take advantage of." Pet. App. 34a. It will gut the Government's ability to recover for false claims if a bad-faith actor can comb regulations post hoc for any arguable ambiguity and defeat scienter on the basis that someone else, somewhere else, could have held a different interpretation.

The question presented also has important implications for the role of administrative agencies because the circuits clash on what constitutes "authoritative guidance." The Seventh Circuit has limited authoritative guidance to "circuit court precedent or guidance from the relevant agency" that speaks to the defendant's interpretation with "a high level of specificity." *Schutte*, 9 F.4th at 471. But the Fourth Circuit considers other sources of guidance—for example, warnings from legal counsel. *See United States ex rel. Lutz v. Mallory*, 988 F.3d 730, 737 (4th Cir. 2021); *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 376 (4th Cir. 2015). This was another issue on which the

4. *See, e.g.*, *Ketroser*, 729 F.3d 825 (Department of Health and Human Services); *United States v. Quicken Loans Inc.*, 239 F. Supp. 3d 1014 (E.D. Mich. 2017) (Department of Housing and Urban Development); *United States v. Savannah River Nuclear Sols., LLC*, No. 1:16-cv-00825-JMC, 2016 U.S. Dist. LEXIS 168067 (D.S.C. Dec. 6, 2016) (Department of Energy); *U.S. Dep't of Transp. ex rel. Arnold v. CMC Eng'g, Inc.*, 947 F. Supp. 2d 537 (W.D. Pa. 2013) (Department of Transportation), aff'd, 567 F. App'x 166 (3d Cir. 2014); *United States v. Kellogg Brown & Root Servs., Inc.*, 800 F. Supp. 2d 143 (D.D.C. 2011) (Department of Defense).

panel majority and dissenting judge clashed, with the en banc court providing no resolution. In essence, if the narrower view becomes the norm, the Government would have to play the role of a company's attorney rather than allowing the jury to consider whether the defendant's failure to heed the warnings of attorneys or employees.

III. This Case Plays An Essential Role In Answering The Question Presented

The question presented in this petition was the sole issue decided by the panel majority that was vacated by the Fourth Circuit en banc. Because the en banc court was deadlocked seven-to-seven, it left the key issue substantively unaddressed—what is the role subjective intent plays in FCA scienter in the face of an ambiguous legal requirement?

There are several petitions before the Court presenting similar questions but among those petitions, this one plays a distinct role. The procedural posture of this case gives the Court an actual controversy to which it can moor any determination of whether and how the subjective intent can be addressed at the pleadings stage, rather than at the summary judgment stage. After all, the key aspect of the decision making below was whether an "objective reasonableness" test precludes courts from considering facts alleged in a complaint establishing that the defendant had actual knowledge and/or acted with deliberate ignorance at the time it submitted the false claims because the defendant's post hoc reasonable interpretation of a statute forms an impenetrable shield behind which all three FCA scienter standards may hide.

Further, this case provides this Court a vehicle to hold that the warned-away analysis is not "purely legal"—*see, e.g.*, *Purcell*, 807 F.3d at 288—and resolve whether warned away can be decided on the pleadings and/or address the limits of a court's pleadings-based warned-away analysis.

For these reasons, the related questions presented in the similar cases should be considered together—the range of procedural postures provides the Court a greater opportunity to address the legal issues and evidentiary issues that have arisen in the various cases.

IV. The Decision Below Is Incorrect

Under the current state of play, if the underlying appeal had been decided under Sixth, Ninth, Tenth, or Eleventh Circuit's precedent, the panel would not have analyzed the case under the *Safeco* standard, and the court would have reversed the district court's dismissal and remanded the case.

If the DC Circuit or Eighth Circuit had heard the appeal, the panel may have subjected the Complaint to an analysis under *Safeco* but would have reversed the district court. The district court would then have addressed arguments and evidence related to Defendant's subjective intent at the summary judgment stage.

In the Seventh Circuit, this case would have been dismissed under *Schutte* assuming the panel found the Defendant's interpretation objectively reasonable. Under the Seventh Circuit's rule, even a defendant that believes it is presenting, wants to present, and actually does present a false claim is not liable under the FCA if its lawyers

can later concoct a reasonable interpretation of the law that covers its conduct. Thus, rather than encourage contractors to turn square corners when dealing with the Government, the Seventh Circuit's rule encourages the opposite behavior: taking as much public money as possible and relying on skilled lawyering to whitewash the misconduct after the fact. This approach contravenes the FCA's text and this Court's precedents.

And because the Fourth Circuit was deadlocked seven-to-seven after en banc rehearing in this case, future parties can do no more than hope to be lucky when drawing a panel of judges.

The Fourth Circuit would have issued a substantive decision had it given the proper weight to the FCA's text. The statutory definition of "knowingly" lays out three independent ways to meet it: "(i) ha[ving] actual knowledge of the information; (ii) act[ing] in deliberate ignorance of the truth or falsity of the information; or (iii) act[ing] in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). These three paths have distinct meanings. A core distinction is that "actual knowledge" and "deliberate ignorance" are centrally concerned with one's subjective knowledge whereas "reckless disregard" also adds an objective standard. Compare Knowledge, Black's Law Dictionary (11th ed. 2019) ("An awareness or understanding of a fact or circumstance; a state of mind in which a person has no substantial doubt about the existence of a fact."); and Deliberate, *id.* ("Intentional; premeditated; fully considered."), with Reckless Disregard, *id.* ("[I]ntentional commission of a harmful act or failure to do a required act when the actor knows or has reason to know[.]").

Moreover, "'it is a settled principle of interpretation that, absent other indication, Congress intends to incorporate the well-settled meaning of the common law terms it uses.' And the term 'fraudulent' is a paradigmatic example of a statutory term that incorporates the common-law meaning of fraud." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 187 (2016) (citation and brackets omitted). In *Escobar*, the Court examined the very FCA provision at issue here and concluded that, besides no longer requiring specific intent, "Congress retained all other elements of common-law fraud that are consistent with the statutory text." *Id.* at 187 n.2.

Congress thus retained an emphasis on subjective belief, which plays a central role in assessing scienter for common law fraud. Under the Second Restatement of Torts:

> A misrepresentation is fraudulent if the maker (a) knows or believes that the matter is not as he represents it to be, (b) does not have the confidence in the accuracy of his representation that he states or implies, or (c) knows that he does not have the basis for his representation that he states or implies.

Restatement (Second) of Torts § 526. The comments to the Restatement repeatedly emphasize the relevance of subjective belief. *See id.* cmt. c ("[K]nowledge of falsity is not essential; it is enough that he believes the representation to be false."); *id.* cmt. d ("[I]t is a matter to be taken into account in determining the credibility of the defendant if he testifies that he believed his

representation to be true."); *id.* cmt. e ("[F]raud is proved if it is shown that a false representation has been made without belief in its truth[.]"). The Restatement definition is fully consistent with the FCA's definition of "knowingly," signaling Congress's intention to retain this common law understanding.

The Restatement is not the only source emphasizing that subjective intent matters. The relevance of subjective belief is a bedrock principle throughout the common law of fraud. *See* George Spencer Bower, The Law of Actionable Misrepresentation §§ 99-100, at 107-08 (2d ed. 1927) ("[W]here this 'honest belief in its truth' is not to be found, the misrepresentation is fraudulent . . . ." *Id.* at 105).

To the extent the FCA departs from the common law, it is only to protect the Government from fraud. As Senator Grassley explained, "Congress intended the FCA's scienter standard to be less rigorous, not more rigorous, than specific intent statutes." Grassley *Schutte* Amicus Br. 10. When amending the FCA, Congress intended to "close the door on technical scienter defenses." *Id.*

> Congress not only set out three alternative means of proving it, but also took pains to make clear that the scienter bar should be lower than in criminal and other specific intent statutes. Congress achieved that outcome by emphasizing that "no proof of specific intent to defraud" would be required under the FCA. 31 U.S.C. § 3729(b)(1)(B).

Id. Recent circuit court opinions have departed from both the language and intent of the statutory scheme to such an extent that even uncontested proof of specific

intent to defraud would be insufficient if an enterprising attorney can conjure a post hoc "objectively reasonable" interpretation of a statute. *See Halo*, 579 U.S. at 105 ("someone who plunders a patent—infringing it without any reason to suppose his conduct is arguably defensible—can nevertheless escape any comeuppance under § 284 solely on the strength of his attorney's ingenuity."). The decision to subject any FCA Complaint to a threshold objective-reasonableness test cannot be squared with the statute's enactment history or its plain meaning.

The Fourth Circuit should have followed this precedent. In *Escobar*, for example, the Court rejected the argument that a defendant cannot know that a requirement is a condition of payment unless the Government expressly calls it so. 579 U.S. at 191. Under *Escobar*'s scienter analysis, "[i]f the Government failed to specify that guns it orders must actually shoot, but the defendant knows that the Government routinely rescinds contracts if the guns do not shoot, the defendant has 'actual knowledge.'" *Id.* Likewise, *Escobar* recognized the potential for a finding of "deliberate ignorance" or "reckless disregard" of a requirement's materiality "even if the Government did not spell this out." *Id.* But the Fourth Circuit allowed a bad-faith actor to escape liability in the absence of circuit court precedent or highly specific agency guidance.

The Fourth Circuit also failed to follow this Court's long-standing approach to parties claiming taxpayer money. The Court generally requires such parties to "turn square corners" when "seek[ing] to spend the Government's money"—imposing on any such party "a duty to familiarize itself with the legal requirements for cost reimbursement." *Heckler*, 467 U.S. at 63, 64 (quoting *Rock Island Ark.*, 254 U.S. at 143). Contractors and other

providers are expected to determine—before they claim public funds—whether their claims are eligible. They are not allowed simply to take whatever they can unless the Government specifically forbids it. "There is simply no requirement that the Government anticipate every problem that may arise in the administration of a complex program such as Medicare." *Id.* at 64.

The courts that have rejected the reasoning of *Escobar* and *Heckler* have instead looked to the Court's decision in *Safeco*. However, *Safeco* interpreted a different word ("willfully" not "knowingly"), under a different statute (Fair Credit Reporting Act not FCA), and appealed to a different common law tradition ("reckless disregard of a person's physical safety," not fraud). *Safeco*, 551 U.S. at 52, 69. Moreover, *Safeco* itself emphasized that "willfully" is a "word of many meanings whose construction is often dependent on the context in which it appears." *Id.* at 57 (citation omitted).

The threshold objective-reasonableness test rests heavily, and incorrectly, on footnote 20 in *Safeco*, which indicated that in the Fair Credit Reporting Act context, the defendant's subjective belief was not relevant. Any suggestion that this Court intended to revolutionize the law of fraud in a footnote of an opinion about the Fair Credit Reporting Act is manifestly incorrect. Indeed, in *Halo*, this Court refused to extend *Safeco*'s footnote 20 to the distinct context of enhanced damages under the Patent Act. The Court understood that bad faith had always been a basis for awarding such damages, and nothing in *Safeco* disturbed that status quo. *Halo*, 579 U.S. at 106 n.*. So too here: The text and purpose of the FCA make it clear that bad faith has always been relevant to scienter. *See* S. Rep. No. 99-345, at 7, 21.

The Court in *Halo* recognized that "culpability is generally measured against the knowledge of the actor at the time of the challenged conduct." *Halo*, 579 U.S. at 105. Moreover, the Court rejected the proposition that *Safeco* creates a shield that allows defendants to escape liability through a lawyer's post hoc ingenuity. *Id.* at 106 ("Nothing in *Safeco* suggests that we should look to facts that the defendant neither knew nor had reason to know at the time he acted."). The Court should apply the same reasoning in the FCA context—a defendant that believes it is presenting false claims, wants to present false claims, and in fact presents false claims, acted "knowingly."

CONCLUSION

Certiorari should be granted. Alternatively, Sheldon respectfully requests that the Court hold this petition pending the Court's decisions in *Schutte* and *Proctor* and then dispose of this petition as appropriate.

Respectfully submitted,

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APPENDIX

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APPENDIX A — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT, DATED SEPTEMBER 23, 2022

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 20-2330

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.

UNITED STATES OF AMERICA; TAXPAYERS AGAINST FRAUD EDUCATION FUND,

Amici Supporting Appellant,

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

Amici Supporting Appellee.

Appendix A

September 15, 2022, Argued
September 23, 2022, Decided

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

Before GREGORY, Chief Judge, WILKINSON, NIEMEYER, MOTZ, KING, AGEE, WYNN, DIAZ, THACKER, HARRIS, RICHARDSON, QUATTLEBAUM, RUSHING, and HEYTENS, Circuit Judges.

ON REHEARING EN BANC

PER CURIAM:

On rehearing en banc, the panel opinions in *United States ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340 (4th Cir. 2022), are vacated, and the judgment of the district court is affirmed by an equally divided court.

AFFIRMED

APPENDIX B — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT, DATED JANUARY 25, 2022

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 20-2330

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.

UNITED STATES OF AMERICA; TAXPAYERS AGAINST FRAUD EDUCATION FUND,

Amici Supporting Appellant.

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

Amici Supporting Appellee.

Appendix B

October 28, 2021, Argued
January 25, 2022, Decided

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

Before WILKINSON, WYNN, and RICHARDSON, Circuit Judges. Judge Wilkinson wrote the opinion, in which Judge Richardson joined. Judge Wynn wrote a dissenting opinion.

WILKINSON, Circuit Judge:

Plaintiff Troy Sheldon filed a False Claims Act *qui tam* suit against his employer, Forest Laboratories, LLC. He alleged that Forest engaged in a fraudulent price reporting scheme under the Medicaid Drug Rebate Statute, 42 U.S.C. § 1396r-8, by failing to aggregate discounts given to separate customers for purposes of reporting "Best Price." Because Forest's reading of the Rebate Statute was at the very least objectively reasonable and because it was not warned away from that reading by authoritative guidance, it did not act "knowingly" under the False Claims Act. As a result, we affirm the district court's dismissal of Sheldon's complaint.

We thank our friend for his thoughtful dissent. We do of course agree with him that "[t]he False Claims Act is the government's primary litigative tool for the recovery of losses sustained as the result of fraud against

the government." Dissenting Op. at 32 (quoting *Avco Corp. v. U.S. Dep't of Just.*, 884 F.2d 621, 622, 280 U.S. App. D.C. 182 (D.C. Cir. 1989)). Regrettably, despite all protestations, the dissent nullifies the whole concept of scienter about which the Supreme Court has shown an especial solicitude. The FCA unquestionably has a punitive aspect, and the kinship between civil scienter and criminal mens rea in this case is closer than Sheldon or the dissent is willing to acknowledge.

Sheldon's position takes the FCA a very long step toward a strict liability statute. It conflates factual fraud and legal fraud, thereby facilitating steep liability for those whose factual representations are not alleged to be either false or duplicitous and those whose legal position is not only arguable but correct. Sheldon does not so much as allege reckless disregard or deliberate indifference or nefarious knowledge here with respect to, in the operative word of the statute, the "information." 31 U.S.C. § 3729(b)(1)(A). Yet the relator's position instead makes sinister actors out of parties who have followed the law in every respect and sought administrative guidance where none was ever provided. Given the veritable thicket of Medicaid regulations, it is not too much to expect something more in the way of clarity and direction than was ever offered here. To reward the state with treble damages for this treatment of parties in the private sector is something no court should do.

Sheldon would disregard Judge Hollander's sound counsel that the Rebate Statute's "plain and natural reading" did not require aggregating discounts, along

with her sensible conclusion that there was not "a single example where CMS explicitly state[d] that manufacturers must aggregate discounts to different customers along the supply chain in a given sale." *United States ex rel. Sheldon v. Forest Laboratories, LLC*, 499 F. Supp. 3d 184, 209, 211 (D. Md. 2020). Sheldon in addition recommends we ignore all our sister circuits which have followed the framework that the Supreme Court has set forth in *Safeco Insurance Co. of America v. Burr*, 551 U.S. 47, 127 S. Ct. 2201, 167 L. Ed. 2d 1045 (2007), thus opening wide a stark circuit split. *See United States ex rel. Schutte v. SuperValu Inc.*, 9 F.4th 455, 459 (7th Cir. 2021); *United States ex rel. Streck v. Allergan, Inc.*, 746 F. App'x 101, 106 (3d Cir. 2018); *United States ex rel. McGrath v. Microsemi Corp.*, 690 F. App'x 551, 552 (9th Cir. 2017); *United States ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC*, 833 F.3d 874, 879-80 (8th Cir. 2016); *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 290-91, 420 U.S. App. D.C. 176 (D.C. Cir. 2015). Moreover, Sheldon proposes to disregard the Supreme Court's insistence that the concept of scienter be given "rigorous" application, *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 136 S. Ct. 1989, 2002, 195 L. Ed. 2d 348 (2016), and the dissent dismisses as "dictum" Supreme Court guidance which it finds inconvenient, Dissenting Op. at 31. All this—at all three levels of the judicial system—Sheldon and the dissent would overturn, in deference to a view that is not sustainable under law or under any notion of notice and due process with which we are familiar.

Appendix B

I.

A.

Medicaid offers federal financial assistance to states that reimburse certain medical expenses for eligible individuals. *Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 650, 123 S. Ct. 1855, 155 L. Ed. 2d 889 (2003). One of those expenses is prescription drugs. 42 U.S.C. § 1396d(a)(12). To make sure that Medicaid programs receive "the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser," H.R. Rep. No. 101-881, at 96 (1990), Congress enacted the Medicaid Drug Rebate Statute in 1990, *see* 42 U.S.C. § 1396r-8.

Under the Rebate Statute, manufacturers seeking to have their drugs covered by Medicaid must enter into Rebate Agreements with the Secretary of Health and Human Services and provide quarterly rebates to states on Medicaid sales of covered drugs. *Id.* § 1396r-8(a)(1), (c)(1)(A). The manufacturer reports the "Average Manufacturer Price" and the "Best Price" for its covered drugs to the Centers for Medicare & Medicaid Services (CMS); CMS then calculates the rebate amount that the manufacturer must pay to the states for each drug. *See id.* § 1396r-8(b)(3)(A). For covered drugs, the rebate amount is the greater of two numbers: (1) the statutory minimum rebate percentage, or (2) the difference between the Average Manufacturer Price and the Best Price. *Id.* § 1396r-8(c)(1)(A). Federal payments to each state are reduced by the rebates that the state receives from manufacturers. *Id.* § 1396r-8(b)(1)(B).

Appendix B

The Rebate Statute defines Best Price as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity," which "shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates." *Id.* § 1396r-8(c)(1)(C)(i), (ii)(I). CMS regulations likewise define Best Price as "the lowest price available from the manufacturer during the rebate period to any entity in the United States," including "all sales and associated rebates, discounts and other price concessions provided by the manufacturer to any entity." 42 C.F.R. § 447.505(a) (2007). Best Price "shall be net of cash discounts . . . and any other discounts or price reductions and rebates . . . which reduce the price available from the manufacturer." *Id.* § 447.505(e)(1) (2007). And the Rebate Agreement defines Best Price as "the lowest price at which the manufacturer sells the [covered drug] to any purchaser in the United States," which "shall be adjusted by the manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized." J.A. 213; *see* 56 Fed. Reg. 7049, 7050 (Feb. 21, 1991).

Acknowledging Medicaid's complexity, the Rebate Agreement provides that "[i]n the absence of specific guidance," manufacturers should "make reasonable assumptions in [their] calculations of . . . Best Price, consistent with the requirements and intent of [the Rebate Statute], Federal regulations and the terms of this agreement." J.A. 217. In subsequent rulemaking, CMS has reaffirmed the need for manufacturers to make such

reasonable assumptions. *See, e.g.*, Medicaid Program; Prescription Drugs, 72 Fed. Reg. 39,142, 39,164 (July 17, 2007).

Because Medicaid involves submitting claims to the government, it implicates the False Claims Act (FCA). Relevant here, the FCA imposes liability if a person "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation . . . to the Government" or "knowingly conceals or knowingly and improperly avoids or decreases an obligation . . . to the Government." 31 U.S.C. § 3729(a)(1)(G). The FCA defines "knowingly" to mean that a person "(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." *Id.* § 3729(b)(1)(A). It "require[s] no proof of specific intent to defraud." *Id.* § 3729(b)(1)(B).

The FCA allows private individuals known as relators to bring *qui tam* actions "for the person and for the United States Government." *Id.* § 3730(b)(1). The United States can choose to intervene in the relator's action if it wishes. *Id.* § 3730(b)(2), (4). When, as here, the government declines to intervene, the relator generally receives 25-30% of any proceeds of the action, plus attorney's fees and costs. *Id.* § 3730(d)(2). If an FCA action succeeds, defendants are liable for treble damages as well as a civil penalty of up to $10,000 per claim. *Id.* § 3729(a).

Appendix B

B.

Relator Troy Sheldon filed this FCA suit against his employer Forest Laboratories, LLC in 2014.[1] In essence, Sheldon alleged that Forest gave discounts to separate customers along distribution chains but failed to account for the combined amount of all discounts in calculating Best Price, which led to the submission of false pricing reports to the government. This allegedly reduced the rebates that Forest paid to participating states and resulted in the federal government paying at least $680 million more than it would have if Forest had accurately reported Best Price.

To give an example: on one covered drug, Sheldon alleged that in FY2013 Forest gave a 20% discount to a patient's insurance company and a 10% discount to the same patient's pharmacy—two different entities on the distribution chain. *See* J.A. 98. Sheldon alleged that Forest was required to aggregate these discounts, report a Best Price of 70%, and give Medicaid a 30% rebate. Instead, Forest did not aggregate these discounts because they were given to different entities, reported a Best Price

1. Troy Sheldon died after filing this action and Deborah Sheldon, his wife, was substituted as plaintiff. And in 2018, Forest merged into Allergan Sales, LLC. For clarity, we refer to Troy Sheldon rather than Deborah and to Forest rather than Allergan.

Sheldon sued on behalf of the United States. The suit was initially filed under seal. *See* 31 U.S.C. § 3730(b)(2). After a five-year investigation and every opportunity to intervene, the government declined to do so, and the suit was unsealed in October 2019.

of 80% (based on the highest discount given to a single entity), and gave Medicaid a 23.1% rebate (the statutory minimum rebate percentage for that year, *see* 42 U.S.C. § 1396r-8(c)(1)(B)(i)(VI)). Sheldon alleges that this led to the federal government paying 6.9% more for this drug than it would have if Forest had accurately reported Best Price.

Forest moved to dismiss Sheldon's complaint, and the district court in a thoughtful opinion granted Forest's motion. 499 F. Supp. 3d 184. The district court found that Sheldon had failed to plead both that the claims at issue were false and that Forest had made them knowingly.[2] Relevant here, it held that Forest had offered "a plausible and objectively reasonable interpretation" of the Rebate Statute. *Id.* at 209. Beginning with the statutory text, the district court found that its "plain and natural reading" did not require aggregating discounts. *Id.* And looking at the regulatory language and history, the district court did not find "a single example where CMS explicitly state[d] that manufacturers must aggregate discounts to different customers along the supply chain in a given sale." *Id.* at 211. The district court then concluded that CMS guidance "was not so clear as to warn Forest away from its interpretation," especially considering the complexity of the statutory scheme. *Id.* at 212. So it held that Forest did not act with the requisite scienter when submitting Best Price reports to the government.

2. Because we hold that Forest did not act knowingly under the FCA, we have no occasion to address the district court's holding as to falsity.

Appendix B

II.

We review de novo the dismissal of a relator's complaint under Rule 12(b)(6). *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 700 (4th Cir. 2014). To plead his FCA claim, Sheldon must plausibly allege that Forest (1) made a false statement; (2) with the requisite scienter ("knowingly"); (3) that was material; and (4) that caused the government to pay out money. *Id.*; *see also* 31 U.S.C. § 3729(a)(1)(G). Here, we interpret the second element, scienter, in line with the Supreme Court's guidance in *Safeco*. Applying that analysis, we hold that Forest did not act knowingly under the FCA.

A.

1.

We are tasked with "strict enforcement" of the FCA's "rigorous" scienter requirement. *Escobar*, 136 S. Ct. at 2002. As noted, the FCA defines "knowingly" to mean that a person "(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). Yet it does not further define these terms or signify how they apply in situations where it is unclear if a defendant complied with the law.

Fortunately, we are not without guidance in this area. In *Safeco*, the Supreme Court interpreted the Fair Credit Reporting Act's analogous scienter provision. Like every

other circuit to consider the issue, we hold that *Safeco* applies with equal force to the FCA's scienter requirement. *See Schutte*, 9 F.4th at 459; *Streck*, 746 F. App'x at 106; *McGrath*, 690 F. App'x at 552; *Donegan*, 833 F.3d at 879-80; *Purcell*, 807 F.3d at 290-91.

Safeco interpreted the scienter requirement of the Fair Credit Reporting Act (FCRA), which required defendants to act "willfully." *See* 15 U.S.C. § 1681n(a). Because the FCRA did not define this common law term, the Court looked to its common law meaning. *Safeco*, 551 U.S. at 58. It interpreted the FCRA's "willfulness" requirement to cover both knowing and reckless violations of the statute. *Id.* at 57. Then it defined recklessness as "conduct violating an objective standard: action entailing 'an unjustifiably high risk of harm that is either known or so obvious that it should be known.'" *Id.* at 68 (quoting *Farmer v. Brennan*, 511 U.S. 825, 836, 114 S. Ct. 1970, 128 L. Ed. 2d 811 (1994)). Accordingly, it found a defendant's subjective intent irrelevant: "To the extent that [plaintiffs] argue that evidence of subjective bad faith can support a willfulness finding even when the company's reading of the statute is objectively reasonable, their argument is unsound." *Id.* at 70 n.20.

The *Safeco* Court set forth a two-step analysis as to reckless disregard, first asking whether defendant's interpretation was objectively reasonable and then determining whether authoritative guidance might have warned defendant away from that reading. *Id.* at 69-70. Because defendant's reading "was not objectively unreasonable" and "ha[d] a foundation in the statutory

text," it did not act recklessly—even though its reading was ultimately "erroneous." *Id.* And defendant had no guidance from the courts of appeals or the implementing agency that "might have warned it away from the view it took." *Id.* at 70. "Given this dearth of guidance and the less-than-pellucid statutory text, [defendant's] reading was not objectively unreasonable, and so falls well short of raising the 'unjustifiably high risk' of violating the statute necessary for reckless liability." *Id.* Failure to meet this recklessness standard precluded a finding of knowledge as well: "Where, as here, the statutory text and relevant court and agency guidance allow for more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation as a knowing or reckless violator." *Id.* at 70 n.20.

As noted above, several of our sister circuits have applied *Safeco*'s scienter analysis to the FCA. And with good reason. The FCA defines "knowingly" as including actual knowledge, deliberate ignorance, and reckless disregard. 31 U.S.C. § 3729(b)(1)(A). *Safeco* interpreted "willfully" to include both knowledge and recklessness. 551 U.S. at 57, 68. Given this parallel, we hold that *Safeco*'s reasoning applies to the FCA's scienter requirement. Under the FCA, a defendant cannot act "knowingly" if it bases its actions on an objectively reasonable interpretation of the relevant statute when it has not been warned away from that interpretation by authoritative guidance. This objective standard precludes inquiry into a defendant's subjective intent.

In adopting this standard, we join each and every circuit that has considered *Safeco*'s applicability to the FCA. For example, the Seventh Circuit reasoned that *Safeco* "defined a similar common law term . . . which the Court interpreted as encompassing the same common law scienter terms used in the FCA." 9 F.4th at 465. It rightly concluded that *Safeco* "announced a standard inquiry for reckless disregard" and found "no reason why the scienter standard established in *Safeco* (for violations committed knowingly or with reckless disregard) should not apply to the same common law terms used in the FCA." *Id.* After all, the Supreme Court has held that the FCA "does employ the common law meaning" for other common law terms like false and fraudulent, so long as there are no textual indicia to the contrary. *Id.* (citing *Escobar*, 136 S. Ct. at 1999 & n.2). Finding none here, there was "no barrier to importing the *Safeco* standard to the FCA." *Id.*

Sheldon claims that *Safeco* should not apply, alluding to *Halo Electronics, Inc. v. Pulse Electronics, Inc.*, 579 U.S. 93, 136 S. Ct. 1923, 195 L. Ed. 2d 278 (2016). But that case does not suggest a different result. *See Schutte*, 9 F.4th at 466-67 (finding *Safeco* more analogous to FCA than *Halo Electronics*). *Halo Electronics* interpreted § 284 of the Patent Act, which allowed for treble damages in certain infringement cases but did not specify scienter. 136 S. Ct. at 1928; *see* 35 U.S.C. § 284 ("[T]he court may increase the damages up to three times the amount found or assessed."). The Court found that such damages "are generally reserved for egregious cases of culpable behavior" and clarified that a showing of objective recklessness was not necessary in a context of "such

deliberate wrongdoing." *Id.* at 1932. It also emphasized the district court's discretion and the lack of textual limitations on that discretion. *Id.* at 1931-32. The Court acknowledged *Safeco*'s standard but did not apply it in the context of the Patent Act because its "precedents [made] clear that 'bad-faith infringement' *is* an independent basis for enhancing patent damages." *Id.* at 1933 n.*. In this situation, a test of objective recklessness "impermissibly encumber[ed] the statutory grant of discretion to district courts." *Id.* at 1932 (quoting *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 553, 134 S. Ct. 1749, 188 L. Ed. 2d 816 (2014)).

Context matters, and here two differences stand out. First, § 284 did not include a scienter requirement, while the FCA clearly limits liability to claims that are made "knowingly." And the Supreme Court has instructed that this "rigorous" requirement ought to find "strict enforcement" in the courts. *Escobar*, 136 S. Ct. at 2002. Second, while § 284 concerned whether district courts could issue a particular amount of damages after finding liability, the relevant provision here concerns whether liability exists at all. Taking these differences into account, the gap between the FCA and the Patent Act is much wider than that between the FCA and the FCRA—both of which include an explicit scienter standard (covering both knowledge and recklessness) that speaks to liability rather than damages.

Sheldon also argues that *Safeco* improperly collapses the FCA's statutory definitions. But applying *Safeco* does not sap the FCA's three scienter definitions of independent

meaning. *Safeco* itself recognized that recklessness and knowledge were separate subcategories of willfulness. 551 U.S. at 60. Yet it still held that its standard served as the starting point for both, refusing to treat a defendant who adopted a reasonable interpretation "as a knowing *or* reckless violator." *Id.* at 70 n.20 (emphasis added). The same is true here. That actual knowledge, deliberate ignorance, and reckless disregard are distinct—which we do not dispute—does not preclude them from sharing a threshold requirement. *See Schutte*, 9 F.4th at 468. Nor does it preclude them from functioning as a hierarchy, as is commonly understood. Reckless disregard has been called the "most capacious," *United States ex rel. Watson v. King-Vassel*, 728 F.3d 707, 712 (7th Cir. 2013), the "loosest," *Purcell*, 807 F.3d at 288, and the "baseline," *Schutte*, 9 F.4th at 465, of the FCA's scienter standards. So if a defendant has not acted with reckless disregard in its view of the statute, "it follows *a fortiori*" that it has not acted with deliberate ignorance or actual knowledge, which "plainly demand[] even more culpability." *Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1058 n.15 (11th Cir. 2015).

2.

Safeco does not apply to all FCA suits. There are two general categories of false claims under the FCA: those that are factually false and those that are legally false. *See United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011). The paradigmatic FCA action targets factually false claims—those in which someone "has submitted an incorrect description of goods

or services provided or a request for reimbursement for goods or services never provided." *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 741 (10th Cir. 2018) (citation omitted); *see, e.g.*, *United States ex rel. Citynet, LLC v. Gianato*, 962 F.3d 154, 157 (4th Cir. 2020) (complaint alleged that defendant billed the federal government for "material and labor it did not provide, and for [projects] that were not constructed"); *Affinity Living Grp., LLC v. StarStone Specialty Ins. Co.*, 959 F.3d 634, 636 (4th Cir. 2020) (complaint alleged that defendant "submitted reimbursement claims for resident services that were never provided"). Of a different vintage are legally false claims, which "generally require knowingly false certification of compliance with a regulation or contractual provision as a condition of payment." *Polukoff*, 895 F.3d at 741.

Safeco simply does not reach factually false claims, where the law is clear. Instead, it is narrowly cabined to legally false claims—like the one here—which involve contested statutory and regulatory requirements. As we have recognized, "establishing even the loosest standard of knowledge, i.e., acting in reckless disregard of the truth of falsity of the information, is difficult when falsity turns on a disputed interpretive question." *United States ex rel. Complin v. N.C. Baptist Hosp.*, 818 F. App'x 179, 184 (4th Cir. 2020) (quoting *Purcell*, 807 F.3d at 288). After all, "[a] defendant might suspect, believe, or intend to file a false claim, but it cannot *know* that its claim is false if the requirements for that claim are unknown." *Schutte*, 9 F.4th at 468.

Nor does *Safeco* write defendants a blank check. To start, *Safeco*'s first step requires an *objectively* reasonable reading of the statute. If a defendant bases its actions on an unreasonable view of the law, it runs a considerable litigation risk. Knowing an FCA claim is waiting in the wings, it takes a serious chance that a court will find liability if it attempts to concoct strained justifications for its actions. Much better to steer clear of danger than to risk it all defending a questionable interpretation in court.

And not every objectively reasonable reading will suffice. *Safeco*'s second step allows the government to issue authoritative guidance that clarifies its interpretation of the law and so warns defendants away from otherwise reasonable interpretations. The test thus "does not shield bad faith defendants that turn a blind eye to guidance indicating that their practices are likely wrong." *Id.* But it does put the burden where it belongs. If the government wants to hold people liable for violating labyrinthine reporting requirements, it at least needs to indicate a way through the maze. *See, e.g.*, *Gates & Fox Co. v. OSHRC*, 790 F.2d 154, 156, 252 U.S. App. D.C. 332 (D.C. Cir. 1986) (Scalia, J.) (citation omitted) ("If a violation of a regulation subjects private parties to criminal or civil sanctions, a regulation cannot be construed to mean what an agency intended but did not adequately express.").

Safeco's standard duly ensures that defendants must be put on notice before facing liability for allegedly failing to comply with complex legal requirements. Without such notice, defendants are not likely to receive due process. "A fundamental principle in our legal system is that laws

which regulate persons or entities must give fair notice of conduct that is forbidden or required." *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253, 132 S. Ct. 2307, 183 L. Ed. 2d 234 (2012). Such "clarity in regulation is essential to the protections provided by the Due Process Clause of the Fifth Amendment," *id.*, especially when, as here, defendants are faced with "damages that are essentially punitive in nature," *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784, 120 S. Ct. 1858, 146 L. Ed. 2d 836 (2000) (describing FCA); *see also Tex. Indus. v. Radcliff Materials, Inc.*, 451 U.S. 630, 639, 101 S. Ct. 2061, 68 L. Ed. 2d 500 (1981) ("The very idea of treble damages reveals an intent to punish past, and to deter future, unlawful conduct, not to ameliorate the liability of wrongdoers.").

It is profoundly troubling to impose such massive liability on individuals or companies without any proper notice as to what is required. *Safeco* avoids this trouble by making the government "provide a reasonably clear standard of culpability to circumscribe the discretion of the enforcing authority and its agents." *United States v. Hoechst Celanese Corp.*, 128 F.3d 216, 224 (4th Cir. 1997) (citation omitted). Rightly so. As the Supreme Court has made clear, "concerns about fair notice and open-ended liability can be effectively addressed through strict enforcement" of the FCA's "rigorous" scienter requirement. *Escobar*, 136 S. Ct. at 2002 (citation omitted). *Safeco*'s careful analysis is just the right means to further this end. *See, e.g.*, *Purcell*, 807 F.3d at 287 ("Strict enforcement of the FCA's knowledge requirement helps to . . . avoid[] the potential due process problems posed

by penalizing a private party for violating a rule without first providing adequate notice of the substance of the rule.") (citation omitted). We therefore decline Sheldon's invitation to make our circuit an outlier.

B.

Applying *Safeco*'s test to Forest's conduct, we conclude that Forest did not act "knowingly" under the False Claims Act. Forest's reading of the Rebate Statute was not only objectively reasonable but also the most natural. And Forest was not warned away from its reading by authoritative guidance from CMS. As a result, Sheldon failed to plead scienter as required by the FCA.[3]

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3. Sheldon argues that it was improper for the district court to decide the scienter question on a motion to dismiss. Yet the Supreme Court has generally urged us to resolve cases on a motion to dismiss when a claim is not "plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009) (quoting *Bell Atl. Corp v. Twombly*, 550 U.S. 544, 570, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007)). This plausibility standard "asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* And that standard bars Sheldon's claim, which does not allege any plausible theory of recovery. In addition, we have specifically held that a "district court did not err in deciding the issue of [FCA] scienter at the Rule 12(b)(6) motion-to-dismiss stage," *Complin*, 818 F. App'x at 183 n.5 (citing *Rostholder*, 745 F.3d at 703)—even when the case involved the question of whether a defendant was warned away from its interpretation, *see id.* at 184 n.6. Other circuits have similarly conducted the *Safeco* analysis in the FCA context of a motion to dismiss. *See, e.g.*, *Streck*, 746 F. App'x 101; *United States ex rel. Hixson v. Health Mgmt. Sys., Inc.*, 613 F.3d 1186 (8th Cir. 2010). This is especially appropriate when, as here, the question of whether a defendant has been warned away depends upon the interpretation of legal materials.

Appendix B

1.

We must first determine whether Forest's reading was objectively reasonable by examining the text of the statute. *Safeco*, 551 U.S. at 69-70. The Rebate Statute defines Best Price as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity." 42 U.S.C. § 1396r-8(c)(1)(C)(i). The plain language here indicates that Best Price is one offered to a single entity.

Notably, both "price" and all of the entities listed are singular, joined by the disjunctive "or." And "any" usually means a single member in a class if used with singular nouns. *Any*, Oxford English Dictionary (3d ed. 2021). This linguistic construction (singular nouns plus the disjunctive) strongly advises against aggregating discounts to multiple entities. Change some nouns to see why. If, when striking a deal for baseball equipment, the thrifty Kansas City Royals asked for "the lowest price available from the manufacturer to any wholesaler, retailer, professional baseball team, minor-league organization, or collegiate program," no one would think that the equipment company needs to aggregate prices. The Royals are just asking for the best deal that any one of the other entities received. Or imagine you ask a friend about "the lowest apple price available to any wholesaler, grocery store, or restaurant." You would not expect your friend to aggregate prices between grocery stores and restaurants, but instead report to you the single lowest price at which someone can readily purchase apples.

Finally, "available" means "suitable or ready for use," "at hand," or "readily obtainable." The Random House Dictionary of the English Language 142 (2d ed. 1987). The statute is thus talking about an actual price, not something that is purely hypothetical. A price is not "available" to an entity if the manufacturer must first aggregate other prices.

Overall, this plain language conveys that Forest was not required to aggregate discounts given to separate customers. Yet this does not give Forest a free ride. The Rebate Statute most naturally reads as requiring drug manufacturers to give Medicaid the lowest price that was provided to any single purchaser. This includes aggregating discounts to a single entity even if given at different points in time. But the statute cannot be stretched beyond this singular point.

Other provisions in the Rebate Statute confirm this reading. For example, the Rebate Statute defines Average Manufacturer Price as "the average price paid to the manufacturer for the drug" by "wholesalers" and "retail community pharmacies." *Id.* § 1396r-8(k)(1)(A)(i)-(ii). An "average," by definition, requires some sort of combination. And something "paid to the manufacturer" might incorporate discounts to different entities. Yet Average Manufacturer Price is also limited to a narrower class of entities than is Best Price, making the reporting problem less onerous. We refuse to ignore such distinctions in the statutory scheme. Congress chose dissimilar language for the two terms, and these linguistic differences must be given legal effect. *See, e.g.*, *Soliman v. Gonzales*, 419 F.3d

276, 283 (4th Cir. 2005) ("Where Congress has utilized distinct terms within the same statute, . . . we endeavor to give different meanings to those different terms.").

Beyond faithfulness to the statutory text, this reading also accords with practical realities. Well has it been said that Medicaid statutes and regulations "are among the most completely impenetrable texts within human experience." *Rehab. Ass'n of Va., Inc. v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994). And discount aggregation in particular raises some of the thorniest issues in government price reporting. *See, e.g.*, *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 115, 131 S. Ct. 1342, 179 L. Ed. 2d 457 (2011) ("Calculation of a manufacturer's 'average' and 'best' prices . . . is a complex enterprise."). Numerous entities—including state Medicaid agencies, Pharmacy Benefit Managers, manufacturers, wholesalers, and pharmacies—are involved in increasingly complicated customer relationships. *See, e.g.*, Rachel Dolan & Marina Tian, *Pricing and Payment for Medicaid Prescription Drugs*, Kaiser Family Foundation (Jan. 23, 2020), https://www.kff.org/medicaid/issue-brief/pricing-and-payment-for-medicaid-prescription-drugs/ (depicting "complex drug supply and payment chain" for prescription drugs covered by Medicaid). Because of these complex sales practices, "manufacturers may find it difficult to determine how to treat certain sales practices when calculating prices." U.S. Department of Health & Human Services, Office of Inspector General, *Reasonable Assumptions in Manufacturer Reporting of AMPs and Best Prices* 3-4 (Sept. 2019), https://oig.hhs.gov/oei/reports/oei-12-17-00130.pdf (OIG Report). Given this considerable difficulty,

it makes good sense to think that manufacturers are expected to report a price actually given to a purchaser, rather than cobbling together bits and pieces to fashion a price never "available" to any actual entity.

We turn next to the CMS regulations. Of course, courts, not agencies, are the ultimate interpreters of statutes. *See, e.g.*, *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842-43, 104 S. Ct. 2778, 81 L. Ed. 2d 694 (1984) (limiting deference in statutory interpretation to situations where the law is ambiguous and the agency interpretation is reasonable). And to the extent that CMS regulations are relevant, here they simply mirror the statutory language. CMS defines Best Price as "the lowest price available from the manufacturer during any rebate period to any entity in the United States." 42 C.F.R. § 447.505(a) (2007). Again, each term is singular, most naturally referring to the lowest price given to a single entity. Likewise, the Rebate Agreement (also promulgated by CMS regulation) defines Best Price as "the lowest price at which the manufacturer sells the [covered drug] to any purchaser in the United States." J.A. 213; *see* 56 Fed. Reg. at 7050. This straightforward language—"any purchaser," again singular—counsels in favor of Forest's interpretation. And while Sheldon makes much of three other words in the Rebate Agreement ("prices actually realized") to argue that discounts must be aggregated, these words cannot be wrenched out of context or used to subvert the Rebate Statute's natural meaning. Read consistently with the governing statute (to which it is subordinate), the Rebate Agreement's "prices actually realized" simply means prices the manufacturer receives on sales to each individual customer.

Clearly, Forest's reading "has a foundation in the statutory text." *Safeco*, 551 U.S. at 69-70. Not only that; it is the best reading of that text. We agree with the district court that the "plain and natural reading" of the Rebate Statute means that Best Price entails "the lowest price available by the manufacturer, including all price concessions, to any one of the listed entities, but not to multiple entities." *Sheldon*, 499 F. Supp. 3d at 209. There is nothing in the statute to suggest that Best Price requires aggregating discounts given to separate entities. Thus, we hold that Forest has offered, at minimum, an objectively reasonable reading of the Rebate Statute. It in turn becomes more difficult to conclude that a party "knowingly" presented a false claim, 31 U.S.C. § 3729(b)(1)(A), when that claim is premised on such a textually sound view.

2.

Next we ask whether authoritative guidance warned Forest away from its interpretation. *See Safeco*, 551 U.S. at 70. To function as a warning, authoritative guidance requires both the right source and sufficient specificity. When it comes to source, either circuit court precedent or guidance from the relevant agency is required. *See id.*; *Schutte*, 9 F.4th at 471 (limiting authoritative guidance to these two sources); *Purcell*, 807 F.3d at 289 (considering only these two sources); *Streck*, 746 F. App'x at 106, 108 (considering only these two sources). And the guidance must "canvass the issue" with sufficient specificity to be able to function as a warning. *Safeco*, 551 U.S. at 70 n. 19. It does not suffice for agency guidance merely to be related to the question at hand; instead, "authoritative guidance must have a high level of specificity to control an issue."

Schutte, 9 F. 4th at 471; *see also Safeco*, 551 U.S. at 70 n.20 (agency guidance did not warn away when it "allow[ed]" defendant's interpretation). Because CMS never clearly stated that discount aggregation to different entities was required, it did not act with the specificity necessary to warn Forest away from its interpretation.

CMS knew as early as 2006 that manufacturers were not aggregating discounts given to different entities along supply chains. After CMS submitted its proposed rule on Medicaid drug pricing, several manufacturers, including Forest, offered comments. These comments expressed a uniform view that Best Price "has *always* been interpreted to mean the single lowest price to a particular customer." J.A. 239; *accord* J.A. 271 ("[Best Price] is the single lowest price at which the manufacturer sells the product to a single customer."); J.A. 285 ("We therefore request that CMS confirm that best price will continue to be the lowest price at which a drug is actually sold."); J.A. 305 ("Best price is not calculated as a price derived by aggregating price concessions to different customers."). And the manufacturers asked CMS to "clarify" or "confirm" that it would continue to be so. J.A. 239, 271, 285.

CMS nonetheless failed to clarify and thereby maintained strategic ambiguity. But in all material respects, the final rule adopted the proposed rule's Best Price definition. 72 Fed. Reg. at 39,242-43. As we have seen, that language simply reflected the Rebate Statute, which most naturally supports Forest's interpretation.

Sheldon points to two CMS responses to comments that, he says, should have warned Forest away. While

both were related to the broad issue here—Best Price reporting and discounts—neither spoke directly to whether manufacturers were required to aggregate discounts given to separate entities on the supply chain. As a result, they were not sufficient to warn Forest away from its objectively reasonable interpretation.

The first scenario involved Pharmacy Benefit Managers (PBMs), which the proposed rule had initially included in Best Price. *See* Medicaid Program; Prescription Drugs, 71 Fed. Reg. 77,174, 77,197 (Dec. 22, 2006) (proposing that 42 C.F.R § 447.505(c)(2) include PBM rebates). After receiving public comments, CMS agreed to generally remove PBM rebates from Best Price calculation in its final rule but noted one situation where PBM rebates might be included. *See* 72 Fed. Reg. at 39,198, 39,242; 42 C.F.R § 447.505(d)(13) (2007) ("Best price excludes PBM rebates, discounts, or other price concessions except . . . where such rebates, discounts, or other price concessions are designed to adjust prices at the retail or provider level."). As Sheldon conceded below, this example has nothing to do with whether discounts should be aggregated in calculating Best Price; instead, "CMS's comments involving PBMs simply addressed how rebates to an *excluded* entity might nevertheless fall within Best Price." D. Ct. Docket 79 at 22. It thus does not provide sufficient specificity to warn Forest away from its position on aggregating discounts to included entities.

The second scenario proves similarly lacking, as it concerned two discounts administered through a single entity. One commenter asked if Best Price calculations

required aggregating prompt pay discounts to wholesalers and wholesaler chargeback agreements, and CMS confirmed that they did. 72 Fed. Reg. at 39,199. Yet as the district court noted, "the different price concessions . . . both actually function as price concessions to [a] single entity—the wholesaler." *Sheldon*, 499 F. Supp. 3d at 211. The prompt pay discount lowers the wholesaler's price at the time of sale. And the chargeback agreement means that "the wholesaler delivers the product to the favored purchaser at the discounted price and then 'charges back' the manufacturer for the difference." *In re Brand Name Prescription Drugs Antitrust Litig.*, No. 94-cv-897, 1996 U.S. Dist. LEXIS 4335, 1996 WL 167350, at *2 (N.D. Ill. Apr. 4, 1996). It thus functions as a lagged price concession to the wholesaler and is properly included in a Best Price calculation because it affects the price available to a single entity. The Rebate Statute, after all, does require aggregating discounts if they are given to a single entity. But as the district court noted, CMS's comments here "did not actually clarify whether there is a requirement to aggregate concessions from multiple entities in separate arrangements." *Sheldon*, 499 F. Supp. 3d at 211. So they were not precise enough to warn Forest away.

Sheldon's other examples fare no better.[4] Mostly, they involve language about "prices actually realized" or stay

4. While Sheldon twice alleged that Forest's conduct continued "to the present," J.A. 106, 107, his complaint contains no factual allegations concerning Forest's conduct after 2014 (when Forest terminated Sheldon). Two conclusory references about continuing conduct are simply insufficient to meet Rule 12(b)(6)'s standard, which requires *some* level of "factual content." *Iqbal*, 556 U.S. at 678.

at high levels of generality. This is simply insufficient. All told, Sheldon has not, in the words of the district court, "pointed to a single example where CMS explicitly state[d] that manufacturers must aggregate discounts to different customers along the supply chain in a given sale." *Id.* It thus did not warn Forest away from its well-grounded interpretation.[5]

Instead of a warning, CMS issued manufacturers like Forest a permission slip. CMS's Rebate Agreement provides that "in the absence of specific guidance," manufacturers should "make reasonable assumptions in their calculations of . . . Best Price, consistent with the requirements and intent of [the Rebate Statute], Federal regulations and the terms of this agreement." J.A. 217. In the very rulemaking that Sheldon highlights, CMS reaffirmed the need to make reasonable assumptions—not once, not twice, but *nine* times. *See* 72 Fed. Reg. at 39,164, 39,166, 39,167, 39,171, 39,191, 39,211. Combine this exhortation with the complex statutory scheme and it is no wonder that reliance on reasonable assumptions is widespread. *See* OIG Report at 24.

In fact, a 2019 HHS Inspector General report found that eighty percent of manufacturers reported making reasonable assumptions about the precise issue here: whether discounts given to separate entities must be aggregated. *Id.* at 9. And this issue is far from unique.

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5. Because *Safeco* focuses on objective reasonableness and forecloses inquiry into subjective beliefs, *see* 551 U.S. at 70 n.20, Sheldon's allegations regarding Forest's motivation for undertaking a data audit are simply irrelevant.

More than fifty percent of responding manufacturers reported making reasonable assumptions in fourteen different areas identified by the Inspector General. *Id.* at 9-10. Importantly, it is not the case that manufacturers are taking advantage of CMS's silence; almost two thirds reported a desire for additional guidance on these very issues. *Id.* at 11. Facing these requests, CMS demurs. Indeed, "CMS specifically instructs manufacturers not to submit their assumptions to the agency, and states that if a manufacturer does so, CMS will not review the assumptions." *Id.* at 20.

What CMS once gave with one hand it now wants to take away with the other. Having told manufacturers to rely on reasonable assumptions, the government cannot receive damages when Forest has done exactly that. Moreover, it cannot do so when CMS has refused to respond to manufacturer requests for clarification. What a troubling result: companies ask for explanation and at first are told to do their best but then are subjected to potentially ruinous liability for following those instructions. How can this—which looks more like Calvinball than the rule of law—possibly qualify as a sufficient warning? *See* Bill Watterson, *The Calvin & Hobbes Tenth Anniversary Book* 129 (1995) ("People have asked how to play Calvinball. It's pretty simple: you make up the rules as you go.").

Of course, CMS may not wish to specify its position on the issue. From its vantage point, that might be understandable. Clear regulations constrain regulatory power and limit future flexibility, which is why an agency

might find them undesirable. *See, e.g.*, *Kisor v. Wilkie*, 139 S. Ct. 2400, 2440-41, 204 L. Ed. 2d 841 (Gorsuch, J., concurring in the judgment) ("Whether purposeful or not, the agency's failure to write a clear regulation winds up increasing its power."). To be sure, there are plenty of reasons why agencies might prefer ambiguity. But such reasons are not necessarily permissible. Retaining ambiguity in order to expand potential liability for regulated entities cannot pass muster. In a world where the administrative state "wields vast power and touches almost every aspect of daily life," *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 499, 130 S. Ct. 3138, 177 L. Ed. 2d 706 (2010), allowing agencies to take advantage of companies like this would not be right.

CMS did not warn Forest away from its objectively reasonable reading. None of its guidance dealt with aggregating discounts to different entities, and it even invited Forest to make reasonable assumptions. So the district court correctly dismissed Sheldon's complaint for failure to allege scienter.

III.

Safeco's two prongs are interrelated; though separate, they are not totally divorced. Looking at both the statute's text and the agency's guidance, a coherent picture emerges. Forest made eminently reasonable assumptions based on the statutory text, and CMS invited assumptions precisely of this sort. The False Claims Act does not assess liability through ambush. Companies must instead *knowingly* submit a false claim to be liable. And Forest simply did not do so here.

We cannot accept the idea that a defendant acts "knowingly" when its reading of a statute is both objectively reasonable and in fact the best interpretation; when the agency's regulation mirrors, rather than repudiates, that interpretation; when the agency resists attempts to get it to clarify its view; and when the agency explicitly invites regulated parties to make reasonable assumptions. It is not plausible to accuse Forest of acting "knowingly" in these circumstances.

All that said, the government is not without recourse. Should Congress so wish, it can alter the Rebate Statute to require the aggregate reporting of discounts to separate entities. But the burden is on the government to be clear. As the district court recognized, this case presents no sound rationale for the immense consequences the relator would have this court impose.

The judgment of the district court is hereby affirmed.

AFFIRMED

Appendix B

WYNN, Circuit Judge, dissenting:

Those who believe that some judicial decisions usurp the power of elected legislatures by making the law rather than merely interpreting it can add another tally to their ledgers. Today, with the stroke of a pen, my thoughtful friends in the majority opinion effectively neuter the False Claims Act—the Government's primary tool for fighting fraud—by eliminating two of its three scienter standards (actual knowledge and deliberate ignorance) and replacing the remaining standard with a test (objective recklessness) that only the dimmest of fraudsters could fail to take advantage of.

Over thirty years ago, Congress grew concerned that years of restrictive court interpretations had artificially narrowed the False Claims Act's scienter requirement. To remedy this problem, Congress crafted three distinct and expansive scienter standards. Today's majority opinion undoes that work by making a new law that reads two of those three scienter standards right out of existence. In their place, the majority opinion erects its own threshold scienter test that allows fraudsters to escape *any* liability so long as they can come up with a post hoc legal rationale that passes the smell test.

But the majority opinion's legal hand-waving cannot cover the stench here. Troy Sheldon plausibly alleges that for years, pharmaceutical giant Forest Laboratories, LLC failed to include stacked rebates when reporting its best drug prices to the Government. When alerted that its scheme was unlawful, Forest hired a data-scrubbing

firm to identify and eliminate rebate stacking for many of its customers. However, it continued to pay out stacked rebates to its preferred customers, rebates that it then failed to report in its best price calculations for years to come. That fraudulent scheme bilked the federal Government out of $680 million.

Yet, the majority opinion finds it unnecessary to even address these facts due to its wholesale revision of the False Claims Act's scienter standard. But what, you might ask, empowers judges to trade in their judicial robes for congressional pins, rewrite the statute, and ignore the factual record? The underwhelming answer: a dictum single footnote buried at the end of a Supreme Court opinion on credit reporting.

Tellingly, the majority opinion spends 4/5 of its *introduction* cavalierly dismissing the recognition of its judicial overreach as mere "protestations." Majority Op. at 3. But the fact that it found the need to say so with a first breath pontification—without providing *any* context for the reader—says otherwise.

At any rate, that first breath does nothing to dispel the substantive concerns identified in this dissenting opinion: it does not, for example, tangle with the damning facts of this case, explain why importing mismatched common law into the False Claims Act is a good idea, or, most importantly, defend its decision to write two of the Act's three scienter standards out of existence. Instead, it accuses the dissenting opinion—which seeks to maintain the statutory status quo by *keeping* the three scienter

standards created by Congress—of somehow taking a "very long step toward a strict liability statute." *Id.* And without any sense of irony, it protests that the dissenting opinion "nullif[ies] the whole concept of scienter" for the False Claims Act. *Id.* But as explained below, that is precisely what the majority opinion accomplishes by rewriting the Act's scienter standard to suit its own policy ends.

Because I cannot join in this judicial overhaul of the False Claims Act—an overhaul that will require further congressional correction—I dissent.

I.

"The False Claims Act 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, 280 U.S. App. D.C. 182 (D.C. Cir. 1989) (citing S. Rep. No. 99-345, at 1 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5266). However, the Act only reaches "knowingly" false conduct. 31 U.S.C. § 3729(a)(1)(A)-(B).

Individuals act "knowingly" if they (1) have "actual knowledge of the [falsity of the] information"; (2) act "in deliberate ignorance of the truth or falsity of the information"; or (3) act "in reckless disregard of the truth or falsity of the information." *Id.* § 3729(b)(1)(A). Thus, though the Act does "not punish honest mistakes or incorrect claims submitted through mere negligence," *United States ex rel. Owens v. First Kuwaiti Gen. Trading*

& Contracting Co., 612 F.3d 724, 728 (4th Cir. 2010) (citation omitted), it does require "those doing business with the Government . . . to make a limited inquiry to ensure the claims they submit are accurate," *United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1155-56 (11th Cir. 2017) (quoting S. Rep. No. 99-345, at 7, 1986 U.S.C.C.A.N. at 5272).

A careful review of the full record here reveals no "honest mistakes," "negligence," or adequate inquiry. In fact, the record shows a deliberate plan to frustrate the requirements of the Medicaid Rebate Act and bilk the federal Government out of $680 million. Though the majority opinion dismisses these inconvenient facts—and the record itself—as "simply irrelevant" to its allegedly purely legal inquiry, Majority Op. at 26 n.5, it is worth describing the facts it skimmed over in detail. With this context in mind, I then turn to the majority's ill-fated application of *Safeco Insurance Co. of America v. Burr*, 551 U.S. 47, 127 S. Ct. 2201, 167 L. Ed. 2d 1045 (2007), to the fraud context. Finally, I conclude that even if *Safeco* applied, the majority erred by finding that Forest wasn't "warned away" from its stacked-rebate scheme.

A.

When ruling on a Rule 12(b)(6) motion to dismiss, "a judge must accept as true all of the factual allegations contained in the complaint" and must "draw all reasonable inferences in favor of the plaintiff." *E.I. du Pont de Nemours & Co. v. Kolon Indus.*, 637 F.3d 435, 440 (4th Cir. 2011) (citation omitted). The following facts are largely taken from Sheldon's amended complaint.

Appendix B

Under the Medicaid Drug Rebate program, drug manufacturers that wish to sell their drugs to state Medicaid agencies must first enter into rebate agreements with the Secretary of Health and Human Services. 42 U.S.C. § 1396r-8(a). These agreements require the manufacturers to provide states with rebates on drugs purchased for Medicaid beneficiaries. *Id.* § 1396r-8(b). These rebates are then passed along to the federal Government by offsetting them against federal Medicaid assistance provided to the states. *Id.* § 1396r-8(b)(1)(B).

Calculating these rebates "is a complex enterprise requiring recourse to detailed information about the company's sales and pricing." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 115, 131 S. Ct. 1342, 179 L. Ed. 2d 457 (2011). For most drugs, the rebate amount is equal to the greater of two numbers: (1) the statutory minimum rebate percentage of the "average manufacturer price" (currently 23.1%) and (2) "the difference between the average manufacturer price and the best price." 42 U.S.C. § 1396r-8(c)(1)(A), (c)(1)(B)(i)(VI). The "average manufacturer price" means "the average price paid to the manufacturer for the drug in the United States by . . . wholesalers . . . [and] retail community pharmacies." *Id.* § 1396r-8(k)(1)(A). The "best price" is "the lowest price available from the manufacturer . . . to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity." *Id.* § 1396r-8(c)(1)(C)(i).

Allergan Sales, LLC and its predecessors Forest Laboratories, LLC and Forest Pharmaceuticals

(collectively "Forest") is a leading pharmaceutical-drug manufacturer. In 2014, Forest's expected annual revenues topped $15 billion. A significant portion of this business is supported by drug reimbursements from state Medicaid programs.

From the 1990s until 2014, relator Sheldon worked at Forest. Sheldon served in several managerial roles and was responsible for billions of dollars in revenue streams. Sheldon was also directly involved in the sale of Forest's drugs, including the negotiation of discounts, rebates, and other incentives. As a result, he had "direct, personal knowledge of the drug rebates and other discounts given to Forest customers that impact[ed] the reported Best Price for each drug." J.A. 63.

In 2005, Sheldon discovered that Forest was failing to account for rebates provided to two separate customers on the same dispensed drug unit. Specifically, Forest was providing one rebate to private insurance companies and another to pharmacy providers or group purchasing organizations ("GPOs"). Because some of the patients treated by these pharmacies or GPOs were also covered by these private insurers, Sheldon believed that Forest was benefiting from double rebates but illegally reporting only one rebate as the basis of its "[b]est [p]rice." J.A. 67.

Shortly after Sheldon's discovery, the Centers for Medicare & Medicaid Services ("CMS") proposed a rule that would codify and clarify the definition of "best price," among other things. Medicaid Program; Prescription Drugs, 71 Fed. Reg. 77,174 (proposed Dec.

22, 2006). That 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." *Id.* at 77,197 (emphases added). 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," and required manufacturers to "adjust the best price for a rebate period if cumulative discounts, rebates, or *other arrangements subsequently adjust* the prices available from the manufacturer." *Id.* at 77,198 (emphases added). In the preamble, 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).

Forest submitted written comments on the rulemaking, noting that "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*." J.A. 239 (emphases added). It urged CMS 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." J.A. 239 (emphasis added). It believed the "statutory definition of best price has always been interpreted to mean the single lowest price *to a particular customer*," and that "prices to unrelated entities in the chain of distribution should not

be aggregated . . . even if they concern the same unit of a drug." J.A. 239-40 (emphasis added). Several other drug manufacturers submitted similar comments.

Nearly a year later, CMS published its final rule. Medicaid Program; Prescription Drugs, 72 Fed. Reg. 39,142 (July 17, 2007) (codified at 42 C.F.R. pt. 447). CMS *declined to change the offending language* identified by Forest or the other drug manufacturers, reiterating that the "best price represents the lowest price available from the manufacturer to any entity . . . [and] 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*." *Id.* at 39,150 (emphases added).

CMS also took the opportunity to clear up confusion regarding a stacked-rebate situation involving pharmacy benefit managers ("PBMs"). These entities serve as middlemen between drug manufacturers, pharmacies, health insurance companies, and end users. Linda L. Ujifusa & J. Mark Ryan, *Pharmacy Benefit Managers: The Mystery Bureaucrats Managing your Prescription Drugs*, Uprise RI (Aug. 25, 2021), https://upriseri.com/pharmacy-benefit-managers/. Originally, CMS proposed including rebates paid to PBMs when determining best price. 71 Fed. Reg. at 77,182-83. Some "industry analysts" believed that this proposal obligated manufacturers "to add concessions paid to PBMs to the concessions paid to customers of the PBMs in calculating best price." 72 Fed.

Reg. at 39,198. Multiple commentators objected, arguing 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.'" *Id.* (emphasis added). In conclusion, they asked that "CMS reaffirm that best price is the lowest price available from the manufacturers" to a single customer. *Id.*

In no uncertain terms, CMS replied that "[w]e do not agree with the commenters." *Id.* It noted that although the final rule had largely removed any requirement that rebates paid to PBMs be included in best price, the rule reiterated that best price must "reflect the lowest price available from the manufacturer to any purchaser, inclusive of rebates, discounts, or price concessions that *adjust the price realized*." *Id.* (emphasis added).[1]

In response, top-level managers at Forest prepared reports and held a series of meetings that examined the

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1. The majority argues that this example is irrelevant because, "[a]s Sheldon conceded below, this example has nothing to do with whether discounts should be aggregated in calculating Best Price; instead, 'CMS's comments involving PBMs simply addressed how rebates to an *excluded* entity might nevertheless fall within Best Price.'" Majority Op. at 24 (quoting Res. in Opp'n to Def.'s Mot. to Dismiss Am. Compl. at 22, *United States ex rel. Sheldon v. Forest Lab'ys*, (D. Md. 2020), ECF No. 79). However, Sheldon did not concede anything of the sort, *see* Res. in Opp'n to Def.'s Mot. to Dismiss Am. Compl., *supra*, at 4 (arguing that this example showed that "CMS explicitly *rejected* Forest's interpretation"), and the majority opinion offers no explanation for CMS's express repudiation of the commentators' single-customer approach.

stacked-rebate issue. As the result of these meetings, Forest decided to hire a data-audit firm to identify stacked rebates claimed by its commercial customers—mostly private insurance companies—"for the same dispensed drug units to the same patient." J.A. 69. After claims involving double rebates were identified, Forest paid the first entity that claimed a rebate but refused to pay the second. Forest was able to do this because its sales contracts at the time—for these customers, at least—included a "clause providing that Forest would only pay one company when there are two entities claiming a rebate for the same drug to a single patient." J.A. 35-36. The purpose of only allowing a single rebate to be claimed was to ensure that stacked "discounts on the same pill would [not] have to be added together" when reporting best prices to CMS. J.A. 69.

But Forest took a different tack with its preferred customers: pharmacy providers, GPOs, and certain private insurance companies. To "avoid negatively impacting its relationships" with these entities, Forest declined to audit their rebates or add a first-come-first-serve rebate clause to their sales contracts. Instead, it continued to pay these entities stacked rebates on the same drug unit "quarter after quarter," while only reporting one of those rebates as the basis of its best price. J.A. 70. By Sheldon's calculation, this led to Forest underpaying its rebates to state Medicaid programs—and by extension, the federal Government—by over *$680 million* between 2005 and 2014.

B.

Although these damning facts strongly suggest that Forest was actually aware it was submitting false best-price reports, the majority finds said facts "simply irrelevant" due to the Supreme Court's decision in *Safeco*. Majority Op. at 26 n.5. That decision interpreted the scienter requirement for the Fair Credit Reporting Act. The majority claims that if we import *Safeco*'s common-law definition of reckless disregard from the Fair Credit Reporting Act into the False Claims Act, then any defendant who "bases its actions on an objectively reasonable interpretation of the relevant statute when it has not been warned away from that interpretation" "cannot act 'knowingly.'" *Id.* at 12; *see also id.* at 11 ("Failure to meet this [objective] recklessness standard *preclude[s] a finding of knowledge as well*." (emphasis added)). In other words, the actual-knowledge and deliberate-ignorance standards are mere surplusage; a purely legal "threshold" recklessness test is now the alpha and the omega of False Claims Act scienter. *Id.* at 14.

But *Safeco* itself and the Supreme Court's subsequent decision in *Halo Electronics, Inc. v. Pulse Electronics, Inc.*, 579 U.S. 93, 136 S. Ct. 1923, 195 L. Ed. 2d 278 (2016), counsel against importing *Safeco* wholesale into a vastly different statutory context. And even if we did, neither *Safeco* nor the majority opinion's sketchy logic justifies finding that *Safeco*'s objective-recklessness test allows us to scrap two of the False Claims Act's three scienter standards.

Appendix B

1.

Safeco concerned a narrow issue: the proper interpretation of the Fair Credit Reporting Act's scienter requirement. *Safeco*, 551 U.S. at 52. While the Fair Credit Reporting Act requires "willful[]" violations, it does not further define this term. *Id.* at 56-57 (quoting 15 U.S.C. § 1681n(a) (2007)). As a result, the Court looked to the common law and held that "willfulness" includes both "knowing *and* reckless disregard of the law"—but not before exhaustively examining whether "*Congress had something different in mind*." *Id.* at 59, 69 (emphases added).

To start, the Court pored over the drafting history of the Fair Credit Reporting Act, finding some support for the notion that "liability was supposed to attach only to knowing violations," but dismissing such evidence as "shaky, and certainly no match for the following clue in the text as finally adopted." *Id.* at 58-59. Specifically, the Court noted that the Fair Credit Reporting Act imposed heightened liability for "knowing[]" violations. *Id.* at 59. But if "willfully" only meant "knowingly," then this heightened liability standard would be both "superfluous and incongruous." *Id.* Since the Court's primary directive was to "[g]ive effect, if possible, to every clause and word of a statute," the Fair Credit Reporting Act's scienter term had to encompass both knowing and reckless violations. *Id.* at 60 (quoting *United States v. Menasche*, 348 U.S. 528, 538-39, 75 S. Ct. 513, 99 L. Ed. 615 (1955)).

Next, the Court reasoned that since the Fair Credit Reporting Act did not define recklessness, it made sense to invoke the common law once more—but not before again assessing whether "*Congress had something different in mind*." *Id.* at 69 (emphasis added). After concluding it did not, the Court held that "a company *subject to [the Fair Credit Reporting Act]* does not act in reckless disregard of [that statute]," *id.* (emphasis added), unless it runs an "unjustifiably high risk" of violating the law "that is either known or so obvious that it should be known," *id.* at 68 (quoting *Farmer v. Brennan*, 511 U.S. 825, 836, 114 S. Ct. 1970, 128 L. Ed. 2d 811 (1994)).

Ultimately, the Supreme Court recognized that a scienter term's "construction is often dependent on the context in which it appears." *Id.* at 57 (quoting *Bryan v. United States*, 524 U.S. 184, 191, 118 S. Ct. 1939, 141 L. Ed. 2d 197 (1998)). Thus, the Court carefully parsed through the Fair Credit Reporting Act's legislative history, considered appropriate statutory context, and adopted a common-law definition that gave effect to "every clause and word of [the] statute." *Id.* at 60 (quoting *Menasche*, 348 U.S. at 538). In simple terms, the Supreme Court took the time and effort to truly understand whether any evidence "point[ed] to something different in [the Fair Credit Reporting Act]" that would require a "deviat[ion] from the common law." *Id.* at 58, 69.

2.

The same cannot be said of today's majority opinion. Its "analysis" of whether it makes sense to import the

Safeco Court's common-law definition of recklessness into the False Claims Act spans all of three sentences: "The [False Claims Act] defines 'knowingly' as including actual knowledge, deliberate ignorance, and reckless disregard. *Safeco* interpreted 'willfully' to include both knowledge and recklessness. Given this parallel, we hold that *Safeco*'s reasoning applies to the [False Claims Act]'s scienter requirement." Majority Op. at 12 (citations omitted). But what the majority opinion passes off as reasoning is no more than say-so. That should not be sufficient to upend the law of frauds in our Circuit.

Instead, it is necessary to take the time—as the *Safeco* Court said we must—to ask whether "*Congress had something different in mind*" with the False Claims Act. By doing so, it becomes evident that we should not import the Fair Credit Reporting Act's objective recklessness standard, for a few reasons.

To start, the Fair Credit Reporting Act's and False Claims Act's vastly different contexts make them a poor match for common-law cross-pollination. The Fair Credit Reporting Act is a primarily prescriptive statute intended "to ensure fair and accurate credit reporting, promote efficiency in the banking system, and protect consumer privacy." *Safeco*, 551 U.S. at 52. The False Claims Act is an entirely proscriptive statute intended to prevent fraud. *Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 181-82, 136 S. Ct. 1989, 195 L. Ed. 2d 348 (2016). And fraud often revolves around a defendant's *subjective* state of mind. *See* Restatement (Second) of Torts § 526 cmts. c, e (Am. L. Inst. 1977) (noting scienter

for fraud can be established when a defendant has actual "knowledge of falsity," "believes the representation to be false," or makes a false representation with "careless [disregard] of whether it is true or false"); *see also United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 384 (4th Cir. 2015) (holding that the "*subjective* inquiry" of whether a defendant "knew that its claims were in violation of the [law is] covered under the [False Claims Act's] knowledge element" (emphasis added)).

Therefore, it makes little sense to import the Fair Credit Reporting Act's *objective* recklessness test into the False Claims Act—especially when this "threshold" test effectively becomes a be-all-and-end-all scienter requirement. *See Halo*, 579 U.S. at 104, 106 n.* (declining to import *Safeco*'s recklessness test into the patent context because "bad faith" was relevant in that context and a "threshold [objective recklessness] requirement excludes from discretionary punishment many of the most culpable offenders").

The majority opinion's wholesale adoption of this Fair Credit Reporting Act test makes even less sense when one considers the sources of common law underlying it. In *Safeco*, those sources were the Restatement (Second) of Torts § 500 (Am. L. Inst. 1963-1964) and the Court's previous decision in *Farmer v. Brennan*. But the Restatement (Second) § 500 pertains not to the common law of *fraud*, but rather to the common law of *physical safety. See* § 500 (stating that conduct "must involve an easily perceptible danger of death or substantial physical harm" to qualify as reckless). Likewise, *Farmer*'s "civil-

law recklessness" definition—which drew on § 500's physical-safety standard—also relied on the common law of physical injury. 511 U.S. at 837; *id.* at 836 (finding its recklessness standard equivalent to "deliberate indifference to a substantial risk of *serious harm to a prisoner*" (emphasis added)). Both sources, therefore, are inapposite in the fraud context. In fact, the Restatement (Second) has another section that deals specifically with the scienter requirement for common-law fraud. *See* Restatement (Second) of Torts § 526. And though this directly relevant body of common law surely has bearing on the meaning of reckless disregard in fraud, the majority opinion ignores it.

The majority opinion counters that "every other circuit to consider the issue" has "h[e]ld that *Safeco* applies with equal force to the [False Claims Act]'s scienter requirement." Majority Op. at 10. Not so. In *United States ex rel. Phalp v. Lincare Holdings, Inc.*, the Eleventh Circuit received extensive briefing on the recklessness standard recognized in *Safeco* and declined to import it into the False Claims Act.[2] *See* 857 F.3d at 1155 (rejecting the conclusion—recognized in *Safeco*—"that a finding of scienter can be precluded by a defendant's identification of a reasonable interpretation of an ambiguous regulation").

To be sure, other courts have gone the other way, but most of these cases are either unpublished or easily distinguishable. *See United States ex rel. Streck v. Allergan,*

2. Though the *Phalp* opinion did not explicitly cite to *Safeco*, it squarely rejected the very holding the majority claims is commanded by *Safeco*.

Inc., 746 F. App'x 101, 106 (3d Cir. 2018) (unpublished); *United States ex rel. McGrath v. Microsemi Corp.*, 690 F. App'x 551, 552 (9th Cir. 2017) (unpublished); *United States ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC*, 833 F.3d 874, 879-80 (8th Cir. 2016) (citing *Safeco* only to explain that the plaintiff had not created a material issue of fact regarding whether the defendant was warned away from its reasonable interpretation); *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 290-91, 420 U.S. App. D.C. 176 (D.C. Cir. 2015) (citing *Safeco* in holding that a reasonable interpretation of a *contract* precluded False Claims Act liability). And all but one either predates or fails to distinguish the Supreme Court's decision in *Halo*. *But see United States ex rel. Schutte v. SuperValu Inc.*, 9 F.4th 455, 467 (7th Cir. 2021) (foreshadowing the majority opinion's flawed attempt to distinguish *Halo*).

Because *Halo* explicitly declined to import *Safeco*'s objective recklessness test into an analogous context, it deserves further explanation. In *Halo*, the Supreme Court interpreted the scienter requirement for enhanced damages under § 284 of the Patent Act. 579 U.S. at 97. Though the Patent Act does not include a specific scienter standard for these damages, for "nearly two centuries" the Supreme Court and the courts of appeal had "[c]onsistent[ly]" interpreted the statute to require "willful misconduct." *Id.* at 106. But in 2007, the Federal Circuit created a test for "willful" infringement that wholly relied on *Safeco*'s definition of objective recklessness. *See In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007), *abrogated by Halo*, 579 U.S. 93, 136 S. Ct. 1923, 195 L. Ed. 2d 278 (2016). Like the standard crafted by the majority

opinion, the Federal Circuit's objective-recklessness test was a "threshold requirement" for liability. *Halo*, 579 U.S. at 104; *see also id.* ("Under *Seagate*, a district court may not even consider enhanced damages for [a willful] pirate, unless the court first determines that his infringement was 'objectively' reckless."); *see* Majority Op. at 14.

The *Halo* Court squarely rejected the Federal Circuit's *Safeco* test. Though the Fair Credit Reporting Act and § 284 share the same scienter requirement—willfulness—the *Halo* Court noted that "'willfully' is a word of many meanings whose construction is often dependent on the context in which it appears." *Halo*, 579 U.S. at 106 n.* (quoting *Safeco*, 551 U.S. at 57). And because the "*subjective willfulness* of a patent infringer, intentional or knowing, may warrant enhanced damages, without regard to whether his infringement was objectively reckless," the Federal Circuit erred by crafting a threshold objective test for § 284. *Id.* at 105 (emphasis added); *see also id.* at 106 n.* (rejecting the respondents' argument that *Safeco*'s footnote required the Court to find that "bad faith was not relevant absent a showing of objective recklessness" because "'bad-faith infringement' *is* an independent basis for enhancing patent damages"). *Safeco*'s common-law definition of "willfulness" simply did not apply. *Id.* at 104-106; *cf. Farmer*, 511 U.S. at 840 (declining to adopt an objective-recklessness test for Eighth Amendment violations based on textual and contextual clues).

It's hard to see much daylight between *Halo* and the present case. Both address the use of a "threshold" *Safeco* test that precludes inquiry into "deliberate wrongdoing."

Halo, 579 U.S. at 104. Both concern the application of said test to statutes that revolve around the "subjective willfulness" or subjective knowledge of the statutory violator—unlike the Fair Credit Reporting Act—and punish transgressions with up to treble damages. *Id.* at 105, 109. And in both cases, as explained in more detail below, an unthinking application of *Safeco*'s test would "mak[e] dispositive the ability of the [statutory violator] to muster a reasonable (even though unsuccessful) defense at . . . trial." *Id.* at 105. Because of these serious contextual concerns, the *Halo* Court declined to import *Safeco*'s test into § 284. *See id.* at 105-07. We should too.

The majority opinion struggles to explain why *Halo* should not control. In the end, it lands on two weak distinctions between the False Claims Act and § 284: (1) "§ 284 d[oes] not include a scienter requirement, while the FCA clearly limits liability to claims that are made 'knowingly,'" and (2) "while § 284 concerned whether district courts could issue a particular amount of damages after finding liability, the relevant provision here concerns whether liability exists at all." Majority Op. at 13. Neither distinction holds any water.

To start, while § 284 might not include an explicit scienter requirement, *for almost two centuries* courts have interpreted the Patent Act to require "willful" violations for enhanced damages. *Halo*, 579 U.S. at 106. When Congress enacted § 284 in 1952, it legislated "against this backdrop." *Id.* at 100. Thus, whether the courts, as ratified by Congress, or Congress itself created § 284's "willful" standard, its standard remains the same

as the Fair Credit Reporting Act's. If anything, § 284 is an even closer analog to the Fair Credit Reporting Act than the False Claims Act; while § 284 and the Fair Credit Reporting Act have the *exact same* scienter standard—willfulness—the False Claims Act requires only knowing violations. *See* 31 U.S.C. § 3729(a)(1)(A)-(B). Instead of acknowledging this potentially critical difference, the majority opinion simply ignores it. *See* Majority Op. at 12 (noting simply that the Fair Credit Reporting Act and False Claims Act have "parallel" scienter requirements).

The majority opinion's second distinction is even weaker. While it attempts to draw a hard line between scienter terms for "damages after [a] finding [of] liability" and those for "liability" alone, it does not, and perhaps cannot, explain why this distinction is important. *Id.* at 13 (simply noting that these "differences" create a "gap" between the False Claims Act and the Patent Act). In fact, neither statute suggests that this difference is meaningful at all: a patent infringer is only "liab[le] for enhanced damages" if they acted willfully, *Halo*, 579 U.S. at 104, just as a fraudster is only "liable" for treble damages if they acted knowingly, 31 U.S.C. § 3729(a).

Nonetheless, the majority opinion doubles down, arguing that the False Claims Act and the Fair Credit Reporting Act are analogs because both "speak[] to liability rather than damages." Majority Op. at 14. But even if this was a relevant point of analysis, it simply isn't so. The relevant section of the Fair Credit Reporting Act plainly states that "[a]ny person who willfully fails to comply" with the statute "with respect to any

consumer is *liable* to that consumer . . . [for] any actual *damages*[;] . . . punitive *damages* as the court may allow; and . . . reasonable attorney's fees as determined by the court." 15 U.S.C. § 1681n(a) (emphases added). So if the discussion of § 284 in *Halo* is irrelevant for our purposes in understanding the False Claims Act because § 284 "concern[s] whether district courts [can] issue a particular amount of damages after finding liability" whereas the False Claims Act "concerns whether liability exists at all," Majority Op. at 13, then the statute upon which the majority hangs its hat—the Fair Credit Reporting Act, as understood in *Safeco*—is irrelevant for precisely the same reason. In other words, the very statute the majority opinion claims to be analogizing to elides the very distinction it attempts to make.

At the end of the day, though the majority opinion ironically spends more time distinguishing the False Claims Act from § 284 than analogizing the False Claims Act to the Fair Credit Reporting Act, its facile analysis still fails. Nor does it provide any answer for the most troubling concern identified by the *Halo* Court—that adopting *Safeco*'s objective recklessness test makes "deliberate wrongdoing" completely irrelevant, despite Congress's clear intention to impose liability in such circumstances. *Halo*, 579 U.S. at 104 ("In the context of such deliberate wrongdoing . . . it is not clear why an independent showing of objective recklessness . . . should be a prerequisite" to recovery.).

3.

It would seem to be enough to point out that the majority treads on thin ice by copying and pasting mismatched common law into the False Claims Act. But instead of retreating after hearing the cracking beneath its feet, it takes yet another step and plunges into the depths below.

That next step occurs when the majority opinion holds that if we adopt *Safeco*'s objective-recklessness test for False Claims Act allegations, then a "[f]ailure to meet this recklessness standard *preclude[s] a finding of knowledge as well*." Majority Op. at 11 (emphasis added). The majority opinion claims this result is commanded by *Safeco* and logic. Failing that, it makes undisguised appeals to notions of public policy. Neither argument withstands even the slightest scrutiny.

i.

The majority opinion's *Safeco* argument can be traced to a single footnote at the very end of that opinion. That footnote proclaims that "[w]here, as here, the statutory text and relevant court and agency guidance allow for more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation as a *knowing or reckless* violator." *Safeco*, 551 U.S. at 70 n.20 (emphasis added). According to the majority opinion, this single footnote gives it permission to strike the "actual knowledge" and "deliberate ignorance" standards from the text of the

False Claims Act, at least with regard to "legally false claims." Majority Op. at 14-15.

But nothing suggests that the Supreme Court intended to upend the law of frauds in a terse footnote in an opinion on credit-reporting requirements. In fact, the Court clarified—in the very same footnote—that it was focused on whether "subjective bad faith must be taken into account in determining whether a company acted knowingly or recklessly *for purposes of § 1681n(a)" of the Fair Credit Reporting Act. Safeco*, 551 U.S. at 70 n.20 (emphasis added). So, the Court's seemingly broad references to "a defendant," "knowing or reckless violator[s]," and "subjective bad faith," *see id.*, are limited to the Fair Credit Reporting Act context—as the Court itself plainly noted in *Halo*, 579 U.S. at 106 n.* (rejecting an analogy to *Safeco*'s footnote because a "showing of bad faith was not relevant absent a showing of objective recklessness" *under the Fair Credit Reporting Act*, while "'bad-faith infringement' *is* an independent basis for enhancing patent damages").

Even if we ignored this critical context—which we should not—*Safeco*'s conclusory conflation of knowing and reckless violations would be dictum. *Safeco* did not involve any *knowing* violation of the Fair Credit Reporting Act; the plaintiffs' entire action rested on allegedly *reckless* failures. *Safeco*, 551 U.S. at 52-58. Therefore, the Supreme Court's discursion on "knowing" violations is a classic example of a "peripheral" statement that "may not have received the full and careful consideration of the court that uttered it" and "that could have been deleted without

seriously impairing the analytical foundations of the holding." *Payne v. Taslimi*, 998 F.3d 648, 654-55 (4th Cir. 2021) (quoting *Pittston Co. v. United States*, 199 F.3d 694, 703 (4th Cir. 1999)). And while we give "great weight to Supreme Court dicta," *NLRB v. Bluefield Hosp. Co.*, 821 F.3d 534, 541 n.6 (4th Cir. 2016), dicta "cannot serve as a source of binding authority in American jurisprudence," *United States v. Pasquantino*, 336 F.3d 321, 329 (4th Cir. 2003) (en banc), *aff'd*, 544 U.S. 349, 125 S. Ct. 1766, 161 L. Ed. 2d 619 (2005).

Undeterred, the majority opinion insists that even if *Safeco*'s footnote is not controlling, when "a defendant has not acted with reckless disregard in its view of the statute, 'it follows *a fortiori*' that it has not acted with deliberate ignorance or actual knowledge, which 'plainly demand[] even more culpability.'" Majority Op. at 14 (quoting *Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1058 n.15 (11th Cir. 2015)).

As support, it offers a syllogism with a major premise stating that reckless disregard is the "most capacious," "loosest," or "baseline" scienter standard, and a deeply flawed minor premise stating that actual knowledge and deliberate ignorance necessarily fall within the "capacious" reckless-disregard standard. *Id.* at 14 (citations omitted). That minor premise is foreclosed by *Safeco* itself, which said that "action falling within the knowing subcategory *does not simultaneously fall within* the reckless alternative." *Safeco*, 551 U.S. at 60 (emphasis added); *see also Halo*, 579 U.S. at 105 ("The subjective willfulness of a patent infringer, intentional or

knowing, may warrant enhanced damages, *without regard* to whether his infringement was objectively reckless." (emphasis added)).

And there are even stronger reasons to reject the majority opinion's overall result. At the outset, it is a "cardinal rule of statutory construction that we are 'obliged to give effect, if possible, to every word Congress used.'" *Taylor v. Grubbs*, 930 F.3d 611, 617 (4th Cir. 2019) (quoting *Nat'l Ass'n of Mfrs. v. Dep't of Def.*, 138 S. Ct. 617, 632, 199 L. Ed. 2d 501 (2018)); *see also Safeco*, 551 U.S. at 60 (recognizing its obligation to "[g]ive effect, if possible, to every clause and word of a statute" (citation omitted)). But the majority opinion's test creates a "threshold requirement" that renders the statutory text's "actual knowledge" and "deliberate ignorance" standards totally superfluous. Majority Op. at 14. Taking the majority opinion at its word: the objective-recklessness standard is a *threshold* inquiry. That means that if one *can* satisfy the majority's objective-recklessness standard, there is no need to assess actual knowledge or deliberate ignorance, since liability has already been established. If one *cannot* satisfy the majority's objective-recklessness standard, then we are precluded from assessing these other scienter standards at all. *Id.* at 12. There is no escaping this result. Yet, the majority opinion claims that "applying *Safeco* does not sap the FCA's three scienter definitions of independent meaning." *Id.* at 14. But claiming it to be so does not make it so.

That's because reading two of the three scienter standards out of the statute is not only inconsistent

with a cardinal rule of statutory construction but also inconsistent with *Safeco* itself. That decision teaches us that "a common law term in a statute comes with a common law meaning" *unless* "*Congress had something different in mind*." *Safeco*, 551 U.S. at 58, 69 (emphasis added). The fact that Congress crafted *three* distinct scienter standards—not *one* threshold objective-recklessness test—compels the conclusion that it *did* have something different in mind.

In case there was any doubt about this, the drafting history of the False Claims Reform Act confirms it. Over thirty years ago, Congress grew concerned that overly "restrictive court interpretations" of the False Claims Act were "thwart[ing] the effectiveness of the statute." S. Rep. No. 99-345, at 4, 1986 U.S.C.C.A.N. at 5269. In particular, "inappropriate" narrowing of the Act's scienter requirement was hamstringing the Government's ability to fight "rampant fraud." *Id.* at 7, 13, 1986 U.S.C.C.A.N. at 5272, 5278. To remedy this problem, Congress crafted three distinct and expansive scienter standards and eliminated any requirement to show bad faith. 31 U.S.C. § 3729(b)(1). The clear intent of these amendments was to adopt a broad, "remedial" scienter standard that would allow the Government to "hold responsible those corporate officers who insulate themselves from knowledge of false claims submitted by lower-level subordinates." S. Rep. No. 99-345, at 7, 1986 U.S.C.C.A.N. at 5272. In other words, Congress was trying to capture *more* fraud, not less.

Yet rather than turning to this history, the majority opinion instead repeats the mistakes made by courts

before Congress amended the False Claims Act in 1986 by adopting its own overly "restrictive" interpretation of the Act. *Id.* at 4, 1986 U.S.C.C.A.N. at 5269. Thusly, it reads two of the three scienter standards right out of existence: the actual-knowledge and deliberate-ignorance standards that concern "*deliberate* wrongdoing." *Halo*, 579 U.S. at 104 (emphasis added). By striking these two standards from the statute, the majority effectively "insulat[es] some of the *worst* [scammers] from *any* liability" whatsoever. *Id.* (emphasis added). The majority opinion's new law thereby frustrates the clear intent of Congress—as evidenced by both the text *and* legislative history—to expand False Claims Act liability to cover situations precisely like that alleged by Sheldon today.

Perhaps sensing the weight of authority against it, the majority opinion claims that its redlined version of the Act will "not apply to all [False Claims Act] suits." Majority Op. at 14. Rather, it contends the opinion "is narrowly cabined to *legally* false claims—like the one here—which involve *contested* statutory and regulatory requirements." *Id.* at 15 (emphases added). But this is not a minor universe of cases. It might take a lifetime just to *list* all of the contested statutory and regulatory requirements out there. Even if we only consider what requirements might conceivably be contested for a *single* program like Medicaid, the mind reels. After all, as the majority itself acknowledges, "Medicaid statutes and regulations 'are among the most completely impenetrable texts within human experience,'" *id.* at 20 (quoting *Rehab. Ass'n of Va., Inc. v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994)), involving "complex" and "labyrinthine reporting

requirements" that "raise[] some of the thorniest issues in government price reporting," *id.* at 16, 20. If this is true, then what qualifies as a *contested* Medicaid requirement is only limited by the "ingenuity" of defense attorneys. *Halo*, 579 U.S. at 105.

In other words, the majority opinion's "narrow[]" holding is actually as broad as defendants want it to be. Majority Op. at 15. So long as a legal fraudster can "muster a reasonable (even though unsuccessful) defense" at trial—which should not be much of a lift, especially for complex programs like Medicaid—they can "escape any comeuppance." *Halo*, 579 U.S. at 105. This creates a truly perverse incentive; the more that defendants steal via fraud, the easier it is for them to hire high-priced attorneys who can dream up reasonable explanations to justify said fraud after the fact.

Post hoc rationalizations like these are only possible because under the majority opinion's test, a defendant does not need to have "act[ed] on the basis of the defense" or "even [be] aware of it" at the time the fraud was committed. *Id.* They just need to advance an "objectively reasonable" interpretation that "ha[s] a foundation in the statutory text," even if that reading is ultimately "erroneous." Majority Op. at 11 (quoting *Safeco*, 551 U.S. at 69-70). Whether the defendant was actually operating under this interpretation when it committed the alleged fraud is both unnecessary and impossible to discern under the majority's test because any "inquiry into a defendant's subjective intent" or "subjective beliefs" is completely precluded. *Id.* at 12, 26 n.5. Forbidding such

an inquiry, however, violates another cardinal principle: that "culpability is generally measured against the knowledge of the actor at the time of the challenged conduct." *Halo*, 579 U.S. at 105. It also allows the "most culpable offenders"—those who commit fraud with actual knowledge and "without any reason to suppose [their] conduct is arguably defensible"—to craft their own get-out-of-jail-free cards whenever they like. *Id.* at 104-105.

The majority opinion counters that any concerns about deliberate fraudsters escaping liability are blunted by *Safeco*'s second step. That step asks "whether authoritative guidance might have warned [the] defendant away from [their objectively reasonable] reading." Majority Op. at 11. According to the majority opinion, a defendant cannot truly *know* that they are filing a false claim until they obtain authoritative guidance from either the courts of appeal or the relevant agency that "clarifies [their] interpretation of the law and so warns defendants away from otherwise reasonable interpretations." *Id.* at 16. Before this point, a "defendant might suspect, believe, or intend to file a false claim, but it cannot *know* that its claim is false." *Id.* at 15 (quoting *Schutte*, 9 F.4th at 468).

That borders on the nonsensical. It is self-aggrandizing to suppose that the biggest pharmaceutical companies on the planet, with some of the highest-paid experts in health care law, are incapable of reading a statute or regulation and "knowing" they are breaking the law until a court or CMS spells it out for them. And even if a lack of authoritative guidance precludes "*actual* knowledge"—which it shouldn't—it certainly could not

preclude a finding of "*deliberate ignorance*." 31 U.S.C. § 3729(b)(1)(A) (emphases added). After all, this standard is intended to reach the "'ostrich' type situation where an individual has 'buried his head in the sand' and failed to make simple inquiries which would alert him that false claims are being submitted." S. Rep. No. 99-345, at 21, 1986 U.S.C.C.A.N. at 5286. In other words, the False Claims Act's deliberate-ignorance standard is designed to capture the very conduct the majority says cannot be captured under *Safeco*'s second step: situations where a defendant "suspect[s]" or "believe[s]" they are committing fraud but avoids making inquiries that would confirm their suspicions. Majority Op. at 15 (quoting *Schutte*, 9 F.4th at 468).

Applying *Safeco*'s second step here also leads to absurd results. For example, under the majority opinion's test, a defendant could *know* they are committing fraud, be told by a *court* that they are doing so, and nevertheless escape liability because (1) they advance a post hoc explanation that, while wrong, is still "reasonable," and (2) neither the Government nor the court had said anything "authoritative" at the time of the fraud.

It also has the effect of basically freezing judicial interpretation of the statute at issue. *Cf. Camreta v. Greene*, 563 U.S. 692, 706, 131 S. Ct. 2020, 179 L. Ed. 2d 1118 (2011) (noting that the doctrine of qualified immunity, as applied to claims under 42 U.S.C. § 1983, "may frustrate the development of constitutional precedent" because courts need not reach the merits of the constitutional claim where qualified immunity applies (internal quotation

marks omitted)). As noted above, under *Safeco*'s first step, a defendant need only advance an objectively reasonable statutory interpretation. When analyzing this claim, a court does not have to decide what the statute actually says; it only has to determine if the defendant's reading is "reasonable." This is precisely what happened below, and precisely what the majority does today. Majority Op. at 22 ("[W]e hold that Forest has offered, at minimum, an objectively reasonable reading of the Rebate Statute."). The problem is that by doing so, the court necessarily forgoes the opportunity to provide "authoritative guidance," which is needed at *Safeco*'s second step to warn the defendant away from their fraudulent scheme. With judicial interpretation stalled, the defendant is free to continue committing knowing fraud as long as they desire unless CMS steps in with new guidance.

And even that might not be enough. For example, though CMS issued new guidance in 2007 that clearly warned Forest away from most of its rebate stacking—as evidenced by its high-level meetings, data scrubbing, sales contracts, and its "first come, first served" rebate policy—the majority opinion decides, as a matter of law and without considering these facts, that this warning-away could not possibly have occurred.[3] *Id.* at 23.

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3. In 2016, CMS issued a new rulemaking stating that "[i]f a manufacturer offers multiple price concessions to two entities for the same drug transaction . . . all discounts related to that transaction which adjust the price available from the manufacturer should be considered in the manufacturer's final price of that drug when determining the best price to be reported for the drug." Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5170, 5253 (Feb. 1,

Its legal arguments exhausted, the majority opinion next turns to naked considerations of public policy. It accuses CMS—without *any* basis in the record—of deliberately "maintain[ing] strategic ambiguity" in its Medicaid regulations "in order to expand potential liability for regulated entities." Majority Op. at 23, 27; *see also id.* at 27 ("Clear regulations constrain regulatory power and limit future flexibility, which is why an agency might find them undesirable."). In other words, the majority opinion baldly accuses the executive branch of regulating in bad faith in order to saddle innocent companies with "potentially ruinous liability."[4] *Id.* at 27. Incredibly, the majority opinion then doubles down, alleging that CMS is simply "mak[ing] up the rules as [it] go[es]" along, *id.* (quoting Bill Watterson, *The Calvin & Hobbes Tenth Anniversary Book* 129 (1995)), and trying "to take advantage of companies like [Forest]" "through ambush," *id.* at 27-28.

Finally, the majority opinion circles back to the False Claims Act, finding it "profoundly troubling" that the Act could be used to impose "massive liability on individuals

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2016) (codified at 42 C.F.R. pt. 447). CMS believed this understanding was consistent with the regulation promulgated in 2007. *Id.* But the majority opinion fails to even mention this rulemaking.

4. This is likely an overstatement. As explained above, Forest's *annual* revenues top $15 billion per year. Therefore, the majority opinion's teeth-gnashing over the "potentially ruinous liability" for pharmaceutical companies like Forest is sorely misplaced. Majority Op. at 27.

or companies without any proper notice as to what is required." *Id.* at 17. The majority opinion then states that since the Act imposes "damages that are essentially punitive in nature," a lack of appropriate notice means that "defendants are not likely to receive due process." *Id.* at 16-17 (citations omitted). However, it says adopting *Safeco* allows us to "avoid[] this trouble" because it forces courts to "strict[ly] enforce[]" the False Claims Act's "rigorous" scienter requirement. *Id.* at 17 (quoting *Escobar*, 579 U.S. at 192). Having set up this artificial construct, the majority concludes that *Safeco*'s standard provides "just the right means to further [the majority's] end": preventing the ever-expanding "administrative state" from "tak[ing] advantage of companies" like Forest. *Id.* at 17, 27.

But "[t]he seriousness of [the majority opinion's] policy concerns cannot justify imposing an artificial construct such as the [*Safeco*] test on the" False Claims Act. *Halo*, 579 U.S. at 109. This is especially true when imposing such a construct obviates the clear commands of Congress. Ironically, while it is the majority opinion that accuses CMS of "mak[ing] up the rules as [it] go[es]" along, it is the *majority opinion* that ends up playing its own version of "Calvinball" by using *Safeco* to shred two of the Act's scienter standards. Majority Op. at 27 (quoting Watterson, *supra*, at 129). The majority opinion claims that this outcome is justified by the Supreme Court's command to "strict[ly] enforce[]" the Act's "rigorous" scienter requirement. *Id.* at 17 (quoting *Escobar*, 579 U.S. at 192). But there is a big difference between strictly *enforcing* all three scienter standards created by Congress and *deleting* two of them altogether. And because nothing

even suggests that the False Claims Act, as currently written, violates due process, we must give effect to all three standards—not rewrite them based on our own notions of a better public policy.

C.

For the reasons explained above, *Safeco* should not be imported into the False Claims Act. But even if it is, Sheldon has plausibly alleged a claim under the *Safeco* framework. Under *Safeco*'s first step, we assess whether Forest's reading of the Rebate Statute is objectively reasonable. While I agree that its reading would be reasonable if we were interpreting on a blank slate, we aren't. Even if Forest survives *Safeco*'s first step, the majority errs by finding—at *Safeco*'s second step—that Forest was not warned away from its fraudulent scheme.

1.

Though the majority opinion barely mentions it, our interpretation of the Rebate Statute is governed by the familiar framework articulated in *Chevron U.S.A. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 104 S. Ct. 2778, 81 L. Ed. 2d 694 (1984). Under *Chevron*, courts first examine "whether Congress has directly spoken to the precise question at issue." *Id.* at 842. If it has, "that is the end of the matter." *Id.* But "[i]f the statute is ambiguous, courts then 'move to *Chevron*'s second step and defer to the agency's interpretation so long as it is based on a permissible construction of the statute.'" *Sierra Club v. U.S. Army Corps of Eng'rs*, 909 F.3d 635,

643 (4th Cir. 2018) (cleaned up) (quoting *King v. Burwell*, 759 F.3d 358, 367 (4th Cir. 2014), *aff'd*, 576 U.S. 473, 135 S. Ct. 2480, 192 L. Ed. 2d 483 (2015)).

i.

The Rebate Statute's definition of "best price" is certainly ambiguous. Best price means "the lowest price available from the manufacturer . . . to *any* wholesaler, retailer, provider, health maintenance organization, nonprofit entity, *or* governmental entity . . . inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates." 42 U.S.C. § 1396r-8(c)(1)(C) (emphases added). In general, Congress's "use of the word 'any' suggests an intent to use that term expansive[ly]." *Smith v. Berryhill*, 139 S. Ct. 1765, 1774, 204 L. Ed. 2d 62 (2019) (quoting *Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 218-19, 128 S. Ct. 831, 169 L. Ed. 2d 680 (2008)). "Any" can mean "one, some, or all," depending on context. *Any*, Merriam Webster Dictionary, https://www.merriam-webster.com/dictionary/any (last visited Dec. 19, 2021). And the context here is the statute's broadly remedial purpose: ensuring that Medicaid programs pay the same rate as private entities for prescription drugs. H.R. Rep. No. 101-881, at 96 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108. Therefore, it seems reasonable to read "any" to refer to one or more of the entities listed—especially since Congress did not say "any single" or "any particular" entity, for example. After all, if spreading rebates for the same drug unit around to different entities in the supply chain was not captured in the "*best* price," it would not make much sense to call it that.

Appendix B

As the majority opinion notes, two context clues suggest that "any" here means "one" and not "some" or "all." Majority Op. at 18-19. But neither can bear the weight the majority opinion would place upon them in its bid to render the text unambiguous. First, each of the entities in the statute is listed in the singular form. And "when 'any' is used in context of the singular noun," it ordinarily refers to a "single" item. *United States v. Dunford*, 148 F.3d 385, 389-90 (4th Cir. 1998) (nonetheless rejecting this reading). But neither Forest nor the majority opinion account for the Dictionary Act—"which supplie[s] rules of construction for all legislation," *Ngiraingas v. Sanchez*, 495 U.S. 182, 190, 110 S. Ct. 1737, 109 L. Ed. 2d 163 (1990) (citation omitted)—which says that "words importing the singular include and apply to several persons, parties, or things." 1 U.S.C. § 1. Second, the statute includes the disjunctive "or," which also suggests that each entity must be considered apart from the other. But this is not determinative. "Unsurprisingly, statutory context can overcome the ordinary, disjunctive meaning of 'or.'" *Encino Motorcars, LLC v. Navarro*, 138 S. Ct. 1134, 1141, 200 L. Ed. 2d 433 (2018); *see also Confederated Tribes & Bands of Yakama Nation v. Yakima Cnty.*, 963 F.3d 982, 990 (9th Cir. 2020) ("[C]ourts are often compelled to construe 'or' as meaning 'and,' and again 'and' as meaning 'or.'" (quoting *United States v. Fisk*, 70 U.S. 445, 447, 18 L. Ed. 243 (1865))). And again, the context here is Congress's broad intent to stop "pay[ing] overly inflated prices for prescription drugs." 136 Cong. Rec. S12,954 (daily ed. Sept. 12, 1990) (statement of Sen. David Pryor).

The majority opinion makes several other arguments, but none clear up the issue. To start, it provides a few simplistic examples using baseballs and apples to suggest "aggregating discounts to multiple entities" cannot be required by the Rebate Statute. Majority Op. at 19. But by their very nature, these everyday examples lack the critical legislative context animating the best-price provision. They do not, for example, assume that the "thrifty Kansas City Royals" or your "friend" have been repeatedly swindled and forced to pay exorbitant amounts for the same goods purchased by everyone else at a much lower price. *Id.* Nor do they account for the overlapping nature of the supply chain for drug manufacturing and delivery.

Next, the majority opinion suggests that since the statute says "the lowest price *available* from the manufacturer" and "'available' means 'suitable or ready for use,'" the statute must be "talking about an actual price, not something that is purely hypothetical." *Id.* at 19 (emphasis added). But the majority opinion itself recognizes that "available" is a more elastic word than this argument suggests. For example, it notes that "wholesaler chargeback agreements"—discounts that the wholesaler delivers to its customers and later "charges back" to the manufacturer—can be included in best price, even though they are not "at hand" or immediately "available" from the manufacturer and in fact operate as a "lagged price concession." *Id.* at 19, 24-25.

The majority opinion also points out differences between the definitions of best price and "[a]verage

[m]anufacturer [p]rice." *Id.* at 19-20. Specifically, the former refers to "the lowest price available *from* the manufacturer" while the latter refers to the "the average price *paid to* the manufacturer." 42 U.S.C. § 1396r-8(c)(1)(C)(i), (k)(1)(A) (emphases added). The majority opinion vaguely notes that "something 'paid to the manufacturer' might incorporate discounts to different entities" but fails to explain why this is true, or how "paid" and "from" create a meaningful "distinction[] in the statutory scheme." Majority Op. at 20.

It also seems odd to interpret these standards in dramatically different ways since the difference between the two is what determines the manufacturer's rebate payment. *See* 42 U.S.C. § 1396r-8(c)(1)(A)(ii). Mathematically, it usually only makes sense to subtract like terms from each other. *Addition and Subtraction of Algebraic Expressions*, Cuemath, https://www.cuemath.com/algebra/addition-and-subtraction-of-algebraic-expressions/ (last visited Dec. 19, 2021) ("Unlike terms cannot be combined by adding or subtracting."). But if average manufacturer price could incorporate stacked rebates but best price could not, then drug manufacturers would be stuck subtracting apples from oranges. It also would lead to bizarre results: normally, we would expect the best price to be lower than the average price. But if average price could include rebates from multiple entities but best price cannot, the difference between the two would diminish or even disappear. Such a result would be out of step with Congress's intent, which was to "achieve significant Medicaid savings" by getting the "same discounts" that private entities enjoy. H.R. Rep. No. 101-881, at 96, 98, 1990 U.S.C.C.A.N. at 2108, 2110.

The majority opinion counters that aggregating prices to different entities is difficult, so it makes sense to read the statute to not require manufacturers to do so. Majority Op. at 21. But that's not a canon of construction—whether compliance with the law is taxing has no bearing on what the law itself requires.

In sum, the Rebate Statute is ambiguous which means *Chevron*'s second step is implicated.

ii.

Addressing *Chevron's* second step, it is worth pointing out from the outset that no one debates that CMS has the authority to make rules interpreting the Rebate Statute with the "force of law." *See United States v. Mead Corp.*, 533 U.S. 218, 226-27, 121 S. Ct. 2164, 150 L. Ed. 2d 292 (2001) (limiting *Chevron* deference to interpretations made by agencies acting with the "force of law" pursuant to that authority). The real question is whether there is any reasonable agency interpretation to defer to in the first place. *See Fogo De Chao (Holdings) Inc. v. U.S. Dep't of Homeland Sec.*, 769 F.3d 1127, 1135, 413 U.S. App. D.C. 39 (D.C. Cir. 2014) ("[W]here 'the underlying regulation does little more than restate the terms of the statute itself[,]' the agency has left the statute as it found it, adding nothing material to Congress's language and providing nothing of its own in which to ground an interpretation to which a court might defer." (quoting *Gonzales v. Oregon*, 546 U.S. 243, 257, 126 S. Ct. 904, 163 L. Ed. 2d 748 (2006))). The majority opinion finds that CMS's regulations "simply mirror the statutory language," so no deference is appropriate. Majority Op. at 21. Not so.

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CMS has issued three distinct notice-and-comment rulemakings on best price.[5] In 1991, CMS promulgated the Rebate Agreement, which copied the statutory language on "best price" but added that 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*." Medicaid Program; Drug Rebate Agreement, 56 Fed. Reg. 7049, 7050 (Feb. 21, 1991). In 2007, CMS promulgated a regulation defining "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*." 72 Fed. Reg. at 39,242 (emphases added). It further clarified that best price "shall be [the] *net* of cash discounts . . . which reduce the price available from the manufacturer," and required manufacturers to "adjust the best price for a rebate period if cumulative discounts, rebates, *or other arrangements subsequently adjust the prices available from the manufacturer*." *Id.* at 39,242-43 (emphases added). Finally, in 2016, CMS promulgated another regulation that best price must include "all prices, including applicable discounts, rebates, or other transactions that adjust prices either *directly or indirectly* to the best price-eligible *entities*" listed in the statutory definition. 81 Fed. Reg. at 5351 (emphases added).[6]

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5. "When an agency's interpretation derives from notice-and-comment rulemaking, it will almost inevitably receive *Chevron* deference." *Sierra Club*, 909 F.3d at 644 (citation and internal quotation marks omitted).

6. Forest claims this regulation is irrelevant because Sheldon did not include any particularized factual allegations concerning the company's conduct after 2014. Response Br. at 27-28. Even if this is

These rulemakings' broad references to "any entity," "any pricing structure," "net" cash discounts, "prices actually realized," and "other arrangements subsequently adjust[ing] prices" strongly suggest that CMS is focused on the "net" result—the price the manufacturer actually realizes for the sale of a single drug unit. In fact, it is this "net" result language that prompted Forest and other pharmaceutical companies to suggest 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*." J.A. 239 (emphases added). I agree with the drug companies that this is precisely what CMS intended. I also find that this interpretation is reasonable for the reasons explained above, as well as the fact that it best comports with our obligation to interpret a statute "in light of its object and policy." *United States v. Turpin*, 65 F.3d 1207, 1210 (4th Cir. 1995).

Ultimately, despite the majority opinion's protestations, we must defer to the reasonable interpretation of CMS. If we do, then we must find that Forest acted under an objectively unreasonable reading of the Rebate Statute.[7]

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true, the regulation still shows that CMS has consistently interpreted the Rebate Act to require stacked rebates be included in best price. 81 Fed. Reg. at 5253 (noting that the 2016 regulation is consistent with the 2007 regulation).

7. A final note on the interpretation of the Rebate Statute. Though the majority opinion's statutory analysis is couched in absolute terms, its holding is much more modest: it only concludes "that Forest has offered, at minimum, an objectively reasonable reading of the Rebate Statute." Majority Op. at 22. Therefore, the majority opinion's reading of the statute is not binding on this or any other court.

2.

Even if we conclude that Forest's reading was reasonable, it still falters at *Safeco*'s second step because it was warned away from that reading. But before I get to that, I must first address the majority opinion's flawed warned-away standard.

According to the majority opinion, a defendant may only be warned away from an erroneous statutory reading by two "authoritative" sources: "circuit court precedent or guidance from the relevant agency." Majority Op. at 22. As support, it cites *Safeco* and several out-of-circuit cases. *Id.* However, *Safeco* did not expressly limit the warned-away exception to just these two sources. *See* 551 U.S. at 70 (addressing "guidance from the courts of appeals or the [relevant agency]" but not expressly limiting the inquiry to these sources only). And in fact, we have already held that the warned-away exception extends beyond these two sources.

In *United States ex rel. Lutz v. Mallory*, 988 F.3d 730 (4th Cir. 2021), we considered whether a blood-testing lab knowingly violated the Anti-Kickback Statute and thus ran afoul of the False Claims Act. *Id.* at 735-36. At trial, the Government offered evidence that the defendants' own attorneys warned them their scheme might violate the statute. *Id.* at 736. In addition, the Government "offered evidence that outside lawyers warned all three [of the] [d]efendants about the illegality of the[ir kickbacks]." *Id.* at 736-37. The jury found the defendants had knowingly violated the Anti-Kickback Statute, and we declined to reverse as a matter of law. *Id.* at 735-36.

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The defendants argued that "because the Anti-Kickback Statute is ambiguous, they could have reasonably concluded that the statute did not prohibit [their scheme], and so they cannot have knowingly violated the False Claims Act." *Id.* at 737. We disagreed, noting that "[the d]efendants were repeatedly 'warned away from [their] interpretation' of purportedly ambiguous terms, *including by legal practitioners*." *Id.* (emphasis added) (quoting *Purcell*, 807 F.3d at 288). Because the *Mallory* Court expressly held that guidance from legal practitioners can satisfy the "warned-away" exception, the majority opinion's attempt to limit the same exception to appellate precedent and agency guidance must fail. *United States v. Spinks*, 770 F.3d 285, 290 (4th Cir. 2014) (explaining that "if two circuit precedents conflict, the earlier one . . . controls over the later").

The majority opinion's failure to heed our precedent leads it to make yet another error by holding that Forest was not warned away as a matter of law. Majority Op. at 22-28. To wit, because the majority opinion erroneously considers only appellate precedent or agency guidance relevant, it finds it can resolve the entire warned-away issue by interpreting these "legal materials" on its own. *Id.* at 18 n.3. However, *Mallory* forecloses this view. 988 F.3d at 737 (recognizing the fact-intensive nature of the warned-away exception). And other courts, including the D.C. Circuit in *United States ex rel. Purcell v. MWI Corp.*—a case the majority opinion repeatedly relies on—have consistently held that whether an entity was warned away "cannot readily be labeled as a 'purely legal' question." *See, e.g., Purcell*, 807 F.3d at 288; *see also id.* at

289 ("[T]he factual question remains whether there was sufficient evidence that [the defendant] was warned away from its interpretation."); *United States ex rel. Brown v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1051 (C.D. Cal. 2016) ("Whether [the defendant] was warned away from the view it took is a question of fact."); *United States ex rel. Streck v. Bristol-Myers Squibb Co.*, 370 F. Supp. 3d 491, 497 (E.D. Pa. 2019) (noting "a factual determination remains whether [the defendant] had been warned away from its interpretation by CMS[]").

This makes sense when you take the time to think about what being "warned away" means. A full warned-away inquiry might require determining what legal guidance existed, what it said, who said it, how authoritative it was, when the defendant knew or should have known about it, how the defendant responded, and what other advice the defendant might have received from its own or outside attorneys. *See, e.g., Mallory*, 988 F.3d 736-37 (reviewing a timeline of legal memos, board meetings, emails, agency commentary, judicial opinions, and legal opinions authored by outside lawyers to assess whether the defendants were warned away). At most, this is a mixed question of law and fact. Therefore, the majority opinion errs by finding that Forest could not have been warned away as a pure matter of law.

With the proper framework in mind, there is no doubt that Sheldon plausibly alleged Forest was warned away. As explained at length above, Forest explicitly asked CMS to remove language from the 2007 regulation it believed would require rebate stacking. CMS refused, and

expressly rejected a "customer-by-customer" approach to best price.[8] 72 Fed. Reg. at 39,198. In response, Forest held a series of high-level meetings and instituted a data audit to eliminate rebate stacking. It also introduced language prohibiting its customers from claiming stacked rebates and instituted a "first come first serve" policy for rebates on the same drug units to avoid having to report double rebates to CMS. Thus, Forest was not only "warned away" by CMS, but also clearly took that warning to heart—at least for its non-preferred customers. Unfortunately, under the majority opinion's purely legal—and purely impermissible—warned-away test, the jury will never get to consider these facts and make its own assessment of Forest's liability under the False Claims Act.

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8. The majority opinion counters that this same rulemaking repeatedly urged manufacturers like Forest "to make reasonable assumptions" when calculating best price. Majority Op. at 26. But as the majority acknowledges, a manufacturer may only make such assumptions "[i]n the absence of specific guidance," and such assumptions must be "consistent with the general requirements and the intent of the [Rebate Statute], [and] Federal regulations." 72 Fed. Reg. at 39,164. For the reasons explained above, the majority opinion errs by finding the 2007 guidance was not specific; after all, it was specific enough to trigger Forest to conduct a data audit, alter its sales-contract language, and refuse to make stacked-rebate payments for most of its customers. Similarly, the majority opinion cannot explain how Forest's neat trick—directly paying out rebates to different customers instead of paying one rebate to its wholesaler to avoid reporting double rebates to CMS—is consistent with the intent of the Rebate Statute.

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II.

If the majority opinion wants to consider the impact this decision has on policy, then here are some facts from which we can take judicial notice.

Every year, between $100 and $360 billion are lost to health care fraud. *See* National Health Care Anti-Fraud Association, *The Challenge of Health Care Fraud*, https://www.nhcaa.org/tools-insights/about-health-care-fraud/the-challenge-of-health-care-fraud/ (last visited Dec. 19, 2021). And these numbers are only growing. *See, e.g.*, Mike Stankiewicz, *Medicaid Wasted $37B on Improper Payments in 2017, CMS Shrugs Off GAO Advice*, Fierce Healthcare (Apr. 13, 2018), https://www.fiercehealthcare.com/payer/medicaid-wasted-37b-improper-payments-gao (noting fraud has "spiked in recent years").

In this swelling sea of fraud, the Government is bailing out with an ever-shrinking teaspoon. In fiscal year 2020, the Government recovered only $1.8 billion in settlements and judgments for health care fraud using the False Claims Act. Press Release, U.S. Dep't of Justice, *Justice Department Recovers Over $2.2 Billion from False Claims Act Cases in Fiscal Year 2020* (Jan. 14, 2021) (noting over 80% of the total fraud recovery in 2020 related to the health care industry). This was almost a 30% decline from the amount recovered in 2019, and over a 40% decline from the $3.1 billion high-water mark in 2012. *Id.* Thus, it is not only the "sad truth . . . that [fraud] against the Government often *does* pay," S. Rep. No. 99-345, at 3, 1986 U.S.C.C.A.N. at 5268, but getting away with it is also getting *easier*.

Unfortunately, today's majority opinion only worsens this trend. In doing so, the majority opinion joins a long and ignominious line of cases that have "thwart[ed] the effectiveness of the [Act]" by adopting overly "restrictive" scienter standards. *Id.* at 4, 1986 U.S.C.C.A.N. at 5269.

Thirty years ago, Congress stepped in to correct the worst of these judicial abuses. If the majority decision stands, Congress will be forced—unnecessarily—to do the same again. With respect for my colleagues in the majority, I dissent.[9]

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9. The majority opinion finds it unnecessary to address the district court's falsity finding because it concludes that Sheldon did not plausibly allege scienter. Majority Op. at 9 n.2. But the falsity finding was plainly inconsistent with the text of the False Claims Act and our precedent.

The district court found that the False Claims Act only punishes "objective falsehoods," *United States ex rel. Sheldon v. Forest Lab'ys*, 499 F. Supp. 3d 184, 212 (D. Md. 2020)—those "expressions of fact" that are capable of "empirical verification" and, thus, can be shown to be empirically false, *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 377-78 (4th Cir. 2008) (quoting *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 792 (4th Cir. 1999)). Since Forest acted under an objectively reasonable interpretation of the statute, the district court concluded, its best-price reports were not verifiably and objectively "false" for False Claims Act purposes. *Sheldon*, 499 F. Supp. 3d at 212.

There are three major problems with this analysis. First, on its face, the False Claims Act is not limited to "objective falsehoods"—it merely requires "a false or fraudulent claim" or "statement." 31 U.S.C. § 3729(a)(1)(A)-(B). And at common law, "false or fraudulent claims" include "more than just claims containing express [or empirical] falsehoods." *Escobar*, 579 U.S. at 187; *see also id.* at 188 (noting that even statements that are technically true can be "actionable misrepresentations").

Second, injecting "objectivity" at this stage impermissibly conflates scienter with falsity. *See Mallory*, 988 F.3d at 737 (holding that whether a defendant failed to comply with an "ambiguous" statutory term "go[es] to whether the government proved knowledge" (quoting *Purcell*, 807 F.3d at 287)); *United States ex rel. Oliver v. Parsons Co.*, 195 F.3d 457, 463 (9th Cir. 1999) ("[W]hile the reasonableness of [a defendant's] interpretation of the applicable [statute] may be relevant to whether it knowingly submitted a false claim, the question of 'falsity' itself is determined by whether [a defendant's] representations were accurate in light of applicable law."). Forest "either complied with" the Rebate Statute "or [it] didn't"; its allegedly "reasonable" reading of the statute plays no part in the falsity inquiry. *Drakeford*, 792 F.3d at 383-84.

Third, even if we conclude that the False Claims Act requires an "objective falsehood," the district court erred by concluding that compliance with the law in this case is not empirically verifiable. This Court has held that whether an entity complied with the law is an "*objective* inquiry." *Id.* at 384 (emphasis added). Again, Forest's statements "either complied with" the Rebate Statute "or [they] didn't." *Id.* at 383-84. And, if they did not, then they would be *objectively* false. The district court never determined whether that was the case here.

APPENDIX C — OPINION OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND, DATED NOVEMBER 5, 2020

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

Civil Action No. ELH-14-2535

UNITED STATES, *et al.*, *ex rel.*
DEBORAH SHELDON,

Plaintiffs,

v.

FOREST LABORATORIES, LLC, *et al.*,

Defendants.

November 5, 2020, Decided;
February 5, 2021, Filed

Ellen L. Hollander, United States District Judge.

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]

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

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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 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."

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, 131 S. Ct. 1885, 179 L. Ed. 2d 825 (2011); *ACLU v. Holder*, 673 F.3d

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

245, 246-51 (4th Cir. 2011) (describing history and current provisions of FCA).

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.

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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.

Appendix C

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 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.

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.

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]

7. Under the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, pharmaceutical drug companies must submit to the FDA a

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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.

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,

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listing of every drug product in commercial distribution. 21 U.S.C. § 355.

8. [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.

> 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.
>
> The best prices shall be inclusive of cash discounts, free goods, volume discounts, and rebates, (other than rebates under section 1927 of the Act).
>
> 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.

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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.
>
> 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):

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(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.

***

(e) Further clarification of best price.

(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.

***

(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.

> *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.
>
> *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 *different* 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 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.*

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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.

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, 133 S. Ct. 1709, 185 L. Ed. 2d 758 (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, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (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, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009) ("Our decision in *Twombly* expounded the pleading standard for 'all civil actions' . . . ." (citation omitted)); *see also Fauconier v. Clarke*, 966 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, 135 S. Ct. 346, 190 L. Ed. 2d 309 (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, 106 S. Ct. 2932, 92 L. Ed. 2d 209 (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, 132 S. Ct. 1960, 182 L. Ed. 2d 772 (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. Brivo 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, 125 S. Ct. 479, 160 L. Ed. 2d 356 (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, 199 L. Ed. 2d 447 (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, 127 S. Ct. 2499, 168 L. Ed. 2d 179 (2007); *Katyle v. Penn Nat'l Gaming, Inc.*, 637 F.3d 462, 466 (4th Cir. 2011), *cert. denied*, 565 U.S. 825, 132 S. Ct. 115, 181 L. Ed. 2d 39 (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 U.S. Dist. LEXIS 15722, 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, 135 S. Ct. 85, 190 L. Ed. 2d 38 (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, 130 S. Ct. 1396, 176 L. Ed. 2d 225 (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, 196 L. Ed. 2d 340 (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 Dickinson & 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 P*atient 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, 130 S. Ct. 1396, 176 L. Ed. 2d 225 (2010); *see United States ex rel. Moore*

v. Cardinal Fin. Co., L.P., CCB-12-1824, 2017 U.S. Dist. LEXIS 46983, 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 U.S. Dist. LEXIS 47857, 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 U.S. Dist. LEXIS 105343, 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 U.S. Dist. LEXIS 37830, 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, 304 U.S. App. D.C. 347 (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. 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

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.

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, 195 L. Ed. 2d 348 (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, 420 U.S. App. D.C. 176 (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, 341 U.S. App. D.C. 459 (D.C. Cir. 2000) (quoting 31 U.S.C. § 3729(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 U.S. Dist. LEXIS 168067, 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, 200 L. Ed. 2d 75 (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, 204 L. Ed. 2d 522 (2019) (quoting *Nat'l Ass'n of Home Builders v. Defs. of Wildlife*,

551 U.S. 644, 666, 127 S. Ct. 2518, 168 L. Ed. 2d 467 (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, 134 S. Ct. 870, 187 L. Ed. 2d 729 (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, 114 S. Ct. 655, 126 L. Ed. 2d 615 (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, 122 S. Ct. 941, 151 L. Ed. 2d 908 (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. Gonzales*, 419

F.3d 276, 283 (4th Cir. 2005) (citing *United States v. Nordic Village*, 503 U.S. 30, 36, 112 S. Ct. 1011, 117 L. Ed. 2d 181 (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, 200 L. Ed. 2d 695 (2018); *Ali v. Federal Bureau of Prisons*, 552 U.S. 214, 218-19, 128 S. Ct. 831, 169 L. Ed. 2d 680 (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, 124 S. Ct. 1555, 158 L. Ed. 2d 291 (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.

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

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.

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 U.S. Dist. LEXIS 4335, 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 Coop. Finance Corp.*, No. 8:08-48, 2011 U.S. Dist. LEXIS 27196, 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

APPENDIX D — RELEVANT STATUTORY PROVISIONS

31 U.S.C. § 3729 provides in relevant part:

§ 3729. False claims

(a) LIABILITY FOR CERTAIN ACTS.—

(1) IN GENERAL.—Subject to paragraph (2), any person who—

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);
>
> (D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;
>
> (E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending

to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

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

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

is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410[1]), plus 3 times the amount of damages which the Government sustains because of the act of that person.

* * *

1. So in original. Probably should read "Public Law 101-410".

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

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

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

(i) has actual knowledge of the information;

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

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

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

* * *