No. 20-2330

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

UNITED STATES EX REL. DEBORAH SHELDON,
EXECUTRIX OF THE ESTATE OF TROY SHELDON,

Plaintiff-Appellant,

v.

ALLERGAN SALES, LLC

Defendant-Appellee.

On Appeal from the United States District Court for the District of Maryland
Case No. 1:14-cv-02535-ELH

BRIEF OF *AMICI CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA IN SUPPORT OF DEFENDANT-APPELLEE

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, the Pharmaceutical Research and Manufacturers of America states that it has no parent corporation and no corporation or publicly held company owns 10% or more of its stock, and the Chamber of Commerce of the United States of America states that it has no parent corporation and no publicly held company owns 10% or more of its stock.

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INTEREST OF *AMICI CURIAE*

Pursuant to Federal Rule of Appellate Procedure 29, *amici curiae* Pharmaceutical Research and Manufacturers of America ("PhRMA") and the Chamber of Commerce of the United States of America ("Chamber") submit this brief in support of Defendant-Appellee and affirmance.[1]

PhRMA is a non-profit association that represents the nation's leading biopharmaceutical and biotechnology companies. PhRMA's mission is to advocate for public policies that encourage the discovery of life-saving and life-enhancing medicines. PhRMA's members invest billions of dollars each year to research and develop new drugs. PhRMA's members closely monitor legal issues that affect the entire industry, and PhRMA often offers its perspective in cases raising such issues.

The Chamber is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly

[1] No counsel for a party authored this brief in whole or part. No one other than the *amici curiae*, their members, and their counsel made any monetary contribution intended to fund its preparation and submission. The parties have consented to this filing.

files *amicus curiae* briefs in cases that raise issues of concern to the nation's business community, including cases involving the False Claims Act ("FCA").

Amici have a strong interest in this appeal because it concerns the scope of FCA liability. *Amici*'s members, many of which are subject to complex and detailed regulatory schemes, have successfully defended scores of FCA cases arising out of government contracts, grants, and participation in federal programs. With alarming frequency, private relators (only rarely joined by the government itself) have asserted that *amici*'s members' objectively reasonable interpretations of arguably ambiguous statutes, regulations, and contract provisions can give rise to FCA liability and trigger the statute's "essentially punitive" regime of treble damages. *See Vt. Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 784–85 (2000). That is not how the FCA was intended to work. Exposing companies to draconian penalties for adopting reasonable interpretations of legal requirements would unmoor the FCA from its fraud-prevention purpose. And accepting the Relator-Appellant's invitation to reject the "objective falsity" and "objectively reasonable" scienter standards applied by the district court would expose *amici*'s members to substantial liability *for acting reasonably* in their efforts to comply with an ever-increasing number of complex and indeterminate rules. *Amici* urge the Court to reject that invitation and affirm the judgment below.

BACKGROUND

A complex web of statutory, regulatory, and contractual obligations governs drug manufacturers that provide drugs to Medicaid patients. The Centers for Medicare and Medicaid Services ("CMS") has decided to approach the inherent indeterminacy in that regulatory regime in an unusual way: CMS instructs drug manufacturers, when they encounter unclear regulatory obligations, to make and act upon "reasonable assumptions" about how those ambiguous statutes and regulations operate. Appellant Sheldon, a *qui tam* relator, proposes to undermine this system, while allowing relators like herself to profit. In particular, she seeks to impose massive FCA liability on manufacturers that adopt objectively reasonable constructions of legal requirements—so long as the relator can later persuade a court that some other construction was preferable. *Amici* urge the Court to reject that radical expansion of the FCA.

This case illustrates the dangers of Relator's approach. At issue is a complicated aspect of the Medicaid program, under which drug manufacturers provide rebates to states, who in turn partially remit them to the federal government, to reduce the price that states and the federal governments pay for prescription drugs. Under the terms of 42 U.S.C. § 1396r-8 (the "Rebate Statute"), a manufacturer of certain outpatient drugs must enter into a Rebate Agreement with the United States Department of Health and Human Services ("HHS") to qualify for Medicaid

coverage. *Id.* § 1396r-8(a)(1). The Rebate Statute and the Rebate Agreement require manufacturers to send regular reports to HHS calculating the average manufacturer price ("AMP") and the "best price" for its covered drugs. *Id.* § 1396r-8(b)(3)(A); App.217.

To calculate "best price," drug manufacturers must navigate Medicaid's complex statutory and regulatory scheme. The Rebate Statute defines "best price" as "the lowest price available from the manufacturer during the rebate period" to best price eligible customers, which consist of "any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States." 28 U.S.C. § 1396r-8(c)(1)(C). The statute does not further define "best price," but it does name things that should *not* be included in calculating best price and then provides "[s]pecial rules" that apply to the calculation. *Id.* The Rebate Agreement also provides that "'Best Price' means … the lowest price at which the manufacturer sells the Covered Outpatient Drug to any purchaser in the United States in any pricing structure … in the same quarter for which the AMP is computed." App.213. But neither the Rebate Agreement nor the Rebate Statute tells manufacturers exactly how they should calculate best price. And neither speaks at all to whether (and, if so, how) pricing mechanisms commonly used in the industry, like rebates, might affect best price.

Recognizing the complexity of the Medicaid Program, CMS encourages manufacturers to make "reasonable assumptions" about the operation of the statute in the absence of clear guidance or a definitive interpretation. *Medicaid Program; Prescription Drugs*, 72 Fed. Reg. 39,142, 39,164 (July 17, 2007) ("We remind manufacturers that in the absence of specific guidance, they may make reasonable assumptions."); *see Medicaid Program; Covered Outpatient Drugs*, 81 Fed. Reg. 5170 (Feb. 1, 2016) (final rule mentioning manufacturers' reasonable assumptions more than 80 times). The Rebate Agreement reiterates this directive. It specifically provides that where the statute and relevant regulations are unclear, manufacturers should make "reasonable assumptions" "consistent with the requirements and intent of [the Rebate Statute], [f]ederal regulations[,] and the terms of [the Agreement]." App.217. Reliance on such reasonable assumptions is thus commonplace. *See* HHS Office of Inspector General, *Reasonable Assumptions in Manufacturer Reporting of AMPs and Best Prices* (2019), https://bit.ly/2Qohfzg ("OIG Report") ("[T]he use of reasonable assumptions is common practice among responding manufacturers, and … nearly two-thirds reported wanting additional guidance from CMS on assumptions-related issues.").

Drug makers often must develop these reasonable assumptions and perform their own best price calculations with little or no guidance from CMS. As this case illustrates, even when the agency purports to provide guidance on calculating best

price, the guidance itself can be ambiguous or confusing. For example, CMS has not offered definitive advice to *amici*'s members about whether they must attempt to track and aggregate discounts given to each separate entity in the distribution chain on different transactions for each individual drug unit. In communications with the agency, drug manufacturers and PhRMA have clearly expressed their view that the best price definition "has always been interpreted to mean the single lowest price to a *particular customer* unless the customer or transaction is exempt." App.239 (emphasis added); *see* App.305 (letter from PhRMA stating "[b]est price is not calculated as a price derived by aggregating price concessions to different customers … [a]nd nothing in the … guidance issued by CMS would support such an interpretation"). Guidance from the agency has alternately used the phrase "price available from the manufacturer" and "price actually realized" without any explanation or acknowledgement of the potential differences between these phrases. *Compare* 42 C.F.R. § 447.505(a), (e) (2007), *with* App.251 (Medicaid Drug Rebate Program Release No. 14).

Despite several requests for clarity from manufacturers, CMS has never contradicted manufacturers' clear position that these discounts do not need to be aggregated across multiple entities. *See* App.239 ("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."); App.271

("CMS should clarify that [the language is] not intended to require a manufacturer to aggregate discounts offered to *different* entities."); App.285 ("We therefore request 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."). CMS is therefore well aware of manufacturers' position on discount aggregation, and has allowed manufacturers to continue operating on that reasonable assumption.

This appeal asks whether a drug manufacturer can nevertheless be made to pay massive damages to the United States—and a substantial bounty to a *qui tam* relator—under the FCA for doing nothing more than adopting, at the government's own urging, an objectively reasonable construction of an (at worst) ambiguous statute. The answer is no.

ARGUMENT

Assuming the best-price statute is even unclear about aggregation, a *qui tam* relator cannot state a claim against a drug manufacturer that rests on the manufacturer's objectively reasonable construction of an ambiguous statute. To prevail on an FCA claim on behalf of the United States, a relator must show: (1) "there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter [knowledge]; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due." *U.S. ex rel. Rostholder*

v. Omnicare, Inc., 745 F.3d 694, 700 (4th Cir. 2014) (alterations in original). But a manufacturer's reasonable interpretation of a statute cannot qualify as objectively false, and a manufacturer cannot act with scienter for adopting it. Adhering to these clear rules not only comports with applicable precedent, but also prevents the FCA from becoming an abusive litigation tool detached from its underlying purposes.

I. An Objectively Reasonable Interpretation Of An Ambiguous Statute Cannot Satisfy The FCA's Falsity Element.

A. A Reasonable Interpretation Of An Ambiguous Statute Cannot Be Objectively False.

The FCA exists to deter fraudulent claims for money from the Treasury, not to permit *qui tam* relators to collect money over reasonable interpretive disputes. As this Court's precedent makes clear, "the statement or conduct alleged must represent an *objective falsehood*." *U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376 (4th Cir. 2008) (emphasis added). Under that standard, where a party's legal obligations are "not exactly clear" due to ambiguity in the governing legal instrument, that is "precisely the sort of claim that courts have determined not to be a false statement under the FCA." *Id.* at 377. Thus, as this Court and other circuits have recognized, "imprecise statements or differences in interpretation growing out of a disputed legal question are … not false under the FCA." *Id.* (quoting *U.S. ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999)); *see Hagood v. Sonoma Cnty. Water Agency*, 81 F.3d 1465, 1477 (9th Cir. 1996) ("[A] disputed

legal issue … is not enough to support a reasonable inference that the allocation was *false* within the meaning of the [FCA].").

The underlying reason for this rule is that "fraud may only be found in expressions of fact which (1) admit of being adjudged true or false in a way that (2) admit of empirical verification." *Wilson*, 525 F.3d at 377–78. Objectively reasonable interpretations of ambiguous statutes do not satisfy those criteria. Rather, as the Third Circuit has recently recognized in a similar false statement context, such an interpretation is not "false" unless it is "false under each alternative, objectively reasonable interpretation" of the statute. *United States v. Harra*, 985 F.3d 196, 215 (3d Cir. 2021).

Indeed, in other areas of false-statement law, it is well established that a statement depending on legal construction cannot be false unless there is no other objectively reasonable interpretation of the statute. To hold otherwise would run afoul of the "fundamental principle" of our legal system "that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required." *Id.* at 212 (quoting *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012)). In *Harra*, for example, a securities fraud case involving an ambiguous reporting requirement, the Third Circuit held that "fair warning demands that the Government prove a defendant's statement false under each objectively reasonable interpretation of the relevant requirements." 958 F.3d at 213–14; *see United States v. Whiteside*,

285 F.3d 1345, 1351 (11th Cir. 2002) ("In a [false statement] case where the truth or falsity of a statement centers on an interpretive question of law, the government bears the burden of proving beyond a reasonable doubt that the defendant's statement is not true under a reasonable interpretation of the law."); *United States v. Johnson*, 937 F.2d 392, 399 (8th Cir. 1991) (in a false statements case, "the government must negative any reasonable interpretation that would make the defendant's statement factually correct").

It follows from those principles that a regulated entity's reasonable interpretation of a statute does not become false because a federal agency, or even a court, later disagrees with it. There is no basis (and it would be patently unfair) to interpret the FCA to make a drug manufacturer's objectively reasonable construction arguably correct one day, and then "false" the next day, suddenly exposing manufacturers to potential treble damages, 31 U.S.C. § 3729(a)(1). Rather, given the "backdrop of that unpredictability, an agency must have clearly communicated its policies *before* a private party may be sanctioned … for violating them." *Harra*, 985 F.3d at 213 (emphasis added).

On that score, non-binding agency guidance or interpretive rules are not enough to fix the meaning of a statute for FCA purposes. Agencies can use those tools to change their interpretations of statutes for any number of policy reasons, including a change of Administration. *See, e.g.*, *Perez v. Mortg. Bankers Ass'n*, 575

U.S. 92, 102 (2015) (agencies are permitted "to promulgate freely [interpretive] rules—whether or not they are consistent with earlier interpretations"); *Ass'n of Flight Attendants-CWA v. Huerta*, 785 F.3d 710, 713 (D.C. Cir. 2015) (an "agency may change its policy statements as it sees fit"). Because the FCA is "essentially punitive," however, *Vt. Agency of Nat. Res.*, 529 U.S. at 784, its severe penalties should not turn on agency whim. Regulated entities are entitled to know, with reasonable certainty and in advance, what kinds of reimbursement claims will be punished as objectively false.

Here, as PhRMA has explained, "[b]est price is not calculated as a price derived by aggregating price concessions to different customers." App.305. But even if there were ambiguity as to the meaning of best price, the principles discussed above apply with particular force to a drug manufacturer's representations regarding its best price calculations—particularly where, as here, the relevant federal agency refuses to provide *even non-binding guidance* on the relevant questions. Instead, CMS tells manufacturers to form their own reasonable assumptions about how the statute works. A drug manufacturer's responsibility under the Rebate Agreement is to calculate and report its best price according to the Rebate Statute. App.217. But the Rebate Agreement provides that "[i]n the absence of specific guidance in [the Rebate Statute], Federal regulations[,] and the terms of this agreement, the

Manufacturer may make reasonable assumptions in its calculations of AMP and Best Price." *Id.*

Under those circumstances, a manufacturer's objectively reasonable best-price calculation cannot be a false statement just because a court later disagrees with it. That is because the manufacturer *is not stating* that its best-price interpretation represents the Platonic ideal for the Rebate Statute, or that there is no other reasonable interpretation possible. Rather, the manufacturer is stating (A) that it has adopted X interpretation and (B) that X interpretation is reasonable. Unless either of (A) or (B) is untrue, the statement cannot be false.

The law of securities fraud provides a useful analogue. As the Supreme Court explained in *Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund*, 575 U.S. 175 (2015), statements of opinion about a company's legal obligations cannot be false unless either (1) it is not the entity's sincerely held opinion or (2) the opinion does not align with the known facts. *Id.* at 182–86. Courts have extended this principle to the FCA, determining that "[a] properly formed and sincerely held [opinion] is not untrue" for purposes of FCA falsity even if a different entity "later contends that the judgment is wrong." *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1297 (11th Cir. 2019); *see U.S. ex rel. Loughren v. Unum Grp.*, 613 F.3d 300, 310 (1st Cir. 2010) (an opinion may only "qualify as a false statement for

purposes of the FCA where the speaker knows facts which would preclude such an opinion").

Omnicare's framework makes sense here, too. The Rebate Agreement expressly authorizes drug manufacturers to calculate best price using reasonable assumptions, and manufacturers certify only that their best price *in fact* reflects these assumptions. It would not undermine the objective truth of that certification if the government later disagreed with the manufacturer's interpretation—for the obvious reason that the company never represented that the government *would* agree. Instead, just as in *Omnicare*, drug manufacturers "express[] … a view, not a certainty, about legal compliance" in calculating best price for purposes of their rebate payments. 575 U.S. at 184. Such representations cannot be objectively false unless the drug manufacturer does not actually believe that these representations reflect a reasonable interpretation of the statute and meet the other requirements that CMS has explained apply to reasonable assumptions, *i.e.*, that the assumptions are consistent with the statute, federal regulations, the terms of the Rebate Agreement, and generally accepted business practices. *See id.* at 184–85; App.217; 72 Fed. Reg. at 39,191 (explaining that reasonable assumptions should take into account general business practices).

B. Objective Falsity Is a Matter of Law.

The objective-falsity standard should be enforced at the pleading stage. That is already the law of this Circuit. In *Wilson*, for example, this Court affirmed dismissal on Rule 12(b)(6) grounds, stating that "differences in interpretation growing out of a disputed legal question" are not objectively false and therefore did not satisfy the first element of an FCA claim as a matter of law. *Wilson*, 525 F.3d at 375–77.

Although Relator contends that the district court improperly dismissed her claims on falsity grounds, Appellant Br. 27, *Wilson*'s approach is sound. Courts routinely determine that statutes are ambiguous as a matter of law—in the *Chevron* deference context, for example. And judges, rather than juries, are best equipped to decide what constitutes a reasonable statutory interpretation, using the familiar legal tools of statutory construction. *See Bonkowski v. Oberg Indus., Inc.*, 787 F.3d 190, 203 (3d Cir. 2015) ("While juries make factual findings, it is the responsibility of the judiciary to decide legal questions. This obligation clearly encompasses disputes regarding the meaning of federal statutes and federal regulations."). In other cases requiring proof of a false statement, where the question turns on the "reasonableness of a defendant's asserted understanding of applicable law, the judge, and not the jury, must resolve the dispute." *United States v. Prigmore*, 243 F.3d 1, 18 (1st Cir. 2001) (case involving conspiracy to defraud the United States).

Dismissing challenges to a manufacturer's objectively reasonable statutory interpretation also serves judicial economy and fairness in precisely the way Rule 12(b)(6) is designed to do. *See Robbins v. Oklahoma*, 519 F.3d 1242, 1248 (10th Cir. 2008) (motions to dismiss serve "to weed out claims that do not … have a reasonable prospect of success"). Drug manufacturers must make reasonable assumptions about how to interpret the best price statute, despite the lack of definitive guidance from CMS even when manufacturers ask for such guidance. *See supra* pp. 5–7. Under Relator's approach, these manufacturers would face suits for treble damages whenever the government adopts a different interpretation. Given the financial pressures of *qui tam* actions, the more protracted the litigation is, the more likely relators will succeed in using mere unmeritorious allegations "to extract settlements." Sean Elameto, *Guarding the Guardians: Accountability in Qui Tam Litigation Under the Civil False Claims Act*, 41 Pub. Cont. L.J. 813, 824 (2012). Meritless FCA claims produce "social costs such as wasting taxpayer dollars by consuming the scarce resources of the courts, delaying meritorious claims, burdening legitimate businesses with defense litigation costs, and causing serious economic and reputational damage to the parties involved." *Id.* at 826.

C. Relator Did Not Plead Objective Falsity.

Applying these principles, the Court should affirm the dismissal of Relator's complaint. As the district court has explained, the best price statute is at worst

ambiguous with regard to whether discounts must be aggregated across multiple entities. App.354–358. Forest's interpretation of that statute as only requiring aggregation of discounts given to the same entity is objectively reasonable. App.354–358; Allergan Br. 16–30. That should end the matter. Neither CMS nor any court has announced a "correct" interpretation of whether or how discounts should be aggregated, much less done so in a way that binds Forest and other regulated parties. Relator does not dispute that. *See* App.51–62. As a result, she cannot plead an FCA claim, because Forest's reasonable interpretation of the genuinely disputed best price statute is not objectively false. *See Wilson*, 525 F.3d at 376–77.

The cases Relator cites do not help her. Relator points to *U.S. ex rel. Drakeford v. Tuomey*, 792 F.3d 364 (4th Cir. 2015), to claim that "a statement is false if it does not comply with the statute's mandates," because the "defendant 'either complied with [the law], or it didn't,'" Appellant Br. 22 (quoting *Drakeford*, 792 F.3d at 383–84). But *Drakeford* is far afield. It did not involve a *genuinely* disputed legal question to which there was no clear correct answer. The court never analyzed whether the provision at issue was subject to another interpretation, and the inquiry was "objective" precisely because there was no ambiguity regarding whether the defendant had violated the statute. 792 F.3d at 383–84. And, of course, in *Drakeford* the government did not explicitly tell the defendant to make reasonable assumptions

about the operation of the governing statute, as drug manufacturers were repeatedly instructed to do here.

In addition, Relator failed to plead that Forest's calculations did not in fact represent Forest's reasonable assumptions about the best price statute. As in *Omnicare*, then, Forest did no more than "express[] … a view, not a certainty, about legal compliance." 575 U.S. at 184. Thus, Forest "could not be liable for a false statement of fact—even if [it] afterward discovered a longtime violation of law." *Id.*

II. A Manufacturer Cannot Act With Scienter In Relying On A Reasonable Interpretation Of An Ambiguous Statute.

Relying on an objectively reasonable interpretation of an ambiguous statute cannot count as scienter. A defendant is not liable under the FCA unless it acted knowingly. 31 U.S.C. § 3729(a)(1). "An entity acts knowingly under the FCA by (1) having actual knowledge, (2) acting in deliberate ignorance, or (3) acting in reckless disregard. 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." *U.S. ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 287 (D.C. Cir. 2015).

A. A Manufacturer Cannot Have Knowledge When The Governing Statute Is Ambiguous and Its Interpretation Is Objectively Reasonable.

A manufacturer cannot have the requisite scienter for an FCA claim if the manufacturer's allegedly false statement is based on an objectively reasonable interpretation of an ambiguous statutory or regulatory obligation. That rule flows

from *Safeco Insurance Company of America v. Burr*, 551 U.S. 47 (2007). There, the Supreme Court held that an entity cannot act in reckless disregard of a statute's meaning unless its interpretation is "objectively unreasonable." *Id.* at 69–70. Every court of appeals to consider the question has held that *Safeco*'s objective standard applies to the FCA's scienter requirements. *See Purcell*, 807 F.3d at 290–91; *U.S. ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC*, 833 F.3d 874, 879–80 (8th Cir. 2016); *U.S. ex rel. Streck v. Allergan, Inc.*, 746 F.App'x 101, 106 (3d Cir. 2018); *see also U.S. ex rel. McGrath v. Microsemi Corp.*, 690 F.App'x 551, 552 (9th Cir. 2017); *U.S. ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645, 657–60 & n.39 (5th Cir. 2017) (citing *Safeco* with approval).

Applying *Safeco*'s holding to the FCA, the D.C. Circuit has explained that "establishing 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 (internal quotation marks omitted). A manufacturer cannot know that its objectively reasonable interpretation is "false," so long as no definitive declaration of the "correct" interpretation exists, nor does it act recklessly by adopting that interpretation. *See U.S. ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825, 831–32 (8th Cir. 2013) (a reasonable interpretation of ambiguous legal obligations "belies the scienter necessary to establish a claim of fraud under the FCA"). Relator thus bears the burden of "show[ing] that there is no

reasonable interpretation of the law that would make the allegedly false statement true." *U.S. ex rel. Hixson v. Health Mgmt. Sys., Inc.*, 613 F.3d 1186, 1191 (8th Cir. 2010).

Relator argues that the court's assessment of scienter should include evidence of whether the defendant otherwise had "actual knowledge" or acted with "deliberate ignorance" of falsity. Appellant Br. 38–45. But the Court in *Safeco* rejected the argument that the actor's "subjective bad faith" should be taken into account in determining whether the requisite scienter was met. 551 U.S. at 70 n.20. The Supreme Court explained "[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." *Id.* That holding controls here.

B. Warning a Manufacturer Away From a Reasonable Interpretation Requires Binding Agency Action.

A party may be warned away from its otherwise reasonable interpretation of a statute if sufficiently authoritative guidance exists making clear that its interpretation is impermissible. *See Donegan*, 833 F.3d at 879 (explaining that relator has burden of producing evidence that defendant was warned away from its reasonable interpretation of an ambiguous statute). But such guidance must be formal and *binding* on the party to establish scienter. *Safeco*, 551 U.S. at 70 (explaining that because "no court of appeals had spoken on the issue, and no

authoritative guidance has yet come from the FTC," the Court could reject warned-away argument). In administrative law more generally, authoritative agency pronouncements are those that speak with "the force of law." *See Christensen v. Harris Cnty.*, 529 U.S. 576, 587 (2000) ("[I]nterpretations contained in policy statements, agency manuals, and enforcement guidelines, all … lack the force of law ….."). The Court should hold that only such binding pronouncements can legally warn a manufacturer away from an otherwise objectively reasonable interpretation.

That rule would protect regulated entities from abuse. An agency's interpretation of a statute does not normally alter an entity's legal obligations unless the agency abides by the Administrative Procedure Act's requirements. *See Casa De Maryland v. U.S. DHS*, 924 F.3d 684, 702 (4th Cir. 2019) (noting that if an agency pronouncement is binding, "then the APA calls for notice and comment"); *Sierra Club v. U.S. Army Corps of Eng'rs*, 909 F.3d 635, 643 (4th Cir. 2018) ("[W]hen an agency does not act with 'the force of law,' the agency action is not entitled to *Chevron* deference."). As Supreme Court has recognized, "formal administrative procedure tend[s] to foster the fairness and deliberation that should underlie a pronouncement of such force." *United States v. Mead Corp.*, 533 U.S. 218, 230 (2001). Those same considerations apply here: The fairness and deliberation necessary to speak with the force of law should underlie any agency decision that

expands companies' liability for the FCA's severe penalties by excluding otherwise reasonable interpretations.

In contrast, Relator treats ambiguous statements in proposed rules and agency letters as authoritative. *See* Appellant Br. 49–52. That approach would make an already confusing and complex regulatory scheme nearly impossible for regulated entities to navigate. Regulated entities would have to parse every stray statement from CMS on ambiguous statutory language to determine whether it is sufficiently weighty to warn manufacturers away—and would have to pay treble damages if they read the tea leaves wrong. This Court should reject that result; instead, it should ensure that agencies give fair notice (through appropriate formal procedures) when they choose to warn away.

C. Scienter Can Be Decided as a Matter of Law.

Whether a manufacturer's interpretation of the best price statute was objectively reasonable, thus negating scienter, is a question of law. Courts routinely decide these issues as a matter of law. *See e.g.*, *Safeco*, 551 U.S. at 55 (addressing the question on summary judgment); *U.S. ex rel. Complin v. N.C. Baptist Hosp.*, 818 F.App'x 179, 180, 183–84 (4th Cir. 2020) (affirming Rule 12(b)(6) dismissal for lack of scienter); *Donegan*, 833 F.3d at 879 (affirming grant of summary judgment because whether an interpretation is objectively reasonable "is an issue of law");

Streck, 746 F.App'x at 105–06 (affirming grant of motion to dismiss); *McGrath*, 690 F.App'x at 552 (determining relator could not establish "scienter as a matter of law").

Whether the entity was warned away from its reasonable interpretation can also be decided as a question of law. Relator must plead that *authoritative* guidance exists sufficient to warn the entity away from its reasonable interpretation of the statute. Only then does the issue of whether the entity was in fact warned away from its interpretation become a question of fact for the jury. *Donegan*, 833 F.3d at 879 (noting that the only instance in which this is a question of fact is if relator "produces sufficient evidence of government guidance" to show that the government warned defendant away from its interpretation).

Non-authoritative guidance is insufficient *as a matter of law* to warn an entity away from a reasonable statutory interpretation. In *Safeco*, for example, the Supreme Court found on summary judgment that a non-binding staff opinion disclaiming the defendant's interpretation was insufficient to warn the defendant away from its interpretation. 551 U.S. at 70 n.19. Similarly, *Purcell* overturned a jury verdict because the "informal guidance" of an official "is not enough to warn a regulated defendant away from an otherwise reasonable interpretation it adopted." 807 F.3d at 289–91; *see also Complin*, 818 F.App'x 184 & n.6 (affirming decision on a Rule 12(b)(6) motion that "non-precedential and non-binding" agency decision was insufficient to warn defendant away from interpretation); *Streck*, 746 F.App'x

at 104 (affirming grant of a motion to dismiss where guidance had created "confusion" on calculation of AMP). A question for the jury arises *if and only if* a relator produces sufficient evidence of authoritative guidance, and the question is then whether the defendant had sufficient knowledge of that *authoritative* guidance to be warned away from its interpretation. *See Donegan*, 833 F.3d at 879.

D. Scienter Does Not Exist In These Circumstances.

Relator's complaint here was properly dismissed because it does not adequately plead scienter. The statutory and regulatory obligations underlying Relator's FCA claim are at worst ambiguous (even assuming Forest's interpretation is not a better one). *See* App.354–360. Were it otherwise, there would be no need for both CMS and drug manufacturers to rely on reasonable assumptions to fill in the statutory gaps. The district court correctly recognized that "CMS has accounted for the complexity of the Rebate Statute and price reporting requirements"—which is to say their ambiguous nature—by "encourag[ing] manufacturers to make 'reasonable assumptions' in calculating Best Price." App.361.

Here, Forest's interpretation was reasonable, App.354–60; Allergan Br. 16–29, and Relator cannot show otherwise. Relator points to no judicial decisions endorsing her interpretation of the statute, or otherwise casting doubt on Forest's interpretation. *See* App.46–62. Nor has Relator pleaded any *authoritative* guidance sufficient to warn Forest away from its interpretation. *See Safeco*, 551 U.S. at 70

(explaining that because "no authoritative guidance has yet come from the FTC," warned-away argument could be rejected as a matter of law). On the contrary, Relator relies entirely on non-authoritative program releases, GAO reports, proposed rules, informal guidance, and inapplicable preamble language. Appellant Br. 36–38.

Indeed, the lack of an authoritative interpretation of the best price statute is confirmed by (and is the whole reason for) the agency's decision to ask manufacturers to supply their own reasonable assumptions. As the district court recognized, App.361–62, courts have rejected claims that defendants could be "warned away" from reasonable interpretations in circumstances such as these where the agency's guidance shows, at the very most, considerable confusion on the issue. *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); *see also Streck*, 746 F.App'x at 110 (due to confusion regarding calculation of AMP, defendants were not warned away from their interpretation).

III. These Standards Ensure The FCA Achieves Its Purposes.

The FCA fundamentally "is a fraud prevention statute." *U.S. ex rel. Owens v. First Kuwaiti Gen. Trading & Contracting Co.*, 612 F.3d 724, 728 (4th Cir. 2010). The objective-falsity standard and the *Safeco* rule help ensure that the FCA actually protects the government against fraud, instead of incentivizing meritless nuisance

lawsuits against any private entities that interact with the government in complicated regulatory areas. "[E]ssentially punitive" remedies, *Vt. Agency of Nat. Res.*, 529 U.S. at 784–85, should be deployed to punish actual fraud, not "good-faith" mistakes, *Complin*, 818 F. App'x at 184.[2]

A basic problem with Relator's position is that the United States government is *both* the entity that tells manufacturers to rely on their own reasonable assumptions *and* the entity receiving damages if Relator succeeds in making it actionable for a manufacturer to follow the government's instructions. It is the government that receives any punitive damages assessed by the FCA. *See* 31 U.S.C. § 3730(d); *U.S. ex rel. Brooks v. Lockheed Martin Corp.*, 237 F.App'x 802, 803 (4th Cir. 2007) ("Although a *qui tam* relator is entitled by statute to a share of the recovery if his action is successful, the United States is the real party in interest."). In other words, according to Relator, the United States can both refuse to clarify the meaning of a statute at the request of regulated parties and then be *paid damages* when manufacturers do their best, exactly as the agency has directed.

[2] *Amici* do not dispute that the FCA plays an important role in preventing fraud, and *amici*'s members dedicate significant financial resources to complying with fraud statutes. *Amici*'s argument here pertains specifically to representations about manufacturers' objectively reasonable interpretations of the best price statute under the reasonable assumptions regime—that these representations simply cannot constitute *fraud*, which is what the FCA is designed to guard against.

It is impossible to call that fact pattern fraud on the government. Fraud is "any kind of artifice by which another is deceived." *Fraud*, Black's Law Dictionary (11th ed. 2019) (emphasis omitted) (quoting John Willard, *A Treatise on Equity Jurisprudence* 147 (Platt Potter ed., 1879)). But CMS is hardly *deceived* by the fact that manufacturers rely on reasonable assumptions to navigate the best price statute; doing so was CMS's idea in the first place. And there is no reason to permit the United States to recover money through FCA litigation (whether prosecuted by a *qui tam* relator or the Department of Justice) based on conduct the government actively encouraged.

Relator's proposal is particularly problematic given how pervasive reasonable assumptions are in the Medicaid reimbursement scheme. A 2019 OIG report found that "[a]lmost *all* … manufacturers reported making reasonable assumptions that affected the AMPs and [best prices] used to determine Medicaid rebates and 340B discounts." OIG Report, *supra*, at 9 (emphasis modified). That report found that 80 percent of manufacturers made assumptions about the pricing mechanism at issue here, "when it is and is not appropriate to stack price concessions in determining [best price]." *Id.* at 10. The report also listed 14 *additional* issues arising under the Rebate Statute—such as bona fide service fees, bundled sales, and prompt pay discounts—about which more than 50 percent of manufacturers surveyed reported making reasonable assumptions in their AMP and best price calculations. *Id.*

Adopting the Relator's rule allowing the United States to seek treble damages each time a manufacturer makes a reasonable but "incorrect" choice about how the statute applies, at the express direction of CMS, would wreak havoc on the Medicaid reimbursement scheme. This Court should avoid such a far-reaching result and determine that truly reasonable assumptions about the Rebate Statute cannot serve as the basis for FCA claims.

The broader problems surrounding *qui tam* litigation reinforce the need for affirmance. Courts should be vigilant in protecting against over-broad standards of liability, as even the Department of Justice has recognized that there have been "record increases" in *qui tam* suits in the past several years. Memorandum from Michael D. Granston to Attorneys, Commercial Litigation Branch, Fraud Section (Jan. 10, 2018), https://bit.ly/3oHszDq. Subjecting entities to FCA liability, based on reasonable attempts to comply with an array of ambiguous and unsettled statutory, regulatory, or contractual requirements increases the already considerable financial and reputational costs of defending *qui tam* suits, which often result in no recovery to the government. *See* Elameto, *supra*, at 826–27. And the risk of crippling treble damages and statutory penalties would force many businesses to settle even meritless cases that, under the standards Relator advocates for, could not be resolved on the pleadings. *See AT&T Mobility LLC v. Concepcion*, 563 U.S. 333, 350 (2011) (recognizing that procedural vehicles that pressure parties to settle "questionable

claims" should be avoided). Indeed, the Department of Justice itself has recognized that many *qui tam* actions are "[m]eritless" or "[p]arasitic or [o]pportunistic" and has encouraged the *government* to seek dismissal of such suits. Granston, *supra*, at 3–4 (emphases omitted).

Objective standards, applicable at the pleading phase, are essential to cabining expansive FCA liability on non-meritorious claims. Strict enforcement of the falsity and scienter requirements is particularly important because of the complex contractual and regulatory schemes that businesses routinely face when they interact with the government. Loose pleading requirements that allow *qui tam* suits based on every potentially ambiguous statute or regulation will harm not only private entities, but ultimately the public too, should the threat of overbroad FCA liability deter private entities from participating in government programs.

CONCLUSION

The judgment of the district court should be affirmed.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(B), I hereby certify that the textual portion of the foregoing brief (exclusive of the disclosure statement, tables of contents and authorities, certificates of service and compliance, but including footnotes) contains 6,454 words as determined by the word counting feature of Microsoft Word 2016.

s/John C. O'Quinn
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CERTIFICATE OF SERVICE

I hereby certify that on May 26, 2021, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

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