PUBLISHED

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.

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

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

Before WILKINSON, WYNN, and RICHARDSON, Circuit Judges.

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Affirmed by published opinion. Judge Wilkinson wrote the opinion, in which Judge Richardson joined. Judge Wynn wrote a dissenting opinion.

ARGUED: Joshua Yrion Dos Santos, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C.; Joseph M. Callow, Jr., KEATING, MUETHING & KLEKAMP PLL, Cincinnati, Ohio, for Appellant. John Patrick Elwood, ARNOLD & PORTER KAYE SCHOLER LLP, Washington, D.C., for Appellee. **ON BRIEF:** Gregory M. Utter, Paul R. Kerridge, Collin L. Ryan, KEATING MUETHING & KLEKAMP PLL, Cincinnati, Ohio; Joel D. Hesch, THE HESCH FIRM, LLC, Lynchburg, Virginia, for Appellant. Michael A. Rogoff, Paula R. Ramer, New York, New York, Jeffrey L. Handwerker, Christian D. Sheehan, ARNOLD & PORTER KAYE SCHOLER LLP, Washington, D.C., for Appellee. Brian M. Boynton, Acting Assistant Attorney General, Michael S. Raab, Charles W. Scarborough, Civil Division, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Amicus United States of America. Jacklyn De Mar, TAXPAYERS AGAINST FRAUD EDUCATION FUND, Washington, D.C.; John W. Black, Samuel J. Buffone, Jr., BLACK & BUFFONE PLLC, Washington, D.C., for Amicus Taxpayers Against Fraud Education Fund. John M. Masslon II, Cory L. Andrews, WASHINGTON LEGAL FOUNDATION, Washington, D.C., for Amicus Washington Legal Foundation. James C. Stansel, Melissa B. Kimmel, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Washington, D.C., for Amicus Pharmaceutical Research and Manufacturers of America. Tara S. Morrissey, Andrew R. Varcoe, UNITED STATES CHAMBER LITIGATION CENTER, Washington, D.C., for Amicus Chamber of Commerce of the United States of America. John C. O'Quinn, Matthew S. Owen, Matthew D. Rowen, Andrea R. Butler, KIRKLAND & ELLIS LLP, Washington, D.C., for Amici Pharmaceutical Research and Manufacturers of America and Chamber of Commerce of the United States of America.

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 (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 (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 (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, 136 S. Ct. 1989, 2002 (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.

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 (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).

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).

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 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)).

[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.

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.

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] 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.

(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 (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.*, 136 S. Ct. 1923 (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 (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 (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 (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 (2000) (describing FCA); *see also Tex. Indus. v. Radcliff Materials, Inc.*, 451 U.S. 630, 639 (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]

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

[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 (2009) (quoting *Bell Atl. Corp v. Twombly*, 550 U.S. 544, 570 (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.

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 (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 (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 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 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

[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.

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. 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

[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.

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 (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 (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

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 (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 (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.

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 (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 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

[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.

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 (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.

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 (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 (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 (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 (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, 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*

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

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 (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 (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 (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 (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 (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.

ii.

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.

[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, 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.

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 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 (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 (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 (2019) (quoting *Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 218–19 (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.

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 (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 (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 (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 (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 (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 (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.

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

[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).

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]

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).

[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 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).

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]

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

[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.

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.

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.

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*,

[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.

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.

(Continued)

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.