No. _____

In the
Supreme Court of the United States

ELI LILLY AND COMPANY,
Petitioner,

v.

UNITED STATES, *et al.*, EX REL., RONALD J. STRECK,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

The False Claims Act ("FCA") permits private parties, known as *qui tam* relators, to prosecute on behalf of the United States alleged fraud on the government. These private bounty hunters "inhabit[] something of a constitutional twilight zone," performing Article II functions but operating free of executive supervision. *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 449 (2023) (Thomas, J., dissenting). The pervasive problems with this privatized prosecution regime came to a head in this case, where a serial relator sued Eli Lilly and Company ("Lilly") under the FCA, alleging that Lilly defrauded the government by employing a reading of a byzantine area of the Medicaid laws that the Third Circuit—in a case brought by the same relator—had already unanimously held reasonable, and that Lilly had repeatedly disclosed to the government. The district court blessed the relator's gambit, leading to nearly $200 million in treble damages and penalties against Lilly for (purportedly) misreading the law. Expressly "diverg[ing]" from the Third Circuit, Pet.App.29, the Seventh Circuit affirmed, holding that Lilly's widely shared view of the law was not only wrong, but so "objectively unreasonable" as to constitute "highly probative circumstantial evidence of a culpable state of mind," Pet.App.38.

The questions presented are:

1. Whether the False Claims Act's *qui tam* provisions are unconstitutional.

2. Whether a legal interpretation can be deemed so "objectively unreasonable" as to constitute "highly probative" evidence of scienter under the False Claims

Act when it was widely held throughout the industry, no government actor rejected it, and four federal judges expressly found it reasonable.

PARTIES TO THE PROCEEDING

Petitioner Eli Lilly and Company was the defendant-appellant below.

Respondent United States of America ex rel. Ronald Streck was the plaintiff-appellee below.

CORPORATE DISCLOSURE STATEMENT

Eli Lilly and Company is a publicly held entity traded on the New York Stock Exchange (stock symbol LLY). No publicly held company owns 10% or more of its stock.

STATEMENT OF RELATED PROCEEDINGS

The following proceedings are directly related to this case within the meaning of Rule 14.1(b)(iii):

- *United States ex rel. Streck v. Takeda Pharms. America, Inc., et al.*, No. 14-cv-9412 (N.D. Ill.), judgment entered on February 28, 2022.
- *United States ex rel. Streck v. Eli Lilly and Co.*, Nos. 23-2134, 23-2216, 23-2958, 23-3035, 24-1352, 24-1884 (7th Cir.), judgment entered on September 11, 2025.

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PETITION FOR WRIT OF CERTIORARI

The decision below offends two bedrock principles of our constitutional order: First, the Executive—and the Executive alone—enforces federal law on behalf of the United States. Second, private parties must have fair notice of laws before they can be punished for breaking them. The Seventh Circuit bypassed both constraints to saddle petitioner Eli Lilly and Company ("Lilly") with a nearly $200 million judgment for adopting a reading of a federal law that Lilly repeatedly disclosed to the government and that four federal judges expressly found reasonable.

To calculate rebates that federal law requires them to pay state Medicaid programs, pharmaceutical manufacturers must determine the "average manufacturer price" (or "AMP") of a drug. That is no easy feat; the statute is byzantine, pointing in different directions on some issues and staying silent on others. Given that complexity, manufacturers have long sought guidance from the government on how to calculate AMP. But the most the agency charged with administering the program would tell them is to make "reasonable assumptions." Lacking any more clarity than that, Lilly and several other manufacturers concluded that certain adjustments to fees owed to wholesalers (and vice versa) should not be included when calculating AMP. But a serial *qui tam* relator named Ronald Streck has long disagreed—and long tried to convince courts to hold that manufacturers who do not abide by his reading of the statute not only are wrong, but have defrauded the government under the False Claims Act ("FCA").

In Streck's first suit against a bevy of manufacturers (including Lilly), the district court rejected his claims, and the Third Circuit unanimously affirmed, holding that the interpretation of the law employed by much of the industry was reasonable—which ought to be enough to avoid FCA liability in a context where the government has only ever instructed them to make "reasonable assumptions" in their AMP submissions. Here, however, the Seventh Circuit adopted Streck's position wholesale, concluding that his view (which the government has never endorsed) is clearly correct—indeed, so clearly correct as to make the position blessed by four federal judges in Streck's first foray so "objectively unreasonable" as to constitute "highly probative circumstantial evidence of a culpable state of mind." Pet.App.38. In other words, the Seventh Circuit not only created a circuit split on whether the legal view embraced by Lilly and other manufacturers for years was "objectively reasonable," but concluded that anyone who claimed otherwise—including not only much of the industry, but, presumably, the Third Circuit and the district court before it—likely was acting in bad faith.

That startling result would warrant review even if it had been produced by the Executive—particularly given the agency's refusal to provide manufacturers with the guidance they repeatedly sought on a regulatory regime that is hardly the model of clarity. But the need for this Court's review is especially acute since that result comes at the hands of a private bounty hunter who is not appointed by, removable by, or accountable to the President in any way, and who is (by Congress's design) motivated far more by

personal profit than by any desire for regulatory clarity. The decision below vividly illustrates the core problems at the heart of the FCA's *qui tam* regime: It creates a powerful incentive for the government to shirk pleas to clarify complex laws and regulations, while preserving its ability to reap massive windfall judgments procured by bounty hunters pressing theories that the government is unwilling to use its own resources to advance. That trap for the unwary—or, in this case, trap for manufacturers who begged regulators for guidance and hewed to judicially approved legal constructions—cannot be reconciled with the Constitution's structural protections of liberty or bedrock principles of due process.

Three Justices have recently voiced these concerns, recognizing "substantial arguments that the *qui tam* device is inconsistent with Article II" and proposing that the Court address them "in an appropriate case." *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 442 (2023) (Kavanaugh, J., concurring); *see also id.* at 451-52 (Thomas, J., dissenting). This is an excellent vehicle to do so, as this case vividly illustrates the real-world problems with the FCA's *qui tam* regime. The government declined request after request to clarify its ambiguous regulations, then stood idly by while Streck accepted Congress's invitation to usurp the Executive's enforcement role and punish Lilly for conduct that the government itself was unwilling to say violated the law.

It is bad enough when the government engages in "Calvinball," where "you make up the rules as you go." *United States ex rel. Sheldon v. Allergan Sales, LLC*,

24 F.4th 340, 355-36 (4th Cir. 2022), *opinion vacated on other grounds*, 49 F.4th 873 (4th Cir. 2022) (mem.). It is that much worse when the government never tells private parties they are wrong, and the surprise is sprung by an unaccountable relator purporting to stand in its shoes. This Court should grant certiorari and ensure that unappointed and unaccountable *qui tam* relators cannot capitalize on the government's strategic ambivalence and subject private parties to potentially ruinous liability for finding themselves on the wrong side of an invisible line.

OPINIONS BELOW

The Seventh Circuit's opinion, 152 F.4th 816, is reproduced at Pet.App.1-63. The district court's opinion, 2022 WL 595308, is reproduced at Pet.App.66-101.

JURISDICTION

The Seventh Circuit issued its opinion on September 11, 2025, Pet.App.1, and denied a timely rehearing petition on November 21, 2025, Pet.App.64-65. This Court has jurisdiction under 28 U.S.C. §1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The relevant provisions of the Medicaid Act are reproduced at Pet.App.103-78. The relevant provisions of the Constitution are reproduced at Pet.App.102.

STATEMENT OF THE CASE

A. Factual and Legal Background

1. Pharmaceutical manufacturers typically do not sell their medicines directly to pharmacies; they contract with wholesale distributors to do so. D.Ct.Dkt.77 ¶¶15-16, 76-77. Before 2005, manufacturers generally did not pay wholesalers fees for their distribution services. Wholesalers instead made money by buying medicines at list prices and stockpiling them hoping prices would go up, at which point they would resell the hoarded medicines at the new, higher price. CA7.App.482:7-10, 498:7-10. This arbitrage practice caused disruptions in the supply chain for needed medicines. CA7.App.499:17-500:7. To remedy that problem, many manufacturers (including Lilly) transitioned to fee-for-service arrangements, under which they pay wholesalers fees covering distribution, inventory management, data reporting, and other services. CA7.App.224, 319 ¶63; D.Ct.Dkt.77 ¶77.

The fee-for-service model aimed to eliminate the arbitrage approach. CA7.App.490:17-491:3, 501:22-502:12, 506:13-20. But the incentive remained for wholesalers to stockpile medicines in hopes of manufacturer price increases. In fact, the temptation was even stronger; because wholesalers were guaranteed a flat fee, they could afford to hoard for longer. To eliminate the incentive to squirrel away life-saving medicines and reap double profits, many manufacturers (including Lilly) incorporated into their wholesaler compensation formulas what have become known as Price Increase Values ("PIV"). CA7.App.491:4-24, 504:3-10, 552:14-22.

For Lilly, the compensation formula worked as follows. Lilly would determine the total distribution fee it owed a wholesaler for its services, calculated as a percentage of the wholesaler's transactions. CA7.App.470. If the value of the medicine increased before the wholesaler resold it to pharmacies, Lilly would deduct that increase in value—i.e., the PIV—from the total distribution fee owed. Lilly would then pay the wholesaler the remainder of the distribution fee. CA7.App.509. This way, wholesalers would not be double-compensated if they held onto medicines until their price increased.

To illustrate, suppose a wholesaler's service fee for a particular quarter was $40 million. If the value of the wholesaler's inventory on hand increased by $5 million owing to price increases before it was sold, then the wholesaler could sell that inventory at that higher price, but the additional $5 million it earned owing to the price increase—i.e., the PIV—would be deducted from the $40 million service fee. So the wholesaler's total compensation for the quarter would remain the same ($40 million); the price increase would impact only what portion of the fee was paid in cash by Lilly versus secured through sales of higher-priced inventory. With the addition of that PIV offset, the fee-for-service model renders the wholesaler indifferent to post-purchase, pre-sale price increases, eliminating the incentive to stockpile medicines.

In 2009, Lilly changed the form of this model, but not its function. Lilly originally offset price appreciation *before* paying wholesalers their service fees, but it later shifted to paying wholesalers the full distribution fee and clawing back any earnings owing

to price increases. The end result was the same: The incentive to hoard medicines was eliminated. CA7.App.502:6-12, 511:22-512:3, 528:3-19, 529:7-531:2.

2. The PIV model achieved its principal goal. Wholesalers ceased hoarding medicines in anticipation of price increases. *E.g.*, CA7.App.319 ¶¶23-58; *see also* CA7.App.484:4-10, 487:17-488:4. As a result, more patients were able to get the life-saving medicines they needed when they needed them. But it gave rise to questions about manufacturers' rebate obligations under Medicaid.

If a pharmaceutical manufacturer wants the federal government to reimburse the cost of its medicines for Medicaid patients, it must participate in the Medicaid Drug Rebate Program ("Rebate Program"), which requires manufacturers to pay quarterly rebates to states to offset costs they incur paying for medicines for Medicaid patients. *See* 42 U.S.C. §1396r-8(a)(1), (b)(1), (k)(8). That rebate, in turn, reduces what the federal government must pay states under its agreements to help finance their Medicaid programs. *See id.* §1396r-8(b)(1)(B).

To participate in the Rebate Program, manufacturers must execute a written agreement with the Department of Health and Human Services ("HHS"), under which they must regularly report to the Department's Centers for Medicare and Medicaid Services ("CMS") the AMPs for certain of their medicines. 42 U.S.C. §1396r-8(a)(1), (b)(3); *see also id.* §1396r-8(k)(1). CMS uses AMP to determine the rebate manufacturers owe. The rebate amount is the greater of either (A) a medicine's AMP minus its "best

price" (another statutory term) or (B) a set percentage of AMP. *Id.* §§1396r-8(c)(1), (c)(3)(B)(iii). Generally, the higher the AMP, the higher the rebate a manufacturer owes. Conversely, owing to complexities in how the federal government's obligations to states under Medicaid are calculated, the lower the AMP, the lower the rebate amount from the manufacturer, and the more the federal government must pay. *See* Pet.App.4-5.

As that interrelationship illustrates, the stakes for correctly calculating AMP are high. If manufacturers miscalculate, they risk potentially breaching their contracts with the government. *See* CA7.App.445 (rebate agreement). And, as this case shows, some courts allow such breaches to serve as the predicate for severe backward-looking liability, including civil monetary penalties and punitive treble damages, under the FCA. *See* 31 U.S.C. §§3729-3731.

Yet determining how to calculate AMP has proven notoriously difficult. The Medicaid Act defines AMP as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts." CA7.App.6. But it provides precious little guidance on what that means when it comes to the complexities of how manufacturers' agreements with wholesalers actually work. Indeed, HHS's Office of the Inspector General ("OIG"), which Congress tasked with "review[ing] the requirements for, and manner in which, manufacturers determine AMPs," lamented in 2006 that "[e]xisting requirements for determining certain aspects of AMPs are not clear and

comprehensive, and manufacturers' methods of calculating AMPs are inconsistent." CA7.App.6. And while Congress has tinkered with the definition over the years, many of the details remain dizzying.

Discerning how best to calculate AMP has proven particularly challenging when it comes to the fee-for-service model. Because the Medicaid Act defines AMP as the average price paid *to* the manufacturer for the drug in the United States *by* wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts, 42 U.S.C. §1396r-8(k)(1)(A)-(B), many manufacturers concluded that the distribution fees they pay to wholesalers should not be included in their AMP calculations. Others concluded that these fees *should* be included—a position Congress ultimately rejected in 2010, *see id.* §1396r-8(k)(1)(B)(i)(II). Still others concluded that the distribution fee generally should not be included, but that *the PIV component* should be, on the theory that it is a form of "discount." CA7.App.157-60.

CMS, which oversees the Rebate Program, did little to help resolve this confusion. CMS has long admitted that AMP calculation is "an extremely complex and technical topic," and it has acknowledged the widespread "confusion among drug manufacturers about what sales and price concessions must be included when calculating AMP." CA7.App.68. Rather than supply the clarity regulated entities sorely lacked, however, CMS effectively abdicated its responsibility, instructing manufacturers to figure it out themselves by making "reasonable assumptions." CA7.App.434; *see also* CA7.App.458; 81 Fed. Reg. 5,170, 5,174 (Feb. 1, 2016). Indeed, the agency's

guidance (such as it was) on fees paid to wholesalers continuously shape-shifted during the period at issue here—the agency promulgated a final rule in 2007,[1] withdrew it three years later,[2] proposed a new rule in 2012,[3] never adopted that rule, and ultimately landed in 2016 more or less where it started nearly a decade earlier.[4] The one constant was CMS's instruction to make "reasonable assumptions" when determining what to include in AMP.

3. Lacking clear guidance on this complex topic, Lilly turned to regulators to try to get some direction—to no avail. In 2005, Lilly met with OIG. CA7.App.225; CA7.App.522:4-524:24. Lilly informed OIG that it "ha[d] decided to exclude the wholesaler service fees from its [AMP] calculation … since doing so results in the most favorable outcome for the Medicaid programs." CA7.App.228. OIG did not offer a contrary position.

Lilly also turned to CMS. Despite CMS's rather remarkable policy of "request[ing] that manufacturers *not* submit their assumptions for … AMP … methodology to CMS," CA7.App.458 (emphasis added), Lilly went the extra mile and contacted CMS in 2008 to explain its reasonable assumptions, expressing its "belie[f]" that sharing them "results in greater transparency," CA7.App.314-15. "[I]n furtherance of complete disclosure," Lilly informed CMS (as relevant here) that its practice was to exclude

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[1] 72 Fed. Reg. 39,142, 39,191 (July 17, 2007).

[2] 75 Fed. Reg. 69,591, 69,593 (Nov. 15, 2010).

[3] 77 Fed. Reg. 5,318, 5,332 (Feb. 2, 2012).

[4] 81 Fed. Reg. 5,170 (Feb. 1, 2016).

"service fee arrangement[s]" in their entirety. CA7.App.315-18. Lilly received no response. In 2011, Lilly again contacted CMS, thoroughly explaining the PIV component of its service-fee calculation. CA7.App.393-96. Once again, however, CMS took no action and offered no response. CA7.App.540:13-17.

During an OIG audit in 2013, Lilly yet again divulged that it treated PIV as part of the distribution fee excluded from AMP. CA7.App.400-04, 483. And in 2014, OIG released a report concluding that the "methodolog[y]" Lilly and others used "to determine AMPs generally [was] consistent with Federal requirements." CA7.App.415.

B. Procedural Background

1. For the past 17 years, Ronald Streck has sought to profit from the uncertainty the federal government has fomented over whether to include wholesaler service fees and/or PIV when calculating AMP. Streck does not work for the government. Nevertheless, he has been unleashed to sue pharmaceutical manufacturers on behalf of the United States under the FCA's *qui tam* provisions. The FCA creates civil liability for any person who "knowingly presents, or causes to be presented … a false or fraudulent claim for payment or approval" by the United States. 31 U.S.C. §3729(a)(1). In addition to the Attorney General, *see id.* §3730(a), the FCA authorizes private parties to enforce its terms "in the name of the Government," but for their own private benefit, by appointing (or anointing) themselves relators, *id.* §3730(b)(1). Streck has repeatedly done just that, peddling the theory that manufacturers' efforts to prevent wholesalers' stockpiling resulted not just in

technical violations of a Medicaid reporting requirement, but in fraud on the United States.

Streck's quest began in 2008, when he brought a *qui tam* action in Pennsylvania that named as defendants more than 30 manufacturers, including Lilly. *United States ex rel. Streck v. Allergan, Inc.* (*Streck I*), 894 F.Supp.2d 584 (E.D. Pa. 2012). One set of manufacturers treated the fees they paid distributors as discounts (which get deducted from AMP) rather than as "bona fide service fees" (which do not). *Id.* at 589. The other set *did* treat them as bona fide service fees—but he said they violated the FCA, too. *Id.* In his view, the one and only right answer was to include the PIV adjustment, but exclude the rest of the fee.

After Streck sued, Lilly conducted a comprehensive evaluation of its AMP methodology. Lilly ultimately concluded that it was more reasonable to exclude the entire distribution fee from AMP than to adopt Streck's interpretation, which no authoritative source had endorsed. CA7.App.533-34. Lilly contemporaneously informed CMS—and did so again repeatedly over the next several years. CA7.App.393; *see also* pp.10-11, *supra*.

Streck eventually voluntarily dismissed Lilly (and some others) to focus on what he considered his more meritorious claims. But the district court found even those claims meritless, and in 2012 dismissed all claims against the remaining defendants, concluding that it was objectively reasonable for manufacturers to exclude PIV from AMP given the statutory text, the regulations, and the "dearth of guidance." *Streck I*,

894 F.Supp.2d at 600. The Third Circuit unanimously affirmed. 746 F.App'x 101, 103 (3d Cir. 2018).

2. Streck tried again in a different forum. In 2014, he filed this lawsuit against 15 pharmaceutical manufacturers, including Lilly. D.Ct.Dkt.1. As in *Streck I*, he claimed the defendants violated the FCA by miscalculating and misreporting AMP. In Streck's telling, excluding PIV from AMP unlawfully "understat[ed]" Lilly's AMPs, which "caused the states to receive less in rebates than they were entitled to" under Medicaid and, in turn, "caused the federal government to pay more." D.Ct.Dkt.77 ¶¶88-89. (Streck did not dispute that manufacturers properly excluded the rest of their distribution fees. D.Ct.Dkt.77 ¶¶10-24, 78-80.)

The case eventually was winnowed down to just Lilly. Lilly filed a motion to dismiss, which the district court denied. D.Ct.Dkt.122. Following discovery, Streck and Lilly cross-moved for summary judgment. D.Ct.Dkts.311, 314. The district court denied Lilly's motion, but it granted Streck's motion in part—specifically, as to the "falsity" of Lilly's AMP representations. Pet.App.66, 99. According to the court, the "alternative readings of the statute as proposed by Lilly"—which the district court and three appellate judges in *Streck I* found reasonable—are in fact not just "unreasonable," but "objectively" so, rendering any statement made in reliance on them "false." Pet.App.98.

The case proceeded to trial on the remaining elements of an FCA claim, with the court instructing the jury that Lilly's statements were false as a matter of law (but not "objectively unreasonable").

CA7.App.577:1-5. The jury returned a verdict in Streck's favor for over $61 million, which was automatically trebled under the FCA. D.Ct.Dkt.486; *see* 31 U.S.C. §3729(a)(1). The court then added $9,838,992 in statutory penalties, plus $886,443.91 in pre-judgment interest, for a total of $194,413,086.91. D.Ct.Dkt.543.

3. The Seventh Circuit affirmed in relevant part, concluding that Lilly's interpretation of the FCA rendered its calculation of AMP "false" as a matter of law, and affirming the scienter finding. Pet.App.3, 30-46.

The court began by concluding that "the legal framework unequivocally supports" Streck's reading of the statute, not Lilly's. Pet.App.20. While the court framed that discussion as an inquiry into "The Reasonableness of Lilly's AMP Calculation," Pet.App.17, at no point did it explain what makes a legal interpretation "objectively unreasonable." And while the court acknowledged that the Third Circuit had previously held that the very same interpretation of the Medicaid Act that Lilly (told the government it) used was at least reasonable, it rejected the Third Circuit's conclusion for the same reasons that it held Lilly's reading to be incorrect. Pet.App.29-30.

Turning to falsity, the court again proceeded on the assumption that its conclusion that "the legal framework unequivocally supports" Streck's reading of the statute, Pet.App.20, sufficed to show that Lilly's contrary view was not just wrong, but "objectively unreasonable." Pet.App.38-39. And the court declared Lilly's AMP calculations "false" because they did not comport with that reading. Pet.App.32-33.

For good measure, the court then gratuitously opined that it should not matter if the defendant's view of the law was reasonable, and that falsity should instead turn only on whether it is correct, Pet.App.33-36—even though the government's only "guidance" (if it could be called that) throughout the relevant period here was to tell manufacturers to make "reasonable assumptions."

As for scienter, the court acknowledged (with considerable understatement) that scienter was "a closer call." Pet.App.36. But on that issue as well, the court came back to its (unexplained) view that Lilly's reading of the law was not just wrong, but "objectively unreasonable," positing that "Lilly's objectively unreasonable interpretation of the relevant law is highly probative circumstantial evidence," Pet.App.38—a puzzling proposition since the jury was not instructed that Lilly employed an "objectively unreasonable" view of the law (only that Lilly's statements were false as a matter of law), and thus could not have based its scienter finding on that view.

Even so, the Seventh Circuit went out of its way to "express [its] dismay at the government's lethargy, or perhaps regulatory capture." Pet.App.45. "The government allowed companies to make reasonable assumptions," yet refused to "so much as review a letter" (let alone weigh in on any company's approach). Pet.App.45. That confounding practice "runs the risk of rule-making by regulatory prosecution" and creates "clear" "incentives to abuse … discretion," and "the lack of industry-wide oversight likely cost taxpayers dearly." Pet.App.45-46.

4. Lilly sought rehearing en banc, challenging the panel's FCA holdings and renewing its argument that the FCA's *qui tam* provisions violate the Constitution. The court denied rehearing. Pet.App.64-65. And even though Lilly had expressly preserved the argument in its panel-stage briefing, *see* CA7.Dkt.37 at 66 n.11, the three-judge panel posited that Lilly had "forfeited if not waived its constitutional argument." Pet.App.65.

REASONS FOR GRANTING THE PETITION

The Constitution does not permit prosecution by private vigilantes. Nor does it allow regulation by hindsight. And it certainly does not tolerate combining the two to subject unwitting regulated entities to massive treble damages verdicts. Yet that is the result the Seventh Circuit sanctioned below. The court allowed a private citizen to wield core executive power by charging fraud in the name of the United States with a legal theory the government itself never embraced—even though he is not vested with his position in a manner that satisfies the Appointments Clause, his power to enforce federal law lacks any legitimate source, and Congress gave him that power for the admitted goal of usurping executive prerogatives. And the Seventh Circuit allowed this private bounty hunter to impose nearly $200 million in treble damages and penalties on Lilly just for failing to follow a view of a byzantine and notoriously unclear regulatory regime that no politically accountable person has ever endorsed.

That result is no more reconcilable with the FCA than it is with our constitutional order. As this Court recently reiterated, because the FCA is a *fraud* statute, it focuses on subjective knowledge and

intentions—not abstract inquiries into whether a particular view of the law is "reasonable." *See United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 749-57 (2023). Yet the decision below collapsed the "reasonableness" inquiry into scienter all over again, treating the bare fact that a court later deems a statute unambiguous as "highly probative" evidence that anyone who claims otherwise is likely a fraudster. Pet.App.37. That result would be troubling enough on its own, but it is truly remarkable when *four federal judges* expressly found reasonable the very same reading of the statute that the Seventh Circuit said no reasonable person could seriously believe. As decades of experience with *Chevron* confirmed, ambiguity was not even a particularly workable test for deciding whether to defer to the views of an agency. *A fortiori*, it cannot be the right metric for trying to suss out whether someone intended to defraud the federal government—especially when (as here) the government declined opportunity after opportunity to embrace the view of the law that was purportedly so clear that no one could dispute it in good faith.

The Court should grant certiorari and ensure that an unaccountable relator cannot secure a massive windfall just because he managed to persuade one court of appeals (but not another) that his preferred reading of an impenetrable federal statutory regime was unambiguously correct.

I. This Court Should Grant Certiorari To Decide Whether The FCA's *Qui Tam* Regime Violates The Separation Of Powers.

In recent years, a chorus of jurists have raised concerns with the FCA's *qui tam* device. *See, e.g.*,

Wisc. Bell, Inc. v. United States ex rel. Heath, 604 U.S. 140, 167 (2025) (Kavanaugh, J., concurring) ("The Act's *qui tam* provisions raise substantial constitutional questions under Article II."). This case provides an opportunity for this Court to answer those "substantial" questions—and to confirm that the Constitution does not tolerate the FCA's private outsourcing of core executive power.

"Under our Constitution, the 'executive Power'—all of it—is 'vested in a President.'" *Seila Law LLC v. CFPB*, 591 U.S. 197, 203 (2020) (quoting U.S. Const. art. II, §1, cl. 1). That means executive power cannot be disseminated among or executed by other branches. It also means that a legislative enactment that farms out law-execution to private citizens, "dispers[ing] some quantum of executive authority amongst the general public," transgresses constitutional limits. *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 750 (9th Cir. 1993); *see also, e.g.*, *United States ex rel. Montcrief v. Peripheral Vascular Assocs., P.A.*, 133 F.4th 395, 410-12 (5th Cir. 2025) (Duncan, J., concurring); *Consumers' Rsch. v. FCC*, 88 F.4th 917, 933-938 (11th Cir. 2023) (Newsom, J., concurring).

Yet the FCA's *qui tam* device does precisely that. The FCA puts the "choice of how to prioritize and how aggressively to pursue legal actions" within the "purview of private plaintiffs," who are "not accountable to the people and are not charged with pursuing the public interest in enforcing a defendant's general compliance with regulatory law." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 429 (2021). Fundamentally executive authority is bestowed upon private citizens with no meaningful supervision or

direction, transforming bounty hunters into ersatz executive officers and paying them (and their private attorneys) a pretty penny in the process. None of that is consistent with our constitutional structure.

1. The power of a *qui tam* relator under the FCA is staggering. Relators enjoy wide discretion to select defendants, legal theories, and claims. Even though "prosecutorial discretion [may] counsel against [the government] bringing a False Claims Act suit," *Constitutionality of the Qui Tam Provisions of the False Claims Act*, 13 Op. O.L.C. 207, 217 (1989), relators need not obtain the government's permission to file suit "for" and "in the name of the Government," 31 U.S.C. §3730(b)(1). And once a relator does so, the Executive is on the relator's clock: It has 60 days to evaluate national priorities and decide whether to intervene. *See id.* §3730(b)(2).

In the "vast majority of actions," the government stays out of the fray, leaving relators free to pursue cases with enormous impact on the public fisc, private parties, and federal law with no direction or oversight. *United States ex rel. Zafirov v. Fla. Med. Assocs., LLC*, 751 F.Supp.3d 1293, 1301-02 (M.D. Fla. 2024). But a relator "has no obligation whatsoever to pursue the best interests of the United States"; he is free—indeed, incentivized—to "negotiate a settlement in his own interest," but nominally on behalf of the United States. *Riley v. St. Luke's Episcopal Hosp.*, 252 F.3d 749, 762 (5th Cir. 2001) (en banc) (Smith, J., dissenting). "As a class of plaintiffs," then, "*qui tam* relators are different in kind than the Government": "They are motivated primarily by prospects of monetary reward rather than the public good."

Hughes Aircraft Co. v. United States ex rel. Schumer, 520 U.S. 939, 949 (1997).

Meanwhile, the Executive is effectively sidelined. To be sure, the government can request copies of pleadings and deposition transcripts, 31 U.S.C. §3730(c)(3); move to temporarily stay discovery, *id.* §3730(c)(4); and file a statement of interest. But the government has no power to guide the relator's self-interested litigation, which proceeds "with or without" the Executive, "sometimes alerting targets of criminal investigations; sometimes resulting in disclosure of key information in [its] possession[;] … and sometimes complicating attempts to prepare a comprehensive plea arrangement and civil settlement." 13 Op. O.L.C. at 217. The government's only true recourse is to move to dismiss the suit wholesale—a request it cannot even make unless it intervenes in a lawsuit it may not have interest in pursuing and participates in a hearing to justify dismissal. *See* 31 U.S.C. §3730(c)(2)(A).

It is little wonder, then, that abuses of the *qui tam* system proliferate. *See* Memorandum from Michael Granston, Dir., Com. Lit. Branch, Fraud Div., *Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A)* at 3-6 (Jan. 10, 2018) (discussing relators' filing of meritless cases; duplication and contravention of ongoing government investigations; interference with agency program administration; potential disclosure of classified information; and unjustifiable drain on government coffers).

2. The Article II problems with this regime go deeper. Under this Court's Appointments Clause cases, anyone who "exercise[s] significant authority

pursuant to the laws of the United States" and who occupies a "continuing position established by law" is an executive officer. *Lucia v. SEC*, 585 U.S. 237, 245 (2018). And under the Constitution, all such officers must be appointed by "the President alone, in the Courts of Law, or in the Heads of Departments." U.S. Const. art. II, §2, cl. 2. Relators plainly fit that bill. Yet they are not appointed in accordance with the Clause. Instead, they appoint themselves.

There can be no serious dispute that relators wield immense authority under federal law. They "conduct[] civil litigation in the courts of the United States for vindicating public rights," a function that "may be discharged only by persons who are 'Officers of the United States.'" *Buckley v. Valeo*, 424 U.S. 1, 140 (1976) (per curiam). They prosecute with nearly unbounded discretion when the government declines to intervene, which happens in most cases. *See* p.19, *supra*. And even if the government *does* intervene, the relator continues to enjoy "the right to continue as a party to the action" he initiated and shaped. 31 U.S.C. §3730(c)(1). "That is textbook 'significant authority.'" *Zafirov*, 751 F.Supp.3d at 1309 (quoting *Buckley*, 424 U.S. at 138-39).

Relators also occupy a continuing position established by law. While different individuals may assume the role, the office itself persists by virtue of the FCA. *See, e.g.*, *Morrison v. Olson*, 487 U.S. 654, 664, 671 (1988). Relators' "duties, salary, and means of appointment for th[e] office are specified by statute"—not assigned *ad hoc* by government officials. *Freytag v. Comm'r*, 501 U.S. 868, 881 (1991); *see* 31 U.S.C. §3730(d) (specifying the authority,

compensation, and duties of a relator). The role of relator is not "occasional or temporary," but rather "continuing and permanent." *Lucia*, 585 U.S. at 245.

Yet a relator is not appointed by the President, the courts, or an agency head; again, he appoints himself. And the President cannot remove a relator "under any circumstances." *Riley*, 252 F.3d at 763 & n.19 (Smith, J., dissenting). None of that can be squared with the Appointments Clause.

3. This usurpation of executive power was no accident. It was the intended result of legislators' "distrust of, and dissatisfaction with, the way the executive branch was carrying out its law enforcement responsibilities." 13 Op. O.L.C. at 230.

Granted, certain *other* types of *qui tam* actions are well pedigreed. As early as the thirteenth century, "*qui tam* suits … consolidated royal and private interests" in England. Note, *The History and Development of Qui Tam*, 1972 Wash U.L.Q. 81, 83. But the FCA's modern *qui tam* provisions are a far cry from their predecessors. The 1986 amendments to the FCA drastically "expand[ed]" relators' power—and drastically *undermined* the power of the Article II branch. *See* 31 U.S.C. §3730(c)(1), (2); H.R. Rep. No. 99-660, at 23-24 (1986). That was the point. Though these amendments, Congress aimed to transform relators into "a check that the Government does not neglect evidence, cause undu[e] delay, or drop the false claims case without legitimate reason," and a means to "keep pressure" on the Executive. S. Rep. No. 99-345, at 25-26 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5,266, 5,290-91; 132 Cong. Rec. 29,322

(1986). Such branch-on-branch violence is antithetical to the Constitution.

Congress's vesting of executive power in the hands of freewheeling prosecutors rebuffs these constitutional limitations. Yet it is unclear where Congress's purported authority to do so comes from. "The structure of the Constitution does not permit Congress to execute the laws; it follows that Congress cannot grant to an officer under its control what it does not possess." *Bowsher v. Synar*, 478 U.S. 714, 726 (1986). Not only, then, does the *qui tam* device contravene Article II and the separation of powers more generally; it also likely runs afoul of Article I.

* * *

In short, this structure—unaccountable and uncontrollable private prosecutors pursuing their own ends in the name of the United States—is fundamentally incompatible with our Constitution. *Cf. TransUnion*, 594 U.S. at 429. "The President cannot 'take Care that the Laws be faithfully executed' if he cannot oversee the faithfulness of the officers who execute them." *Free Enter. Fund. v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 484 (2010). Nor can the President "accomplish[] [his] constitutionally assigned functions" when a private person outside the Executive Branch is empowered to usurp them. *Nixon v. Adm'r of Gen. Servs.*, 433 U.S. 425, 443 (1977). This case provides an opportunity to reassert the primacy of the Framers' design.

II. The Seventh Circuit's Approach To The Issue Of "Objective Unreasonableness" Turns This Court's Precedent Upside Down.

1. In *United States ex rel. Schutte v. SuperValu Inc.*, this Court corrected the Seventh Circuit's mistake of placing too much weight on whether an FCA defendant's interpretation of the governing law was "objectively reasonable." 598 U.S. at 748-49. Under the precedent the Court granted *Schutte* to consider, the Seventh Circuit treated the objective reasonableness of a legal position as dispositive of scienter: If "a defendant's acts were consistent with any objectively reasonable interpretation of the relevant law that had not been ruled out by definitive legal authority or guidance," then the defendant could not have "knowingly" made a false statement, "regardless of whether the defendant actually believed such an interpretation at the time." *Id.* at 748. This Court unanimously rejected that approach, concluding that scienter under the FCA turns on a defendant's *subjective* knowledge and beliefs, not whether "legal interpretations that [a defendant] did not believe or have reason to believe" were objectively reasonable. *Id.* at 755. By rendering "defendants' subjective beliefs … irrelevant to their scienter," the Seventh Circuit embraced a view of the scienter requirement that departed from its core goal—namely, to determine whether the defendant acted with a "culpable state of mind." *Id.* at 752-53.

Here, the Seventh Circuit essentially committed the same mistake in reverse. The court began its analysis by explaining why, applying tools of statutory construction, it concluded that "the legal framework

unequivocally" supports Streck's reading of the statute. Pet.App.20. Based on that alone, the court held that Lilly's reading was not just wrong, but "objectively unreasonable." *See* Pet.App.20-24; *see also* Pet.App.38-39. The court then posited that "Lilly's objectively unreasonable interpretation of the relevant law" not only rendered its calculation of AMP "false," but "is highly probative circumstantial evidence of a culpable state of mind"— though the jury did not even know that a court had deemed that construction "objectively unreasonable." Pet.App.38. The court thus once again baked into the scienter analysis its after-the-fact views about what readings of the law an "objectively reasonable" person could hold, with little, if any, regard for what the defendant *subjectively* believed about its obligations.

Perhaps that might be forgivable if the court had at least pointed to some criteria beyond its own view of how best to read a statute to decide what makes a legal interpretation "objectively unreasonable." It could, for example, reach that conclusion by saying an interpretation is not only is wrong as a matter of law, but has been rejected by the agency tasked with interpreting a statute, or by the government in litigation, or by courts that have confronted it, etc. But the court did not even do that. Nor could it have reached the conclusion that Lilly's interpretation was "objectively unreasonable" under any of these criteria—because every single one points in the opposite direction. CMS never provided any guidance on the issue at all—even though Lilly and others implored it to do so. The government never weighed in on any of the litigation that presented it—even though it was FCA litigation ostensibly brought on its

behalf. Several manufacturers embraced the same reading that Lilly did. And until this case, every jurist to consider the question had concluded that Lilly's view of the law was at the very least reasonable. The Seventh Circuit thus concluded that Lilly could not plausibly have believed something that no one save a single private bounty hunter seeking to capitalize on the FCA's *qui tam* provisions had ever before said was wrong, simply because three Seventh Circuit judges did not think that Lilly (or three Third Circuit judges) got the law right.

That turns *Schutte* on its head. The "objectively reasonable" concept is a vestige of the rule *Schutte* rejected, under which some courts held that FCA defendants could not have acted in reckless disregard of their obligations as a matter of law, regardless of their subjective intent, if they adopted an "objectively reasonable" reading of the law. *See Schutte*, 598 U.S. at 748-49. The decision below essentially morphs the concept into a converse principle—i.e., if a reading is *not* objectively reasonable, then the defendant could not really have held it. Neither position is correct, as *Schutte* makes clear that scienter is about "subjective beliefs," not about what an "objectively reasonable" person would believe—let alone about whether a statute is ambiguous. *Id.* at 749.

The Seventh Circuit's contrary approach cannot be reconciled with the reality that the FCA is a statute about *fraud*. *But see* CA7.App.572:2-9 (relator telling the jury, "This is not a fraud case."). It is one thing to use a lack of statutory ambiguity as a metric for determining whether an agency exceeded the bounds of its authority. But as this Court admonished in

Schutte, the FCA's scienter requirement is about determining whether someone acted with a "culpable state of mind." 598 U.S. at 752. The scores of *Chevron* cases under which agency interpretations were rejected as foreclosed by the unambiguous text of a statute ought to be powerful evidence that people are quite capable of misreading an unambiguous statute in good faith.

Making matters worse, decades of experience under *Chevron* teaches that "plain meaning" (or, conversely, ambiguity) is often "in the eye of the beholder," *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 737 (1985), "and cannot be readily determined on an objective basis," *Wooden v. United States*, 595 U.S. 360, 378 (2022) (Kavanaugh, J., concurring). One need look no further than this case. The same relator sued the same parties under the same legal theory in another court—and lost—because *that* court thought the statute was ambiguous. 746 F.App'x at 108. Yet the Seventh Circuit reached the opposite conclusion, creating a circuit split on whether a particular legal interpretation was "objectively unreasonable" and putting this Court in the position of having to referee disputes not just about what the byzantine laws governing the calculation of AMP mean, but about whether contrary readings are so wrong as to be "objectively unreasonable."

2. There is a better way. If the "objective" reasonableness of a legal position is to impact not just falsity, but scienter too, then it must be measured by some metric beyond simply which reading of the law a court thinks is best—e.g., agency guidance, contemporaneous judicial decisions, official

government positions taken in litigation, or longstanding industry practice. After all, "[e]ven in the civil context, fair warning requires that government agencies communicate their interpretation of their own regulations with 'ascertainable certainty' before subjecting private parties to punishment under that interpretation." *United States v. Harra*, 985 F.3d 196, 213 (3d Cir. 2021). Without at least that much, the "objectively reasonable" inquiry—which is largely just a vestige of the rule this Court rejected in *Schutte* anyway—simply is not up to the task of informing the critical question of whether the defendant actually acted with a "culpable state of mind." *Schutte*, 598 U.S. at 752.

Unsurprisingly, other courts have recognized that better way. For instance, in *United States ex rel. Sheldon v. Allergan Sales, LLC*, --- F.4th ----, 2026 WL 706428 (4th Cir. Mar. 19, 2026), a *qui tam* relator sued a manufacturer under the FCA for allegedly miscalculating the prices it reported as part of the Rebate Program. *Id.* at *5. The Fourth Circuit held that Sheldon adequately pled scienter—but on reasoning quite different than the Seventh Circuit's here. As the court there explained, "the scienter standard is a subjective one that focuses on the defendant's thoughts and beliefs," not whether the law was "ambiguous." *Id.* at *10. The court thus focused not on whose reading of the law was correct, but on whether there was evidence that the defendant "was subjectively aware of a substantial risk that CMS interpreted the Rebate Statute to require drug manufacturers to" calculate "rebates and other discounts" a particular way. *Id.* at *11. And it concluded that Sheldon pleaded sufficient facts to

support scienter by, among other things, pointing to correspondence that allegedly showed that the defendant subjectively "understood CMS[]" to have embraced a legal position contrary to its own. *Id.*

The Seventh Circuit did not point to anything like that here. Nor could it, as nothing put Lilly on anything approaching fair notice that the legal interpretation on which it relied was wrong—let alone contrary to the agency's position, or so patently wrong that the bare act of embracing it could be considered "highly probative" evidence of scienter. To the contrary, every objective source indicated that Lilly was taking an eminently reasonable view of a legal question that (until now) all admitted was at the very least debatable.

First, the statutory text has never squarely addressed the question at hand. Until 2010, the statute defined AMP as the "average price paid to the manufacturer for the drug in the United States by … wholesalers," but it did not address how payments *to* wholesalers should be treated. 42 U.S.C. §1396r-8(k)(1). Compounding the uncertainty, Congress amended the statute in 2010 to make clear that service fees paid to wholesalers should be *excluded* from the AMP calculation—but in doing so said nothing about separating out offsets that account for price increase values, even though that practice was by then common. *Id.* §1396r-8(k)(1).

CMS never squarely addressed the issue either—though it had ample opportunity to do so. For the relevant period, the agency either had *no* rule about fee-for-service arrangements (2005-2007 and 2010-2016) or had a rule that instructed parties to exclude

service fees that represent the "fair market value" for services (2007-2010). *See* pp.9-10, *supra*. The agency not only acknowledged, but defended, this regulatory vacuum, explaining that it had "not further defined 'fair market value' so that manufacturers have *the flexibility to determine fair market value* consistent with industry accepted methods." 72 Fed. Reg. at 39,184 (emphasis added). Lilly, which at that point had been using the PIV approach to ensure that wholesalers received only fair market value, took the government at its word. And while a 2012 notice of proposed rulemaking *proposed* that some types of PIV arrangements (albeit not necessarily Lilly's) should be included in the AMP calculation, thus confirming that CMS was well aware of the uncertainty on that score, CMS did not adopt that position when it issued its final rule several years later. 77 Fed. Reg. at 5,332. CMS thus knew full well that parties were unclear on how to treat PIV arrangements, yet it declined to provide definitive guidance—which is itself powerful evidence that the agency did *not* think there was only one reasonable answer to that question.

Nor has the federal government ever weighed in in its litigating capacity—again, not for lack of opportunity. When Streck brought his first lawsuit, the United States did nothing. It did not support the litigation, and it did not step in to support him even after he lost and sought en banc review in the Third Circuit. And the United States did not weigh in on the statutory interpretation question in any of the other *qui tam* litigation involving disputes over whether or how fee-for-service arrangements and their various components should be treated when calculating AMP.

As for judicial authority, while the Seventh Circuit only "briefly note[d] [its] divergence" with the Third Circuit, Pet.App.29, there are no two ways about it: The Third Circuit (and the district court) in *Streck I* held the exact opposite of what the Seventh Circuit held here. To be sure, the Third Circuit acknowledged that "a price-appreciation credit that remits value back to a manufacturer *could* be considered a component of the cumulative value a manufacturer receives for a drug." 746 F.App'x at 108 (emphasis added). But it stressed that "neither the word 'initial' nor the word 'cumulative' appears before 'price' in … the statute." *Id.* And the "absence of such temporal language" gave the Third Circuit "pause before concluding that 'price' unambiguously refers to the cumulative price paid, rather than the initial price paid." *Id.* The Third Circuit thus concluded that "the statute is ambiguous" on this point, *id.*—and, particularly in light of the "confusion regarding the calculation of AMP during the relevant time period," squarely held that "it was *not* objectively unreasonable" for manufacturers to exclude PIV from AMP, *id.* at 110 (emphasis added). The notion that Lilly could be held liable *for fraud* because it adopted a view of the law that four federal judges said was reasonable "sounds absurd, because it is." *Sekhar v. United States*, 570 U.S. 729, 738 (2013).

Finally, of course, is the fact that Lilly repeatedly disclosed its legal position to both CMS and OIG, in hopes of obtaining some clarity on whether they thought it was correct. *See* pp.10-11, *supra.* Yet Lilly's pleas fell on deaf ears, as the agency embraced an affirmative policy of *refusing* to give manufacturers guidance on whether the "reasonable assumptions" it

tasked them with making were, in its estimation, actually "reasonable." "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." *Sheldon*, 24 F.4th at 356.

The Seventh Circuit thus did not and could not point to any authoritative source that would have put Lilly on notice that a view widely shared by industry members was in fact so objectively unreasonable that the bare act of embracing it would be deemed "highly probative" evidence of a culpable mind. It instead just concluded that "the legal framework unequivocally" dooms Lilly's position. Pet.App.20-33. That conclusion is hard to defend as a matter of statutory interpretation, for the reasons the Third Circuit explained. *See* 746 F.App'x at 108. But even assuming that the Third Circuit's reading of the law was incorrect, it is hardly the stuff of "objective unreasonableness." To be sure, "statutes, no matter how impenetrable, do—in fact, must—have a single, best meaning." *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 400 (2024). But when it comes to imposing "essentially punitive" liability, *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784 (2000), in the context of a regime where the only "guidance" the government provides is a generic direction to make "reasonable assumptions," it must take much more than mere failure to discern what a court later deems to be the best reading of a statute to infer that the defendant acted with a culpable state of mind. *Cf. FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012) (parties "should know what is required of them so they may act accordingly").

The Seventh Circuit's contrary view largely eliminates the "fraud" component from the FCA, leaving liability to turn almost entirely on what one court later decides is the best reading of a statute. By its telling, defendants who plead for guidance and tell the government exactly what they are doing and why can still be slapped with punitive liability even when four federal judges agree that their position was reasonable, all because a different set of judges reads a statute differently. That cannot be the law. Only this Court can set things right.

III. The Questions Presented Are Exceptionally Important.

This petition provides an excellent opportunity for this Court to step in and remedy flagrant constitutional abuses that are occurring day in, day out, in federal courtrooms across the country. It presents legal questions of profound constitutional and practical significance. For the separation-of-powers issue, multiple Justices have noted the need for resolution, *see* pp.17-18, *supra*, and several courts of appeals are currently grappling with the issue, *see, e.g.*, *United States ex rel. Zafirov v. Fla. Med. Assocs., LLC*, Nos. 24-13581 & 24-13583 (11th Cir. oral argument held Dec. 12, 2025); *United States ex rel. Penelow v. Janssen Prods., L.P.*, No. 25-1818 (3rd Cir. oral argument held Mar. 18, 2026).

Qui tam litigation is a pervasive feature (or, rather, bug) of federal-court practice. Plaintiffs' lawyers can raise "the possibility of colossal liability" by threatening the magnifying effect of statutory penalties especially for small value claims, and they frequently seek to extract "blackmail settlements,"

even for otherwise non-meritorious cases. *Coinbase Inc. v. Bielski*, 599 U.S. 736, 743 (2023). The numbers are staggering. In 2024, plaintiffs' lawyers filed 979 *qui tam* FCA lawsuits—"the highest number" ever—and settlements and judgments under the statute exceeded $2.9 billion. Press Release, U.S. Dep't of Justice, *False Claims Act Settlements and Judgments Exceed $2.9B in Fiscal Year 2024* (Jan. 15, 2025), https://perma.cc/NG5V-EDP4 ("DOJ Press Release"). Simply put, this pervasive problem is not going away unless and until this Court puts a stop to it.

The problems with the Seventh Circuit's view of the FCA are equally (if not more) pernicious. FCA litigation routinely involves disputes about what the governing law means, as evidenced by the circuit split the Seventh Circuit acknowledged over whether an incorrect reading of the law suffices to prove falsity. *Compare, e.g.*, *United States ex rel. Oliver v. Parsons Co.*, 195 F.3d 457, 463 (9th Cir. 1999) ("falsity" "is determined by whether [defendant's] representations were accurate in light of applicable law"), *and United States ex rel. Walker v. R&F Properties of Lake Cnty.*, 433 F.3d 1349 (11th Cir. 2005) (same), *with United States ex rel. Siewick v. Jamieson Sci. & Eng'g, Inc.*, 214 F.3d 1372, 1378 (D.C. Cir. 2000) (falsity requires "facts … that the speaking party could reasonably classify as true or false"), *United States ex rel. Thomas v. Siemens AG*, 593 F.App'x 139, 143 (3d Cir. 2014) (same), *and United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376-77 (4th Cir. 2008) (same). If all it took to unlock treble damages was persuading one court that a statute is unambiguous, then the already-hydraulic pressure to

settle FCA cases would increase by orders of magnitude.

That is particularly problematic in the context of prescription-drug pricing. In nearly every corner of pharmaceutical price reporting lies a Federal Register entry declining to answer the myriad hard questions the industry faces and instead just advising manufacturers to make "reasonable assumptions." Manufacturers must make hundreds upon hundreds of those assumptions each year to comply with their many reporting obligations. And no matter how they read the relevant law, and no matter how many times they tell the government what they are doing and why, they will inevitably be sued by private bounty hunters claiming they got it wrong—as evidenced by the fact that Streck sued virtually every major manufacturer, including some who took entirely different legal positions on how to incorporate their fee-for-service arrangements into AMP. *See* pp.11-13, *supra*. And, as Streck's personal circuit split shows, even if one court blesses an interpretation (and that blessing gets affirmed on appeal), another court could still disagree and sanction crippling punitive liability. It is little surprise, then, that more than half of the settlements and judgments in *qui tam* suits in 2024 involved the healthcare industry. DOJ Press Release, *supra*. The law as it stands leaves the industry no viable way out.

That untenable situation cries out for this Court's review, and this case supplies the Court with a vital opportunity to provide it. There is of course no obstacle to reviewing the Seventh Circuit's FCA holding. And while the court in denying Lilly's en banc petition said that Lilly had "forfeited if not

waived its constitutional argument," Pet.App.65, Lilly expressly preserved that argument in its panel-stage briefing, CA7.Dkt.37 at 66 n.11, which is all that is required when an argument is foreclosed by circuit precedent. In all events, this Court has often "exercised its discretion" to consider non-jurisdictional claims implicating the separation of powers. *Freytag*, 501 U.S. at 878. And it would make particularly good sense to do so when a relator produced a one-man circuit split that left Lilly on the losing end saddled with a nearly $200 million judgment for embracing a reading of the law that four federal judges found reasonable.

CONCLUSION

For the foregoing reasons, this Court should grant the petition.

Respectfully submitted,

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March 21, 2026

APPENDIX

TABLE OF APPENDICES

Appendix A

UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

Nos. 23-2134, 23-2216, 23-2958,
23-3035, 24-1352, & 24-1884

UNITED STATES, et al., EX REL. RONALD J. STRECK,

Plaintiff-Appellee/
Cross-Appellant,

v.

ELI LILLY AND COMPANY,

Defendant-Appellant/
Cross-Appellee.

Argued: Sept. 18, 2024
Decided: Sept. 11, 2025

Before: Ripple, Jackson-Akiwumi, and Kolar,
Circuit Judges.

OPINION

KOLAR, *Circuit Judge*. Relator Ronald Streck first publicly accused pharmaceutical companies of reporting falsely deflated drug prices to the government in 2011. Over a decade later, a jury decided in his favor against Eli Lilly, one of the largest drug companies in the world. We affirm.

At a broad level, we think the jury verdict underscores a useful lesson: overcomplicated and hyper technical interpretations cannot defeat common-sense plain readings of text. Here, federal law required Lilly to tell the government the average price it received for drugs covered by Medicaid. In its supply chain, Lilly sold drugs to wholesalers, who then sold the product to retail pharmacies. From 2005 to 2017—the relevant period—Lilly charged the wholesalers at two stages for its drugs. First, the wholesalers paid the initial drug price Lilly set. Second, if Lilly raised the price after the wholesalers took possession of the drugs, but before the wholesalers resold to a pharmacy, Lilly required the wholesalers to credit the subsequent price increase. In other words, when Lilly sold a drug for $10 on Monday, and raised the price to $11 before the wholesaler sold it on Wednesday, the wholesaler needed to remit Lilly an additional dollar of value.

Lilly only reported the initial sales price as its Average Manufacturer Price (AMP) to the government; Streck argues it should have included both the initial price and any subsequent price increases. One may question why a company would under report the price it charges customers. The answer lies in the agreement Lilly had with the government and related regulations. Under federal law, the size of Lilly's payments to the federal government for participating in Medicaid directly correlated with its AMPs. The higher the AMP for a given drug, the more money Lilly owed to the government for the privilege of participating in Medicaid.

Despite the lengthy opinion that follows, the crux of this appeal asks a few rather simple questions. First, using the example above, did Lilly realize a price of $10 or $11 for its drug? The plain language of the relevant texts, Medicaid's clear purpose, and common sense point to a clear answer: it sold the drug for $11. Lilly's AMP calculations were false. Second, did Lilly know its AMPs were false? Lilly was entitled to, and did, argue to the jury that it did not mean to mislead the government and that it made reasonable assumptions about AMP. Nonetheless, the jury reasonably found Lilly knowingly hid the truth. And third, were Lilly's underreported AMPs material to the government deciding to continue doing business with the company? Here again, because Lilly deprived the government of over $60 million, while amassing over $600 million in revenue from subsequent price increases during the relevant period, the jury reasonably concluded the false AMPs were material.

I. Background

A. Regulatory Background

In 1965, the federal government created Medicaid, which helps pay for medical costs to low-income Americans. *See* Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286, 286 (1965). Yet by the late 1980s, rising drug prices threatened federal and state Medicaid programs' ability to simultaneously fund prescription drug and "other health care needs of the elderly and [the] poor...." Majority Staff of Special Comm. on Aging, 101st Cong., *Prescription Drug Prices: Are We Getting Our Money's Worth?* 1 (Comm. Print 1989). In 1990, Congress responded by creating the Medicaid Drug

Rebate Program (MDRP), which "[r]equires drug manufacturers to comply with rebate agreements" with the federal government to benefit state programs. H.R. Conf. Rep. No. 101-964, at 822-23 (1990), *as reprinted in* 1990 U.S.C.C.A.N. 2374, 2527-28; *see also* 42 U.S.C. §1396r-8(a)(1). More simply, if a drug manufacturer wanted Medicaid to cover a given drug, the manufacturer had to subsidize some of the cost. *Vanda Pharms., Inc. v. Centers for Medicare & Medicaid Servs.*, 98 F.4th 483, 487 (4th Cir. 2024), *cert. denied*, 145 S. Ct. 1047 (2025).

When Medicaid covers a prescription drug, a drug manufacturer must pay a quarterly rebate to the Secretary of Health and Human Services (HHS). 42 U.S.C. §1396r-8(a)(1), (b)(1)(A), (k)(8). The rebate payments are the heart of the MDRP and help "ensure the availability of payment for covered drugs...." H.R. Conf. Rep. No. 101-964 at 822; *see also* 42 U.S.C. §1396r-8(a)(1).

The rebate owed for a given drug is often a function of multiplying a percentage of the drug's "average manufacturer price," or AMP, by the quantity sold during that quarter. 42 U.S.C. §1396r-8(c)(1)(A). Simply, the AMP directly affects the amount a manufacturer pays. 42 U.S.C. §1396r-8(k)(1). Here's how. Every quarter, a drug's manufacturer must determine its AMP by calculating the "average price paid to the manufacturer for the drug in the United States...." *Id.* §1396r-8(k)(1)(A). The drug's AMP, in turn, affects the amount a manufacturer owes as a rebate in one of two ways. *Id.* §1396r-8(c)(1)(A). The first method takes the difference between the AMP and the drug's lowest sale

price during the rebate period; the second option multiplies the AMP by a fixed percentage. *Id.* §1396r-8(c)(1)(A)(ii)(I)-(II), (c)(1)(C)(i).[1] Either way, an increase or decrease in a drug's AMP will have a corresponding effect on its rebate amount—the higher the AMP, the more the manufacturer will owe.

To complete the picture, the government must reimburse pharmacies for drugs sold to Medicaid beneficiaries. For brand name drugs, that payment is the smaller of two numbers: the amount a pharmacy actually paid plus a dispensing fee; or the "usual and customary charges to the general public" for the drug. 42 C.F.R. §447.512(b). So, the federal government's obligation turns on the amount end-users (pharmacies or customers) paid for the drug. When the "usual and customary charges" of a brand name drug increase for a retail pharmacy or its customers, the federal government must pay more.

The price the government pays and the manufacturers' contribution from the AMP are supposed to correlate. As a brand name drug price goes up, the government pays more. At the same time, that price increase should push up the AMP, and result in a higher corresponding rebate. Lilly increased prices, took more profit, but did not increase the AMP. It pocketed part of the rebate owed to the government.

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[1] Since January 1, 2010, the fixed statutory percentage is 23.1% of a drug's AMP, and before that, it had been 15.1% since January 1, 1996. 42 U.S.C. §1396r-8(c)(1)(B)(i)(V)-(VI).

B. Factual Background

1. Eli Lilly's Rebate Obligations and Business Model

Lilly is a drug manufacturer that has participated in the MDRP since 1991. Lilly's MDRP agreement detailed its obligations. For one, Lilly had to adjust its AMPs if "cumulative discounts or other arrangements subsequently adjust the prices [Lilly] actually realized" for its drugs. The agreement also required Lilly to "keep records (written or electronic) of the data and any other material from which the calculations of AMP … were derived." Lilly retained the flexibility to "make reasonable assumptions in its calculations of AMP" "[i]n the absence of specific guidance" under federal law, regulations, or other MDRP agreement provisions. Those assumptions, however, had to be "consistent with the intent" of 42 U.S.C. §1396r-8, its regulations, "and the terms of [the rebate] agreement."

Lilly's response to an inefficiency in the pharmaceutical supply chain prior to 2005 gives rise to this case. Lilly sold its drugs to wholesale suppliers, who in turn resold the drugs to pharmacies. Before 2005, if Lilly sold a drug to a wholesaler but raised the drug's price before the wholesaler resold the inventory, the wholesalers would reap the profit of the price increase.[2] This was how wholesalers made their money. Lilly did not pay for the wholesalers' services (packing, storing, distributing drugs); the wholesalers engaged in "speculative buying" of drugs, stockpiling

[2] A Lilly executive testified that Lilly set prices for wholesalers and could choose to raise them as it saw fit, though market pressure con-strained Lilly to some extent.

inventory and awaiting a price increase, which they could then pass on in their sales to pharmacies.

Then, in 2005, Lilly changed to a "fee-for-services" distribution model, where Lilly paid the wholesaler directly for packing, storing, and distributing. Wholesalers received a set "Distribution Fee," calculated as a small portion (approximately one percent) of the cost of drugs they purchased from Lilly. The wholesalers could receive their compensation in two ways: (1) ordinary cash payments and (2) "Price Increase Value."[3] Cash payments were simple—Lilly paid the wholesalers for the services, but Price Increase Value worked differently. It depended on how the price of a drug changed between the time when Lilly sold a drug to the wholesalers and the wholesalers sold the drug to pharmacies. If the price of the drug increased during that period, then the wholesalers would owe Lilly the difference in price for the drug it held in stock. That amount would be deducted from Lilly's bill. From 2009 to 2016, Lilly made the arrangement simpler. The company paid the Distribution Fee in full and then invoiced the wholesalers for the price increase values of the past quarter.

As Lilly explained at trial, the differences in the earlier and later price increase models were a matter of form, not substance. Either way, Lilly gained the value of the price increases. Under the earlier model, price increases reduced how much Lilly paid to wholesalers in distribution fees. Lilly paid the

[3] We also refer to the Price Increase Value mechanism as "clawback" adjustments or increases because the mechanism clawed back value from the wholesalers.

wholesaler less out-of-pocket to distribute the drugs. Under the later model, Lilly paid the full fee and the wholesalers sent price increases back in cash. The wholesalers' bottom lines remained unaffected by any interim price changes. For instance, even during the early period when Lilly deducted the price increases from the Distribution Fee, the wholesalers ended up with the same money on their ledgers. Instead of Lilly paying the entire Distribution Fee, the pharmacies purchasing the drugs bore that incremental cost. Altogether, Lilly received more revenue, the wholesalers ended up in the same position, and pharmacies paid more.

2. Regulatory and Statutory Background on Clawback Increases

In 2007, the Centers for Medicare & Medicaid Services (CMS), a subagency of HHS, promulgated a final rule that tweaked how manufacturers calculated their AMPs. Medicaid Program; Prescription Drugs, 72 Fed. Reg. 39,142 (July 17, 2007) (codified at 42 C.F.R. §447.500 *et seq.*). Manufacturers could exclude "fees paid by a manufacturer to an entity" (such as a wholesaler) "for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service agreement…." *Id.* at 39,240, 39,242 (codified at 42 C.F.R. §§447.502, 504(h)(19)). But, bona fide services did not include any fees that were "passed on in whole or in part to a client or customer of an entity," i.e. the pharmacies (customers) who buy drugs from the wholesalers (the entities). *Id.* at 39,240. Like Lilly's MDRP agreement, the comments to the 2007 regulation allowed

manufacturers, "[i]n the absence of specific guidance," to "make reasonable assumptions in [their] calculations" so long as those assumptions were "consistent with the general requirements and the intent of the Act." *Id.* at 39,164.

Three years later, the federal government enacted the Patient Protection and Affordable Care Act (ACA), which modified the statutory definition of AMP and its relevant exclusions. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010). As relevant here, the ACA mirrored CMS's 2007 regulation, exempting bona fide service fees that manufacturers pay to wholesalers or retail community pharmacies from AMP calculations. 124 Stat. at 311 (codified at 42 U.S.C. §1396r-8(k)(1)(B)(i)(II)). Thus, "discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies" remain included in a manufacturer's AMP. *Id.* (codified at 42 U.S.C. §1396r-8(k)(1)(B)(ii)). CMS also rescinded the parts of its 2007 rule that instructed how to calculate AMP "[g]iven the amendments made by the [ACA]" and reminded manufacturers to "operate consistent with the Medicaid drug rebate statute, and regulations" other than those that had been withdrawn until future rulemaking occurred. Medicaid Program; Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs, 75 Fed. Reg. 69,591, 69,593 (Nov. 15, 2010).

3. Lilly's Price Increase Value Exclusion

Lilly excluded its entire "Distribution Fee" to wholesalers from its AMPs during the 2005 to 2017 period. Critically, despite the 2007 regulation and 2010 ACA amendments, Lilly considered the Price Increase Value mechanism as part of this Distribution Fee, even though the wholesalers' clients or customers (the retail pharmacies) paid rather than Lilly. Those exclusions resulted in lower AMPs, and thus, lower contributions to the government. Meanwhile, because Medicaid's payments for brand name drugs hinged on the "usual and customary" price at the pharmacies, its costs increased.[4]

Heather Dixson was Lilly's "government pricing specialist" given responsibility for Lilly's AMP calculations. Dixson was promoted to lead government pricing—including calculating AMP—in April 2005, two months after the price increase provision came into effect. She did not remember discussing Price Increase Value with her predecessor. But while Dixson managed the AMP method, she testified that CMS demanded Lilly's CEO, CFO, or a direct report to one of those two executives certify the accuracy of the AMPs. Frank Cunningham, one of the executives who

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[4] At oral argument, Lilly's counsel wisely admitted price increases "allow[ed] the wholesaler to raise its price and that increase[d] the price the retailers pa[id]" for the drugs. Oral Argument 18:20-40. Moreover, if the Price Increase Value did not get passed down the supply chain, the wholesalers received less total payment since Lilly's contract reduced its payment of the Distribution Fee by the increase. The logic of the Price Increase Value provision demands that the wholesalers capture that value in the final sale to pharmacies.

certified AMPs and supervised Dixson in her government pricing work, did not recall ever reading the MDRP agreement, or discussing why Lilly first decided to exclude price increase values from AMP; he relied on Dixson.

Dixson also vaguely testified at trial about how she made the decision to exclude price increase values from AMP. Although she was unable to recall any specifics about her thought process, she stated that she would have consulted with Lilly's in-house counsel as a matter of regular practice in the decision. Nonetheless, Lilly lacked any actual documentation justifying why it excluded the price increase values from AMP calculations between 2005 and 2011, despite the MDRP agreement's express requirement to "keep records (written or electronic) of the data and any other material from which the calculations of AMP ... were derived."

Then, in July 2011, a lawsuit that Relator Ronald Streck filed against other pharmaceutical companies became public. Streck alleged that certain manufacturers violated the False Claims Act (FCA) when they submitted AMP calculations to the government that improperly excluded price increases—like Lilly's price increase values—as bona fide service fees. *United States ex. rel. Streck v. Allergan, Inc.*, 894 F. Supp. 2d 584, 587-89 (E.D. Pa. 2012).

The lawsuit prompted Lilly to first document its exclusion of price increase values from its AMP

calculations.[5] As part of that process, in July 2011, Lilly sent CMS a letter explaining its "reasonable assumptions."

That letter described how Lilly would "claw back" wholesaler payments stemming from an increase in price of a wholesaler's on-hand inventory. The company believed that it could "exclude[] service fees paid to wholesalers or distributors, including the claw back adjustment, from its … AMP … calculations." The exclusion was permissible, Lilly contended, because of "CMS's adoption of the bona fide service fee guidance...."

Unsurprisingly, Lilly never received a response from CMS. As Lilly's witnesses recognized at trial, CMS had instructed manufacturers not to send letters outlining reasonable assumptions about AMP. Instead, CMS told Lilly that a "manufacturer [that] disregard[s] these instructions and submit[s] such assumptions," will not have anything reviewed "and their receipt should not be considered as acquiescence to CMS to the submitted assumptions." Dixson sent the letter anyway. Still, she admitted that CMS rarely reacted to Lilly's Medicaid letters. And when CMS had responded, it simply told Lilly that the agency was not reading the submissions and that Lilly should stop sending letters. As the jury saw, Lilly's explanation in the letter that it had every reason to think would go unreviewed was far more fulsome than its later

[5] Lilly originally submitted this exhibit under seal in the district court. It was admitted later at trial and included (unsealed) in Lilly's Appendix on appeal.

response to the CMS audit that Lilly knew government officials would read.

4. Continued Regulatory Changes

Although CMS did not respond to Lilly's 2011 letter, the AMP calculations drew CMS's attention. In 2012, CMS conducted an audit of 20 drug manufacturers (including Lilly) "to determine [whether] AMPs for drugs reimbursed by Medicaid [complied] with Federal requirements." The agency requested that Lilly provide "a description of [its] current AMP calculation methodology including a detailed description of all sales transactions that are included and excluded as well as any price concessions or other remunerations that are included and excluded from the calculation" along with "a listing and explanation of all assumptions made in connection with the AMP calculation."

Lilly responded with a 79-page document that mentioned its price increase value exclusion only once.[6] In a footnote, Lilly explained:

> Lilly also claws back a portion of the value by which a wholesaler's inventory on hand increases due to price changes made by Lilly. These offsets are applied against the service fee payment and are, similarly, excluded from the calculations if the underlying bona fide service fee test elements are satisfied. Lilly presented its position on these offsets to CMS

[6] Lilly also originally submitted this exhibit under seal in the district court. It was admitted later at trial and included (unsealed) in Lilly's Appendix on appeal.

> by letter dated July 25, 2011, but will continue to review the issue.

HHS published its audit report in 2014. The report made various recommendations not relevant to this appeal about future rulemaking opportunities. It did not mention clawback increases.

Lilly's price increase value exclusions started to wind down in 2016. In February of that year, CMS promulgated a final rule that revived the 2007 rule's definition of "bona fide service fees." Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5,170, 5,179-80, 5,347 (Feb. 1, 2016) (codified at 42 C.F.R. §447.502). CMS explained that it continued to believe "price appreciation credits would likely not meet the definition of bona fide service fee." *Id.* at 5,228.[7] That followed because "price appreciation credits are not issued for the purposes of payment for any service or offset for a bona fide service performed on behalf of the manufacturer, but … to adjust (increase) the wholesaler's purchase price of the drugs … when the drugs were purchased at a certain price and are remaining in the wholesaler's inventory at the time the manufacturer's sale price of the drug increased." *Id.*

Lilly met with CMS the following month to discuss its AMP methodology with the agency. There, it again referenced its 2011 letter to CMS as a prior disclosure. At no point did CMS expressly approve or reject Lilly's interpretation of how best to calculate its AMP. In December 2017, Lilly began including price

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[7] "Price appreciation credits" are another industry term for price increase values or clawbacks.

increase values as part of its AMP calculations moving forward, and backdated that practice to April 1, 2016, the month after its meeting with CMS.

C. Procedural Background

In 2014, Streck filed a *qui tam* action against Lilly and 14 other drug manufacturers in the Northern District of Illinois. He alleged that Lilly's falsely lowered AMPs between 2005 and 2017 led to $61 million in Medicaid underpayments, violating the FCA, *see* 31 U.S.C. §3729(a)(1)(A)-(B), (G).

Both Streck and Lilly moved for summary judgment. The district court denied Lilly's motion and granted Streck's motion in part. It reasoned that Lilly's AMP calculations "and related certifications were factually and legally false" under the FCA. At the same time, the questions as to whether Lilly's statements were material or made with scienter advanced to trial.

As discussed in detail later, before and during trial, Streck made several evidentiary arguments implicating how to count the number of FCA violations at issue. The district court denied Streck's various pretrial and evidentiary motions. Then, the parties chose not to submit the issue of counting FCA violations to the jury.

Lilly requested a jury instruction on materiality based on the Supreme Court's decision in *Universal Health Servs., Inc v. United States*, 579 U.S. 176 (2016) ("*Escobar*"). The district court instead gave a jury instruction on materiality directly from the statutory text of the FCA. 31 U.S.C. §3729(b)(4).

The jury returned a verdict in Streck's favor of $61,229,217. The FCA trebled the monetary award to $183,687,651. Lilly appealed, challenging the district court's summary judgment ruling on falsity, as well as the jury's determination on scienter and materiality. Streck cross-appealed, arguing that the district court incorrectly calculated the number of violations under the FCA.

II. Discussion

The False Claims Act "imposes liability on those who knowingly present a false or fraudulent claim for payment or approval" to the government. *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 747 (2023) (cleaned up). The statute expresses Congress's desire to prevent fraud against the federal government, prompted by the "sordid picture of how the United States had been billed for nonexistent or worthless goods, charged exorbitant prices ... and generally robbed in purchasing the necessities of [the Civil W]ar." *Escobar*, 579 U.S. at 181-82 (quoting *United States v. McNinch*, 356 U.S. 595, 599 (1958)).

As relevant for Lilly's appeal, Streck's FCA claims revolved around proving three elements: (1) Lilly presented false claims or records to the government, (2) that it did so "knowingly," and (3) that the false representations were material to the government's decision making. *United States ex rel. Heath v. Wisconsin Bell, Inc.*, 92 F.4th 654, 659-60 (7th Cir.), *aff'd and remanded*, 145 S. Ct. 498 (2025).[8] In his

[8] The claim for payment must also involve government funds, *see Wisconsin Bell, Inc. v. United States ex rel. Heath*, 145 S. Ct.

cross-appeal, Streck attempts to challenge the appropriate damages calculation, but relies on evidentiary rulings and arguments not presented to the district court. We will address each point, but first turn to an overarching issue that we must settle.

A. The Reasonableness of Lilly's AMP Calculation

While the multi-faceted nature of this appeal demands the thorough discussion below, we begin more modestly. The reasonableness of Lilly's assumptions impacts the disposition of its scienter, materiality, and falsity arguments. Thus, much of the dispute between Lilly and Streck reduces to a single question: was Lilly's decision to exclude price increase values from AMP a reasonable one based on the law, its MDRP agreement, and CMS regulations? Without qualification, the answer is no.

1. Excluding Price Increase Values from AMP Was Unreasonable

Throughout trial and on appeal, Lilly pressed a theory of good-faith confusion. According to the company, the regulatory world of Medicaid is hopelessly confusing, rife with byzantine requirements, gaping voids that regulations ought to occupy, and impenetrable ambiguity. Lilly reminds us that Medicaid regulations "are among the most completely impenetrable texts within human experience," that make for "dense reading of the most tortuous kind...." *Abraham Lincoln Mem'l Hosp. v. Sebelius*, 698 F.3d 536, 541 (7th Cir. 2012) (quoting

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498, 502 (2025), but it is undisputed that Streck met his burden on this element.

Rehab. Ass'n of Va. v. Kozlowski, 42 F.3d 1444, 1450 (4th Cir. 1994)). True enough, as a general proposition. "But the question here concerns a specific provision, not the entire Medicaid code," and it is axiomatic that "[c]omplexity in the code as a whole does not mean ambiguity in a specific provision." *Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 24 (D.C. Cir. 2011) (Kavanaugh, J., concurring). It does Lilly no good that parts of the Medicaid statute are complicated, or even that parts of AMP calculation are unclear; the relevant question is solely whether the legal landscape rendered the role of price increase values in AMP calculations ambiguous. After all, "[e]ven the most complicated labyrinth has an outer boundary...." *United States ex rel. Drummond v. BestCare Lab'y Servs., L.L.C.*, 950 F.3d 277, 281 (5th Cir. 2020).

Lilly needed to submit AMPs for each of its Medicaid-covered drugs on a quarterly basis. In an attempt to show the law's confusion, Lilly points to another aspect of AMP calculation. Only drugs that wholesalers sell to retail pharmacies become part of the AMP. 42 U.S.C. §1396r-8(k)(1)(A) (2010); 42 U.S.C. §1396r-8(k)(1) (2005). Lilly highlights how the MDRP fails to exhaustively list which other sales transactions AMPs include. For example, any drug sales to the Department of Defense (as explained at trial) or hospitals are excluded. 42 U.S.C. §1396r-8(k)(1)(B)(i)(IV). But sales to mail order or specialty pharmacies are nary mentioned, so Lilly needed to decide whether those entities fell within the retail pharmacies category. Operating in this gray zone, Lilly tried its best.

We do not disagree that some of the calls Lilly needed to make when calculating AMP were difficult. CMS acknowledged the same, permitting Lilly, in the face of ambiguity, to make and document "reasonable assumptions" consistent with the intent of the Medicaid statute. The bedrock reasonable assumptions principle was established in the 1991 MDRP agreement and reaffirmed in the 2007 and 2016 rules. 72 Fed. Reg. at 39,164 (2007 regulation); 81 Fed. Reg. at 5,209 (2016 regulation). For those decisions outside the law's contemplation and directive—like categorizing mail order or specialty pharmacies under the retail pharmacy umbrella—Lilly right-fully exercised its discretion. CMS, too, recognized as early as 2006 that "determining certain aspects of AMPs are not clear and comprehensive ... [s]pecifically" noting "the need to clarify the definition of retail class of trade … in AMP calculations." We do not question the wisdom of Lilly's decisions on which transactions to include in AMP calculations.

But the issue at bar is not *which* sales mattered—this case has nothing to do with those decisions—but *what revenue* received from retail pharmacy sales counted as the price realized. When turning to this precise question, we cannot follow Lilly's logic.

In his summary judgment order, the late Judge Leinenweber invoked a simple and effective illustration of the pricing scheme. *United States ex rel. Streck v. Takeda Pharms. Am., Inc.*, No. 14-cv-9412, 2022 WL 595308, at *13 (N.D. Ill. Feb. 28, 2022). Assume Lilly sold Drug A to a wholesaler for $10. *Id.*[9]

[9] We changed Judge Leinenweber's hypothetical by one dollar.

The next day, after Lilly raises the price by one dollar, the wholesaler sells the same Drug A to a retail pharmacy for $11. Lilly's contracts with the wholesalers require them to credit Lilly not only the initial $10, but also the additional $1 of price increase. *Id.* Now, the one-hundred-eighty-million-dollar-question: did Lilly sell Drug A for $10 (as Lilly believes) or $11 (as Streck contends)?

As a matter of basic math and economics, it is clearly the latter. *Id.* The point in time of recoupment strikes us as a red herring—the bottom line is the contracts obligated the wholesalers to transmit the full sticker price the retail pharmacies paid. Following Lilly's reasoning to its limits exposes the absurdity of its position. Imagine Lilly sold Drug A to the wholesaler for only $1 and then raised the price to $11 the next day. The wholesaler then sells Drug A for $11 and sends $10 back to Lilly. To say the average price Lilly received for Drug A was $1, rather than $11 ($1 + $10 increase) defies sense. Yet that was precisely Lilly's position.

But more important than tidy examples, the legal framework unequivocally supports our conclusion. We primarily analyze three sources of interlacing authority: §1396r-8 (the statute), Lilly's MDRP agreement, and CMS regulations governing AMP. We make two preliminary points. First, although canons of statutory and contract interpretation are not coterminous, the following analysis deploys interpretive methods accepted across both fields. Namely, the clear plain language and ordinary meaning of a text controls unless it leads to absurd results contrary to the obvious intent of the drafters.

See BKCAP, LLC v. CAPTEC Franchise Tr. 2000-1, 572 F.3d 353, 359-60 (7th Cir. 2009) (discussing this principle in contract law); *Jefferson v. United States*, 546 F.3d 477, 483-84 (7th Cir. 2008) (same for statutory interpretation). And importantly, "[t]he same rules of construction apply to administrative rules as to statute." *Exelon Generation Co., LLC v. Loc. 15, Int'l Bhd. of Elec. Workers, AFL-CIO*, 676 F.3d 566, 570 (7th Cir. 2012). Second, §1396r-8 sculpts our view of the contract and regulations because both subordinate documents explain that any reasonable assumption Lilly made must be consistent with the statute's intent and requirements. 72 Fed. Reg. at 39,164; 75 Fed. Reg. at 69,593-94.

First, since 2005, §1396r-8(k)(1) has consistently defined AMP as "the average price paid to the manufacturer for the drug ... by wholesalers…." (emphasis added). The law draws no distinction between payments received in lump sum or over time, and we see no reason why it should. Amortization is foundational to the American economy. But more, the 1991 MDRP agreement made clear that "[t]he Average Manufacturer Price for a quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized." A CMS Program Release said the same three years later,[10] as did the 2007 regulation. 72 Fed. Reg. at 39,242. So, the plain text of Lilly's contract

[10] CMS Program Releases are not binding regulatory authority. Nonetheless, we find them instructive as supplemental guidance when they mirror other legally controlling documents. At trial, Lilly also admitted that it read and analyzed the Program Releases.

with the government and relevant regulations underscored that it must adjust the AMP if post-sale "arrangements" affected "the price actually realized."[11] Simply put, AMP is the price the manufacturer realizes for its drugs regardless of subsequent arrangements.

Lilly counters that the paragraphs discussing "other arrangements" only detail subsequent discounts or rebates on sales prices, where the AMP would lessen, rather than increase. Thus, Lilly says, it was reasonable to think the catchall "other arrangements" that "subsequently adjust the price actually realized" only contemplated mechanisms leading to lower, not higher AMPs.

Even putting aside that interpretation's irreconcilable tension with the text, it leads us to a nonsensical destination inconsistent with the statute's clear purpose. *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982) ("[I]nterpretations of a statute which would produce absurd results are to be avoided if alternative interpretations consistent with the legislative purpose are available."). Because "[i]t is a fundamental canon of statutory interpretation" that words "must be read in their context and with a view to their place in the overall statutory scheme," we free

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[11] *See E.O.H.C. v. Sec'y United States Dep't of Homeland Sec.*, 950 F.3d 177, 192 (3d Cir. 2020) (stating settled rule that courts interpret contracts in which the federal government is a party according to federal common law); *Est. of Jones v. Children's Hosp. & Health Sys. Inc. Pension Plan*, 892 F.3d 919, 923 (7th Cir. 2018) (noting federal common law "embraces general principles of contract interpretation," including that we give language its plain and ordinary meaning).

ourselves from the isolated provisions. *Roberts v. Sea-Land Servs., Inc.*, 566 U.S. 93, 101 (2012) (citation omitted). Courts must interpret statutes "as a symmetrical and coherent regulatory scheme, and fit, if possible, all parts into a harmonious whole." *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (cleaned up), *superseded by statute on other grounds*.

Recall, Medicaid "is a cooperative federal-state program that provides federal funding for state medical services to the poor." *Frew ex rel. Frew v. Hawkins*, 540 U.S. 431, 433 (2004). Before the MDRP's passage in 1991, "the Medicaid statute did not specifically address outpatient prescription drug coverage." *Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 651 (2003). Congress enacted the MDRP so drug manufacturers shouldered some of the cost to keep government spending manageable. *Vanda Pharms.*, 98 F.4th at 487. Its innovation was to condition a drug company's ability to participate in Medicaid on agreeing to pay some of the cost of the drugs. *Walsh*, 538 U.S. at 652. In this way, Congress advanced Medicaid's goal of providing health insurance to the needy while reducing costs. *Id.* at 663 (plurality opinion). Lilly's reading—that any revenue received for its drugs post-sale is irrelevant to its rebate obligations—defeats the entire MDRP regime.

Tethering pharmaceutical companies' rebates to AMPs works in tandem with another pricing structure in Medicaid—how much the government pays for covered drugs. Medicaid's reimbursement to pharmacies for brand name drugs turns on the "usual and customary" price of the drug to the public. 42

C.F.R. §447.512(b)(2). Putting it together, the government's Medicaid payments depend on the pharmacies point of sale price while the manufacturers' rebates hinge on the compensation they received for the drugs.

Although AMP and "usual and customary" prices the public pays are different calculations, the Medicaid regime only makes sense when these two bear some relation to each other. Lilly's position that the only number that mattered for AMP was the money received when the company first offloaded its drug to the wholesalers, no matter how much subsequent compensation wholesalers remitted, risks opening a chasm between these calculations. An arrangement where Lilly's AMPs only reflected the initial price paid by the wholesalers could result in AMPs dramatically lower than the "usual and customary" price for customers. In other words, the government would still be paying the full cost of the brand name drug—the usual and customary price—but without any meaningful contribution from Lilly—the nominal AMP. Such a reading is not "consistent with the intent" of 42 U.S.C. § 1396r-8, which works by conditioning Lilly's participation in Medicaid on bearing some of its price tag. Lilly asks us to accept a loophole that undermines the law's central conceit. We decline to do so.

2. The Price Increase Values Fail the Bona Fide Service Fee Test

That brings us to Lilly's main objection: price increase values were part of the bona fide services provided by the wholesalers. As discussed, beginning in 2005, Lilly paid the wholesalers a Distribution Fee

for their services (packing, storing, and shipping drugs). The Distribution Fee was a flat percentage of the sales price, approximately 1%. From 2005 to 2009, and then again after 2016, Lilly deducted the value of its price increases from the distribution fee owed. During the six years between 2009 and 2016, the mechanism was simpler: Lilly paid the full distribution fees and invoiced the wholesalers for the clawback amounts every quarter. Regardless of the "form" of the clawbacks, Lilly was adamant at trial that the "substance" of the clawbacks was the same.

So, to go back to Drug A: if Lilly sold Drug A for $10, owed the wholesaler $1 in distribution fee, and was owed $1 in price increase, the distribution fee and price increase would cancel out from 2005 to 2009. Or, in the 2009 to 2016 period, the wholesalers would simply send $1 back in cash.

The parties agree that Lilly properly excluded the flat Distribution Fee as a bona fide service fee from the AMP calculation.[12] Bona fide service fees represent compensation to wholesalers for their "itemized service[s] ... that the manufacturer would otherwise perform (or contract for) in the absence of the service agreement…." 72 Fed. Reg. at 39,240. We focus on two requirements for a transaction to qualify as a "bona fide service fee." One, it cannot be "paid by, or passed through to" retail pharmacies. 42 U.S.C. §1396r-8(k)(1)(B)(ii); 72 Fed. Reg. at 39,240. And two, it must

[12] While the term bona fide service fee does not appear until CMS's 2007 regulation, Streck appears to accept that Lilly could reasonably exclude bona fide service fees from the calculation as early as 2005.

be a fee "paid by manufacturers to wholesalers." 42 U.S.C. §1396r-8(k)(1)(B)(i)(II); 72 Fed. Reg. at 39,240.

Lilly claims to view the clawbacks as part of the bona fide service fee. Streck argues that the clawbacks are unrelated to the fee. Lilly writes in its opening brief:

> From the outset, Lilly and wholesalers agreed to calculate quarterly payments by offsetting the value of any price appreciation in Lilly's products in the wholesalers' inventories, treating that as a form of compensation to the wholesalers.[13] As a result, Lilly consistently viewed price-appreciation value as part of wholesaler compensation and thus its bona fide service fees (merely offsetting further *monetary* payments)—not as a separate revenue stream to Lilly, much less an adjustment to the wholesaler's *acquisition* price.

The best we can make of this somewhat convoluted explanation is that Lilly considered the Price Increase Value mechanism an in-kind payment to the wholesalers. Instead of paying cash to the wholesalers for their services, Lilly gave them something of equivalent worth, a more valuable drug to sell. Or, to use a lay example, it was akin to paying for something with an expensive baseball card, rather than currency.

At a high level of generality, Lilly's point has some merit. True enough, hard cash is not the only medium

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[13] This is not factually accurate. From 2009 to 2016 Lilly paid the entire Distribution Fee in cash, and the wholesaler compensated the full price increase the same way.

with recognizable value. Lilly could have paid the wholesalers in gold, tradeable commodities, or valuable antiques. None of those decisions would have likely affected the bona fide service test.

But we do not operate on a general level—we look at the facts in front of us. Lilly's "in-kind" payment was not an antique with independent market value, but a commodity that Lilly chose, at its sole discretion, to increase in price after the wholesaler took possession. Recognizing Lilly's near-total market power is critical to appreciating how the company's interpretation was an easy tool for graft. Because Lilly had complete control over price, it could sell drugs to wholesalers at depressed prices, followed by a pre-planned, immediate, and steep increase, which the wholesalers would have to pay. If the subsequent price hike was an excludable "bona fide service fee," Lilly could unilaterally exploit the timing of the wholesalers' payments to manipulate its AMP, and corresponding rebate to the government. That gaping loophole finds no home in the relevant law.

Concretely, the clawbacks unequivocally failed both relevant elements of the bona fide service test: (1) the wholesalers passed the increases down to the retail pharmacies, and (2) they were not payments by a manufacturer. 42 U.S.C. §1396r-8(k)(1)(B)(i)(II), (ii); 72 Fed. Reg. at 39,240.

Lilly concedes (for good reason) that the price increases were "passed through to" retail pharmacies. 42 U.S.C. §1396r-8(k)(1)(B)(ii). In fact, that was the entire premise of the claw-backs. The clawback provision originated to smooth out the pre-2005 lumpy distribution networks while ensuring wholesalers

could not double-dip on their compensation. That is, once Lilly was paying a flat fee for the distribution services, the wholesalers should not profit by exploiting subsequent price increases against retail pharmacies. The fix—the clawback provision—ensured Lilly captured the price that the retail pharmacies paid, regardless of how much wholesalers were initially charged. No doubt the entire reason the wholesalers agreed to accept this form of "in-kind" compensation from Lilly was because they could sell the drugs at higher prices to the pharmacies and receive more revenue. No matter how we slice the issue, nor how many syntactical configurations Lilly conjures, the basic fact is that Lilly recouped the value of the prices retail pharmacies paid for its drugs, whether by cash or credit.

This brings us to Lilly's second failure to meet the bona fide service fee test. The wholesalers paid Lilly the clawback value—an inescapable conclusion—not the reverse. *Cf.* 42 U.S.C. §1396r-8(k)(1)(B)(i)(II). And the wholesalers could only afford to do so because the retailers made up the difference by buying the marked-up drugs. Say Lilly owed the wholesaler $5 in distribution fees, and price increases credited Lilly $1. Lilly pays the wholesaler $4 for its fee, and then the wholesaler obtains the last dollar by selling the drugs to pharmacies for a dollar more. The wholesaler credits Lilly the dollar, and the pharmacies, not Lilly, pay the wholesaler the final dollar of the distribution fee.[14] But only fees paid *by Lilly*, not pharmacies,

[14] And we reiterate, from 2009 to 2016, Lilly would pay the full $5 in distribution fee and bill the wholesalers the subsequent

count as bona fide services. 42 U.S.C. §1396r-8(k)(1)(B)(i)(II).

Before turning to the False Claim Act, we briefly note our divergence with an unpublished, and non-precedential, order from the Third Circuit. The panel appeared to accept that clawbacks changed the cumulative price of a drug but the "absence" of "temporal language g[ave them] pause … that 'price' unambiguously refer[red] to the cumulative price paid, rather than the initial price paid." *United States v. Aller-gan, Inc.*, 746 F. App'x 101, 108 (3d Cir. 2018). Because "price," as written in the Medicaid statute, did not clearly encompass post-sale compensation, the panel found that manufacturers reasonably disclaimed clawbacks from AMP. *Id.*

We have no qualms with whether "price" "lack[s] tem-poral limitations…." *Id.* The price of a good is simply the "consideration given for the purchase of a thing" or the "[s]um of money which an article is sold for[.]" Price, Black's Law Dictionary 1353 (4th ed. 1968). This definition comports with common knowledge that prices might be paid over time, rather than in one lump sum. From consumer transactions like purchasing a home with a mortgage to multi-billion-dol-lar business deals funded by debt, buyers often pay the "price" long after the initial exchange. There is nothing unu-sual about a business selling a product to another business and agreeing to longer payment schedules. Injecting a rigid distinction between "initial" and "cumulative" price not only

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dollar increase. Under that arrangement, we cannot see how Lilly was "paying" the wholesalers any price increase.

betrays the ordinary understanding of "price," but leads to the implausible scenarios we have already described: under Lilly's logic a manufacturer could "sell" its drug for a nominal fee, send it to the wholesaler, and claw back a subsequently increase price, all the while reporting the trivial "initial" price as the AMP.[15]

B. Falsity and Scienter

Because we once said "it is impossible to meaningfully discuss falsity without implicating the knowledge requirement" of the FCA, we address them together. *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999). We stress, however, that while perhaps interrelated, falsity and scienter are separate questions. In so doing, we discuss our case law and developments from the Supreme Court, which together lay out the relationship between these elements. *See Escobar*, 579 U.S. at 192 (distinguishing "rigorous" scienter requirement from falsity element); *SuperValu Inc.*, 598 U.S. at 747-49 (discussing scienter requirement alone).

We apply different standards of review to each element. Because the district court granted Streck's motion for summary judgment as to falsity, we review that determination *de novo*, "viewing all evidence and drawing all reasonable inferences in the non-moving

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[15] More recent decisions from at least one district court in the Third Circuit have strongly indicated that Price Value Increase should be part of AMP calculations because there "is nothing ambiguous" about how the statutes apply to them. *United States ex rel. Streck v. Bristol-Myers Squibb Co.*, 370 F. Supp. 3d 491, 497 (E.D. Pa. 2019).

party's favor." *EEOC v. Charter Commc'ns, LLC*, 75 F.4th 729, 732 (7th Cir. 2023). We affirm "if 'there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.'" *United States v. King-Vassel*, 728 F.3d 707, 711 (7th Cir. 2013) (quoting Fed. R. Civ. P. 56(a)).

Our review of scienter, however, is more constrained. Because Lilly seeks to disturb a jury finding, we only reverse if "a reasonable jury would not have a legally sufficient basis to find for the party on that issue." *Price v. Carri Scharf Trucking, Inc.*, 140 F.4th 861, 866 (7th Cir. 2025) (citation omitted).[16] We "construe the facts strictly in favor of the party that prevailed at trial," including "drawing all reasonable inferences in that party's favor and disregarding all evidence favorable to the [losing] party that the jury is not required to believe." *May v. Chrysler Grp., LLC*, 716 F.3d 963, 971 (7th Cir. 2013) (citation omitted). We do not make credibility determinations or weigh evidence, because those are "jury functions, not those of a judge." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000) (citation omitted). "In other words, our job is to decide whether a highly charitable assessment of the evidence supports the jury verdict or if, instead, the jury was irrational to reach its conclusion." *May*, 716 F.3d at 971.

[16] Lilly also moved for a new trial under Rule 59, but those arguments only relate to some of its falsity and materiality contentions.

1. The AMP Submissions Were False as a Matter of Law

We begin with falsity. The FCA does not define "what makes a claim 'false' or 'fraudulent,'" so we turn to "the well-settled meaning of the common-law" because "it is a settled principle of interpretation that, absent other indication," Congress intends that use. *Sekhar v. United States*, 570 U.S. 729, 732 (2013); *see also Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 187-93 (2015) (applying the common law falsity definition to a federal statute regulating securities fraud). A false statement encompasses any "words or conduct" that "amount[ ] to an assertion not in accordance with the truth." Restatement (Second) of Torts §525 cmt. b (1977).[17]

Some questions of falsity are rather easy—if someone says the weather is sunny, when it is actually raining, the statement is "literally" and factually false. *United States v. Molina Healthcare of Illinois, Inc.*, 17 F.4th 732, 741 (7th Cir. 2021). But the inquiry can be a bit trickier for legal falsity, which rests "on a false representation of compliance" with a statute, regulation or contract. *United States ex rel. Davis v. District of Columbia*, 793 F.3d 120, 124 (D.C. Cir. 2015). When the certified laws in question are subject

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[17] The Supreme Court recently clarified that "misleading" statements are not false under 18 U.S.C. §1014. *See Thompson v. United States*, 145 S. Ct. 821, 825, 828 (2025). *Thompson* analyzed a different statute and thus likely does not impact the FCA. Either way, our analysis rests on finding the AMP certifications were false as a matter of law, not merely misleading.

to "differences in interpretation growing out of a disputed legal question," the legal falsity question can be challenging. *Lamers*, 168 F.3d at 1018.

Relying on *Lamers*'s suggestion that reasonable interpretations of the law cannot be "false," Lilly argues its AMP certifications were the product of reasonable interpretations of the relevant legal framework. But as discussed at length, *supra*, Lilly's exclusion of clawbacks from AMPs was not objectively reasonable since it contradicted the plain text of the law, regulations, and MDRP agreement, ran against the MDRP's obvious purpose, and resulted in absurd consequences. So, Lilly's falsity argument fails at the outset.

But we ought to say a few more words about "objective falsity" because of its ubiquity across FCA cases. In *Lamers*, the relator alleged that the City of Green Bay had falsely characterized certain public transit bus routes as compliant with federal law when applying for federal funding. *Id.* at 1015, 1019. The question we found dispositive was whether Green Bay knew its routes ran afoul of federal law. *Id.* at 1018-19. We held a violation of the FCA only occurs when someone "knowingly lies" to the government. *Id.* at 1020.

Lilly attempts to use *Lamers* for the proposition that reasonable interpretations of a regulation cannot be false as a matter of law. However, even Lilly apparently acknowledges the interpretation must be reasonable, which we conclude was not the case here. And reading reasonableness out of that requirement would lead to an absurd result where even an admittedly unsupported legal interpretation by a

sophisticated company like Lilly could defeat any FCA claim.

Subsequent Seventh Circuit precedent focuses the question on whether a defendant's representations of regulatory compliance contradicted the terms of its contract with the government. *United States ex rel. Yannacopoulos v. Gen. Dynamics*, 652 F.3d 818, 825-29 (7th Cir. 2011) (holding that defend-ant did not submit a false certification of a contractual provision after determining defendant had abided by the contract's terms). In that inquiry, we simply deploy our well-worn tools of statutory and contract interpretation to answer the falsity question. *Id.*

Turning the falsity question into a contest of reasonableness incurs additional costs. First, it would place an incredible burden on government drafters to avoid any potential ambiguity in complex regulatory environments, or else forfeit its ability to recover against fraudsters. *United States ex rel. Chilcott v. KBR, Inc.*, 2013 WL 5781660, at *7 (C.D. Ill. Oct. 25, 2013).[18] "Congress cannot anticipate (much less account for) every future statutory skirmish," and courts are not to "hold Congress to a 'perfect as we see it' standard of drafting." *Esteras v. United States*, 145 S. Ct. 2031, 2042 (2025). And second, accepting Lilly's argument would "incentivize the intentional twisting of language in order to find profitable erroneous interpretations of the controlling text," even when every-one is "well-aware of its intended meaning." *Chilcott*, 2013 WL 5781660 at *7.

[18] We find the analysis in this unpublished decision persuasive.

The Supreme Court's decision in *Escobar* cuts against Lilly's approach. In *Escobar*, a medical provider lied about the qualifications and supervision of its staff when submitting claims for payments to Medicaid. *See Escobar*, 579 U.S. at 183-85. The Court concluded that regulatory noncompliance can trigger FCA liability when the defendant makes affirmative misrepresentations about its goods or services, and the non-compliance implicates a material requirement of its government contract. *Id.* at 190. Accordingly, *Escobar* urged a broad, rather than "circumscribed view of what it means for a claim to be false or fraudulent," because "concerns about fair notice and open-ended liability can be effectively addressed through strict enforcement of the [FCA's] materiality and scienter requirements," which are "rigorous." *Id.* at 192 (cleaned up).

Then seven years later, the logic of *SuperValu* essentially foreclosed the argument Lilly now forwards. There, certain retail pharmacies faced FCA liability for billing Medicaid inflated "usual and customary" prices for their drugs that excluded significant discounts offered to consumers. *SuperValu, Inc.*, 598 U.S. at 743, 745. The question was whether the pharmacies "could have the scienter required by the FCA if they correctly understood" their reported prices were contrary to the regulation "and thought their claims were inaccurate," even though their interpretation was "objectively rea-sonable." *Id.* at 743, 748. The Supreme Court held what mattered was the defendant's "knowledge and subjective beliefs—not ... what an objectively reasonable person may have known or believed." *Id.* at 749. "The facial ambiguity"

of a regulation "does not by itself preclude a finding of scienter under the FCA." *Id.* at 754.

To be clear, falsity was not at issue in *SuperValu*. But its reasoning implies that the Supreme Court sees falsity as a black-and-white, objective issue and considers state-of-mind at the scienter phase. This reflects the point made in *Chilcott*. 2013 WL 5781660 at *7. At bottom, we reject all variants of Lilly's falsity argument. Because the statute, MDRP agreement, and regulations were clear that Lilly's AMP methodology was improper, the company was not entitled to make reasonable assumptions on this point. But even if Lilly were, its decision to exclude clawbacks was so far afield from the law that the assumption was unreasonable, and therefore finds no refuge in the "reasonable assumptions" framework.[19]

2. The Jury Reasonably Found Lilly Acted with Scienter

Scienter is a closer call. Lilly is right that when the government refuses to accept an explanation of an interpretation, it cannot then turn around and cry foul. Were that the story, we may well have to reverse the jury verdict. But there were two relevant instances of Lilly partially informing the government of its calculations and assumptions. After comparing the opaque and misleading explanation Lilly knew the government would read to the clear and thorough one it knew the government would never open, the jury

[19] For the same reasons we do not think the law was ambiguous as applied to Lilly's AMP methodology, we find Lilly's cursory objection on due process grounds meritless.

was free to find Lilly acted with a culpable state of mind.

A defendant "knowingly" makes a false statement when it speaks with (i) "actual knowledge" of the statement's falsity; (ii) "deliberate ignorance of the truth or falsity of the information;" or, (iii) "in reckless disregard of the truth or falsity of the information…." 31 U.S.C. §3729(b)(1)(A)(i)-(iii). "Deliberate ignorance" describes the defendant who is "aware of a substantial risk that [its] statements are false, but intentionally avoid[s] taking steps to confirm the statement's truth or falsity." *SuperValu Inc.*, 598 U.S. at 751 (citing Black's Law Dictionary 672 (5th ed. 1979)("[v]oluntary ignorance")).

Although "[i]nnocent mistakes or negligence are not actionable" under the FCA, a defendant acts with "reckless disregard"—the most "capacious of the three" mental states—when it "had reason to know of facts that would lead a rea-sonable person to realize that [it] was causing the submission of a false claim," or "failed to make a reasonable and prudent inquiry into that possibility...." *King-Vassel*, 728 F.3d at 712-13 (citing *Yannacopoulos*, 652 F.3d at 832). When amending the FCA to include "reckless disregard," Congress explained it wanted "to reach what has become known as 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) *as reprinted in* 1986 U.S.C.C.A.N. 5,266, 5,286. That language reflected the Supreme Court's admonishment from two years prior: "Protection of the public fisc requires that those who seek public funds

act with scrupulous regard for the requirements of law[,] ... those who deal with the Government are expected to know the law," and have "a duty to familiarize [themselves] with the legal requirements for cost reimbursement." *Heckler v. Cmty. Health Servs. of Crawford County, Inc.*, 467 U.S. 51, 63-64 (1984).

With complex government programs like Medicaid and Medicare, "[t]here is simply no requirement the Government anticipate every problem that may arise…." *Id.* at 64. In such situations, the recipient of public funds has a duty to make a reasonable and prudent inquiry of the law under the circumstances. *United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 892 F.3d 822, 838 (6th Cir. 2018).

We review the jury's scienter finding deferentially. As a preliminary matter, the district court's jury instructions properly tracked the three culpable mental states outlined in the FCA. Contrary to Lilly's objection on appeal, the instructions specifically cautioned that Lilly would "not act knowingly if its conduct was the result of an innocent mistake or negligence."

Once again, Lilly's objectively unreasonable interpretation of the relevant law is highly probative circumstantial evidence of a culpable state of mind. *Cf. Astellas US Holding, Inc. v. Fed. Ins. Co.*, 66 F.4th 1055, 1072 (7th Cir. 2023) (stating that actions "contrary to regulatory guidance" and "objectively unreasonable" can make out FCA knowledge requirement). The decision to exclude the clawbacks was not "based on reasonable but erroneous

interpretations of [Lilly's] legal obligations." *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 287-88 (D.C. Cir. 2015). If we thought the regulations were "ambiguous" or Lilly's interpretation of the guidance was "reasonable" we might look at the verdict differently. *See United States ex rel. Gugenheim v. Meridian Senior Living, LLC*, 36 F.4th 173, 181 (4th Cir. 2022). As we have detailed, Lilly's interpretation would condone an egregious exploitation of the relevant law, allowing it to sell drugs at artificially low prices, obtain the full value in subsequent clawbacks, yet report the initial depressed prices for AMP. The jury was entitled to consider the unreasonableness of that view in finding scienter.

The jurors also heard ample evidence to allow them to infer that Lilly either was aware of, or disregarded, an unjustifiable risk of skirting the law and chose to obfuscate rather than conduct a reasonable inquiry. We begin with Heather Dixson, Lilly's government pricing specialist. She took that position in 2005, the same year the new wholesaler contracts with the clawback provisions took effect. Despite this substantial change in the wholesaler-manufacturer relationship—Lilly started paying wholesalers a Distribution Fee and recouping price increases rather than wholesalers profiting off of arbitrage—Dixson could not specifically recall conferring with any of her supervisors about how she decided to exclude clawbacks from AMP reporting.

And Dixson's supervisors, including one who certified the AMP submissions as true and accurate to the government, consistently disavowed any knowledge of how Lilly made the decision to exclude

clawback increases. That certainly raises the question of what the executives' certifications were based upon, a pointed question the jury was free to infer against Lilly. And as far as the jury heard, Lilly did not turn to its well-stocked armory of legal advisors. Lilly chose to forgo an advice-of-counsel defense. *See United States v. Al-Shahin*, 474 F.3d 941, 947-48 (7th Cir. 2007) (explaining doctrine that a defendant who in good faith relies on attorney advice can rebut charges of fraud). While one of Lilly's lawyers testified about assisting Dixson with government pricing generally, the company decided not to "affirmatively put at issue a specific communication" from counsel about AMP calculations. No doubt, Lilly was free to choose its trial strategy and certainly had no obligation to mount such a defense. Still, the question remains: on what information did the certifiers base their signatures?

At the same time, evidence showed that Lilly knew how much the clawbacks were worth. For accounting purposes, Lilly treated price clawbacks as revenue from the beginning. A chart from presentations to Lilly's senior leadership, reproduced below, detailed the hundreds of millions of dollars earned from 2009 to 2016 through clawbacks.

These documents were key points in negotiations over the wholesaler contracts. Even for a company of Lilly's size, the numbers were large. The clawbacks often approached $100 million a year.

A jury could reasonably view Lilly's deliberate choice to assign Dixson, a middle-management employee, the unchecked and unreviewed discretion over a decision affecting substantial revenue as willfully turning a blind eye to its legal obligations. And more, despite the entirely new distribution scheme, senior Lilly management and the AMP certifiers never bothered to learn why clawbacks were excluded from a drug's AMP, deferring instead to Dixson.

The culpability of Lilly's don't-ask-don't-tell approach crystallized in the years following 2005. Importantly, the MDRP agreement explicitly required that Lilly memorialize how it calculated AMP, including the reasonable assumptions it made. Despite this requirement, Lilly could not produce one shred of paper through 2011 that even discussed the clawback feature, let alone explain why it was

reasonable to exclude it from AMP. Instead, the jury saw that every time Lilly documented and described its AMP methodology to the government, it generally explained its exclusion of bona fide service fees while omitting *how* it calculated that fee; namely, by omitting the crucial fact that it counted clawbacks as part of bona fide service fees despite obviously failing that test. Dixson testified that she was transparent with the government as early as 2005 when she explained to CMS in another letter that Lilly excluded bona fide service fees from AMP. However, Lilly's erasure of all mentions of clawbacks in this letter could be seen as misdirection rather than clarification.

Lilly counters with a plausible alternative. The company failed to mention the clawback provision because it genuinely thought clawbacks were a bona fide service fee. While the evidence lends some support to that view, it does not command it, as it must for reversal. *See Dadian v. Vill. of Wilmette*, 269 F.3d 831, 838 (7th Cir. 2001) (reversal not warranted when a reasonable jury could support verdict, while acknowledging "reasonable men and women" could have come to the opposite conclusion). There was sufficient evidence for the jury to rely upon to find that Lilly was not following a genuine, incorrect interpretation of the term "bona fide service fee."

Still, Lilly claims it did eventually tell the government about the clawback treatment. After Streck brought his 2011 lawsuit, Lilly sent CMS a letter including a two-page explanation for why it believed the clawbacks were part of a bona fide service. Then, two years later in a written response to the government's AMP audit, a mere footnote stated

"Lilly also claws back" price increases and "exclude[s them] from the [AMP] calculations if the underlying bona fide service fee test elements are satisfied." The government never responded to Lilly's 2011 letter and concluded in its audit that manufacturers' methodologies "to determine AMP were generally consistent with Federal requirements."

We continue to believe that when "the government knows and approves of the particulars of a claim for payment before that claim is presented, the presenter cannot be said to have knowingly presented a fraudulent or false claim." *United States ex rel. Durcholz v. FKW Inc.*, 189 F.3d 542, 545 (7th Cir. 1999). But "merely showing *some* government knowledge" of the falsity is not enough; there must be evidence of the government's "cooperation and collaborative problem-solving" or "explicit approval" to undercut scienter. *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 755-57, 759 (3d Cir. 2017) (synthesizing this principle from across sister circuits).

Here again, the evidence goes both ways. The jury was entitled to view Lilly's 2011 CMS letter, in conjunction with its disclosures in 2013, as continued efforts to hide the ball. The 2011 letter was indisputably a candid admission (the first one) of how Lilly excluded clawbacks. However, the government had repeatedly warned Lilly not to send CMS letters explaining its reasonable assumptions. The only response Lilly ever received to its reasonable assumption letters was to stop sending them. Thus, it seems Lilly knew the missive was dead on arrival. At the same time, multiple Lilly employees testified that

they were on first-name bases with CMS employees, had their telephone numbers, and could arrange meetings to communicate with them when needed. When confronted with the "big red flag" of Streck's 2011 lawsuit alleging clawbacks needed to be part of AMP, Lilly curiously chose to "inform" the government of its methodology through a medium CMS flatly rejected, rather than utilize the email addresses or phone numbers it regularly used. That can be seen as no inquiry at all, let alone a reasonable one.

Finally, the 2013 disclosure casts the 2011 letter in a decidedly damaging posture. Whatever shield Lilly thinks the letter serves, a jury could reasonably view it as a cutting sword. Unlike the 2011 letter, the government solicited Lilly's 2013 audit response, so Lilly had every reason to know CMS would read it. But there, Lilly's explanation of the clawback methodology was far from fulsome. In contrast to the 2011 letter's two-page description, Lilly incorporated an equivocal and partial explanation in a footnote: clawbacks were only excluded "if the underlying bona fide service fee test elements are satisfied." A reasonable factfinder could find this highly deceptive. Again, the clawbacks definitively did not satisfy the bona fide service fee test. Lilly's footnote, then, simply restated the law—Lilly excluded financial transactions that met the bona fide service fee test from AMP. What Lilly did not say in 2013, but did in the 2011 letter, was *why* Lilly thought the clawbacks always met the bona fide service fee test. True, Lilly referenced its 2011 letter in the 2013 response, but a reader would have no reason to dig the letter up—according to the 2013 response, Lilly was following the law.

Lilly's stark turnabout in content and tone when it knew government officials were reading, versus when it knew they were not, is revelatory evidence of "'ostrich-like' conduct ... where corporate officers insulate themselves from knowledge of false claims submitted by lower-level subordinates." *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1274 (D.C. Cir. 2010) (cleaned up). So too is it proof of the company "bur[ying its] head in the sand and fail[ing] to make simple inquiries which would alert [it] that false claims are being submitted." *Yates v. Pinellas Hematology & Oncology, P.A.*, 21 F.4th 1288, 1303 (11th Cir. 2021) (citation omitted).

Given Lilly's 2013 submission, the jury need not have credited that the government was aware of Lilly's AMP calculations before the February 2016 meeting. Thus, the government's conclusion in its 2014 audit that Lilly's reported methodology was "generally" consistent with federal requirements was a non-sequitur. Following this reasonable view of events, the 2013 response hid the key point. Only in 2016 did the evidence incontrovertibly show that Lilly directly told CMS that it did not include clawbacks in AMP. The rule published at that time explicitly cautioned against that method, and Lilly ceased the practice the following year. 81 Fed. Reg. at 5,228.

We express our dismay at the government's lethargy, or perhaps regulatory capture. The government allowed companies to make reasonable assumptions. The incentives to abuse this discretion are as clear as the opening bell on the New York Stock Exchange. Yet the government says it would not so much as review a letter. That policy runs the risk of

rule-making by regulatory prosecution. Moreover, the lack of industry-wide oversight likely cost taxpayers dearly. And, it made this case a close call demanding the expenditure of a great deal of judicial resources, both in the district court and on appeal.

C. Materiality

Like scienter, the jury heard evidence regarding materiality. We review deferentially. A statement is material if it has "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. §3729(b)(4). The "inherently fact-specific" nature of materiality eschews bright-line rules in favor of a particularized examination as to whether the misrepresented information could affect a decisionmaker. *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 39-41 (2011) (rejecting, in securities context, categorical rules that "artificially exclude" potentially important information) (citation omitted).

"[T]he materiality standard is demanding." *Escobar*, 579 U.S. at 194. A misrepresentation is not "material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment." *Id.* at 190. As explained in *Escobar*, "minor or insubstantial" noncompliance with a federal law, like a contractor failing to disclose its use of "foreign made staplers" in a shipbuilding contract, notwithstanding a regulation to the contrary, is immaterial when "the Government routinely pays claims despite knowing that foreign staplers were used." *Id.* at 194-96. The materiality question is holistic. Among the non-dispositive factors to consider: (1) "the Government's

decision to expressly identify a provision as a condition of payment," (2) whether the government continued to make payments after learning of the falsehood, and (3) whether the misrepresentation cuts to the "very essence of the bargain" at issue. *Id.* at 194-95, 193 n.5.

Our recent application in *United States ex rel. Heath v. Wisconsin Bell, Inc.* is insightful. Wisconsin Bell faced allegations of violating the FCA by submitting falsely inflated bills to the federal government for its information and telecommunications services. *Heath*, 92 F.4th at 657-60. Like with the Medicaid program, the federal government subsidizes these services to schools and libraries in lower income areas. *Id.* at 657. To cabin those costs, service providers "must follow what is known as the 'lowest-corresponding' price rule and offer schools and libraries 'the lowest price charged to non-residential customers who are similarly situated.'" *Id.* at 658 (quoting 47 C.F.R. §54.500) (cleaned up). Despite knowledge of the rule, Wisconsin Bell did not comply with it for over a decade, all the while submitting invoices to the government for partial reimbursement. *Id.* at 658-59.

We rejected Wisconsin Bell's argument's that violations of the "lowest-corresponding price" rule were immaterial. *Id.* at 664. Distinguishing *Escobar*'s hypothetical stapler example, we explained that the amount of federal money paid was "tied directly to the lowest-corresponding price rule." *Id.* at 664-65. The rule served as "one mechanism" to "keep [telecommunications] services affordable to schools and libraries." *Id.* at 665. Because the "entire purpose" of the program was "to keep costs low," it was

"reasonable to infer that if the government knew of actual overcharges, it would not approve [the] claims." *Id.* In other words, because the misrepresentation went "to the very essence of the bargain," it was material. *Escobar*, 579 U.S. at 193 n.5.

The MDRP framework closely parallels *Heath*. Replace providing telecommunications to underserved communities with furnishing healthcare to the poor and vulnerable. To cabin costs of Medicaid, the government requires manufacturers to pay a percentage of its covered drugs through AMP rebates. If the manufacturers falsely depress that number in violation of the statute, the manufacturers' rebates go down, and the government's payments go up. So, like in *Heath*, the jury was allowed to find the federal government's Medicaid costs and ability to insure the poor were "tied directly" to accurate AMP calculations. 92 F.4th at 665.

Noncompliance with the law resulting in large price differentials in how much the government owes "offers strong support for a finding of materiality." *Molina*, 17 F.4th at 743. AMPs are "a foundational part" of the Medicaid framework, so artificially lowered numbers are not "minor or insubstantial" violations. *United States v. Luce*, 873 F.3d 999, 1007 (7th Cir. 2017) (citation omitted). And more, the certification statement and Lilly's MDRP agreement expressly required the AMP submissions to be in compliance with the MDRP statute and relevant regulations. *Escobar*, 579 U.S. at 194 (noting government's "decision to expressly identify a provision as a condition of payment is relevant"). Giving accurate AMPs was so critical that, under its

MDRP agreement, Lilly faced potential damages of up to $100,000 for "each item" of false information submitted. Since the law and regulations identified here were central to the AMP framework, the requirement to comply with them is probative evidence of materiality. *United States ex rel. Bibby v. Mortg. Invs. Corp.*, 987 F.3d 1340, 1352 (11th Cir. 2021) (reasoning that certifications with law are relevant for materiality when the conditions bear a relationship to the relevant payment).

No doubt, the government's inaction after 2016 "is evidence of immateriality," but it is not on its own "*dispositive*." *United States v. Care Alternatives*, 81 F.4th 361, 375 (3d Cir. 2023). The substantial amount of money misrepresented (hundreds of millions of dollars), the AMP's centrality to the Medicaid program, and the importance of Lilly's drugs to Medicaid all support the jury's verdict. *See United States v. Corp. Mgmt., Inc.*, 78 F.4th 727, 738 (5th Cir. 2023) (affirming jury finding of materiality even though government kept paying defendant where payments were necessary to keep critical access hospital open and there was a substantial amount of money at stake), *cert. denied sub nom.*, 144 S. Ct. 694 (2024). The Supreme Court has never said that government knowledge categorically defeats materiality. Rather, it favors holistic attention to the facts. *Basic Inc. v. Levinson*, 485 U.S. 224, 236 (1988) ("Any approach that designates a single fact or occurrence as always determinative of an inherently fact-specific finding such as materiality, must necessarily be overinclusive or underinclusive.").

Escobar did not change this well-settled understanding. In a vacuum, government payment in full despite "actual knowledge" of the misrepresentation is "very strong evidence" of immateriality. *Escobar*, 579 U.S. at 195. But the facts presented give reasonable alternative explanations for the government's continued payments after the 2016 meeting without rendering the jury's materiality finding irrational. *See Molina*, 16 F.4th at 744. "It may have needed time to work out a way not to prejudice Medicaid recipients who had nothing to do with this problem." *Id.* And Lilly backdated including price increases in AMP to shortly after its 2016 meeting with CMS.

Even more, while Lilly formalistically told the government how it calculated AMP in 2016, Lilly did not explain the consequence of the clawback decision—namely the six-hundred-million-dollar implications. We are wary of imputing "actual knowledge" on the government when it was not told that it had spent tens of millions of dollars it should not have due to Lilly's calculations. *Care Alternatives*, 81 F.4th at 375 (affirming materiality verdict because extent of government's knowledge was unclear). And recall, a statement is material when it is "'capable of influencing' a decision even if those who make the decision are negligent and fail to appreciate the statement's significance." *United States v. Rogan*, 517 F.3d 449, 452 (7th Cir. 2008). That standard is especially relevant here because the federal government "is entitled to guard the public fisc ... by insisting that persons who send bills to the Treasury tell the truth." *Id.*

1. The Materiality Instruction Was Accurate

"We review the legal accuracy of jury instructions *de novo*, but we evaluate their particular phrasing for abuse of discretion." *United States v. Siepman*, 107 F.4th 762, 765 (7th Cir. 2024) (citing *United States v. Edwards*, 869 F.3d 490, 496 (7th Cir. 2017)). So long as the "instructions accurately reflect the law, we will reverse only if it appears that the instructions both misled the jury and prejudiced the defendant." *Id.* (citation omitted). "A district judge is not obligated to describe all valid legal principles in his instructions." *Carter v. City of Wauwatosa*, 114 F.4th 866, 880 (7th Cir. 2024) (quotation omitted). On the contrary, "[a] judge's decision to instruct the jury using the statutory language hardly deprive[s] the defendants of a fair trial." *United States v. Durham*, 766 F.3d 672, 683 (7th Cir. 2014). We have additionally emphasized that a "less is more" principle is often appropriate when announcing jury instructions that include multiple relevant factors to avoid confusion. *United States v. Johnson*, 916 F.3d 579, 586 (7th Cir. 2019).

The materiality jury instruction was a correct statement of law. It came straight from the FCA's text: "[T]he term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Escobar*, 570 U.S. at 192-93 (quoting 31 U.S.C. §3729(b)(4)). Nothing in *Escobar* suggests it changed this well-settled definition. To the contrary, the decision emphasized that "[u]nder any understanding of the concept, materiality looks to the effect on the likely or actual behavior of the recipient of the alleged

misrepresentation." *Id.* at 193 (cleaned up). True, the Court listed several non-dispositive factors courts should consider. *Id.* at 193-95. But those factors were exactly that—non-dispositive in a holistic inquiry. *See United States v. Brown*, 724 F.3d 801, 803 (7th Cir. 2013) (noting it "can be easier" to conduct "holistic analysis" rather than "trudge through factors").

So, the district court correctly stated the law in fashioning its jury instructions on materiality—an "inherently fact-specific finding" requiring balancing of evidence—and it did not abuse its discretion in doing so. Indeed, pattern jury instructions from our Circuit and across the nation reflect the same substantive instruction when defining materiality in analogous false statement contexts. *See, e.g.*, The William J. Bauer Pattern Criminal Jury Instructions of the Seventh Circuit, at 207, 439, 596, 629, 743, 1071 (2023) (same "natural tendency to influence" or "capable of influencing" definition for criminal statutes concerning false statements); Sixth Circuit Pattern Criminal Jury Instructions §§10.01-03B, 10.05 (defining materiality in various fraud statutes in a like manner), 13.01 (same definition for criminal statute prohibiting false statements to the government) (2025); Eleventh Circuit Pattern Criminal Jury Instructions §O11.2 (misstatement is material for criminal False Claims Act liability when it has "a natural tendency to influence or is capable of influencing" decisionmakers) (2024). Pattern jury instructions are not the law, but we find it persuasive that in the nine years since *Escobar*, courts across the nation continue to use the universally accepted definition of materiality for various false statement statutes. *See United States v. Coscia*, 866 F.3d 782,

799 (7th Cir. 2017) (approving of a district court "borrowing from the jury instructions governing analogous areas").

Indeed, when it comes to jury instructions, at times "less is more." *Johnson*, 916 F.3d at 586. "[S]imple and succinct instructions invite the jury to rely on its own intuition and common sense in resolving the cases." *Id.* We find no error.

D. Streck's Cross-Appeal on Damages

Streck cross-appeals one issue. He believes that each individually listed AMP on the quarterly reports counts as a violation, rather than each report constituting one violation. A single quarterly report contains hundreds of AMPs. From a damages perspective, this issue matters greatly. During the period, the FCA imposed maximum statutory damages ranging from $11,000 to $21,916 per violation.[20]

But a fundamental error dooms Streck's appeal at the outset. As a general rule, we will only consider issues the district court actually decided below. *Consumer Fin. Prot. Bureau v. Townstone Fin., Inc.*, 107 F.4th 768, 777 (7th Cir. 2024) (citing *Singleton v. Wulff*, 428 U.S. 106, 120 (1976)). We may exercise our discretion to address an argument not squarely presented below, but normally only do so when "the proper resolution of that issue is beyond any doubt." *AAR Int'l, Inc. v. Nimelis Enter. S.A.*, 250 F.3d 510,

[20] Until November 2015, the statutory damages per violation of the FCA were $5,500 to $11,000. 28 C.F.R. §85.3(a)(9) (1999). After November 2015, the range adjusted with inflation per 28 C.F.R. §85.5 (2015).

523 (7th Cir. 2001) (citation omitted). Streck frames the issue as "whether the District Cout incorrectly held that Lilly's overall quarterly submissions to CMS—irrespective of the number of false AMPs contained within—constituted a single statutory violation." But Streck cannot point to any definitive ruling below rejecting this argument. Instead, throughout the course of this litigation the district court either made only evidentiary rulings or was not squarely presented with the objection Streck now tries to appeal.

1. The Resolution of Streck's Argument is Not Beyond Doubt

Deciding an issue for the first time on appeal is ill-advised when the answer is not clear and benefits from further briefing. *AAR Int'l, Inc.*, 250 F.3d at 523. That is the case here. Subsection 3729(a)(1)(A) focuses on the presentment of "a false or fraudulent claim" for payment, while §3729(a)(1)(B), and §3729(a)(1)(G) penalize the use of "a false record or statement material" to a false claim or obligation to pay the government. *See United States ex rel. Schwedt v. Plan. Rsch. Corp.*, 59 F.3d 196, 199 (D.C. Cir. 1995); *see also Allison Engine Co., Inc. v. United States ex rel. Sanders*, 553 U.S. 662, 671-72 (2008) (discussing §3729(a)(2)'s "record" or "statement" requirement). The FCA specifically defines "claims," but never does the same for "records" or "statements." 31 U.S.C. §3729(b)(2).

The case law on this point is unsettled. The Supreme Court last addressed what constitutes "causative acts" in the FCA almost fifty years ago. *See*

United States v. Bornstein, 423 U.S. 303, 312 (1976).[21] And courts of appeals appear split on whether discrete line items within a single document can trigger separate FCA violations. Some focus exclusively on the act of demanding payment from the government, regardless of how many false statements accompany that request. *See United States v. Krizek*, 111 F.3d 934, 939 (D.C. Cir. 1997) (holding that the relevant act is the defendant's demand for payment); *Hays v. Hoffman*, 325 F.3d 982, 993 (8th Cir. 2003) (adopting *Krizek* and rejecting that a claim for reimbursement on one project can protract into thousands of FCA violations); *United States v. Woodbury*, 359 F.2d 370, 377-78 (9th Cir. 1966) (holding that "each false separate claim for money" was the relevant violation).

But others have suggested every individual statement or record attached to or included with a demand for payment is a separate violation. *See Farfield, Co.*, 5 F.4th at 342 n.25 ("[T]he FCA imposes a civil penalty on any person who 'knowingly makes, uses, or cause to be made or used, *a false record or statement* material to a false or fraudulent claim.'" (quoting 31 U.S.C. §3729(a)(1)(B)); *United States v. Saavedra*, 661 F. App'x 37, 45 (2d Cir. 2016) ("[N]othing in the statute requires the court to impose penalties based on the number of false *claims* under §3729(a)(1)(A), instead of the number of false *statements* under §3729(a)(1)(B)." (emphasis in

[21] *Bornstein* analyzed a predecessor to the modern version of the FCA, which *only* penalized false claims, and did not incur any liability based upon false records or statements. 423 U.S. at 308-09.

original)). We think it particularly ill-advised to reach an unpreserved open issue of law.

2. Streck Did Not Present the Specific Objection to the District Court that He Now Raises on Appeal

To determine what Streck did present to the district court, we begin with one of Streck's pretrial motions in limine. Our review of legal conclusions is *de novo*. *Rexing Quality Eggs v. Rembrandt Enters., Inc.*, 996 F.3d 354, 365 n.52 (7th Cir. 2021). Before trial, Streck asked the district court to determine that "each false AMP in Lilly's *monthly and quarterly* submissions ... constitutes a separate violation" of the FCA. At a pretrial conference, the district court made clear "the jury will determine the precise number" of violations but that the violations are on a "quarterly rather than monthly" basis "because the actual rebates are paid by drug manufacturers on a quarterly basis to the states."

The district court's ruling was undoubtedly correct. Under the MDRP, the rebate Lilly paid depended on quarterly reported AMPs. 42 U.S.C. §1396r-8(k) (defining AMP as the price of a drug during the "rebate period"); *id.* §1396r-8(k)(8) (defining "rebate period" to mean "calendar quarter"). Manufacturers report monthly AMPs for a completely different reason—to determine the upper limit for how much the Federal government reimburses the states for covering drug prescriptions under Medicaid. *Id.* §1396r-8(e)(4)-(5); 42 C.F.R. §447.514 (2016). Streck's argument that monthly AMPs, which are completely irrelevant to Lilly's MDRP obligations to the government, could form the basis of FCA liability was

obviously a non-starter from the get-go. Nonetheless, he advanced that argument in his motion in limine. Thus, to the extent Streck appeals the denial of this ruling, his argument fails.

That brings us to trial. During Streck's examination of his expert witness, Lilly objected to admission of a summary exhibit that displayed the number of individual AMPs included on every quarterly report during the relevant period. At this point, Streck's counsel stated he "couldn't disagree more with the Court's [motion in limine] ruling—or the fact that this implicates the Court's ruling." Instead, counsel stated the district court left open the question of "the counting of the violations to the jury." The proposed exhibit and testimony calculated "the number of quarterly false AMPs" that Lilly submitted. Plaintiff's counsel went on to explain that "each time Lilly submits a quarterly AMP, it's not submitting one big report ... but each individual AMP is an individual record…." The district court reaffirmed that during the pretrial conference it "intended to rule ... that the false claims would be counted on a quarterly basis, not a monthly basis." In denying the admission of the summary exhibit at that time, the court allowed Streck to "revisit" its argument when Dixson testified to show how every AMP was individually certified.

After Dixson testified that Lilly needed to check a box to certify each individual monthly and quarterly AMP, Streck filed a "Motion for Clarification." There, Streck asked the court to "confirm" that the jury will determine whether each "false quarterly AMP" counts as a "separate 'record' or 'statement'" under the FCA. His requested relief was to again admit the same

summary exhibit the court previously rejected. Streck explicitly argued that he was not asking the district court "to reconsider any prior decision, as the Court resolved a ***different*** issue" in the motion in limine, whether the violations were monthly or quarterly. Instead, Streck wanted the court to make clear the jury would determine whether each AMP was a violation and, with that understanding, allow Streck's expert to summarize the number of violations.

The ensuing conference was hotly contested and not a model of clarity. Lilly characterized Streck's motion as a badgering attempt to get the district court to reverse its prior rulings. Streck, for his part, wanted the court to consider whether it was the individual AMPs or the quarterly report that made out a FCA violation. After reading the motion, the district court stated a violation was "the act of submitting the ... actual document which the payment is made," denied the motion, and reaffirmed its motion in limine.

If we construe Streck's appeal to focus on this decision, then we confront an evidentiary call. We review evidentiary decisions under a deferential abuse of discretion standard. *United States v. Tsarnaev*, 595 U.S. 302, 322-23 (2022). Streck must prove the district court resolved the "matter in a way that no reasonable jurist would," or its decision was "fundamentally wrong, arbitrary, or fanciful." *United States v. Purnell*, 701 F.3d 1186, 1189 (7th Cir. 2012) (citation omitted). With evidentiary rulings, we affirm unless "the record contains no evidence on which the district court rationally could have based its ruling." *United States v. Quiroz*, 874 F.3d 562, 569 (7th Cir. 2017) (citation omitted).

First, Streck has not even attempted to make that showing, neglecting to apply this standard of review in his briefing. And the district court considered legitimate reasons for denying the exhibit, like worry that it would confuse the jury. *See, e.g., United States v. Lopez*, 870 F.3d 573, 580-81 (7th Cir. 2017) (affirming the trial court's denial of evidence because of tendency to confuse the jury). Without an argument to address, and based on the murky record before us, the district court's decision to deny a summary exhibit was not outside the bounds of reasonableness. *See United States v. Groce*, 891 F.3d 260, 268 (7th Cir. 2018) (explaining that we give "special deference" on a trial court's evidentiary calls because of its unique familiarity with the parties, evidence, and proceedings).

Even if it were an abuse of discretion, however, Streck would only prevail if the denial of the summary exhibit prejudiced him. When "there is a significant chance that the error affected the jury's verdict," we must grant a new trial. *Barber v. City of Chicago*, 725 F.3d 702, 715 (7th Cir. 2013). Yet again, Streck does not ask for this relief. He does not seek a new trial. But more, any error in denying the summary exhibit necessarily did not affect the jury's verdict, because, as we detail next, the parties agreed that the jury would not decide the issue of the number of violations. The jury could not have decided differently when there was no decision for them to make in the first place. *See Jordan v. Binns*, 712 F.3d 1123, 1137 (7th Cir. 2013).

That brings us to the only possible decision point left—the jury conference. We review the legal accuracy of jury instructions *de novo*. *Siepman*, 107

F.4th at 765. But we reach this question only when the objecting party preserved its exception by stating "distinctly the matter objected to and the grounds for the objection." *Walker v. Groot*, 867 F.3d 799, 803 (7th Cir. 2017) (quoting Fed. R. Civ. P. 51(c)). Lilly's proposed instruction stated that "[t]he total number of violations is the total number of times Lilly submitted to CMS a knowingly false quarterly AMP submission which was material to HHS under the MDRP. You are instructed that only the quarterly AMP submissions may count as a violation…."

Streck objected, but on different grounds than his argument on appeal. He argued that the instruction failed to capture that other government forms could serve as the basis of a FCA violation apart from the AMP certifications. After the district court denied Streck's argument, his counsel proffered having "one more issue relating to counting violations." Before counsel explained his argument, the district court stated he was "going to rule that it's just the quarterly filed with the federal government." Streck made no further objection. At that point, the parties agreed to stipulate to the number of violations, with the court's assurance that they preserved their objections, and removed the counting of violations from the jury's consideration. Then, at the conclusion of the conference, Streck's counsel distilled its objection: "on the issue of counting violations ... throughout the litigation [we] have asserted that each individual false AMP and each individual false certification is a violation."

The discussion at the outset of the jury conference arguably touched on whether each quarterly AMP

constituted a separate violation. Streck never crystallized this objection, but the surrounding record suggests the district court may have "understood the gist" of Streck's objection about the quarterly individual AMPs, which can be sufficient to preserve an objection. *Freislinger v. Emro Propane Co.*, 99 F.3d 1412, 1418 (7th Cir. 1996). And when a district court "tells a litigant he has made a sufficient record on a point," it is unfair to penalize him for not further objecting. *Lawson v. Trowbridge*, 153 F.3d 368, 372-73 (7th Cir. 1998).

But any ambiguity dissipated when Streck clearly formalized his objection at the end of the conference as "each individual AMP and each individual false certification" constituting a FCA violation. That line of reasoning parallels the one he made in his motion in limine, which argued that every AMP on both the *monthly and quarterly* reports was a violation. But as we have discussed, any theory of FCA liability running on a monthly basis was clearly wrong. For good reason then, Streck does not make that argument before us. In other words, Streck's later preservation makes clear that he sought to classify *every* individual AMP on both the monthly and quarterly reports as a FCA violation. Now on appeal, Streck advances a different, much narrower argument—the district court erred in finding the quarterly submissions constituted one, rather than several, violations. But "[c]onsistency is required … to preserve the objection … the party must state the same grounds when objecting to the jury instructions" as it does "on appeal." *Schobert v. Illinois Dep't of Transp.*, 304 F.3d 725, 730 (7th Cir. 2002).

True, the parties submitted a post-trial stipulation positing the district court had decided that "each quarterly AMP submission" constituted one FCA violation. The stipulation did not, however, accurately reflect the record, citing instead to the district court's pretrial ruling on Streck's motion in limine. But recall, the district court did not rule on the individual AMP issue at that time. It ruled only that FCA violations ran on a quarterly, not monthly basis. Even more, in the same post-trial stipulation, Streck "specifically" clarified his trial objections as "(1) whether Lilly's monthly AMP submissions support statutory violations; [and] (2) whether each false AMP on a drug-by-drug basis constitutes a separate violation...." That framing parallels his erroneous motion in limine request: AMPs on both monthly *and* quarterly reports were separate FCA violations. In other words, the stipulation confirms our view that Streck failed to preserve the narrower objection that each quarterly AMP was an FCA violation.

We have repeatedly emphasized that in order to preserve an issue for appeal, a party must name the "specific grounds for the objection" to alert the court of its grounds. *United States v. Davis*, 15 F.3d 1393, 1406-07 (7th Cir. 1994) (collecting cases). And when the party does invoke a specific ground, his argument on appeal "must … be the same as that raised at trial." *United States v. Swan*, 486 F.3d 260, 264 (7th Cir. 2007) (citation omitted). Here, both before and after trial, Streck invoked a general, maximalist position that all AMPs, quarterly and monthly, were FCA violations. We need not address his tailored argument on appeal.

So, altogether we have no "decision" to review in the motion in limine on the counting violations argument before us, *Townstone Fin., Inc.*, 107 F.4th at 777, an evidentiary error that does not warrant reversal, and a jury conference with a different objection. The motion in limine did not decide the issue because the district court did not resolve the number of violations nor settle the method for counting the violations. The motion for clarification similarly failed to capture the argument because its requested relief was for admission of evidence, and its denial could not have swayed the jury, who did not decide the violations issue. And then at the charge conference, when Streck had the opportunity to formally make his legal objection, he reverted to a broad position, rather than the one he now appeals. He confirmed that position in his post-trial stipulation. Perhaps all parties were under the impression a ruling was made. However, that does nothing to change the fact we have no such ruling to review.

III. Conclusion

For the foregoing reasons, we AFFIRM.

Appendix B

UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

Nos. 23-2134, 23-2216, 23-2958,
23-3035, 24-1352, & 24-1884

UNITED STATES, et al., EX REL. RONALD J. STRECK,

Plaintiff-Appellee/
Cross-Appellant,

v.

ELI LILLY AND COMPANY,

Defendant-Appellant/
Cross-Appellee.

Filed: Nov. 21, 2025

Before: Ripple, Jackson-Akiwumi, and Kolar,
Circuit Judges.

ORDER

Petitioner-appellee/cross-appellant, Ronald J. Streck, filed a petition for rehearing and for rehearing en banc on October 27, 2025. No judge in regular active service has requested a vote on the petition for rehearing en banc, and all members of the original panel have voted to deny panel rehearing.

Petitioner-appellant/cross-appellee, Eli Lilly and Company, also filed a petition for rehearing and for rehearing en banc on October 27, 2025. In its petition, Eli Lilly and Company argues the qui tam provision of the False Claims Act, 31 U.S.C. § 3730, is unconstitutional. No judge in regular active service has requested a vote on the petition for rehearing en banc, and all members of the original panel, concluding Eli Lilly and Company forfeited if not waived its constitutional argument, have voted to deny panel rehearing.

It is therefore ordered that the petitions for rehearing and for rehearing en banc are DENIED.

Appendix C

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS

No. 14-cv-09412

UNITED STATES, et al., EX REL. RONALD J. STRECK,
Plaintiff,
v.
TAKEDA PHARMACEUTICALS AMERICA, INC., et al.
Defendants.

Filed: Feb. 28, 2022

MEMORANDUM OPINION AND ORDER

Relator Ronald J. Streck, on behalf of the United States of America and twenty-six states, brings a Partial Summary Judgment Motion against Defendant Eli Lilly and Company. (Dkt. No. 311.) The Relator argues the undisputed material facts show that Defendant Lilly knowingly submitted false statements and certifications to the United States and several states as part of its Medicaid rebate program in violation of the False Claims Act. Defendant Lilly moves for full summary judgment against the Relator, arguing caselaw establishes affirmative defenses that prevent liability. (Dkt. No. 314.) The parties also move, under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509

U.S. 579 (1993), to strike various experts that would otherwise be relied upon in trial. (Dkt. Nos. 293, 295, 297, 299, 301.) For the reasons stated herein, the Court denies Defendant Eli Lilly's Motion for Summary Judgment, denies in part and grants in part Relator's Motion for Summary Judgement, and grants in part and denies in part the Motions to exclude expert opinions and testimony.

I. BACKGROUND

As discussed in the Court's Memorandum Opinion and Order denying the motion to dismiss (Dkt. No. 122), this lawsuit arises from Lilly's participation in the Medicaid Drug Rebate Program ("MDRP"). The United States historically has been the single largest payer of prescription drugs, primarily through the MDRP. For a drug manufacturer to have the benefit of selling drugs to patients enrolled in Medicaid, that manufacturer must pay a rebate back to the state and federal government to lower the cost of the program. The rebate computations are based on the "Average Manufacturer's Price," or "AMP." Congress defined the AMP in the 1991 National Rebate Agreement as "the average unit price paid to the Manufacturer for the drug in the [United] States by wholesalers for drugs distributed to the retail pharmacy class of trade." (Relator's Resp. to Def.'s Stmt. of Facts ("RSOF") ¶ 25, Dkt. No. 330.) As set forth in the definition, the AMP "must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized." (*Id.*)

The 1991 National Rebate Agreement also stated that "[i]n the absence of specific guidance in section

1927 of the Act, Federal regulations, and the terms of this agreement, the Manufacturer may make reasonable assumptions in its calculations of AMP and Best Price, consistent with the intent of section 1927 of the Act, Federal regulations and the terms of this agreement." (*Id.* ¶ 30.) An early dispute in the history of the program focused on whether fees paid by a drug manufacturer to drug distributors should be incorporated as part of the AMP calculations. Following a request from Congress, in 2007 the Center for Medicare and Medicaid Services of the Department of HHS ("CMS") provided the following definition of "bona fide service fees" and stated that these fees were exempt from the AMP calculations:

> fees paid by manufacturer to an entity; that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement; and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

42 U.S.C. § 447.502 (2007).

Upon the passage of the Patient Protection and Affordable Care Act of 2010, CMS removed its definition and directed manufacturers to comply with the newly promogulated statute, which had a similar provision excluding bona fide service fees. In 2012, CMS proposed regulation that contained the preamble, "retroactive price adjustments, sometimes known as price appreciation credits, do not meet the definition of bona fide service fee as they do not reflect

any service or offset of a bona fide service performed on behalf of the manufacturer." 77 Fed. Reg. 5318, 5332 (Feb. 2, 2012). This advice was not formally adopted, however, until 2016. As set forth under the 2016 regulations, CMS stated in its preamble:

> We continue to believe that price appreciation credits would likely not meet the definition of bona fide service fee. Based on our experience with the program, it is our understanding that price appreciation credits are not issued for the purposes of payment for any service or offset for a bona fide service performed on behalf of the manufacturer, but rather are issued by the manufacturer to adjust (increase) the wholesaler's purchase price of the drugs in such instances when the drugs were purchased at a certain price and are remaining in the wholesaler's inventory at the time the manufacturer's sale price of the drug increased. In such situations, these credits would amount to a subsequent price adjustment affecting the average price to the manufacturer and should be recognized for purposes of AMP in accordance with § 447.504(f).

81 Fed. Reg. 5170-01. Starting in 2017, Lilly began including price increase value as part of its AMP submissions. (Def.'s Resp. to Relator's Stmt. of Mat. Facts ("DSOF") ¶ 77, Dkt. No. 334.)

While perhaps counterintuitive, "service fee payments" paid by the drug manufacturer to the drug distributer, if included in the AMP calculations, would reduce the cost of the Average Manufacturer's Price.

The service fee essentially offsets the price of the drug product on paper, which would reduce the "average price unit paid ... by wholesalers for drugs" and thus would decrease the amount due to the government. Prior to CMS clarification, some drug manufacturers were using service fees to artificially lower the AMP calculations, and as stated above, CMS issued a regulation in 2007 to prevent unrelated service fees from being bundled with the price of the unit to manipulate AMP calculations to a lower price. When "service" or "service-related" payments are made in the opposite direction, *i.e.*, by drug distributer to the drug manufacturer, this increases the "average price unit paid ... by wholesalers" and thus increases the amount of the rebate due to the government. Defendant Eli Lilly has excluded all "service-related" payments since 2005. (RSOF ¶ 57.)

Lilly is a pharmaceutical company based in Indianapolis, Indiana. (RSOF ¶ 1.) In 2005, Lilly changed its contract with its three major drug distributors. (RSOF ¶ 7.) Lilly refers to the post-2005 contracts as "fee-for-service" or FFS Agreements. (*Id.*) The FFS Agreements had two provisions that are relevant to the suit.

First, the FFS Agreement included a "service fee" or "distribution fee" that Lilly paid the drug distributers. (*Id.* ¶¶ 9, 13.) This fee paid for distribution services, inventory management services, and data reporting services. (*Id.* ¶ 9.) The service fee was calculated "by multiplying Lilly's quarterly sales of Products ... invoiced to the wholesaler, less Products returned by Wholesaler during the same quarter, by the appropriate Distribution Fee percentage." (*Id.*

¶ 13.) In other words, the more product that the distributors sold, the higher the fee provided by Lilly.

The FFS Agreement also included a "price increase value," ("PIV") also referred to in the Court's prior opinion and throughout this opinion as a "price appreciation credit" or a "PACs." (*Id.* ¶ 11.) The PIV was an adjustment to the "price of Products after Wholesaler has taken possession, but before such Products are purchased by Customers." (*Id.* ¶ 17.) The price adjustment value would be multiplied by the number of products in inventory to create the final PIV. (*Id.*)

The FFS Agreement combined (1) the distribution fee cost to Lilly and (2) the price increase benefit to Lilly as follows:

> Wholesaler shall receive the Distribution Fee through a combination of (1) the value of any price increase by Lilly during the quarter for Products in Wholesaler's inventory ("Price Increase Value") and (2) a payment or credit by Lilly. The Price Increase Value for a Product shall be calculated by multiplying the price increase for the product by the amount of inventory for such Product Wholesaler has on the date of the price increase. … If the Price Increase Value for all Products for a quarter is greater than the total Distribution Fee, any excess shall be carried forward and netted out of future quarterly payments.

(*Id.*) In this way, Lilly would not have to pay any distribution fee unless the drug distributor's sales of Lilly's products were relatively and consistently

higher than any drugs remaining in the inventory that were in the process of being "price adjusted" by Lilly. As testified to by Lilly, this was setup was used to prevent wholesalers who, if anticipating price increases, "increased their stock of a particular drug at the lower, then-current price." (*Id.* ¶ 5.) Lilly's updated 2009 agreements had a substantially similar structure, except Lilly was now entitled to payment of the excess PIV by the drug distributors instead of having the excess carried over onto future distribution fee payments. (*Id.* ¶¶ 13-14.)

The 2016 FFS Agreements noted that the distribution fee and the PIV were "administered together for efficiency." (*Id.* ¶¶ 15-22.) After netting the payments together, any excess in either direction was to be paid within 45 days. (*Id.*) Under all variations of the FFS Agreements, the "economic substance of the transaction" remained unchanged. (*Id.* ¶ 23.)

On September 7, 2018, Relator filed an Amended Complaint alleging three counts under the federal False Claims Act, 18 U.S.C. §§ 3279(a)(1)(A) and (a)(1)(B) (Count 1), § 3729(a)(1)(D) (Count 2), § 3729(a)(1)(G) (Count 3), and twenty-nine claims under various state False Claims Acts. On September 7, 2021, Relator filed a Motion to exclude the opinions and testimony of Charlene Frizzera (Dkt. No. 293), the opinions and testimony of Marcy Imada (Dkt. No. 295), certain opinions and testimony of Heather Bates, (Dkt. No. 297) and the opinions and testimony of Dr. Louis Rossiter. (Dkt. No. 301.) That same day, Eli Lilly filed a Motion to exclude the testimony of Brian C. Becker. (Dkt. No. 299).

On October 7, 2021, Relator filed a Motion for Partial Summary Judgment (Dkt. No. 311) and Defendant Eli Lilly filed a Motion for Full Summary Judgment. (Dkt. No. 314.) The Court now decides all seven pending Motions.

II. STANDARD

Summary judgment is appropriate when there are no genuine issues of material fact, and the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(a). A genuine issue of material fact exists only if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Pugh v. City of Attica*, 259 F.3d 619, 625 (7th Cir. 2001) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). A court uses substantive law to "identify which facts are material." *Anderson*, 477 U.S. 248. Viewing the record in a light most favorable to the nonmoving party, a court then determines whether there is a genuine issue for trial. *Id.* at 242.

Expert testimony is permitted under Federal Rule of Evidence 702. Under the Rules, "the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant but reliable." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993). As a result, a court reviews the following requirements prior to admittance at trial: (1) the witness must be "qualified as an expert by knowledge, skill, experience, training or education," and (2) "the subject matter of the expert's testimony must consist of specialized knowledge that will be helpful or essential to the trier of fact in deciding the case." Fed. R. Evid. 702; *United States v. Lanzotti*, 205 F.3d 951, 956 (7th Cir. 2000). "The party seeking to offer expert

testimony has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence." *Rasmusen v. White*, 970 F.Supp.2d 807, 813 (N.D. Ill. 2013).

III. DISCUSSION

A. Motions to Exclude

1. Motion to Exclude the Opinions and Testimony of Charlene Frizzera

Relator first moves to exclude the opinions and testimony of Charlene Frizzera ("Frizzera"). Frizzera's main qualification is her long tenure at Centers for Medicare and Medicaid Services ("CMS"), where she served, *inter alia*, as Executive Project Officer of Health Care Reform, CMS Acting Administrator, and CMS Chief Operating Administrator, Deputy Director, and Regional Administrator of Philadelphia's Regional Office. (Frizzera CV, Frizzera Expert Report, Ex. B, Dkt. No. 294-1.) Frizzera proffers three opinions, all of which Defendants seek to exclude:

> 1. CMS did not issue any final rule or published guidance clearly instructing manufacturers how to treat price appreciation credits;
>
> 2. CMS charges manufacturers with making reasonable assumptions on AMP calculations in the absence of clear guidance, allowing for more than one reasonable interpretation of AMP rules, including regarding price appreciation credits; and

> 3. Information was available to CMS that would have allowed CMS to take action if it wanted Lilly to change its conduct.

(Frizzera Expert Report at 1, Mem., Ex. 1, Dkt. No. 294-1.) Relator begins by arguing that all three opinions provide improper legal conclusions. Allowing an expert witness to testify as to a legal conclusion creates a risk that a jury may "accord too much weight to that testimony" and use it as legal guidance. *Naeem v. McKesson Drug Co.*, 444 F.3d 593, 610 (7th Cir. 2006). This is particularly true when the legal opinion "determine[s] the outcome of a case." *Id.* (quoting *United States v. Sinclair*, 74 F.3d 753, 757-58 n. 1 (7th Cir.1996). When, as here, the case hinges on a violation of statute, "an expert may not offer opinion testimony as to whether a defendant violated a statute or regulation." *Klaczak v. Consol. Med. Transp. Inc.*, No. 96 C 6502, 2005 WL 1564981, at *4 (N.D. Ill. May 26, 2005).

In support of his argument, Relator cites to Frizzera's testimony, where she asserts the following:

> Q: In your report, you provide opinions about the Medicaid Drug Rebate Program; is that fair?
>
> A: I provide opinions about whether Lilly met the requirements of the rules.

(Frizzera Dep. 65:20-24, Mem. to Exclude Frizzera, Ex. 2, Dkt. No. 494-2.) To the extent that Frizzera intends to testify to that "Lilly met the requirements of the rules," the Court excludes her testimony. Frizzera cannot testify as to how the jury should apply the statute and CMS rules to the case at hand.

On these grounds, the Court also grants the Motion to Exclude Opinion 3 in its entirety. In the third section of the report, Frizzera recounts the facts involved with Lilly's communications with the Federal Government and determines that Lilly "appropriately sought guidance." This applies the recited facts to the case and reaches a legal conclusion as to Lilly's obligations. Building on this conclusion, Frizzera opined that CMS is required to "take action" to create liability once Lilly seeks the appropriate guidance. The Court finds this to be a legal conclusion and, further, a legally unsound opinion. Under the False Claims Act, the burden is on the individual submitting claims to provide accurate information, not on the government entity to act in response to other communications. *Heckler v. Cmty. Health Servs. of Crawford Cty., Inc.*, 467 U.S. 51, 63 (1984) ("[T]hose who deal with the Government are expected to know the law and may not rely on the conduct of Government agents contrary to law.")

The first two opinions of Frizzera's report, when read at face value, do not necessarily reach a legal conclusion. An expert who opines regarding the regulatory process for creating (1) CMS guidance to drug manufacturers generally, and (2) CMS's requirement that drug manufacturers to make "reasonable assumptions" as part of their submissions specifically, would be useful at trial. As an employee of CMS for thirty years, Frizzera has the background necessary to provide this information.

Relator next argues that Frizzera did not employ a reliable methodology. When evaluating methodology, "the trial court is limited to determining

whether expert testimony is pertinent to an issue in the case and whether the methodology underlying that testimony is sound." *Smith v. Ford Motor Co.*, 215 F.3d 713, 719 (7th Cir. 2000). The trial court does not evaluate the underlying facts, but instead evaluates the test administered and the source of information employed. *Walker v. Soo Line R. Co.*, 208 F.3d 581, 587 (7th Cir. 2000).

Relator argues that Frizzera's methodology was to review whether a statute and agency regulation contained the words "average manufacturer price," "price appreciation credits" or "bona fide service fees." Frizzera then opined (1) that there were no clearly published guidelines on price appreciation credits (Opinion 1), and (2) that there could be multiple valid ways to interpret the guidelines as applied to price appreciation credits (Opinion 2).

Relator has two arguments regarding Frizzera's methodology. First, Frizzera's review of the regulations, i.e., searching for "mentions" of the words in the text of the statute, is surface-level and ultimately insufficient to understand the obligations of drug manufacturers. Second, Frizzera does not understand what a "price appreciation credit" means, making her unable to analyze the regulations. In support, Relator highlights the following questions presented at the deposition:

> Q. To make that opinion, do you have to have some sort of understanding of what price appreciation credits are?
>
> A. I have to have an understanding of what the CMS rules and guidance were around price appreciation credits.

Q. And to apply those rules and regulations to price appreciation credits, do you need to know what price appreciation credits are?

A. No. CMS didn't issue any rules or guidelines about price appreciation credits.

Q. Did you do anything to educate yourself about how Lilly uses price appreciation credits?

A. I reviewed the documents that I reviewed—I reviewed the documents I had.

Q. Can you provide the jury with an explanation of how Lilly's price appreciation credits operate?

A. My opinion is that CMS didn't issue any rules or guidance instructing them how to deal with price appreciation credits.

Q. I understand what you're saying with respect to CMS. Do you know sitting here today how Lilly's price appreciation credits function?

A. Can you repeat the question?

Q. Sure. Let me ask it in a more simple way. What is a price appreciation credit?

A. CMS did not issue any rule or guidance regarding price appreciation credits.

Q. Got it. I think I understand your opinion on that. But my question is, what is an actual price appreciation credit?

A. There is no definition of price appreciation credits in the federal rules or guidelines.

> Q. How does Lilly use the term price appreciation credits?
>
> A. Lilly made reasonable assumptions about what price appreciation credits were and how to use them.

(Frizzera Dep 103:21-106:5 (objections omitted).) In response, Lilly argues that Frizzera's methodology consisted of "appl[ying] her experience to a series of agency documents and statements." (Resp. at 13, Dkt. No. 304.) Lilly also argues that Relator is cherry-picking misleading deposition testimony, and that Frizzera demonstrated her knowledge of price appreciation credits from the following exchange:

> Q. And why are bona fide service fees relevant to your report?
>
> A. Lilly—the reason why bona fide service fees are part of my report is because Lilly offset their bona fide service fees by their price appreciation credits.

(Frizzera Dep. 118:1-6.)

The Court finds that the methodology employed for Opinion 1, while simplistic, is straightforward and logical. Relator's arguments about better methods go to the weight of the testimony, and do not merit its exclusion.

Relator's concerns about Frizzera's knowledge of price appreciation credits are less about methodology and more appropriately raised during the second prong of the test. In addition to employing appropriate methodology, the Court must also determine whether the expert has specialized knowledge that would be helpful for the trier of fact. Because Frizzera cannot

articulate any definition of "price appreciation credit," the Court finds that, for Opinion 2, Frizzera lacks the specialized knowledge which is necessary for her to be an expert on price appreciation credits. In Opinion 2, Frizzera states that there is "more than one reasonable interpretation of ... price appreciation credits." (Frizzera Rep. at 34.) The Court does not see how any expert can reliably analyze rules for price appreciation credits without first understanding how price appreciation credits work within the drug manufacturer's pricing system.

Lilly's explanation in response is that Frizzera does not need first-hand information to be an expert on price appreciation credits. Lilly's theory is that Frizzera is an expert through her longtime experience with CMS, similar to, for example, "experienced narcotics investigators [who] applied the knowledge gained through years of experience and, essentially, described for the jury what they knew about narcotics dealers." *United States v. Conn,* 297 F.3d 548, 556 (7th Cir. 2002). But if a narcotics investigator, after describing his or her knowledge of narcotics dealers, then was unable to provide information regarding a specific drug by name, the court would be remiss to think the investigator had enough specialized knowledge to opine on the specifics of that drug. Here, Frizzera has worked for thirty years at CMS, and can provide information about CMS's regulatory processes. Her knowledge, however, does not reach to an understanding of "price appreciation credits," making her unable her to apply her experience to that term beyond her impressions set forth in Opinion 1. The Court grants the Motion to Exclude Opinion 2 and Opinion 3 in Frizzera's report and testimony and

denies the Motion to Exclude Opinion 1. (Dkt. No. 293.)

2. Motion to Exclude the Opinions and Testimony of Marcy Imada

Relator next moves to exclude the opinions and testimony of Marcy Imada ("Imada"). Imada holds two bachelor's degrees and is a long-time consultant in the life sciences and health care industries. (Imada CV, Imada Expert Report, Ex. A, Dkt. No. 296-1.) Imada sets forth three opinions:

> A. Lilly's exclusion of price appreciation credits from is Average Manufacturer's Price calculation was a reasonable practice.
>
> B. Manufacturers often apply regulations and sub-regulatory guidance in differing, but reasonable, manners.
>
> C. Lilly's repeated disclosures and engagements with government agencies align with industry leading practices.

(Imada Expert Report at 16, 27, 29, Mem., Ex. 1, Dkt. No. 296-1.) At the outset, the Court notes that Opinion A is a legal conclusion, and specifically a legal conclusion that is at the heart of this case. If Lilly's price appreciation credits were reasonably excluded, then Lilly did not make a false claim. As a result, this expert testimony is inadmissible. *Good Shepherd Manor Found., Inc. v. City of Momence*, 323 F.3d 557, 564 (7th Cir. 2003) ("Expert testimony as to legal conclusions that will determine the outcome of the case is inadmissible."). The motion to exclude Opinion A is granted.

Relator provides a similar argument in his Motion to Exclude Imada's Opinion B. Relator argues that Opinion B is only relevant "if Lilly's purported interpretation was in fact reasonable, and for the reasons described above, Ms. Imada cannot provide this opinion." (Imada Mem. to Exclude at 11, Dkt. No. 296.) However, while Imada cannot testify as to whether Lilly's decision was reasonable, she can provide information from which the jury themselves can make that determination. As a result, Imada's expert testimony about regulations generally is relevant and admissible.

In the alternative, Relator argues the testimony is inadmissible under Rule 403 because any probative value is substantially outweighed by unfair prejudice, confusing the issues, and wastes the jury's time. The Court finds none of these concerns in the proffered testimony. Imada provides examples of different calculations between drug manufactures under CMS regulations. In one example, some manufacturers calculate AMP using "standard" Average Manufacturer's Price, and some use the "5i" Average Manufacturer's Price. The jury can extrapolate whether differences in calculations between AMPs are similar to Lilly's decision to exclude price appreciation credits, or whether there is a difference in scale or intent such that it was not a reasonable decision. These are arguments that should be presented for the jury.

Finally, Relator moves to exclude Opinion C. Relator argues that Imada's methodology regarding "industry leading practices" is either impermissibly vague or nonexistent. Relator argues that Imada does

not provide enough basis for her opinion on industry standards. For example, Imada does not cite to publications or other sources on which she bases this conclusion and does not provide examples of other companies who communicated with government agencies in a similar manner.

In response, Lilly cites to *Harms v. Laboratory Corporation of America*, 155 F.Supp.2d 891 (N.D. Ill. 2001). In *Harms*, the district court found that Randy Chapman, Operation Manager for Defendant, and fact witness for the trial, could not testify regarding general standards of care, reasoning that industry standards are "classic" expert testimony. *Id.* at 903. However, *Harms* does not allow each and every expert witness to opine on industry standards simply by being designated as experts. An expert witness, even one qualified through experience such as Imada, must explain the "'methodologies and principles' that support [her] opinion; [s]he cannot simply assert a 'bottom line.'" *Metavante Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 761 (7th Cir. 2010) (quoting *Minix v. Canarecci*, 597 F.3d 824, 835 (7th Cir.2010)).

After reciting the relevant facts, Imada's opinion regarding industry standards is three short paragraphs. She provides one principle, explaining that "[o]utreach to government agencies not only allows the manufacturers to confirm their interpretations or assumptions, but it can also direct the agency's attention to topics for which the rules are not clear or further guidance is needed." (Imada Expert Report at 35, Imada Mem. to Exclude, Ex. 1, Dkt. No. 296-1.) To the extent that there is a methodology, it is through Imada's assertion that she

has "routinely advised [her] clients to reach out to regulators." (*Id.* at 34.) While this principle and this methodology, put together, edges slightly beyond a bottom-line assertion rejected by the Seventh Circuit, the Court finds even in the best light these statements fall short of establishing an "industry standard." Ultimately, Imada's opinion cannot be based solely on her own personal prior practices and reasoning. By the nature of the words "industry standards," information beyond the ideas and practices of one expert is required to be established as a methodology.

The Court grants the Motion to Exclude Imada's Opinion A and Opinion C and denies the Motion to Exclude Imada's Opinion B. (Dkt. No. 295.)

3. Motion to Exclude Certain Opinions and Testimony of Heather Bates

Lilly has also proffered the expert Heather Bates ("Bates"), a managing director of a consulting group who holds a bachelor's degree in Economics. (Bates CV, Bates Expert Report, Ex. A, Dkt. No. 298-1.) Bates offers a rebuttal opinion to Relator's damages expert, Eric Kimelblatt. Relator moves to exclude Bates' Opinion 5, which states:

> Mr. Kimelblatt enumerated alleged damages to the Federal government under the Medicaid program but did not consider the impact of Relator's proposed change to Lilly's treatment of PIV credits on Federal government reimbursements under the Medicare and Veteran's Affairs ("VA") programs.

(Bates Expert Report at 22, Mem., Ex. 1, Dkt. No. 298-1.)

Relator first objects to the admissibility of Bates' counter-damages calculations, arguing that any benefits to Government programs beyond Medicaid, such as Veteran's Affairs, are not relevant to this action. Under Seventh Circuit precedent, damages under the False Claims Act should be calculated by "net trebling," as opposed to "gross trebling." *United States v. Anchor Mortg. Corp*., 711 F.3d 745, 749 (7th Cir. 2013). In other words, "[m]itigation of damages is almost universal." *Id.* Assuming the jury finds liability, the Federal Government is entitled to damages offset by the benefits, and Lilly is entitled to present evidence regarding the benefits of their calculations to other government departments.

Relator provides a variety of other arguments, most of which are speculations on how Bates' calculations will affect the state's payments in relation to the Federal Government. The basis of this suit is the failure to pay the Federal Government under Federal law. The Court fails to see how speculations on how the damages will be split constitutes any separation of power issues. The other reasons in Relator's Motion to Exclude do not attack Bates' methodology, but merely critique how her calculations were made. These arguments are appropriate for Relator to bring on cross-examination or in its own rebuttal report. The Court denies the Motion to Exclude certain opinions and testimony of Bates. (Dkt. No. 297.)

4. Motion to Exclude the Opinion and Testimony of Brian C. Becker

Dr. Brian Becker ("Becker") holds a PhD in applied economics and currently works at an

economics consulting firm. (Becker CV, Becker Expert Report, Ex. A, Dkt. No. 300-1.) In his expert report, Dr. Becker provides an economic framework for understanding financials associated with Lilly's contract with drug manufacturers. Dr. Becker's opinion states that the economic difference between paying $100 initially and then a single additional dollar is the exact same as requiring a payment of $101. Lilly argues that Dr. Becker's opinion should be excluded because it is not relevant and outside the scope of an expert testimony.

Lilly argues that Becker's opinion is not relevant because Dr. Becker does not attempt to answer the question as to "whether Medicaid regulations or statutes require price increase value to be included in average manufacturer price." (Mem. at 5, Dkt. No. 300.) However, the purpose of providing experts is not to advise the jury the answer to the ultimate question. It is inadvisable to submit expert testimony that advises on the final decision in the case as it will likely be excluded. The purpose of expert is to provide information which the jury can use to resolve the factual dispute. As explained in *Daubert*, "[t]he study of the phases of the moon, for example, may provide valid scientific 'knowledge' about whether a certain night was dark, and if darkness is a fact in issue, the knowledge will assist the trier of fact." 509 U.S. at 591. To extend the analogy, Lilly here argues that the expert must be excluded unless the expert testifies that the night was dark. But Lilly's requirement that the 'knowledge' be applied by the expert to the factual issue is wrong; instead, an expert should be providing background information from which the jury can deduce that the night was dark.

Becker does exactly that in his report. Assuming the jury learns of Lilly's obligation to provide an Average Manufacturer's Price to CMS from other testimony, the jury can use Dr. Becker's economic analysis of Lilly's contract with drug distributers to determine whether or not their "price increase value" should be considered part of the Average Manufacturer's Price, or if it was reasonable for Lilly to exclude them.

Lilly brings the Court's attention specifically to *Camelback Properties v. Phoenix Ins. Co.*, No. 10 CV 01467, 2013 WL 1568517 (N.D. Ill. Apr. 12, 2013). In *Camelback*, the magistrate court held that a party could not proffer an expert on real estate industry standards to help interpret an insurance contract. The magistrate court cited the lack of legal precedent incorporating real estate standards, such as the "BOMA code," into the separate body of insurance law, and noted that the expert failed to claim that "BOMA standards are commonly used in the insurance industry." *Id.* at *3. For this reason, the magistrate court excluded the expert on the grounds of relevance.

The Court finds this precedent inapplicable. Dr. Becker is not taking unrelated industry standards and applying them to the contract. Economics is a field that is well-suited to analyze the costs associated with the complicated financial transactions in a wide variety of legal settings. The economic result of the contract is useful information for the jury when resolving the factual disputes in this case.

In the alternative, Lilly argues that Dr. Becker did not apply any "scientific, technical, or specialized knowledge" under Federal Rule of Evidence 702. Lilly

argues that the contract is straightforward, and Dr. Becker is not using any of his Ph.D. economics skills besides reading the contract. This argument is belied by the fact that Lilly actively disputes the economics of the contract and in fact hired its own economics professor who came to a markedly different opinion in its rebuttal of Dr. Becker's expert report. The Court denies the Motion to Exclude Dr. Becker's Testimony. (Dkt. No. 299.)

5. Motion to Exclude the Opinion and Testimony of Louis Rossiter

In response to Becker's report, Lilly proffers expert Dr. Louis Rossiter ("Rossiter") in rebuttal. Dr. Rossiter is a research professor at the public policy school at the College of William & Mary and holds a Ph.D. in Economics. (Rossiter CV, Rossiter Rebuttal Report, Ex. A, Dkt. No. 307-1.) Dr. Rossiter offers three opinions in rebuttal to Becker's economic analysis of Lilly's contract:

> A. The introduction of FFS contracts, including their PIV provisions, created a more efficient model for the distribution of pharmaceutical products and eliminated various inefficiencies and market distortions that existed under the prior contracts;
>
> B. Dr. Becker's opinion that the amount of PIV is simply a "part of the price of the drug" fails to consider and articulate the economic rationale and genesis of the PIV provisions as a mechanism for controlling wholesaler inventory levels, one of the specifically enumerated services that wholesalers provide to Lilly; and

> C. Without the PIV provision of the FFS contracts, wholesalers would have continued to engage in speculative buying and received significant additional compensation for performing the same set of services they are compensated for under the FFS contracts. This would have resulted in wholesalers being overcompensated for the services performed.

(Rossiter Rebuttal Report at 7-8, Resp., Ex. 1, Dkt. No. 307-1.) Relator argues that the opinions do not stick to the same subject matter as Dr. Becker's economic analysis and thus are outside the scope of a rebuttal opinion.

Under Federal Rule of Civil Procedure 26(a)(2)(D)(ii), rebuttal evidence is permitted "if the evidence is intended solely to contradict or rebut evidence on the same subject matter identified by another party." Relator reads the words "same subject matter" narrowly and argues that Lilly's rebuttal expert cannot rely on outside information in rebutting Becker's conclusions. The Court finds that Dr. Rossiter's analysis to be based on his own expertise as a health economics professor, and as a result his analysis will differ in sources and conclusions. *See Andersen v. City of Chicago*, 467 F.Supp. 3d 619, 631 (N.D. Ill. 2020) ("[I]t is permissible for [rebuttal expert] Dr. Reich to elaborate on how exactly his own practices and experience informed his opinion.") These differences are not a reason to exclude a rebuttal opinion.

Relator's remaining arguments are that Dr. Rossiter engages in flawed methodologies and that the

introduction of Dr. Rossiter's testimony would confuse the jury. However, Relator's arguments are ultimately disagreements with Rossiter's conclusions. Relator states that Dr. Rossiter "ignores highly probative evidence" without "a single citation to any evidence." (Mem., Dkt. No. 302.) These critiques are better suited to cross-examination before the jury than any premature exclusion. The Court denies the Motion to Exclude Dr. Rossiter's rebuttal report. (Dkt. No. 301.)

B. Motions for Summary Judgment

Relator alleges violations of three components of the federal False Claims Act and a variety of state False Claims Acts. The False Claims Act "prohibits the submission of false and fraudulent claims for payment to the government" and "authorizes private citizens (called "relators") to file civil actions on behalf of the government." *Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907, 912 (7th Cir. 2009).

Count I alleges violations of 18 U.S.C. §§ 3279(a)(1)(A) and (a)(1)(B). Under § 3279(a)(1)(A), a liable individual is one who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." Under § 3279(a)(1)(B), a liable individual is one who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." Count II alleges a violation of § 3729(a)(1)(D), which provides liability for any individual who "has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property."

Count III alleges a violation of § 3729(a)(1)(G) which creates liability for any individual who "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." This is often referred to "reverse false claim." *United States ex rel. Garbe v. Kmart Corp.,* 73 F.Supp. 3d 1002, 1011 (S.D. Ill. 2014), *as amended* (Jan. 12, 2015*), on reconsideration in part sub nom. United States v. Kmart Corp.,* No. 12-CV-0881-NJR-PMF, 2015 WL 11181733 (S.D. Ill. Jan. 9, 2015), *aff'd in part, rev'd in part and remanded,* 824 F.3d 632 (7th Cir. 2016).

FCA civil claims require two primary elements: (1) scienter and (2) falsity. *United States ex rel. Schutte v. Supervalu Inc.*, 9 F.4th 455, 463 (7th Cir. 2021). Falsity is found in the common law meaning of fraud, either "express misrepresentations or 'misrepresentations by omissions.'" *Id.* (quoting *Univ. Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S.Ct. 1989, 1999 (2016)). Scienter requires the liable individual to mean "that a person, with respect to information (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." *Id.* (citing § 3729(b)(1)(A)). It does not require "proof of specific intent to defraud." *Id.* (citing § 3729(b)(1)(B)).

In addition to these two essential elements, the plaintiff "also must prove that the violation

proximately caused the alleged injury" and that defendant's conduct meets "a strict materiality requirement." *United States ex. rel. Prose v. Molina Healthcare of Illinois, Inc.*, 17 F.4th 732, 740 (7th Cir. 2021). In sum, the relator must establish (1) scienter, (2) falsity, (3) causation, and (4) materiality.

In Lilly's motion for summary judgment, Lilly argues that that the Relator cannot meet either the scienter or falsity elements of the claim. Relator cross-motions and asks the Court to find summary judgment as to all four elements. Essentially, Lilly argues that the Relator has a very high burden, and Relator argues that the language is very clear. As is typical in summary judgment motions, both parties make valid points. Relator's burden is very high, and the definitions of "Average Manufacturer's Price" and "bona fide service fees" are also very clear. But while even high burdens are occasionally met, the Court is unable, upon careful review, to find any reasonable interpretation of the statute that would support Lilly's partial exclusion of the price of its drug from its Average Manufacturer's Price. For the reasons set forth below the Court denies Lilly's Motion entirely and denies in part and grants in part Relator's Motion.

1. Scienter

Lilly argues that Relator cannot pass the threshold requirement for scienter set forth in *United States ex rel. Schutte v. Supervalu Inc.*, 9 F.4th 455, 463 (7th Cir. 2021). In *Schutte*, the Seventh Circuit adopted the Supreme Court's scienter standard for the Fair Credit Reporting Act from *Safeco Insurance Company of America v. Burr*, 551 U.S. 47, 127 (2007), and applied it to the False Claims Act's scienter

provision. *Id.* In *Safeco*, the Supreme Court held that "[a] defendant who acted under an incorrect interpretation of the relevant statute or regulation did not act with reckless disregard if (1) the interpretation was objectively reasonable and (2) no authoritative guidance cautioned defendants against it." *Schutte*, 9 F.4th at 464. The Seventh Circuit held that this requirement reaches all three scienter terms that define "knowingly" in the False Claims Act, and as such is a threshold issue. *Id.* at 467.

Lilly argues that undisputed materials facts demonstrate Lilly was not objectively unreasonable in its interpretation of the MDRP requirements and that CMS provided no authoritative guidance to warn Lilly away from its incorrect views. As a result, Lilly argues that the Relator cannot show any level scienter that would make Lilly liable under the False Claims Act.

The Court first reviews whether Lilly was objectively unreasonable in excluding "price increase value" from its AMP calculations. "The objectively reasonable inquiry hinges on the text of the statute or regulation that the defendant allegedly violated and as such is a question of law." *Id.* at 468. The Average Manufacturer's Price is defined as "the average unit price paid to the Manufacturer for the drug in the [United] States by wholesalers for drugs distributed to the retail pharmacy class of trade." The definition further states that AMP "must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized." The Court then compares this text the definition of a "price increase value" in Lilly's FFS Agreements. A "price increase value" is the difference

between the price the wholesaler originally paid for the drug and the current price, multiplied by the number of units. Lilly cannot and does not deny a "price increase value" or "price adjustment credit" was an "adjust[ment]" "paid to the Manufacturer" and "by the wholesalers" on a per unit basis. Instead, Lilly argues that the statute was unclear as to whether Lilly needed to include the entire price or simply the initial price of the product in the AMP. As already explained, the definition of Average Manufacturer's Price states that subsequent price increases and decreases must be included. For this reason, the explicit text of the statute makes Lilly's position unreasonable.

Nevertheless, Lilly argues that the words "price increase value" are not present in the statute in that exact order and therefore the legal landscape was ambiguous. Lilly argues that, under the 1991 National Rebate Agreement, in the absence of "specific guidance," a drug manufacturer is permitted to "make reasonable assumptions in its calculations of AMP." This strains the meaning of "specific guidance." Under Lilly's standard, any creation and subsequent definition of a new phrase in a contract, as present here, would allow drug manufacturers to avoid its clear obligations under statute. Courts have recognized that "[b]y requiring regulations to be too specific [courts] would be opening up large loopholes allowing conduct which should be regulated to escape regulation." *Freeman United Coal Min. Co. v. Fed. Mine Safety & Health Rev. Comm'n*, 108 F.3d 358, 362 (D.C. Cir. 1997) (citing *Ray Evers Welding Co. v. OSHRC*, 625 F.2d 726, 730 (6th Cir.1980)). The Court

declines to allow this loophole reasonable under a plain reading of the statute.

In the alternative, Lilly argues that the "price increase value" could reasonably be considered part of its bona fide service fees. In the FFS agreements drafted by Lilly, the price increase value calculation is in the same paragraph as the bona fide service fees calculation, and the transaction between the two parties happens simultaneously. Lilly argues that CMS has explicitly rejected bona fide fee services from AMP calculations, so Lilly was entitled to add "price increase value" as part of the services fees and thus also exclude them from the AMP.

By definition, bona fide service fees are "fees paid by manufacturer to an entity ... for a ... service." In contrast, a "price increase value" is never paid by the manufacturer and is never for a service. Therefore, the Court finds the proximity of the words "price increase value" to the words "bona fide service fee" in the FFS Agreements irrelevant to the Court's analysis. The history of the bona fide service fees in FFS Agreements furthers this conclusion. As recounted by Lilly in its briefing, CMS specifically rejected the bundling of "service fees" with product pricing in 2007. As noted by Lilly, some drug manufacturers tried to incorporate service fees with the full price of the product, which illegally lowered their AMP calculations and thus their payments to the government. Lilly, characterizing itself as taking "a conservative approach," decided to only bundle price adjustments with service fees. (Mem., Dkt. No. 315.) However, there is nothing conservative about an approach where two distinct transactions that were

explicitly not permitted to be coupled, the price of the product and the service fees, are nonetheless combined to lower AMP calculations. A fundamental truth in mathematics and law is that $10(price) - $1(fee) is equal to $9(price) - $1(fee) + $1(price adjustment). Although one uses more steps, they are the same equation and create the same result. Lilly readily admits that CMS prohibits the first equation ($10 - $1) because it artificially lowers the price of AMP. Therefore, it is decidedly not reasonable for Lilly to assume that it may instead use second equation ($9 - $1 + $1), simply because the steps take place a different or more complicated order.

To support its position, Lilly draws parallels to the findings in *United States ex rel. Schutte v. Supervalu Inc.*, 9 F.4th 455, 463 (7th Cir. 2021). There, the Seventh Circuit found that there were two reasonable ways to interpret the meaning of the word "Usual and Customary Price." *Id.* at 469. The Seventh Circuit found that the definition of "Usual and Customary" might mean the price that is "charged" most frequently for a drug, but it could also indicate the retail rather than discount price." *Id.* As a result, the Seventh Circuit found that Defendant Supervalu did not have an objectively unreasonable interpretation of the statute. *Id.*

The Court finds this precedent inapplicable. Lilly has not proffered, nor has the Court been able to imagine, a reasonable alternative interpretation to both the mechanics and the definition of "price increase value" to be anything other than an adjustment of price and thus within the definition of Average Manufacturer's Price. Instead, the Court

agrees with the district court in *United States ex rel. Streck v. Bristol-Myers Squibb Co.*, 370 F.Supp.3d 491 (E.D. Pa. 2019), who found "nothing ambiguous" in the definition of bona fide service fees and agreed that *Streck* provided sufficient scienter, even under the "objectively unreasonable" standard. 370 F.Supp.3d at 497. Having determined that Lilly's interpretation of Average Manufacturer Price is objectively unreasonable, the Court finds that Lilly reaches the threshold requirement of *Safeco* and denies the motion to grant summary judgment on the basis of scienter.

Relator, in response, moves for summary judgment in the opposite direction. Relator argues that Lilly, at a minimum, acted with reckless disregard or deliberate ignorance and thus knowingly violated the False Claims Act. As part of electing to participate in the National Rebate Agreement, Lilly has "a duty to familiarize itself with the legal requirements for cost reimbursement." *Heckler*, 467 U.S. at 64. For the False Claims Act, reckless disregard holds liable "'only those who act in gross negligence,' that is, those who failed 'to make such inquiry as would be reasonable and prudent to conduct under the circumstances.'" *United States v. King-Vassel*, 728 F.3d 707, 713 (7th Cir. 2013) (quoting S. Rep. No. 99-345, at 20).

While the duty Lilly holds is clear, what Lilly did and the intent with which Lilly did them is hotly contested in the submitted Rule 56.1 statements of material fact. The Court finds that there are insufficient undisputed facts on which the Court can make a summary judgment determination and reserves this question for the jury.

2. Falsity

Lilly also argues that the Relator fails to meet the falsity element of the False Claims Act. A statement may be deemed 'false' for purposes of the False Claims Act if the statement represents "an objective falsehood,'" *U.S. ex rel. Yannacopoulos v. Gen. Dynamics*, 652 F.3d 818, 836 (7th Cir. 2011), or "if it is made in contravention of a statute, regulation, or contract." *Thulin v. Shopko Stores Operating Co., LLC*, 771 F.3d 994, 998 (7th Cir. 2014). There are several types of false statements, including "a claim for payment which is itself literally false and fraudulent," "fraud in the inducement," and "implied false certification." *Prose*, 17 F.4th at 740.

Similar to its scienter argument, Lilly states there is no statute or final regulation that contained the words "price increase value" or "price appreciation credit" until 2016. As a result, Lilly argues no jury could find a "clear obligation" of duty to include this part of the price in the Average Manufacturer's Price. *U.S. ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432 (3d Cir. 2004). Without this obligation, Lilly argues the statute is ambiguous.

To demonstrate the ambiguous nature of the statute, Lilly offers the following alternative interpretation of its obligations under the 1991 National Rebate Agreement: "Congress did not include any temporal limitations on 'price' in the AMP statute, and so one reasonable interpretation is that the undefined term refers to the "initial price" charged to the wholesalers (*i.e.*, excluding PIV)." (Mem. at 33, Dkt. No. 315.) This interpretation is foreclosed by the AMP's definition, which explicitly states that the AMP

"must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized." The Court finds the requirement for the "price actually realized" forecloses Lilly's theory that it is a reasonable interpretation of the guidelines to submit an "initial price" for the ultimate AMP calculations. The definition of the word "price," states, "the amount of money given or set as consideration for the sale of a specified thing." *Price, Merriam-Webster Dictionary* (2022) (https://www.merriam-webster.com/dictionary/price). The fact that Lilly tries to define "price" to mean "initial price" is a contortion of the regular meaning of the word and an internally inconsistent with itself.

Finally, Lilly argues that the "the FCA is not an appropriate vehicle for policing technical compliance with administrative regulations." *U.S. ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999). Lilly argues that, when there is a disputed legal issue as to the falsity of a statement, the Court should avoid punitive payments of the FCA. Because the Court finds, as a matter of law, that alternative readings of the statute as proposed by Lilly are objectively unreasonable, this argument also fails.

Relator's motion for summary judgment asks the Court to find that the record conclusively demonstrates that the statements were false in two respects. First, Relator argues that they were factually false because the AMP and related calculations were factually incorrect. Second, Relator ask the Court to find that the AMP certifications were legally false, because Lilly certified that its AMPs

were calculated in compliance with the law, and they were not.

In response, Lilly presents the same arguments discussed, and rejected, above. Lilly believes that the law was ambiguous, and thus the statements could not be false. As pointed out by the Relator, Lilly has essentially admitted through its actions that the claims were false. Since 2017, Lilly has included "price increase value" in its Average Manufacturer's Price submissions. Lilly does not intend to argue that these new submissions are false, making it impossible to argue the prior ones were not false, particular as the Court has determined as a matter of law that Lilly's interpretation of statute was objectively unreasonable. For these reasons, the Court grants Relator's motion for summary judgment on falsity and holds that Lilly's AMP calculations and related certifications were factually and legally false.

3. Materiality and Causation

Under the False Claims Act, a false statement is material is "a reasonable person would view the condition as important to a choice of action in the transaction" or "the defendant knew or had reason to know that the recipient of the representation attaches importance to that condition." *Prose*, 17 F.4th at 743.

Relator does not seek to apply either of these materiality standards in its briefing. Relator argues that, because Lilly's falsely lowered its Average Manufacturer's Price, it paid less money under the regulatory scheme, and thus materiality is established as a matter of law. This is incorrect. "[S]tatutory, regulatory, and contractual requirements are not automatically material, even if they are labeled

conditions of payment." *Universal Health Servs., Inc. v. United States ex. rel. Escobar*, 579 U.S. 176, 191 (2016). Relator must prove more than a difference in payment to show materiality under the False Claims Act.

In seeking summary judgment on causation, Relator does not even articulate the correct standard for causation in his briefing. The Court does not consider this to be a serious argument. The Motion for Summary Judgment as to both materiality and causation is denied.

IV. CONCLUSION

For the reasons stated herein, the Court rules as follows:

1. Denies Defendant Eli Lilly's Motion for Summary Judgment (Dkt. No. 314);

2. Denies in part and grants in part Relator's Motion for Summary Judgement (Dkt. No. 311); and

3. Grants in part and denies in part the Motions to Exclude Expert Opinions and Testimony. (Dkt. Nos. 293, 295, 297, 299, 301.)

IT IS SO ORDERED.

[handwritten: signature]
Harry D. Leinenweber, Judge
United States District Court

Appendix D

RELEVANT CONSTITUTIONAL AND STATUTORY PROVISIONS

U.S. Const. art. II, §2, cl.2

He shall have Power, by and with the Advice and Consent of the Senate, to make Treaties, provided two thirds of the Senators present concur; and he shall nominate, and by and with the Advice and Consent of the Senate, shall appoint Ambassadors, other public Ministers and Consuls, Judges of the supreme Court, and all other Officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by Law: but the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments.

U.S. Const. art. II, §3

He shall from time to time give to the Congress Information of the State of the Union, and recommend to their Consideration such Measures as he shall judge necessary and expedient; he may, on extraordinary Occasions, convene both Houses, or either of them, and in Case of Disagreement between them, with Respect to the Time of Adjournment, he may adjourn them to such Time as he shall think proper; he shall receive Ambassadors and other public Ministers; he shall take Care that the Laws be faithfully executed, and shall Commission all the Officers of the United States.

42 U.S.C. §1396r-8. Payment for covered outpatient drugs

(a) Requirement for rebate agreement

(1) In general

In order for payment to be available under section 1396b(a) of this title or under part B of subchapter XVIII for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer), and must meet the requirements of paragraph (5) (with respect to drugs purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992) and paragraph (6). Any agreement between a State and a manufacturer prior to April 1, 1991, shall be deemed to have been entered into on January 1, 1991, and payment to such manufacturer shall be retroactively calculated as if the agreement between the manufacturer and the State had been entered into on January 1, 1991. If a manufacturer has not entered into such an agreement before March 1, 1991, such an agreement, subsequently entered into, shall become effective as of the date on which the agreement is entered into or, at State option, on any date thereafter on or before the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

(2) Effective date

Paragraph (1) shall first apply to drugs dispensed under this subchapter on or after January 1, 1991.

(3) Authorizing payment for drugs not covered under rebate agreements

Paragraph (1), and section 1396b(i)(10)(A) of this title, shall not apply to the dispensing of a single source drug or innovator multiple source drug if (A)(i) the State has made a determination that the availability of the drug is essential to the health of beneficiaries under the State plan for medical assistance; (ii) such drug has been given a rating of 1-A by the Food and Drug Administration; and (iii)(I) the physician has obtained approval for use of the drug in advance of its dispensing in accordance with a prior authorization program described in subsection (d), or (II) the Secretary has reviewed and approved the State's determination under subparagraph (A); or (B) the Secretary determines that in the first calendar quarter of 1991, there were extenuating circumstances. The preceding sentence shall not apply to a single source drug or innovator multiple source drug of a manufacturer for any period described in section 5000D(c)(1) of the Internal Revenue Code of 1986 with respect to the manufacturer.

(4) Effect on existing agreements

In the case of a rebate agreement in effect between a State and a manufacturer on November 5, 1990, such agreement, for the initial agreement period specified therein, shall be considered to be a rebate agreement in compliance with this

section with respect to that State, if the State agrees to report to the Secretary any rebates paid pursuant to the agreement and such agreement provides for a minimum aggregate rebate of 10 percent of the State's total expenditures under the State plan for coverage of the manufacturer's drugs under this subchapter. If, after the initial agreement period, the State establishes to the satisfaction of the Secretary that an agreement in effect on November 5, 1990, provides for rebates that are at least as large as the rebates otherwise required under this section, and the State agrees to report any rebates under the agreement to the Secretary, the agreement shall be considered to be a rebate agreement in compliance with the section for the renewal periods of such agreement.

(5) Limitation on prices of drugs purchased by covered entities

(A) Agreement with Secretary

A manufacturer meets the requirements of this paragraph if the manufacturer has entered into an agreement with the Secretary that meets the requirements of section 256b of this title with respect to covered outpatient drugs purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992.

(B) "Covered entity" defined

In this subsection, the term "covered entity" means an entity described in section 256b(a)(4) of this title.

(C) Establishment of alternative mechanism to ensure against duplicate discounts or rebates

If the Secretary does not establish a mechanism under section 256b(a)(5)(A) of this title within 12 months of November 4, 1992, the following requirements shall apply:

(i) Entities

Each covered entity shall inform the single State agency under section 1396a(a)(5) of this title when it is seeking reimbursement from the State plan for medical assistance described in section 1396d(a)(12) of this title with respect to a unit of any covered outpatient drug which is subject to an agreement under section 256b(a) of this title.

(ii) State agency

Each such single State agency shall provide a means by which a covered entity shall indicate on any drug reimbursement claims form (or format, where electronic claims management is used) that a unit of the drug that is the subject of the form is subject to an agreement under section 256b of this title, and not submit to any manufacturer a claim for a rebate payment under subsection (b) with respect to such a drug.

(D) Effect of subsequent amendments

In determining whether an agreement under subparagraph (A) meets the requirements of section 256b of this title, the Secretary shall not take into account any amendments to such section that are enacted after November 4, 1992.

(E) Determination of compliance

A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 256b of this title (as in effect immediately after November 4, 1992) and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after November 4, 1992.

(6) Requirements relating to master agreements for drugs procured by Department of Veterans Affairs and certain other Federal agencies

(A) In general

A manufacturer meets the requirements of this paragraph if the manufacturer complies with the provisions of section 8126 of Title 38, including the requirement of entering into a master agreement with the Secretary of Veterans Affairs under such section.

(B) Effect of subsequent amendments

In determining whether a master agreement described in subparagraph (A) meets the requirements of section 8126 of Title 38, the Secretary shall not take into account any amendments to such section that are enacted after November 4, 1992.

(C) Determination of compliance

A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 8126 of Title 38, (as in effect immediately after November 4, 1992) and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after November 4, 1992.

(7) Requirement for submission of utilization data for certain physician administered drugs

(A) Single source drugs

In order for payment to be available under section 1396b(a) of this title for a covered outpatient drug that is a single source drug that is physician administered under this subchapter (as determined by the Secretary), and that is administered on or after January 1, 2006, the State shall provide for the collection and submission of such utilization

data and coding (such as J-codes and National Drug Code numbers) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates under this section for drugs administered for which payment is made under this subchapter.

(B) Multiple source drugs

(i) Identification of most frequently physician administered multiple source drugs

Not later than January 1, 2007, the Secretary shall publish a list of the 20 physician administered multiple source drugs that the Secretary determines have the highest dollar volume of physician administered drugs dispensed under this subchapter. The Secretary may modify such list from year to year to reflect changes in such volume.

(ii) Requirement

In order for payment to be available under section 1396b(a) of this title for a covered outpatient drug that is a multiple source drug that is physician administered (as determined by the Secretary), that is on the list published under clause (i), and that is administered on or after January 1, 2008, the State shall provide for the submission of such utilization data and coding (such as J-codes and National Drug Code numbers) for each such drug as the Secretary may

specify as necessary to identify the manufacturer of the drug in order to secure rebates under this section.

(C) Use of NDC codes

Not later than January 1, 2007, the information shall be submitted under subparagraphs (A) and (B)(ii) using National Drug Code codes unless the Secretary specifies that an alternative coding system should be used.

(D) Hardship waiver

The Secretary may delay the application of subparagraph (A) or (B)(ii), or both, in the case of a State to prevent hardship to States which require additional time to implement the reporting system required under the respective subparagraph.

(b) Terms of rebate agreement

(1) Periodic rebates

(A) In general

A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this subchapter, a rebate for a rebate period in an amount specified in subsection (c) for covered outpatient drugs of the manufacturer dispensed after December 31, 1990, for which payment was made under the State plan for such period, including such drugs dispensed to individuals enrolled with a medicaid managed care organization if the organization is responsible for coverage of

such drugs. Such rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for the period involved.

(B) Offset against medical assistance

Amounts received by a State under this section (or under an agreement authorized by the Secretary under subsection (a)(1) or an agreement described in subsection (a)(4)) in any quarter, including amounts received by a State under subsection (c)(4), shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1396b(a)(1) of this title.

(C) Special rule for increased minimum rebate percentage

(i) In general

In addition to the amounts applied as a reduction under subparagraph (B), for rebate periods beginning on or after January 1, 2010, during a fiscal year, the Secretary shall reduce payments to a State under section 1396b(a) of this title in the manner specified in clause (ii), in an amount equal to the product of—

(I) 100 percent minus the Federal medical assistance percentage applicable to the rebate period for the State; and

(II) the amounts received by the State under such subparagraph that

are attributable (as estimated by the Secretary based on utilization and other data) to the increase in the minimum rebate percentage effected by the amendments made by subsections (a)(1), (b), and (d) of section 2501 of the Patient Protection and Affordable Care Act, taking into account the additional drugs included under the amendments made by subsection (c) of section 2501 of such Act.

The Secretary shall adjust such payment reduction for a calendar quarter to the extent the Secretary determines, based upon subsequent utilization and other data, that the reduction for such quarter was greater or less than the amount of payment reduction that should have been made.

(ii) Manner of payment reduction

The amount of the payment reduction under clause (i) for a State for a quarter shall be deemed an overpayment to the State under this subchapter to be disallowed against the State's regular quarterly draw for all Medicaid spending under section 1396b(d)(2) of this title. Such a disallowance is not subject to a reconsideration under section 1316(d) of this title.

(2) State provision of information

(A) State responsibility

Each State agency under this subchapter shall report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan during the period, including such information reported by each medicaid managed care organization, and shall promptly transmit a copy of such report to the Secretary.

(B) Audits

A manufacturer may audit the information provided (or required to be provided) under subparagraph (A). Adjustments to rebates shall be made to the extent that information indicates that utilization was greater or less than the amount previously specified.

(3) Manufacturer provision of price and drug product information

(A) In general

Each manufacturer with an agreement in effect under this section shall report to the Secretary—

(i) not later than 30 days after the last day of each rebate period under the agreement—

(I) on the average manufacturer price (as defined in subsection (k)(1)) for covered outpatient drugs for the rebate period under the agreement (including for all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act); and

(II) for single source drugs and innovator multiple source drugs (including all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), on the manufacturer's best price (as defined in subsection (c)(1)(C)) for such drugs for the rebate period under the agreement;

(ii) not later than 30 days after the date of entering into an agreement under this section on the average manufacturer price (as defined in subsection (k)(1)) as of October 1, 1990 for each of the manufacturer's covered outpatient drugs (including for such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act);

(iii) for calendar quarters beginning on or after January 1, 2004, in conjunction with reporting required under clause (i)

and by National Drug Code (including package size)—

(I) the manufacturer's average sales price (as defined in section 1395w-3a(c) of this title) and the total number of units specified under section 1395w-3a(b)(2)(A) of this title;

(II) if required to make payment under section 1395w-3a of this title, the manufacturer's wholesale acquisition cost, as defined in subsection (c)(6) of such section; and

(III) information on those sales that were made at a nominal price or otherwise described in section 1395w-3a(c) (2)(B) of this title;

for a drug or biological described in subparagraph (C), (D), (E), or (G) of section 1395u(o)(1) of this title or section 1395rr(b)(14)(B) of this title, and, for calendar quarters beginning on or after January 1, 2007 and only with respect to the information described in subclause (III), for covered outpatient drugs;

(iv) not later than 30 days after the last day of each month of a rebate period under the agreement, on the manufacturer's total number of units that are used to calculate the monthly average manufacturer price for each covered outpatient drug; and

(v) not later than 30 days after the last day of each month of a rebate period under the agreement, such drug product information as the Secretary shall require for each of the manufacturer's covered outpatient drugs.

Information reported under this subparagraph is subject to audit by the Inspector General of the Department of Health and Human Services. Beginning July 1, 2006, the Secretary shall provide on a monthly basis to States under subparagraph (D)(iv) the most recently reported average manufacturer prices for single source drugs and for multiple source drugs and shall, on at least a quarterly basis, update the information posted on the website under subparagraph (D)(v) (relating to the weighted average of the most recently reported monthly average manufacturer prices). For purposes of applying clause (iii), for calendar quarters beginning on or after January 1, 2022, a drug or biological described in the flush matter following such clause includes items, services, supplies, and products that are payable under part B of subchapter XVIII as a drug or biological.

(B) Verification surveys of average manufacturer price and manufacturer's average sales price

The Secretary may survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed $100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1320a-7a of this title (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(C) Penalties

(i) Failure to provide timely information

In the case of a manufacturer with an agreement under this section that fails to provide information required under

subparagraph (A) on a timely basis, the amount of the penalty shall be increased by $10,000 for each day in which such information has not been provided and such amount shall be paid to the Treasury, and, if such information is not reported within 90 days of the deadline imposed, the agreement shall be suspended for services furnished after the end of such 90-day period and until the date such information is reported (but in no case shall such suspension be for a period of less than 30 days).

(ii) False information

Any manufacturer with an agreement under this section that knowingly provides false information, including information related to drug pricing, drug product information, and data related to drug pricing or drug product information, is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law. The provisions of section 1320a-7a of this title (other than subsections (a), (b), (f)(3), and (f)(4)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(iii) Misclassified drug product or misreported information

(I) In general

Any manufacturer with an agreement under this section that knowingly (as defined in section 1003.110 of title 42, Code of Federal Regulations (or any successor regulation)) misclassifies a covered outpatient drug, such as by knowingly submitting incorrect drug product information, is subject to a civil money penalty for each covered outpatient drug that is misclassified in an amount not to exceed 2 times the amount of the difference between—

(aa) the total amount of rebates that the manufacturer paid with respect to the drug to all States for all rebate periods during which the drug was misclassified; and

(bb) the total amount of rebates that the manufacturer would have been required to pay, as determined by the Secretary using drug product information provided by the manufacturer, with respect to the drug to all States for all rebate periods during which the drug was

misclassified if the drug had been correctly classified.

(II) Other penalties and recovery of underpaid rebates

The civil money penalties described in subclause (I) are in addition to other penalties as may be prescribed by law and any other recovery of the underlying underpayment for rebates due under this section or the terms of the rebate agreement as determined by the Secretary.

(iv) Increasing oversight and enforcement

Each year the Secretary shall retain, in addition to any amount retained by the Secretary to recoup investigation and litigation costs related to the enforcement of the civil money penalties under this subparagraph and subsection (c)(4)(B)(ii)(III), an amount equal to 25 percent of the total amount of civil money penalties collected under this subparagraph and subsection (c)(4)(B)(ii)(III) for the year, and such retained amount shall be available to the Secretary, without further appropriation and until expended, for activities related to the oversight and enforcement of this section and agreements under this section, including—

(I) improving drug data reporting systems;

(II) evaluating and ensuring manufacturer compliance with rebate obligations; and

(III) oversight and enforcement related to ensuring that manufacturers accurately and fully report drug information, including data related to drug classification.

(D) Confidentiality of information

Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A) (other than the wholesale acquisition cost for purposes of carrying out section 1395w-3a of this title) is confidential and shall not be disclosed by the Secretary or the Secretary of Veterans Affairs or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except—

(i) as the Secretary determines to be necessary to carry out this section, to carry out section 1395w-3a of this title (including the determination and implementation of the payment amount and the rebate), or to carry out section 1395w-3b of this title, section 1320f-1(f) of this title, including rebates under

paragraph (4) of such section, or section 1395w-114b of this title,

(ii) to permit the Comptroller General to review the information provided,

(iii) to permit the Director of the Congressional Budget Office to review the information provided,

(iv) to States to carry out this subchapter,

(v) to the Secretary to disclose (through a website accessible to the public) the weighted average of the most recently reported monthly average manufacturer prices and the average retail survey price determined for each multiple source drug in accordance with subsection (f),

(vi) in the case of categories of drug product or classification information that were not considered confidential by the

Secretary on the day before April 18, 2019, and

(vii) to permit the Executive Director of the Medicare Payment Advisory Commission and the Executive Director of the Medicaid and CHIP Payment and Access Commission to review the information provided.

The previous sentence shall also apply to information disclosed under section 1395w-102(d)(2) or 1395w-104(c)(2)(G) of this title and drug pricing data reported under the first sentence of section 1395w-141(i)(1) of this

title. Any information disclosed to the Executive Director of the Medicare Payment Advisory Commission or the Executive Director of the Medicaid and CHIP Payment and Access Commission pursuant to this subparagraph shall not be disclosed by either such Executive Director in a form which discloses the identity of a specific manufacturer or wholesaler or prices charged for drugs by such manufacturer or wholesaler. Such information also shall not be disclosed by either such Executive Director to individual Commissioners of the Medicare Payment Advisory Commission or of the Medicaid and CHIP Payment and Access Commission in a form which discloses the identity of a specific manufacturer or wholesaler or prices charged for drugs by such manufacturer or wholesaler.

(4) Length of agreement

(A) In general

A rebate agreement shall be effective for an initial period of not less than 1 year and shall be automatically renewed for a period of not less than one year unless terminated under subparagraph (B).

(B) Termination

(i) By the Secretary

The Secretary may provide for termination of a rebate agreement for violation of the requirements of the agreement or other good cause shown.

Such termination shall not be effective earlier than 60 days after the date of notice of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(ii) By a manufacturer

A manufacturer may terminate a rebate agreement under this section for any reason. Any such termination shall not be effective until the calendar quarter beginning at least 60 days after the date the manufacturer provides notice to the Secretary.

(iii) Effectiveness of termination

Any termination under this subparagraph shall not affect rebates due under the agreement before the effective date of its termination.

(iv) Notice to States

In the case of a termination under this subparagraph, the Secretary shall provide notice of such termination to the States within not less than 30 days before the effective date of such termination.

(v) Application to terminations of other agreements

The provisions of this subparagraph shall apply to the terminations of agreements described in section 256b(a)(1) of this

title and master agreements described in section 8126(a) of Title 38.

(C) Delay before reentry

In the case of any rebate agreement with a manufacturer under this section which is terminated, another such agreement with the manufacturer (or a successor manufacturer) may not be entered into until a period of 1 calendar quarter has elapsed since the date of the termination, unless the Secretary finds good cause for an earlier reinstatement of such an agreement.

(c) Determination of amount of rebate

(1) Basic rebate for single source drugs and innovator multiple source drugs

(A) In general

Except as provided in paragraph (2), the amount of the rebate specified in this subsection for a rebate period (as defined in subsection (k)(8)) with respect to each dosage form and strength of a single source drug or an innovator multiple source drug shall be equal to the product of—

(i) the total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) subject to subparagraph (B)(ii), the greater of—

(I) the difference between the average manufacturer price and the

best price (as defined in subparagraph (C)) for the dosage form and strength of the drug, or

(II) the minimum rebate percentage (specified in subparagraph (B)(i)) of such average manufacturer price,

for the rebate period.

(B) Range of rebates required

(i) Minimum rebate percentage

For purposes of subparagraph (A)(ii)(II), the "minimum rebate percentage" for rebate periods beginning—

(I) after December 31, 1990, and before October 1, 1992, is 12.5 percent;

(II) after September 30, 1992, and before January 1, 1994, is 15.7 percent;

(III) after December 31, 1993, and before January 1, 1995, is 15.4 percent;

(IV) after December 31, 1994, and before January 1, 1996, is 15.2 percent;

(V) after December 31, 1995, and before January 1, 2010[1] is 15.1 percent; and

[1] So in original. Probably should be followed by a comma.

(VI) except as provided in clause (iii), after December 31, 2009,[2] 23.1 percent.

(ii) Temporary limitation on maximum rebate amount

In no case shall the amount applied under subparagraph (A)(ii) for a rebate period beginning—

(I) before January 1, 1992, exceed 25 percent of the average manufacturer price; or

(II) after December 31, 1991, and before January 1, 1993, exceed 50 percent of the average manufacturer price.

(iii) Minimum rebate percentage for certain drugs

(I) In general

In the case of a single source drug or an innovator multiple source drug described in subclause (II), the minimum rebate percentage for rebate periods specified in clause (i)(VI) is 17.1 percent.

(II) Drug described

For purposes of subclause (I), a single source drug or an innovator multiple source drug described in

[2] So in original. Probably should be followed by "is".

this subclause is any of the following drugs:

(aa) A clotting factor for which a separate furnishing payment is made under section 1395u(o)(5) of this title and which is included on a list of such factors specified and updated regularly by the Secretary.

(bb) A drug approved by the Food and Drug Administration exclusively for pediatric indications.

(C) "Best price" defined

For purposes of this section—

(i) In general

The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding—

(I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of Title 38, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) (including inpatient prices charged to hospitals described in section 256b(a)(4)(L) of this title);

(II) any prices charged under the Federal Supply Schedule of the General Services Administration;

(III) any prices used under a State pharmaceutical assistance program;

(IV) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(V) the prices negotiated from drug manufacturers for covered discount card drugs under an endorsed discount card program under section 1395w-141 of this title; and

(VI) subject to clause (ii)(V), any prices charged which are negotiated by a prescription drug plan under part D of subchapter XVIII, by an MA-PD plan under part C of such subchapter with respect to covered part D drugs or by a qualified retiree prescription drug plan (as defined in

section 1395w-132(a)(2) of this title) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such subchapter, or any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1395w-114a of this title or under the manufacturer discount program under section 1395w-114c of this title.

(ii) Special rules

The term "best price"—

(I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section, section 1395w-3a(i) of this title, or section 1395w-114b of this title);

(II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package;

(III) shall not take into account prices that are merely nominal in amount[3]

[3] So in original. Probably should be followed by a semicolon.

(IV) in the case of a manufacturer that approves, allows, or otherwise permits any other drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, shall be inclusive of the lowest price for such authorized drug available from the manufacturer during the rebate period to any manufacturer, wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding those prices described in subclauses (I) through (IV) of clause (i); and

(V) in the case of a rebate period and a covered outpatient drug that is a selected drug (as referred to in section 1320f-1(c) of this title) during such rebate period, shall be inclusive of the maximum fair price (as defined in section 1320f(c)(3) of this title) for such drug with respect to such period.

(iii) Application of auditing and recordkeeping requirements

With respect to a covered entity described in section 256b(a)(4)(L) of this title, any drug purchased for inpatient use shall be subject to the auditing and

recordkeeping requirements described in section 256b(a)(5)(C) of this title.

(D) Limitation on sales at a nominal price

(i) In general

For purposes of subparagraph (C)(ii)(III) and subsection (b)(3)(A)(iii)(III), only sales by a manufacturer of covered outpatient drugs at nominal prices to the following shall be considered to be sales at a nominal price or merely nominal in amount:

(I) A covered entity described in section 256b(a)(4) of this title.

(II) An intermediate care facility for the mentally retarded.

(III) A State-owned or operated nursing facility.

(IV) An entity that—

(aa) is described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of such Act[4] or is State-owned or operated; and

(bb) would be a covered entity described in section 256b(a)(4) of this title insofar as the entity provides the same type of

[4] So in original. Probably should read "such Code".

services to the same type of populations as a covered entity described in such section provides, but does not receive funding under a provision of law referred to in such section;

(V) A public or nonprofit entity, or an entity based at an institution of higher learning whose primary purpose is to provide health care services to students of that institution, that provides a service or services described under section 300(a) of this title.

(VI) Any other facility or entity that the Secretary determines is a safety net provider to which sales of such drugs at a nominal price would be appropriate based on the factors described in clause (ii).

(ii) Factors

The factors described in this clause with respect to a facility or entity are the following:

(I) The type of facility or entity.

(II) The services provided by the facility or entity.

(III) The patient population served by the facility or entity.

(IV) The number of other facilities or entities eligible to purchase at

nominal prices in the same service area.

(iii) Nonapplication

Clause (i) shall not apply with respect to sales by a manufacturer at a nominal price of covered outpatient drugs pursuant to a master agreement under section 8126 of Title 38.

(iv) Rule of construction

Nothing in this subparagraph shall be construed to alter any existing statutory or regulatory prohibition on services with respect to an entity described in clause (i)(IV), including the prohibition set forth in section 300a-6 of this title.

(2) Additional rebate for single source and innovator multiple source drugs

(A) In general

The amount of the rebate specified in this subsection for a rebate period, with respect to each dosage form and strength of a single source drug or an innovator multiple source drug, shall be increased by an amount equal to the product of—

(i) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period; and

(ii) the amount (if any) by which—

(I) the average manufacturer price for the dosage form and strength of the drug for the period, exceeds

(II) the average manufacturer price for such dosage form and strength for the calendar quarter beginning July 1, 1990 (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index for September 1990.

(B) Treatment of subsequently approved drugs

In the case of a covered outpatient drug approved by the Food and Drug Administration after October 1, 1990, clause (ii)(II) of subparagraph (A) shall be applied by substituting "the first full calendar quarter after the day on which the drug was first marketed" for "the calendar quarter beginning July 1, 1990" and "the month prior to the first month of the first full calendar quarter after the day on which the drug was first marketed" for "September 1990".

(C) Treatment of new formulations

(i) In general

In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the rebate obligation for a rebate period with respect to such drug under this subsection shall be the greater of the amount described in clause (ii) for such drug or the amount described in clause (iii) for such drug.

(ii) Amount 1

For purposes of clause (i), the amount described in this clause with respect to a drug described in clause (i) and rebate period is the amount computed under paragraph (1) for such drug, increased by the amount computed under subparagraph (A) and, as applicable, subparagraph (B) for such drug and rebate period.

(iii) Amount 2

For purposes of clause (i), the amount described in this clause with respect to a drug described in clause (i) and rebate period is the amount computed under paragraph (1) for such drug, increased by the product of—

(I) the average manufacturer price for the rebate period of the line extension of a single source drug or

an innovator multiple source drug that is an oral solid dosage form;

(II) the highest additional rebate (calculated as a percentage of average manufacturer price) under this paragraph for the rebate period for any strength of the original single source drug or innovator multiple source drug; and

(III) the total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).

In this subparagraph, the term "line extension" means, with respect to a drug, a new formulation of the drug, such as an extended release formulation, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation.

(D) Maximum rebate amount

In no case shall the sum of the amounts applied under paragraph (1)(A)(ii) and this paragraph with respect to each dosage form and strength of a single source drug or an innovator multiple source drug for a rebate period beginning after December 31, 2009, and before January 1, 2024, exceed 100

percent of the average manufacturer price of the drug.

(3) Rebate for other drugs

(A) In general

Except as provided in subparagraph (C), the amount of the rebate paid to a State for a rebate period with respect to each dosage form and strength of covered outpatient drugs (other than single source drugs and innovator multiple source drugs) shall be equal to the product of—

(i) the applicable percentage (as described in subparagraph (B)) of the average manufacturer price for the dosage form and strength for the rebate period, and

(ii) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period.

(B) "Applicable percentage" defined

For purposes of subparagraph (A)(i), the "applicable percentage" for rebate periods beginning—

(i) before January 1, 1994, is 10 percent,

(ii) after December 31, 1993, and before January 1, 2010, is 11 percent;[5] and

[5] So in original. The semicolon probably should be a comma.

(iii) after December 31, 2009, is 13 percent.

(C) Additional rebate

(i) In general

The amount of the rebate specified in this paragraph for a rebate period, with respect to each dosage form and strength of a covered outpatient drug other than a single source drug or an innovator multiple source drug of a manufacturer, shall be increased in the manner that the rebate for a dosage form and strength of a single source drug or an innovator multiple source drug is increased under subparagraphs (A) and (D) of paragraph (2), except as provided in clause (ii).

(ii) Special rules for application of provision

In applying subparagraphs (A) and (D) of paragraph (2) under clause (i)—

(I) the reference in subparagraph (A)(i) of such paragraph to "1990" shall be deemed a reference to "2014";

(II) subject to clause (iii), the reference in subparagraph (A)(ii) of such paragraph to "the calendar quarter beginning July 1, 1990" shall be deemed a reference to "the calendar quarter beginning July 1, 2014"; and

(III) subject to clause (iii), the reference in subparagraph (A)(ii) of such paragraph to "September 1990" shall be deemed a reference to "September 2014";

(IV) the references in subparagraph (D) of such paragraph to "paragraph (1)(A)(ii)", "this paragraph", and "December 31, 2009" shall be deemed references to "subparagraph (A)", "this subparagraph", and "December 31, 2014", respectively; and

(V) any reference in such paragraph to a "single source drug or an innovator multiple source drug" shall be deemed to be a reference to a drug to which clause (i) applies.

(iii) Special rule for certain noninnovator multiple source drugs

In applying paragraph (2)(A)(ii)(II) under clause (i) with respect to a covered outpatient drug that is first marketed as a drug other than a single source drug or an innovator multiple source drug after April 1, 2013, such paragraph shall be applied—

(I) by substituting "the applicable quarter" for "the calendar quarter beginning July 1, 1990"; and

(II) by substituting "the last month in such applicable quarter" for "September 1990".

(iv) Applicable quarter defined

In this subsection, the term "applicable quarter" means, with respect to a drug described in clause (iii), the fifth full calendar quarter after which the drug is marketed as a drug other than a single source drug or an innovator multiple source drug.

(4) Recovery of unpaid rebate amounts due to misclassification of covered outpatient drugs

(A) In general

If the Secretary determines that a manufacturer with an agreement under this section paid a lower per-unit rebate amount to a State for a rebate period as a result of the misclassification by the manufacturer of a covered outpatient drug (without regard to whether the manufacturer knowingly made the misclassification or should have known that the misclassification would be made) than the per-unit rebate amount that the manufacturer would have paid to the State if the drug had been correctly classified, the manufacturer shall pay to the State an amount equal to the product of—

(i) the difference between—

(I) the per-unit rebate amount paid to the State for the period; and

(II) the per-unit rebate amount that the manufacturer would have paid to the State for the period, as

determined by the Secretary, if the drug had been correctly classified; and

(ii) the total units of the drug paid for under the State plan in the period.

(B) Authority to correct misclassifications

(i) In general

If the Secretary determines that a manufacturer with an agreement under this section has misclassified a covered outpatient drug (without regard to whether the manufacturer knowingly made the misclassification or should have known that the misclassification would be made), the Secretary shall notify the manufacturer of the misclassification and require the manufacturer to correct the misclassification in a timely manner.

(ii) Enforcement

If, after receiving notice of a misclassification from the Secretary under clause (i), a manufacturer fails to correct the misclassification by such time as the Secretary shall require, until the manufacturer makes such correction, the Secretary may do any or all of the following:

(I) Correct the misclassification, using drug product information provided by the manufacturer, on behalf of the manufacturer.

(II) Suspend the misclassified drug and the drug's status as a covered outpatient drug under the manufacturer's national rebate agreement, and exclude the misclassified drug from Federal financial participation in accordance with section 1396b(i)(10)(E) of this title.

(III) Impose a civil money penalty (which shall be in addition to any other recovery or penalty which may be available under this section or any other provision of law) for each rebate period during which the drug is misclassified not to exceed an amount equal to the product of—

(aa) the total number of units of each dosage form and strength of such misclassified drug paid for under any State plan during such a rebate period; and

(bb) 23.1 percent of the average manufacturer price for the dosage form and strength of such misclassified drug.

(C) Reporting and transparency

(i) In general

The Secretary shall submit a report to Congress on at least an annual basis that includes information on the covered outpatient drugs that have been

identified as misclassified, any steps taken to reclassify such drugs, the actions the Secretary has taken to ensure the payment of any rebate amounts which were unpaid as a result of such misclassification, and a disclosure of expenditures from the fund created in subsection (b)(3)(C)(iv), including an accounting of how such funds have been allocated and spent in accordance with such subsection.

(ii) Public access

The Secretary shall make the information contained in the report required under clause (i) available to the public on a timely basis.

(D) Other penalties and actions

Actions taken and penalties imposed under this clause shall be in addition to other remedies available to the Secretary including terminating the manufacturer's rebate agreement for noncompliance with the terms of such agreement and shall not exempt a manufacturer from, or preclude the Secretary from pursuing, any civil money penalty under this subchapter or subchapter XI, or any other penalty or action as may be prescribed by law.

(d) Limitations on coverage of drugs

(1) Permissible restrictions

(A) A State may subject to prior authorization any covered outpatient drug.

Any such prior authorization program shall comply with the requirements of paragraph (5).

(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if—

(i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6));

(ii) the drug is contained in the list referred to in paragraph (2);

(iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) or in effect pursuant to subsection (a)(4); or

(iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).

(2) List of drugs subject to restriction

The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

(A) Agents when used for anorexia, weight loss, or weight gain.

(B) Agents when used to promote fertility.

(C) Agents when used for cosmetic purposes or hair growth.

(D) Agents when used for the symptomatic relief of cough and colds.

(E) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

(F) Nonprescription drugs, except, in the case of pregnant women when recommended in accordance with the Guideline referred to in section 1396d(bb)(2)(A) of this title, agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.

(G) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

(H) Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.

(3) Update of drug listings

The Secretary shall, by regulation, periodically update the list of drugs or classes of drugs described in paragraph (2) or their medical uses, which the Secretary has determined, based on data collected by surveillance and utilization review programs of State medical assistance programs, to be subject to clinical abuse or inappropriate use.

(4) Requirements for formularies

A State may establish a formulary if the formulary meets the following requirements:

(A) The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State (or, at the option of the State, the State's drug use review board established under subsection (g)(3)).

(B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) (other than any drug excluded from coverage or otherwise restricted under paragraph (2)).

(C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act but is a medically accepted indication, based on information from the appropriate compendia described in subsection (k)(6)), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is

a written explanation (available to the public) of the basis for the exclusion.

(D) The State plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a prior authorization program that is consistent with paragraph (5).

(E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.

A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.

(5) Requirements of prior authorization programs

A State plan under this subchapter may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6)) only if the system providing for such approval—

(A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and

(B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

(6) Other permissible restrictions

A State may impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under this chapter.

(7) Non-excludable drugs

The following drugs or classes of drugs, or their medical uses, shall not be excluded from coverage:

(A) Agents when used to promote smoking cessation, including agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.

(B) Barbiturates.

(C) Benzodiazepines.

(D) Drugs and biological products described in subsection (ee)(1)(A) of section 1396d of this title that are furnished as medical assistance in accordance with subsection (a)(29) of such section and section 1396a(a)(10)(A) of this title.

(E) Drugs and biological products to which section 1396d(a)(4)(F) of this title and subclause (XVIII) in the matter following subparagraph (G) of section 1396a(a)(10) of this title apply that are furnished as medical assistance in accordance with such section or clause, respectively, for the treatment or prevention, of COVID-19, as described in such subparagraph or subclause, respectively, and section 1396a(a)(10)(A) of this title.

(e) Treatment of pharmacy reimbursement limits

(1) In general

During the period beginning on January 1, 1991, and ending on December 31, 1994—

(A) a State may not reduce the payment limits established by regulation under this subchapter or any limitation described in paragraph (3) with respect to the ingredient cost of a covered outpatient drug or the dispensing fee for such a drug below the limits in effect as of January 1, 1991, and

(B) except as provided in paragraph (2), the Secretary may not modify by regulation the formula established under sections 447.331 through 447.334 of title 42, Code of Federal Regulations, in effect on November 5, 1990, to reduce the limits described in subparagraph (A).

(2) Special rule

If a State is not in compliance with the regulations described in paragraph (1)(B), paragraph (1)(A) shall not apply to such State until such State is in compliance with such regulations.

(3) Effect on State maximum allowable cost limitations

This section shall not supersede or affect provisions in effect prior to January 1, 1991, or after December 31, 1994, relating to any maximum allowable cost limitation established by a State for payment by the State for covered outpatient drugs, and rebates shall be made under this section without regard to whether or not payment by the State for such drugs is subject to such a limitation or the amount of such a limitation.

[(4)][6] Establishment of upper payment limits

Subject to paragraph (5), the Secretary shall establish a Federal upper reimbursement limit for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent, regardless of whether all such additional formulations are rated as such and shall use only such formulations when determining any such upper limit.

(5) Use of AMP in upper payment limits

The Secretary shall calculate the Federal upper reimbursement limit established under

[6] See 1993 Amendments note.

paragraph (4) as no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly average manufacturer prices for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. The Secretary shall implement a smoothing process for average manufacturer prices. Such process shall be similar to the smoothing process used in determining the average sales price of a drug or biological under section 1395w-3a of this title.

(f) Survey of retail prices; State payment and utilization rates; and performance rankings

(1) Survey of retail prices

(A) Use of vendor The Secretary may contract services for—

(i) with respect to a retail community pharmacy, the determination on a monthly basis of retail survey prices for covered outpatient drugs that represent a nationwide average of consumer purchase prices for such drugs, net of all discounts and rebates (to the extent any information with respect to such discounts and rebates is available); and

(ii) the notification of the Secretary when a drug product that is therapeutically and pharmaceutically equivalent and bioequivalent becomes generally available.

(B) Secretary response to notification of availability of multiple source products

If contractor notifies the Secretary under subparagraph (A)(ii) that a drug product described in such subparagraph has become generally available, the Secretary shall make a determination, within 7 days after receiving such notification, as to whether the product is now described in subsection (e)(4).

(C) Use of competitive bidding

In contracting for such services, the Secretary shall competitively bid for an outside vendor that has a demonstrated history in—

(i) surveying and determining, on a representative nationwide basis, retail prices for ingredient costs of prescription drugs;

(ii) working with retail community pharmacies, commercial payers, and States in obtaining and disseminating such price information; and

(iii) collecting and reporting such price information on at least a monthly basis.

In contracting for such services, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this subsection, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

(D) Additional provisions

A contract with a vendor under this paragraph shall include such terms and conditions as the Secretary shall specify, including the following:

(i) The vendor must monitor the marketplace and report to the Secretary each time there is a new covered outpatient drug generally available.

(ii) The vendor must update the Secretary no less often than monthly on the retail survey prices for covered outpatient drugs.

(iii) The contract shall be effective for a term of 2 years.

(E) Availability of information to States

Information on retail survey prices obtained under this paragraph, including applicable information on single source drugs, shall be provided to States on at least a monthly basis. The Secretary shall devise and implement a means for providing access to each State agency designated under section 1396a(a)(5) of this title with responsibility for the administration or supervision of the administration of the State plan under this subchapter of the retail survey price determined under this paragraph.

(2) Annual State report

Each State shall annually report to the Secretary information on—

(A) the payment rates under the State plan under this subchapter for covered outpatient drugs;

(B) the dispensing fees paid under such plan for such drugs; and

(C) utilization rates for noninnovator multiple source drugs under such plan.

(3) Annual State performance rankings

(A) Comparative analysis

The Secretary annually shall compare, for the 50 most widely prescribed drugs identified by the Secretary, the national retail sales price data (collected under paragraph (1)) for such drugs with data on prices under this subchapter for each such drug for each State.

(B) Availability of information

The Secretary shall submit to Congress and the States full information regarding the annual rankings made under subparagraph (A).

(4) Appropriation

Out of any funds in the Treasury not otherwise appropriated, there is appropriated to the Secretary of Health and Human Services $5,000,000 for each of fiscal years 2006 through 2010 to carry out this subsection.

(g) Drug use review

(1) In general

(A) In order to meet the requirement of section 1396a(a)(54) of this title, a State shall provide for a drug use review program

described in paragraph (2) for covered outpatient drugs in order to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results. The program shall be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, excessive utilization, inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization, among physicians, pharmacists, and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs including education on therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.

(B) The program shall assess data on drug use against predetermined standards, consistent with the following:

(i) compendia which shall consist of the following:

(I) American Hospital Formulary Service Drug Information;

(II) United States Pharmacopeia-Drug Information (or its successor publications); and

(III) the DRUGDEX Information System; and

(ii) the peer-reviewed medical literature.

(C) The Secretary, under the procedures established in section 1396b of this title, shall pay to each State an amount equal to 75 per centum of so much of the sums expended by the State plan during calendar years 1991 through 1993 as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of this subsection.

(D) States shall not be required to perform additional drug use reviews with respect to drugs dispensed to residents of nursing facilities which are in compliance with the drug regimen review procedures prescribed by the Secretary for such facilities in regulations implementing section 1396r of this title, currently at section 483.60 of title 42, Code of Federal Regulations.

(2) Description of program

Each drug use review program shall meet the following requirements for covered outpatient drugs:

(A) Prospective drug review

(i) The State plan shall provide for a review of drug therapy before each

prescription is filled or delivered to an individual receiving benefits under this subchapter, typically at the point-of-sale or point of distribution. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Each State shall use the compendia and literature referred to in paragraph (1)(B) as its source of standards for such review.

(ii) As part of the State's prospective drug use review program under this subparagraph applicable State law shall establish standards for counseling of individuals receiving benefits under this subchapter by pharmacists which includes at least the following:

> **(I)** The pharmacist must offer to discuss with each individual receiving benefits under this subchapter or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a prescription, matters which in the exercise of the pharmacist's

professional judgment (consistent with State law respecting the provision of such information), the pharmacist deems significant including the following:

(aa) The name and description of the medication.

(bb) The route, dosage form, dosage, route of administration, and duration of drug therapy.

(cc) Special directions and precautions for preparation, administration and use by the patient.

(dd) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

(ee) Techniques for self-monitoring drug therapy.

(ff) Proper storage.

(gg) Prescription refill information.

(hh) Action to be taken in the event of a missed dose.

(II) A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the

following information regarding individuals receiving benefits under this subchapter:

(aa) Name, address, telephone number, date of birth (or age) and gender.

(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

(cc) Pharmacist comments relevant to the individual's drug therapy. Nothing in this clause shall be construed as requiring a pharmacist to provide consultation when an individual receiving benefits under this subchapter or caregiver of such individual refuses such consultation, or to require verification of the offer to provide consultation or a refusal of such offer.

(B) Retrospective drug use review

The program shall provide, through its mechanized drug claims processing and information retrieval systems (approved by the Secretary under section 1396b(r) of this title) or otherwise, for the ongoing periodic examination of claims data and other records

in order to identify patterns of fraud, abuse, gross overuse, excessive utilization, inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization, among physicians, pharmacists and individuals receiving benefits under this subchapter, or associated with specific drugs or groups of drugs.

(C) Application of standards

The program shall, on an ongoing basis, assess data on drug use against explicit predetermined standards (using the compendia and literature referred to in subsection[7] (1)(B) as the source of standards for such assessment) including but not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse and, as necessary, introduce remedial strategies, in order to improve the quality of care and to conserve program funds or personal expenditures.

(D) Educational program

The program shall, through its State drug use review board established under paragraph (3), either directly or through contracts with

[7] So in original. Probably should be "paragraph".

accredited health care educational institutions, State medical societies or State pharmacists associations/ societies or other organizations as specified by the State, and using data provided by the State drug use review board on common drug therapy problems, provide for active and ongoing educational outreach programs (including the activities described in paragraph (3)(C)(iii) of this subsection) to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices.

(3) State drug use review board

(A) Establishment

Each State shall provide for the establishment of a drug use review board (hereinafter referred to as the "DUR Board") either directly or through a contract with a private organization.

(B) Membership

The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

(i) The clinically appropriate prescribing of covered outpatient drugs.

(ii) The clinically appropriate dispensing and monitoring of covered outpatient drugs.

(iii) Drug use review, evaluation, and intervention.

(iv) Medical quality assurance.

The membership of the DUR Board shall be made up at least 1/3 but no more than 51 percent licensed and actively practicing physicians and at least 1/3 * * *[8] licensed and actively practicing pharmacists.

(C) Activities

The activities of the DUR Board shall include but not be limited to the following:

(i) Retrospective DUR as defined in section[7] (2)(B).

(ii) Application of standards as defined in section[7] (2)(C).

(iii) Ongoing interventions for physicians and pharmacists, targeted toward therapy problems or individuals identified in the course of retrospective drug use reviews performed under this subsection. Intervention programs shall include, in appropriate instances, at least:

(I) information dissemination sufficient to ensure the ready availability to physicians and pharmacists in the State of

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[8] So in original.

[7] So in original. Probably should be "paragraph".

[7] So in original. Probably should be "paragraph".

information concerning its duties, powers, and basis for its standards;

(II) written, oral, or electronic reminders containing patient-specific or drug-specific (or both) information and suggested changes in prescribing or dispensing practices, communicated in a manner designed to ensure the privacy of patient-related information;

(III) use of face-to-face discussions between health care professionals who are experts in rational drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention, including discussion of optimal prescribing, dispensing, or pharmacy care practices, and follow-up face-to-face discussions; and

(IV) intensified review or monitoring of selected prescribers or dispensers.

The Board shall re-evaluate interventions after an appropriate period of time to determine if the intervention improved the quality of drug therapy, to evaluate the success of the interventions and make modifications as necessary.

(D) Annual report

Each State shall require the DUR Board to prepare a report on an annual basis. The State shall submit a report on an annual basis to the Secretary which shall include a description of the activities of the Board, including the nature and scope of the prospective and retrospective drug use review programs, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, and an estimate of the cost savings generated as a result of such program. The Secretary shall utilize such report in evaluating the effectiveness of each State's drug use review program.

(h) Electronic claims management

(1) In general

In accordance with chapter 35 of Title 44 (relating to coordination of Federal information policy), the Secretary shall encourage each State agency to establish, as its principal means of processing claims for covered outpatient drugs under this subchapter, a point-of-sale electronic claims management system, for the purpose of performing on-line, real time eligibility verifications, claims data capture, adjudication of claims, and assisting pharmacists (and other authorized persons) in applying for and receiving payment.

(2) Encouragement

In order to carry out paragraph (1)—

(A) for calendar quarters during fiscal years 1991 and 1992, expenditures under the State plan attributable to development of a system described in paragraph (1) shall receive Federal financial participation under section 1396b(a)(3)(A)(i) of this title (at a matching rate of 90 percent) if the State acquires, through applicable competitive procurement process in the State, the most cost-effective telecommunications network and automatic data processing services and equipment; and

(B) the Secretary may permit, in the procurement described in subparagraph (A) in the application of part 433 of title 42, Code of Federal Regulations, and parts 95, 205, and 307 of title 45, Code of Federal Regulations, the substitution of the State's request for proposal in competitive procurement for advance planning and implementation documents otherwise required.

(i) Omitted

(j) Exemption of organized health care settings

(1) Covered outpatient drugs are not subject to the requirements of this section if such drugs are—

(A) dispensed by health maintenance organizations, including Medicaid managed care organizations that contract under section 1396b(m) of this title; and

(B) subject to discounts under section 256b of this title.

(2) The State plan shall provide that a hospital (providing medical assistance under such plan) that dispenses covered outpatient drugs using drug formulary systems, and bills the plan no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan) shall not be subject to the requirements of this section.

(3) Nothing in this subsection shall be construed as providing that amounts for covered outpatient drugs paid by the institutions described in this subsection should not be taken into account for purposes of determining the best price as described in subsection (c).

(k) Definitions

In this section—

(1) Average manufacturer price

(A) In general

Subject to subparagraph (B), the term "average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by—

(i) wholesalers for drugs distributed to retail community pharmacies; and

(ii) retail community pharmacies that purchase drugs directly from the manufacturer.

(B) Exclusion of customary prompt pay discounts and other payments

(i) In general

The average manufacturer price for a covered outpatient drug shall exclude—

(I) customary prompt pay discounts extended to wholesalers;

(II) bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs);

(III) reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction;

(IV) payments received from, and rebates or discounts provided to, pharmacy benefit managers, managed care organizations, health

maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy, unless the drug is an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy[3]

(V) discounts provided by manufacturers under section 1395w-114a of this title or under section 1395w-114c of this title;

(VI) any reduction in price paid during the rebate period to the manufacturer for a drug by reason of application of part E of subchapter XI;

(VII) rebates paid by manufacturers under section 1395w-3a(i) of this title; and

(VIII) rebates paid by manufacturers under section 1395w-114b of this title.

[3] So in original. Probably should be followed by a semicolon.

(ii) Inclusion of other discounts and payments

Notwithstanding clause (i), any other discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies shall be included in the average manufacturer price for a covered outpatient drug.

(C) Exclusion of section 505(c) drugs

In the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under the manufacturer's new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, such term shall be exclusive of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies.

(2) Covered outpatient drug

Subject to the exceptions in paragraph (3), the term "covered outpatient drug" means—

(A) of those drugs which are treated as prescribed drugs for purposes of section 1396d(a)(12) of this title, a drug which may be dispensed only upon prescription (except as provided in paragraph (4)), and—

(i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act;

(ii) (I) which was commercially used or sold in the United States before October 10, 1962, or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a "new drug" (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act; or

(iii) (I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and

(B) a biological product, other than a vaccine which—

(i) may only be dispensed upon prescription,

(ii) is licensed under section 262 of this title, and

(iii) is produced at an establishment licensed under such section to produce such product; and

(C) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act.

(3) Limiting definition

The term "covered outpatient drug" does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this subchapter as part of payment for the following and not as direct reimbursement for the drug):

(A) Inpatient hospital services.

(B) Hospice services.

(C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.

(D) Physicians' services.

(E) Outpatient hospital services.

(F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded.

(G) Other laboratory and x-ray services.

(H) Renal dialysis.

Such term also does not include any such drug or product for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological[9] used for a medical indication which is not a medically accepted indication. Any drug, biological product, or insulin excluded from the definition of such term as a result of this paragraph shall be treated as a covered outpatient drug for purposes of determining the best price (as defined in subsection (c)(1)(C)) for such drug, biological product, or insulin.

(4) Nonprescription drugs

If a State plan for medical assistance under this subchapter includes coverage of prescribed drugs as described in section 1396d(a)(12) of this title and permits coverage of drugs which may be sold without a prescription (commonly referred to as "over-the-counter" drugs), if they are prescribed by a physician (or other person authorized to prescribe under State law), such a drug shall be regarded as a covered outpatient drug.

(5) Manufacturer

The term "manufacturer" means any entity which is engaged in—

(A) the production, preparation, propagation, compounding, conversion, or

[9] So in original. Probably should be "biological product".

processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

(B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(6) Medically accepted indication

The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i).

(7) Multiple source drug; innovator multiple source drug; noninnovator multiple source drug; single source drug

(A) Defined

(i) Multiple source drug

The term "multiple source drug" means, with respect to a rebate period, a covered outpatient drug, including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under

paragraph (4), for which there 2 at least 1 other drug product which—

(I) is rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations"),

(II) except as provided in subparagraph (B), is pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C) and as determined by the Food and Drug Administration, and

(III) is sold or marketed in the United States during the period.

(ii) Innovator multiple source drug

The term "innovator multiple source drug" means a multiple source drug that is marketed under a new drug application approved by the Food and Drug Administration, unless the Secretary determines that a narrow exception applies (as described in section 447.502 of title 42, Code of Federal Regulations (or any successor regulation)).

(iii) Noninnovator multiple source drug

The term "noninnovator multiple source drug" means a multiple source drug that is not an innovator multiple source drug.

(iv) Single source drug

The term "single source drug" means a covered outpatient drug, including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under paragraph (4), which is produced or distributed under a new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application unless the Secretary determines that a narrow exception applies (as described in section 447.502 of title 42, Code of Federal Regulations (or any successor regulation)). Such term also includes a covered outpatient drug that is a biological product licensed, produced, or distributed under a biologics license application approved by the Food and Drug Administration.

(B) Exception

Subparagraph (A)(i)(II) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph

(A)(i)(I), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C).

(C) Definitions

For purposes of this paragraph—

(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity; and

(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence.

(8) Rebate period

The term "rebate period" means, with respect to an agreement under subsection (a), a calendar quarter or other period specified by the Secretary with respect to the payment of rebates under such agreement.

(9) State agency

The term "State agency" means the agency designated under section 1396a(a)(5) of this title to administer or supervise the administration of the State plan for medical assistance.

(10) Retail community pharmacy

The term "retail community pharmacy" means an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.

(11) Wholesaler

The term "wholesaler" means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including (but not limited to) repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including distributor's warehouses, chain drug warehouses, and wholesale drug warehouses) independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.