Exhibit A

In the

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.

Appeals from the United States District Court for the
Northern District of Illinois, Eastern Division.
No. 1:14-cv-09412 — **Harry D. Leinenweber,** *Judge.*

ARGUED SEPTEMBER 18, 2024 — DECIDED SEPTEMBER 11, 2025

Before RIPPLE, JACKSON-AKIWUMI, and KOLAR, *Circuit Judges*.

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.

[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).

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.

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 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

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

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

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 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

[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.

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 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

[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.

later 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 by letter dated

[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.

> 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 increase values as part of its AMP calculations

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

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 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.

[8] The claim for payment must also involve government funds, *see Wisconsin Bell, Inc. v. United States ex rel. Heath*, 145 S. Ct. 498, 502 (2025), but it is undisputed that Streck met his burden on this element.

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 *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 rightfully 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] 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

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

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 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

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[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.

[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).

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 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

[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.

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 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.

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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.

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

[14] And we reiterate, from 2009 to 2016, Lilly would pay the full $5 in distribution fee and bill the wholesalers the subsequent dollar increase. Under that arrangement, we cannot see how Lilly was "paying" the wholesalers any price increase.

pharmacies, 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. Allergan, 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] temporal 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-dollar business deals funded by debt, buyers often pay the "price" long after the initial exchange. There is nothing unusual 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 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

increased 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 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)).

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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).

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.

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

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

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 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

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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.

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 defendant 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 everyone is "well-aware of its intended meaning." *Chilcott*, 2013 WL 5781660 at *7.

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 noncompliance 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

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

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 reasonable." *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

[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.

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 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 reasonable 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

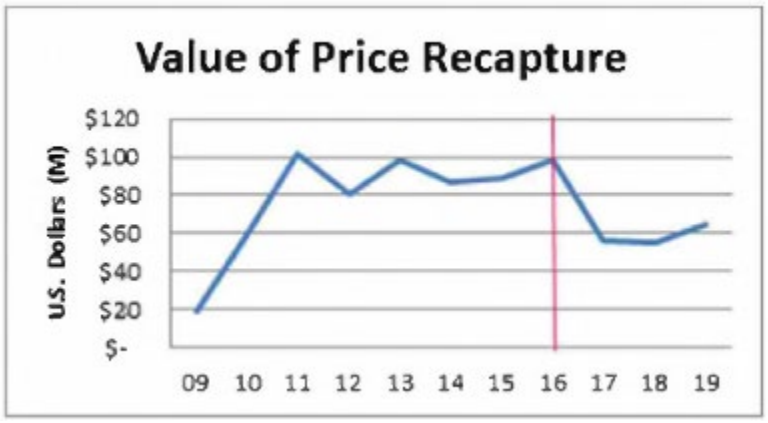
"ambiguous" or Lilly's interpretation of the guidance was "reasonable" we might look at the verdict differently. *See United States ex rel. Gugenheim v. Meridian Senior Living, LLC*, 36 F.4th 173, 181 (4th Cir. 2022). As we have detailed, Lilly's interpretation would condone an egregious exploitation 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, 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

[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).

§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

[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.

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 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.

Exhibit B

United States Court of Appeals

For the Seventh Circuit
Chicago, Illinois 60604

November 21, 2025

Before

KENNETH F. RIPPLE, *Circuit Judge*

CANDACE JACKSON-AKIWUMI, *Circuit Judge*

JOSHUA P. KOLAR, *Circuit Judge*

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.

Appeals from the United States District Court for the Northern District of Illinois, Eastern Division.

No. 1:14-cv-09412

Harry D. Leinenweber, *Judge*.

O R D E R

Plaintiff-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.

Defendant-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*.

* Circuit Judge Pryor and Circuit Judge Taibleson did not participate in the consideration of this petition.