In the

United States Court of Appeals

For the Seventh Circuit

No. 20-3425

UNITED STATES OF AMERICA ex rel.
THOMAS PROCTOR,

Plaintiff-Appellant,

v.

SAFEWAY, INC.,

Defendant-Appellee.

Appeal from the United States District Court for the
Central District of Illinois.
No. 3:11-cv-3406 — **Richard Mills**, *Judge*.

ARGUED SEPTEMBER 9, 2021 — DECIDED APRIL 5, 2022

Before KANNE, HAMILTON, and ST. EVE, *Circuit Judges*.

ST. EVE, *Circuit Judge*. Relator Thomas Proctor alleges that Safeway, Inc. knowingly submitted false claims to government health programs when it reported its "retail" price for certain drugs as its "usual and customary" price, even though many customers paid much less than the retail price. As a result, the government effectively subsidized Safeway's low prices for cash customers by reimbursing Safeway based on

the higher retail price. The district court granted Safeway's motion for summary judgment, concluding that Safeway's pricing practices were "objectively reasonable" and no "authoritative guidance" cautioned against its interpretation of the relevant Medicare and Medicaid regulations.

While this case was pending before the district court, it was an open question in this circuit whether the Supreme Court's decision in *Safeco Ins. Co. of America v. Burr*, 551 U.S. 47 (2007) applied to the False Claims Act ("FCA"). In *United States ex. rel. Schutte v. SuperValu Inc.*, 9 F.4th 455 (7th Cir. 2021), however, we answered that question and held that *Safeco* does apply to the FCA's scienter requirement. In other words, a defendant does not act with reckless disregard as long as its interpretation of the relevant statute or regulation was objectively reasonable and no authoritative guidance warned the defendant away from that interpretation. We also clarified that a failure to satisfy the *Safeco* standard for reckless disregard precludes liability under the FCA's actual knowledge and deliberate indifference provisions, which concern higher degrees of culpability.

The central remaining question in this appeal is whether a footnote in a Centers for Medicare and Medicaid ("CMS") manual constitutes "authoritative guidance" under *Safeco*. We hold that it does not. CMS can (and did) revise the manual at any time, and a single footnote in a lengthy manual does not support treble damages liability in this case. The other sources of guidance Relator has identified are unpersuasive because they do not come from the agency. Accordingly, we affirm the district court's grant of summary judgment in favor of Safeway.

I. Background

This case requires us to consider yet again whether a defendant properly reported its usual and customary ("U&C") prices for prescription drugs when seeking reimbursement from government programs, including Medicare Part D and Medicaid. Before setting out the facts of this case, we briefly survey the regulatory landscape.

Medicare Part D is a federal prescription-drug benefit administered by the Department of Health and Human Services through the CMS. CMS awards contracts to plan "sponsors," or private insurance companies. 42 C.F.R. § 423.505. Sponsors contract with middlemen known as Pharmacy Benefit Managers ("PBMs") to administer an insurance plan's prescription-drug benefits. 42 U.S.C. § 1395w-112(b)(1); 42 C.F.R. § 423.505(i). In turn, PBMs negotiate and contract with pharmacies to set prescription drug prices, process claims, and reimburse pharmacies. PBM contracts specify how pharmacies are reimbursed for prescription drugs. *See* 42 U.S.C. § 1395w-111(i). Notably, the government makes direct payments only to plan sponsors, not PBMs or pharmacies.

Medicaid is a partnership between the federal government and the states that provides healthcare coverage to economically disadvantaged individuals. State Medicaid programs set their own reimbursement criteria for prescription-drug claims, but CMS partially funds and oversees the programs.

The parties agree that the U&C price of a prescription drug generally refers to "the cash price charged to the general public." They disagree as to what "the general public" means and whether Safeway correctly reported its U&C prices when seeking reimbursement under Medicare Part D and Medicaid.

We held in *United States ex rel. Garbe v. Kmart Corp.*, 824 F.3d 632 (7th Cir. 2016) that discount-program prices for prescription drugs were offered to "the general public," so it is now settled in this circuit that pharmacies should report those prices as U&C. *Id*. at 645. Crucially, however, the relevant conduct in this case preceded our decision in *Garbe*.

Prior to *Garbe*, federal regulations did not make clear whether the U&C price for a particular drug includes lower prices offered through pharmacy discount programs. The relevant Medicaid regulation provides that agency payments for prescription drugs "must not exceed, in the aggregate," pharmacies' "usual and customary charges to the general public." 42 C.F.R. § 447.512(b). The regulation does not define "to the general public." *Id*. § 447.512(b)(2). Medicare regulations, by comparison, define U&C as the price "a customer who does not have any form of prescription drug coverage for a covered Part D drug" pays. 42 C.F.R. § 423.100. But PBMs are free to adopt alternative definitions of U&C with pharmacies by contract. *See* 42 U.S.C. § 1395w-111(i). Another Medicare regulation requires plan sponsors to include terms in their contracts with PBMs and other downstream entities stipulating that those entities "must comply with all applicable Federal laws, regulations, and CMS instructions." 42 C.F.R. § 423.505(i)(4)(iv). We need not decide whether the Medicaid definition of U&C applies to Safeway's contracts with PBMs—for purposes of reimbursement under Medicare Part D—because the parties have stipulated that U&C means "the cash price charged to the general public."

A. Factual Background

The following facts are undisputed unless otherwise noted. Safeway is a nationwide grocery chain that operates

pharmacies in many of its stores. Safeway pharmacies serve customers with commercial insurance plans and government health programs, including Medicare Part D, TRICARE, the Federal Employee Health Benefits Program, and state Medicaid programs. In 2006, the year Medicare Part D went into effect, Wal-Mart introduced a low-priced generics program in which all pharmacy customers could receive a 30-day supply of popular generic drugs for just $4. Wal-Mart reported these prices as its U&C prices, meaning that it received a lower reimbursement rate from PBMs.

Pharmacies like Safeway developed a variety of strategies to compete with Wal-Mart. Between 2006 and 2015, Safeway offered three discount programs for prescription drugs at various times and in various locations around the country. The differences among the three programs affect our analysis of their legality under the FCA, so we discuss them in some detail below.

1. Individual Price Matching

Between 2006 and 2015, Safeway pharmacists had discretion to match competitors' lower prices after verifying the published or advertised prices of certain drugs. To receive a discount, Safeway customers needed to request a price match, and the lower price applied only to the transaction on the date requested. After verifying a competitor's price, the pharmacist would manually override the original price at the point of sale. Safeway did not report price matches as the U&C price for a given drug. There is no evidence that participating pharmacies advertised or otherwise publicized the existence of price matching. On July 15, 2015, Safeway discontinued price matching in all of its stores.

2. The $4 Generics Program

Beginning in March 2008, Safeway offered certain generic prescription drugs for $4. The "$4 Generics Program" was limited to four of Safeway's geographic divisions, as well as five pharmacies in its Denver division. The specific drugs available at this rate changed over time, but when Safeway listed a generic drug on its "formulary," customers could receive a 30-day supply of that drug for $4, a 60-day supply for $8, and a 90-day supply for $12. All customers were eligible for these prices, including cash customers, participants in government health programs, and customers with private insurance. The parties agree that Safeway reported $4 as the U&C price for drugs on its formulary at locations participating in the $4 Generics Program. Safeway advertised the availability of its $4 generics formulary until July 2010, when it discontinued the program.

3. Discount Club Programs

Beginning in March 2008, Safeway introduced its Matching Competitor Generic Program ("MCGP") in five other geographic divisions. The MCGP offered certain generic drugs for the same price as the $4 Generics Program: $4 for a 30-day supply, $8 for a 60-day supply, and $12 for a 90-day supply.[1] The primary difference between the two programs was that MCGP prices were not offered to all customers automatically. To receive discounted prices, customers needed to pay in cash (without using insurance) and fill out an enrollment form. There was no fee to enroll, and the enrollment form collected

[1] If a drug was not included on Safeway's formulary, MCGP members received 10% off of branded drug prescriptions and 20% off of generic drug prescriptions.

information that Safeway often already had, including a customer's address, birthdate, dependents, and phone number. Unlike Safeway divisions participating in the $4 Generics Program, divisions participating in the MCGP did not report these prices as their U&C prices. Customers enrolled in the MCGP could also obtain a lower price by requesting that Safeway match a competitor's price.

With one exception not relevant to this appeal,[2] Safeway terminated the MCGP program in July 2010 and replaced it in all divisions with the Loyalty Membership Program ("LMP"). The LMP was functionally identical to the MCGP: all a customer needed to do in order to receive a discount was pay in cash and fill out an enrollment form. There was no enrollment fee, and the enrollment form provided no meaningful information to Safeway. Once again, Safeway did not report prices offered through this program as its U&C prices. Safeway divisions participating in the MCGP and LMP advertised the benefits of the programs to varying degrees. Safeway discontinued the LMP on July 15, 2015, the same day it discontinued its individual price-matching program.

* * *

Safeway concedes that, had it reported its discounted drug prices from the MCGP and LMP programs as its U&C prices, it would have lost revenue. In fact, one Safeway executive estimated that Safeway would have lost $65 million annually if it had adopted Wal-Mart's $4 generics program nationwide.[3]

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[2] The MCGP continued in Safeway's Northern California division between March 2010 and July 15, 2015.

[3] Safeway disputes the accuracy of this estimate but does not appear to dispute that a Safeway employee provided the estimate in January 2008.

Relator's expert estimated that Safeway received $127 million more in reimbursements from government health programs than it would have if it reported its price-match and discount-club prices as its U&C prices.

The parties dispute whether the industry understanding of U&C at the time included "retail prices." Safeway contends that during the relevant period, membership-club transactions accounted for just 26.9% of its total cash sales. Because most cash customers did not receive a discount, Safeway insists its discounted prices could not have been its U&C prices. Relator responds that between 2011 and 2015, discounted sales accounted for a majority of Safeway's total cash sales. And for the top 20 generic drugs sold annually, Safeway sold the vast majority of those drugs at discounted rates. For example, in 2009, 65% of Safeway's cash sales for top 20 generics were at discounted rates. By 2014, 88% of cash sales for top 20 generics were at discounted rates. Relator contends these statistics reveal that Safeway's discounted rates were actually its U&C prices.

Meanwhile, Safeway received a variety of communications from CMS, state Medicaid programs, and PBMs about U&C price reporting. On October 11, 2006, CMS issued a "Lower Cash Price Policy" memorandum to "All Part D Sponsors" from the Director of the Medicare Drug Benefit Group. The memorandum included a revised answer to a question on the Frequently Asked Questions section of CMS's website. A single footnote in the memorandum provided the following example:

> We note that in cases where a pharmacy offers a lower price to its customers throughout a benefit year, this would not constitute a "lower cash price" situation that

> is the subject of this guidance. For example, Wal-Mart recently introduced a program offering a reduced price for certain generics to its customers. The low Wal-Mart price on these specific generic drugs is considered Wal-Mart's "usual and customary" price, and is not considered a one-time "lower cash" price. Part D sponsors consider this lower amount to be "usual and customary" and will reimburse Wal-Mart on the basis of this price. To illustrate, suppose a Plan's usual negotiated price for a specific drug is $10 with a beneficiary copay of 25% for a generic drug. Suppose Wal-Mart offers the same generic drug throughout the benefit for $4. The Plan considers the $4 to take the place of the $10 negotiated price. The $4 is not considered a lower cash price, because it is not a one-time special price. The Plan will adjudicate Wal-Mart's claim for $4 and the beneficiary will pay only a $1 copay, rather than a $2.50 copay. This means that both the Plan and the beneficiary are benefiting from the Wal-Mart "usual and customary" price, and the discounted Wal-Mart price of the drug is actually offered with the Plan's Part D benefit design. Therefore, the beneficiary can access this discount at any point in the benefit year, the claim will be adjudicated through the Plan's systems, and the beneficiary will not need to send documentation to the plan to have the lower cash price count toward TrOOP.[4]

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[4] "TrOOP" stands for true out-of-pocket cost, meaning the amount a Medicare Part D beneficiary must pay before catastrophic coverage kicks in. *See* David Slaughter, *Coordination of Benefits Handbook* ¶ 516 Medicare Part D – Voluntary Prescription Drug Program (2021).

On December 15, 2006, CMS incorporated this footnote verbatim into its Medicare Prescription Drug Benefit Manual (the "CMS Manual").[5] A Safeway executive circulated this version of the CMS Manual to pharmacy staff in an email four days later.

Relator notes that several PBMs also communicated with Safeway about the meaning of U&C. On October 27, 2006, for example, Medco sent Safeway a reminder that "by contract," a pharmacy's U&C price is "the lowest net price a cash patient would have paid on the day that the prescription was dispensed inclusive of all applicable discounts. These discounts include … [a] competitor's matched price, or other discounts offered [to] customers."[6] Similarly, in January 2007, Coventry Health Care sent Safeway a memo regarding its interpretation of U&C, explaining that Safeway needed to include "any applicable discounts" in its U&C pricing. Caremark's February 2007 provider manual echoed this understanding of U&C.[7]

Around the same time, some state Medicaid programs expressed a similar interpretation of U&C. Effective February 1, 2007, Oregon Medicaid amended its model contract for

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[5] Centers for Medicare & Medicaid Services, *Chapter 14—Coordination of Benefits*, *in* Medicare Prescription Drug Benefit Manual 19 n.1 (2006), https://perma.cc/MW6AH4P6.

[6] Relator did not provide a copy of Safeway's contract with Medco until it moved for leave to supplement the record under Fed. R. Civ. P. 59(e), after the district court had entered summary judgment in favor of Safeway.

[7] Safeway notes that, in a separate lawsuit, a Caremark executive declared that Caremark did not include membership club prices as "applicable discounts" for purposes of U&C. Safeway also points to its 2010 contract with Express Scripts, another PBM, which defined U&C to include a $4 generics program but excluded price matching.

pharmacies to make clear that U&C must include any discounts. In April 2008, Texas Medicaid issued an "Rx Update" notifying pharmacies that they should report discounted prices as U&C prices. And in September 2008, Colorado's Department of Health Care Policy and Financing issued a "Provider Bulletin" stating that discount prices must be reported as U&C prices for Medicaid claims.[8]

Before 2016, no federal court of appeals had weighed in on the proper interpretation of "usual and customary." As noted above, that changed with this court's decision in *Garbe*. Like Safeway, Kmart created a discount club for generic drugs not long after the Medicare Part D program went into effect. Unlike Safeway, Kmart charged discounted prices to "nearly all its cash customers," in large part because barriers to joining were "almost nonexistent." *Garbe*, 824 F.3d at 636, 643. A customer could join immediately by paying a onetime $10 fee. *Id*. at 643. This court concluded that "[r]egulations related to 'usual and customary' price should be read to ensure that where the pharmacy regularly offers a price to its cash purchasers of a particular drug, Medicare Part D receives the benefit of that deal." *Id*. at 644. In passing, we observed that the CMS Manual footnote quoted above supported this interpretation. *Id*. (citing CMS Manual at 19 n.1). By the time we decided *Garbe*, however, Safeway had already discontinued its membership and price-matching programs.

B. Procedural Background

Relator filed this *qui tam* suit under seal on behalf of the United States, the District of Columbia, and ten states. The

[8] Note that Relator brought this suit on behalf of Colorado and nine other states, but not Oregon or Texas.

federal government declined to intervene, and the case was unsealed in 2015.[9] The district court ultimately granted Safeway's motion for summary judgment, relying on the Supreme Court's decision in *Safeco*. Relator moved for reconsideration under Rule 59(e) and requested leave to supplement the record with PBM contract terms defining U&C price. The district court denied both requests, and Relator timely appealed.

After the parties submitted their briefs on appeal, this court announced its decision in *United States ex rel. Schutte v. SuperValu, Inc.*, 9 F.4th 455 (7th Cir. 2021). There, we held that *Safeco* applied to the FCA's scienter provision, meaning that a defendant does not act with "reckless disregard" as long as its interpretation of the relevant statute or regulation is "objectively reasonable" and no "authoritative guidance" warned it away from that interpretation. *Id*. at 465. In doing so, we joined every other circuit to address the issue. *Id*. (citing *United States ex rel. Streck v. Allergan*, 746 F. App'x 101, 106 (3d Cir. 2018); *United States ex rel. McGrath v. Microsemi Corp*., 690 F. App'x 551, 552 (9th Cir. 2017); *United States ex rel. Donegan v. Anesthesia Assocs. of Kan. City, PC*, 833 F.3d 874, 879–80 (8th Cir. 2016); *United States ex rel. Purcell v. MWI Corp*., 807 F.3d 281, 284 (D.C. Cir. 2015)); *see also United States ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340, 344 (4th Cir. 2022) (joining consensus).[10] Before oral argument in this case, we asked the parties for supplemental briefing in response to *Schutte*.

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[9] Colorado also declined to intervene, and the district court dismissed claims asserted on its behalf with prejudice.

[10] We decline the dissent's call to revisit our decision in *Schutte*. No court of appeals majority opinion—before or after *Schutte*—has agreed with the dissent's position that *Safeco* does not apply to the FCA.

II. Discussion

We review the district court's grant of summary judgment de novo. *United States v. Luce*, 873 F.3d 999, 1005 (7th Cir. 2017). Summary judgment is appropriate when there is no genuine dispute of material fact, and the moving party is entitled to judgment as a matter of law. *Id.*; Fed. R. Civ. P. 56(a).

A. Legal Standards

The False Claims Act prohibits the submission of materially false claims for payment to the government. 31 U.S.C. § 3729(a)(1)(A); *Univ. Health Servs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176, 190 (2016). Relators—whistleblowers who bring civil suits on behalf of the government—may seek treble damages and are entitled to a share of the proceeds. 31 U.S.C. §§ 3729(a)(1), 3730(d). To prevail, a relator must establish that a claim was false (the falsity prong) and that the defendant acted "knowingly" (the scienter prong). *Id*. § 3729(b)(1)(A). The outcome of this case hinges on the scienter prong.

The FCA defines "knowingly" as having "(i) [ ] actual knowledge of the information; (ii) act[ing] in deliberate ignorance of the truth or falsity of the information; or (iii) act[ing] in reckless disregard of the truth or falsity of the information." *Id*. The Supreme Court has cautioned that the FCA is not "a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Escobar*, 579 U.S. at 194. To mitigate "concerns about fair notice and open-ended liability," the FCA's scienter requirement is "rigorous." *Id.* at 192.

Our recent decision in *Schutte* resolves several of the issues originally briefed in this appeal. Namely, we have already determined that *Safeco* applies to the FCA's "reckless disregard" language, and that a defendant's subjective intent is irrelevant

for purposes of that inquiry. *Schutte*, 9 F.4th at 465–66. In *Safeco*, the Supreme Court interpreted an analogous scienter requirement in the Fair Credit Reporting Act ("FCRA") and held that a defendant does not act with reckless disregard under the FCRA as long as its interpretation of the relevant statute or regulation was "objectively reasonable" and no "authoritative guidance" counseled against that interpretation. *Safeco*, 551 U.S. at 70 & n.20. In *Schutte*, we joined four other circuits in applying the *Safeco* scienter standard to the FCA. *Schutte*, 9 F.4th at 465 (collecting cases). "A defendant might suspect, believe, or intend to file a false claim, but it cannot *know* that its claim is false if the requirements for that claim are unknown." *Id*. at 468 (emphasis in original). Moreover, if a relator cannot show that a defendant acted with reckless disregard under *Safeco*, then the FCA claim fails, regardless of whether the relator can point to evidence of the defendant's subjective awareness that its interpretation might be wrong.

Applying *Safeco* to the facts in *Schutte*, we concluded that the relator failed to satisfy *Safeco*'s demanding scienter standard. As in this case, the relator accused a defendant-pharmacy (SuperValu) of submitting false claims to the government by reporting its "retail" prices as its U&C prices, even though many customers paid a lower price by requesting a price match. *Id*. at 461. Also like this case, pharmacists overrode the price SuperValu would otherwise charge to insured customers, manually entered the price-matched cost, and processed the sale as a cash transaction. *Id*. SuperValu's price-matching program clearly ran afoul of *Garbe*, in that SuperValu was denying Medicare and Medicaid the benefit of the deal it gave to participants in its price-matching program. *Garbe*, 824 F.3d at 644. Nonetheless, we held that the Medicaid definition of U&C (the price that a pharmacy "charges to the general

public") was open to multiple interpretations, and Super-Valu's interpretation was permissible prior to *Garbe*. *Schutte*, 9 F.4th at 469–70 (quoting 42 C.F.R. § 447.512(b)). Put differently, *Garbe* reached only the falsity prong of an FCA claim based on U&C price reporting, not scienter.

Turning to *Safeco*'s authoritative guidance inquiry, we concluded in *Schutte* that the same CMS Manual footnote at issue here was insufficiently specific to warn SuperValu that its price-matching program fell within the definition of U&C price. *Schutte*, 9 F.4th at 471. We noted that the footnote "says nothing about price-match programs," and the bulk of the footnote discussed Wal-Mart's $4 generics program. *Id*. at 472. Because "*Safeco* suggests that authoritative guidance must have a high level of specificity to control an issue," the footnote could not serve as authoritative guidance. *Id*. at 471. In so holding, we expressly reserved the question whether the CMS Manual amounted to "authoritative" guidance even though it was not binding on the agency. *Id*.

Returning to the facts in this case, all agree that after *Garbe*, reporting a pharmacy's retail price as its U&C price would satisfy the FCA's falsity prong. But the time period at issue—2006 to 2015—precedes our decision in *Garbe*. This appeal thus presents the following questions: (1) whether Safeway's interpretation of U&C during the relevant period was objectively reasonable, and (2) whether authoritative guidance warned it away from that interpretation.

B. Objectively Reasonable Interpretation

Safeway used both price-matching and discount clubs in various divisions. We have already concluded that, prior to *Garbe*, the definition of U&C price was open to multiple

reasonable interpretations, one of which would exclude price-matching. *Schutte*, 9 F.4th at 469–70. Safeway's price-matching program differed from SuperValu's in that a price match did not apply automatically to refills. *Id*. at 461. Instead, Safeway customers needed to request a price match each time they filled a prescription. For the same reasons that SuperValu's interpretation of U&C—as excluding price-matching—was objectively reasonable in *Schutte*, Safeway's interpretation also passes muster here.

We had no reason to consider discount clubs in *Schutte*, but the analysis is similar. By enrolling in either the MCGP or the LMP and paying in cash, Safeway customers gained access to lower prices for generic drugs than Safeway reported as its U&C prices. The enrollment form for both programs did not provide Safeway with any meaningful information, and there was no enrollment fee, as in *Garbe*. Notwithstanding this minimal barrier to entry, Safeway argues that the lower prices it offered to discount-club participants were not "charged to the general public" because customers were not automatically enrolled in either program.

With the benefit of hindsight, it is easy to criticize Safeway's interpretation of U&C as applied to its discount clubs. Safeway effectively used its enrollment forms as a fig leaf to disguise a Wal-Mart-style generics program without reporting those prices as U&C. The only thing separating club members from "the general public" was the fact that they took an affirmative step to enroll.[11] As we explained in *Schutte*,

[11] Safeway concedes that a customer must do more than simply walk into a store in order to be eligible for a discount. Otherwise, there would be no

however, an interpretation of U&C that excludes discounted prices available only to program participants "is not inconsistent with the text of the U&C price definition." *Schutte*, 9 F.4th at 469 (citing *Garbe*, 824 F.3d at 644; 42 C.F.R. § 447.512(b)). The mechanism by which a customer received a discount may have differed (price matching or a discount club), but the effect was the same: cash customers paid a lower price than the retail price. In the absence of authoritative guidance warning that U&C must include these discounts, Safeway's interpretation was not objectively unreasonable at the time.

C. Authoritative Guidance

In order for guidance to be "authoritative," it must "come from a source with authority to interpret the relevant text." *Schutte*, 9 F.4th at 471. *Safeco* may not have "flesh[ed] out the boundaries" of the term "authoritative guidance," but "at minimum," such guidance "must come from a governmental source." *Id*. That means we may only consider binding precedent from the courts of appeals or appropriate guidance from the relevant agency. *Id*. (citing *Safeco*, 551 U.S. at 70); *accord Purcell*, 807 F.3d at 289; *Sheldon*, 24 F.4th at 353.

As in *Schutte*, any variations in the PBM contract definitions of U&C are irrelevant in this context because they did not come from the agency.[12] PBMs and pharmacies are of

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way to distinguish between "the general public" and program participants.

[12] Likewise, to the extent that state Medicaid definitions of U&C differ from the federal definition, those differences have no bearing on our analysis. As explained in note 9, the district court dismissed Relator's

course free to agree to their own definitions by contract. *See* 42 U.S.C. § 1395w-111(i). But doing so does not convert a "garden-variety breach[] of contract" into a false claim. *Escobar*, 579 U.S. at 194.

In addition to the source of the purported guidance, we also consider whether that guidance was sufficiently specific. *Schutte*, 9 F.4th at 471–72. This standard "duly ensures that defendants must be put on notice before facing liability for allegedly failing to comply with complex legal requirements." *Sheldon*, 24 F.4th at 350. In *Safeco*, the Court concluded that a letter from the Federal Trade Commission ("FTC") to the defendant was insufficiently authoritative because it "did not canvass the issue." *Safeco*, 551 U.S. at 70 n.19. An FTC staff member wrote the letter to an insurance company lawyer, and the letter explicitly stated that it was "an informal staff opinion ... not binding on the Commission." *Id*.[13] *Safeco* itself demonstrates that guidance is not "authoritative" merely because it comes from the relevant agency: the guidance must also be specific enough to put a defendant on notice that its conduct is unlawful.

Colorado claims with prejudice after Colorado declined to intervene. Relator's proffered guidance from other state Medicaid programs is irrelevant because Relator is not bringing claims under those states' parallel FCA statutes.

[13] The FTC's current website explains that the purpose of warning letters is to "warn of *possible* law violations"; such letters "are not formal enforcement actions, and they may or may not be followed by FTC legal action." Federal Trade Comm'n, *About FTC Warning Letters*, https://www.ftc.gov/news-events/media-resources/truth-advertising/about-ftc-warning-letters (last visited Apr. 4, 2022) (emphasis added).

With those principles in mind, we apply them to the only relevant guidance relator has identified: the CMS Manual.[14]

1. Specificity

Once again, our decision in *Schutte* forecloses relator's argument that the CMS Manual was sufficiently specific to warn Safeway that customer-initiated price-matching fell within the definition of U&C. We observed in *Schutte* that price-matching could fluctuate based on the prices that SuperValu's local competitors charged. *Schutte*, 9 F.4th at 472. This potential for regional variation made SuperValu's price-matching program a poor fit for the CMS Manual's Wal-Mart example. Here, the CMS Manual was also insufficiently specific to address Safeway's ad hoc price-matching program.

Safeway's membership clubs present a closer question. The CMS Manual footnote explains in detail why discount prices in Wal-Mart-style generics programs should be treated as U&C prices. Indeed, in *Schutte*, we interpreted the footnote as "clarif[ying] that a pharmacy's consistent, lower-price offers are included within U&C prices." *Id*. Here, once a Safeway customer enrolled in the MCGP or LMP, he or she gained access to a 30-day supply of popular generics for $4—the exact same pricing structure as Wal-Mart's generics program. Safeway even reported its own $4 generics program as U&C between 2008 and 2010. Because the CMS Manual may have

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[14] Relator also points to the October 2006 CMS memorandum, which contained an identical footnote. We decline to treat that document as authoritative guidance for two reasons. First, the memorandum was addressed to plan sponsors, not pharmacies like Safeway. Second, the Supreme Court's rejection of the FTC letter in *Safeco* suggests that an informal communication is insufficiently authoritative even if it originates from the relevant agency. *See Safeco*, 551 U.S. at 70 n.19.

been specific enough to put Safeway on notice that it should have reported its membership-club prices as its U&C prices, we consider the open question in *Schutte*: whether guidance must be "binding" to amount to "authoritative guidance" under *Safeco*.

2. Binding vs. Nonbinding Guidance

Safeco does not explicitly require that agency guidance be binding on the agency, but dicta suggest the Court might impose such a requirement. Specifically, the Court observed that the FTC "has only enforcement responsibility, not substantive rulemaking authority, for the provisions in question." *Safeco*, 551 U.S. at 70. Our own case law lends support for such a distinction. In *Van Straaten v. Shell Oil Prods. Co. LLC*, 678 F.3d 486 (7th Cir. 2012), we applied *Safeco* to an analogous provision of the Fair and Accurate Credit Transactions Act ("FACTA"). We rejected an FTC "bulletin" as a relevant source of guidance because it "not only lacks a definition but also has no authoritative effect; it is neither an exercise in notice-and-comment rulemaking nor the outcome of administrative adjudication." *Id*. at 488.

Safeway argues that *Van Straaten* already requires that agency guidance be binding for purposes of *Safeco*'s scienter standard. We read *Van Straaten* more narrowly. In context, the language quoted above is dicta. Nonetheless, Safeway is correct that CMS cannot rely on the Manual in enforcement proceedings because it "lack[s] the force of law." *Christensen v. Harris Cnty.*, 529 U.S. 576, 587 (2000) (explaining that "interpretations contained in policy statements, agency manuals, and enforcement guidelines … lack the force of law" and are "entitled to respect" only to the extent that they have the

"power to persuade") (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).[15]

Setting aside whether *Safeco* requires that guidance be binding on the agency, we conclude that the CMS footnote does not constitute authoritative guidance for several reasons. First, the guidance Relator relies on is a single footnote in a fifty-seven-page chapter of the voluminous Medicare Prescription Drug Benefit Manual. The Coordination of Benefits chapter, where the footnote appears, does not discuss U&C pricing anywhere except the footnote. And the placement of the footnote within a section titled "Beneficiary Cash Purchases" suggests that the guidance was directed at correctly calculating a Part D enrollee's out-of-pocket costs, rather than setting out requirements for pharmacies seeking reimbursement under Medicare and Medicaid.[16]

We also find it significant that the footnote went in and out of the Manual during the relevant period. After making its debut in December 2006, the footnote was removed in 2013—two years before Safeway ended its discount programs and

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[15] A*ccord Baylor Cnty. Hosp. Dist. v. Price*, 850 F.3d 257, 261–64 (5th Cir. 2017) (applying *Skidmore* deference to a different CMS Manual because it lacked the force of law); *Clarian Health W., LLC v. Hargan*, 878 F.3d 346, 355–56 (D.C. Cir. 2017) (observing that yet another CMS Manual merely set forth enforcement priorities and was not binding in agency adjudications).

[16] The text preceding the footnote reads: "The [Part D] enrollee must take responsibility for submitting the appropriate documentation to his or her plan in order to have the amount count toward his or her total drug spend and TrOOP balances." CMS Manual at 19.

price-matching nationwide.[17] Relator has not explained why Safeway should be liable for claims submitted after the current version of the Manual went into effect.[18] How can agency guidance be "authoritative" under *Safeco* when that guidance no longer exists? And if CMS removed the footnote without explanation in 2013, was the footnote really "authoritative" during the preceding years or merely illustrative?

In light of the totality of the circumstances, we are not convinced that treble damages liability should hinge on a single footnote in a lengthy manual that CMS can, and did, revise at any time. Such an outcome would raise serious due process concerns because defendants may not receive adequate notice of the agency's shifting interpretation.[19] *See Purcell*, 807 F.3d

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[17] *See* Centers for Medicare & Medicaid Services, *Chapter 14—Coordination of Benefits*, *in* Medicare Prescription Drug Benefit Manual § 50.4.2 (2013), https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter14.pdf (last visited Apr. 4, 2022).

[18] Complicating matters further, the relevant section of the current Manual provides an effective date of June 2010 and an implementation date of January 2011. *Id*. at § 50.4.2 (2013).

[19] Relator has not argued that CMS's interpretation of its own regulation is entitled to deference under the *Auer* doctrine (also known as *Seminole Rock* deference). We therefore take no position on the doctrine's applicability to the CMS Manual in this case or *Safeco*'s authoritative guidance inquiry more generally. *See Auer v. Robbins*, 519 U.S. 452, 461 (1997); *see also Kisor v. Wilkie*, 139 S. Ct. 2400, 2424 (2019) (noting that courts "must assess whether [an agency's] interpretation is of the sort that Congress would want to receive deference").

Admittedly, this court in *Garbe* observed: "An agency's interpretation of its own regulation is given 'controlling weight unless it is plainly

at 287 ("Strict enforcement of the FCA's knowledge requirement helps to ensure that innocent mistakes made in the absence of binding interpretive guidance are not converted into FCA liability …."); *Sheldon*, 24 F.4th at 356 ("The False Claims Act does not assess liability through ambush."). To avoid this dilemma, we heed the Supreme Court's call for "rigorous" enforcement of the FCA's scienter requirement and conclude that the CMS footnote is not authoritative guidance in this case. *Escobar*, 579 U.S. at 192.

Some circuits have hinted that notice-and-comment rulemaking or binding administrative adjudications are the gold standards for guidance to be "authoritative" under *Safeco*. *See Purcell*, 807 F.3d at 287; *Sheldon*, 24 F.4th at 354–55 (concluding that CMS responses to comments on a proposed rule were not authoritative guidance); *Streck*, 746 F. App'x at 109 & n.5 (noting that CMS proposed a rule to clarify an ambiguous statutory definition, but the final rule postdated the relevant period and therefore could not provide guidance). Given the circumstances surrounding the guidance Relator relies on here—a solitary footnote in a lengthy, nonbinding manual that changed over time—we need not address that issue. Accordingly, we leave for another day whether agency guidance must *always* be binding to satisfy *Safeco*'s scienter standard.

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erroneous or inconsistent with the regulation.'" *Garbe*, 824 F.3d at 644 (quoting *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945)). But *Garbe* predated the Supreme Court's admonition in *Kisor* that courts should not apply *Auer* deference reflexively. *Kisor*, 139 S. Ct. at 2414 (cautioning that "not all reasonable agency constructions of [] truly ambiguous rules are entitled to deference"). Without briefing on this issue, we decline to say whether *Auer* deference should apply here.

III. Conclusion

For the foregoing reasons, the district court's judgment is AFFIRMED.

HAMILTON, *Circuit Judge*, dissenting. We should reverse summary judgment for defendant Safeway and overrule *United States ex rel. Schutte v. SuperValu Inc.*, 9 F.4th 455 (7th Cir. 2021). That case misinterpreted the False Claims Act's knowledge definition in 31 U.S.C. § 3729(b)(1) to create "a safe harbor for deliberate or reckless fraudsters whose lawyers can concoct a *post hoc* legal rationale that can pass a laugh test." 9 F.4th at 473 (Hamilton, J., dissenting). We now face a similar False Claims Act case, but with even stronger evidence of fraud and an even less plausible *post hoc* rationale. I respectfully dissent.

My dissent in *SuperValu* explained why the majority's approach to the False Claims Act's knowledge requirement is contrary to the text of § 3729(b)(1), loses sight of its roots in the common law of fraud, and ignores the history and purpose of the Act's "knowledge" provisions. 9 F.4th at 476–80 (Hamilton, J., dissenting); accord, *United States ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340, 357–71 (4th Cir. 2022) (Wynn, J., dissenting) (disagreeing with Fourth Circuit's adoption of our position in *SuperValu*). Without repeating that analysis here, this dissent focuses on the more egregious facts of this case, the high stakes of the manipulation of "usual and customary" drug prices, and the consequences of our mistake in *SuperValu*. If the False Claims Act cannot reach Safeway's conduct here, the Act will neither deter nor remedy many frauds that loot the federal treasury.

Prescription drug prices in the United States are among the highest in the world. They have long been the subject of policy debates. A major focus has been the prices that taxpayers pay to provide drugs under Medicare and Medicaid. Congress has repeatedly decided as a matter of policy not to allow

the government to use its purchasing power to negotiate lower drug prices for those programs. Congress has also chosen not to take advantage of the prices that private health insurers are able to negotiate with their buying power, such as with a "most-favored-nation" requirement.

Instead, Congress has chosen to rely on competitive market forces to ensure that taxpayers pay competitive drug prices in those programs. The strategy caps the price the government pays at the "usual and customary charges to the general public." 42 C.F.R. § 447.512(b)(2) (2020). The "general public," all parties agree, does not include customers whose prescription drugs are covered by private insurance, Medicare, Medicaid, or other government programs. The general public for these purposes is sometimes referred to as cash customers. These cash customers are vastly outnumbered by Medicare, Medicaid, and private insurance customers. Under the policy, therefore, determining the "usual and customary" prices those few cash customers pay has enormous financial stakes.

And for the chosen policy to work, "usual and customary" prices must be reported honestly. Given the high stakes, drug sellers have faced great temptations to cheat. There is ample evidence that some have cheated, on a grand scale and for many years.

As the majority opinion notes, when Walmart launched its $4-per-month generics program in 2006, it put pressure on its competitors to match it. That pressure was magnified by the "usual and customary" price issue. If a competitor reduced its retail cash drug prices to match Walmart's prices, it would have to tell—or at least should have told—the government that it had reduced its "usual and customary" prices (as

Walmart had). The result should have been, as Congress intended, reduced prices for Medicare and Medicaid patients' drugs, taking advantage of the competitive market but magnifying for providers the effects of any price cuts for cash customers.

That's not what happened, at least in many cases. The temptations for prescription drug sellers like SuperValu, Kmart, and Safeway were obvious and powerful. The False Claims Act cases in this circuit alone later turned up evidence of their executives' creative, desperate, and deceptive efforts to match Walmart's prices without reducing the prices the government would pay.

The creativity and desperation produced efforts that a reasonable jury could treat as deliberate or reckless fraud. We saw the lengths SuperValu was willing to go in its case. See 9 F.4th at 461–62; *id.* at 473–76 (Hamilton, J., dissenting) (SuperValu claimed government reimbursement based on supposedly "usual and customary" prices for high-volume drugs that were as much as eight to fifteen times the discounted prices that SuperValu charged cash customers most of the time); see also *United States ex rel. Garbe v. Kmart Corp.*, 824 F.3d 632, 635–37 (7th Cir. 2016) (Kmart charged "nearly all its cash customers" discounted prices while it submitted "significantly" higher "usual and customary" prices to "drive up as much profit as possible out of [third-party] programs" (alteration in original)). The evidence here shows that Safeway was willing to go even further … at least as long as it could avoid putting things in writing. If and to the extent the federal courts tolerate such deception, we enable more fraud in the present and the future. We also place at a competitive

disadvantage the other businesses that resisted the temptation to cheat the government.

The majority opinions here and in *SuperValu* err by misinterpreting the standard of fraudulent intent set forth in the False Claims Act. The result is a deep and basic anomaly in the law. Under both the common law and the False Claims Act, fraud is an intentional wrong. A defendant's state of mind is critical. Subjective intent distinguishes fraud from the proverbial "garden-variety" breach of contract. Yet following the mistaken approach in *SuperValu*, the majority opinion here turns its back on the evidence of Safeway's fraudulent intent at the time it was submitting false claims to the government to keep its drug reimbursements inflated by tens of millions of dollars. As Judge Wynn has written, this approach violates the principle that "'culpability is generally measured against the knowledge of the actor at the time of the challenged conduct.' It also allows the 'most culpable offenders' … to craft their own get-out-of-jail-free cards whenever they like." *Allergan Sales*, 24 F.4th at 369 (Wynn, J., dissenting) (internal citation omitted), quoting *Halo Electronics, Inc. v. Pulse Electronics, Inc.*, 579 U.S. 93, 104–05 (2016); accord, *SuperValu*, 9 F.4th at 476–80 (Hamilton, J., dissenting) (explaining majority's departures from common law and statutory language and history).

We are reviewing a grant of summary judgment, so relator Proctor is of course entitled to the benefit of conflicts in the evidence and reasonable inferences drawn from the evidence favoring him. He has come forward with ample evidence of fraudulent intent, both in Safeway's internal decision-making and in circumstantial evidence—the sheer scale of the differences between Safeway's real prices for cash customers and

the much higher prices it told the government were "usual and customary."

Safeway's responses to the pressure created by Walmart took several forms. It began with various price-matching programs and then developed a "stealth Membership Program." Dkt. 190-1, at 2. Soon, discounted sales covered the majority of cash sales. Dkt. 178-2, at 8 tbl.5. All the while, Safeway kept claiming reimbursements from Medicare and Medicaid based on falsely inflated "usual and customary" prices that were no longer usual or customary. Safeway knew and had good reason to know that the differences between its actual prices and its reported prices meant it was defrauding the government. Safeway recognized the problem immediately. Its solution was to "keep a low profile," Dkt. 190-31, at 2, and to hope that no one would find out. After the relator blew the whistle, Safeway turned to lawyers to try to rationalize and excuse its deception. We should not indulge their *post hoc* rationalizations, especially with facts as egregious as those here.

Walmart announced its new prices in 2006. Safeway executives immediately recognized that the news was "not good for the business of Pharmacy." Dkt. 190-23, at 2. Four days later, a senior manager emailed other Safeway executives and explained that "the $4/script would force us to take a huge margin hit." Dkt. 190-24, at 2. He estimated that adopting Walmart's approach would result in a loss of $8.7 million in profits annually, but that figure did "not take into account any issues [Safeway] may have with U&C." *Id.* That estimate was later updated to a much larger number, an annual loss of $65 million. Dkt. 190-29, at 2–3.

As Safeway considered its response, the federal government's Centers for Medicare and Medicaid Services ("CMS")

issued a "Lower Cash Price Policy" Memorandum addressing Walmart's program. CMS explained: "The low Wal-Mart price on these specific generic drugs is considered Wal-Mart's 'usual and customary' price, and is not considered a one-time 'lower cash' price." Dkt. 195-21, at 2 n.1.

Safeway's initial response was to match prices in a few divisions, *but to keep that a secret from the government*. From the beginning, Safeway chose to claim on paper that it had one "official company stance" that it would not "change our [] usual and customary price on" price-matched prescriptions, Dkt. 190-5, at 2, but to change its practices and to keep that secret: "*We cannot put any of this in writing to stores*," Safeway said, Dkt. 190-6, at 2 (emphasis added). Here are some key points of Safeway's price-matching:

> 1. The official company policy is that we DO NOT match Wal-Mart or HEB program if an unidentified customer calls in. *This is to avoid trouble with the media or competitors*.
>
> 2. If a regular customer known to you asks if we will match either program, the answer is YES.
>
> ….
>
> 5. Do not discount copays to $4.00. Fill the Rx as cash—*do not bill to the third party*.
>
> 6. *We cannot put any of this in writing to stores* because our official policy is we do not match.[1]

[1] Beyond the red flag of the warning against putting anything in writing to stores, point five in this list suggests that if a customer with insurance requested a price match on a prescription, employees would record the sale as if the customer did not have insurance. This practice would have

Dkt. 190-6, at 2 (emphases added). The Director of Pharmacy Operations confirmed the accuracy of these points in an email to other Safeway executives. *Id.* Safeway introduced this program of intentional concealment and deception roughly a month after the Walmart news and two weeks after the CMS notice.

As Safeway began implementing this deception, it received more warnings about "usual and customary" prices. Medco—one of Safeway's largest pharmacy benefit managers—sent Safeway a reminder that by contract, a pharmacy's "usual and customary" price is "the lowest net price a cash patient would have paid on the day that the prescription was dispensed inclusive of all applicable discounts. These discounts include … *competitor's matched price*, or other discounts offered customers." Dkt. 190-7, at 2 (emphasis added) (internal quotation marks omitted). A Safeway director forwarded the notice to executives and said: "I'm sure this has to do with the Walmart initiatives. There 'are' ramifications to normal 3rd party business. [Medco's] [l]anguage is pretty similar in all of our agreements." *Id.* She also explained that Safeway had been trying to "further redefine [U&C]" in its contracts as excluding "all other discounts that Pharmacy may give with respect to any particular cash transaction." *Id.*

Around that time, CMS incorporated its Lower Cash Price Policy Memorandum into the CMS Medicare Prescription Drug Benefit Manual, which is incorporated by reference into

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avoided overriding the customer's copay, which could have alerted the insurance company of a lower price. The tactic suggests that Safeway was willing to forgo insurance reimbursements for certain transactions in the name of program secrecy, which could add further support for inferring fraudulent intent.

drug sellers' Medicare and Medicaid contracts. See 42 C.F.R. § 423.505(i)(4)(iv) (2020). A Safeway director circulated that manual to pharmacy staff and told them: "Please keep abreast of those issues that impact your areas." Dkt. 190-34, at 2. Then in early 2007, another big pharmacy benefit manager, Coventry Health Care, sent a notice similar to Medco's. It explained that Safeway was required by contract to include "any applicable discounts" in its "usual and customary" price. That same Safeway director again forwarded this notice with a message: "Another [e]xample of how plans are reacting, ie, any modified price needs to be offered to the 3rd party if meets U&C definition. Received a similar [notice] from Medco." Dkt. 190-28, at 2. Safeway brushed off these notices and continued reporting only the much higher non-discounted prices as its "usual and customary" prices.

The strategy of concealment continued into 2008, with a remarkably frank admission. A pharmacy manager emailed headquarters to say that Nebraska's Medicaid program told him that "by matching a price, it becomes our usual & customary and any prescription filled that day has to be priced as such." Dkt. 190-18, at 2. The executive who received that message forwarded it to six other executives with this cynical question: "FYI Does anyone think we have an issue here? My question is *how the state of Nebraska will know that we offered to match any price out there*." *Id.* (emphasis added). Catch us if you can….

A few days later, an executive who received that email expressed concerns to a senior vice president: "We may have some issues with U&C and state medicaids with price matching…." Dkt. 190-31, at 4. The executive explained that "if you [match a] price offer, that becomes your usual and customary

for that day and that pricing needs to be extended to medicaid," which he acknowledged Safeway stores currently were not doing. *Id.* at 2. He thus stressed the need to keep things quiet: "If we advertise this price match—it is going to Alert the medicaid programs to start looking.… *need to keep a low profile*." *Id.* (emphasis added). Once again, catch us if you can….

As the deception and concealment continued, Safeway received more notices that its actions were violating Medicare and Medicaid requirements. Later that year, a Safeway executive received a directive from the Food Marketing Institute ("FMI") describing the requirements of the Lower Cash Price Policy in the CMS Manual. FMI wrote in part:

> Since the generic price is your "usual and customary" price, you must submit these claims to the Part D plan sponsor.… Below is the applicable section from Chapter 14 of the Medicare Prescription Drug Benefit Manual. I've also pasted a link to the manual below. *Specifically pay attention to the foot note at the end*.

Dkt. 190-17, at 2 (emphasis added). The executive forwarded this notice to the Director of Compliance and other employees with a message that can be understood as either remarkably naïve or a cynical effort to deflect responsibility: "Please note and ensure we are in compliance. Thx." *Id.*[2]

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[2] We explained in *Kmart* what this same footnote meant: "The CMS Manual has long noted that 'where a pharmacy offers a lower price to its customers throughout a benefit year' the lower price is considered the 'usual and customary' price rather than 'a one-time "lower cash" price'…." 824 F.3d at 644, quoting Centers for Medicare & Medicaid Services, *Chapter*

That executive testified in his deposition in this case that he assumed his employees were "doing the right thing" and complying with the rules and regulations, which would include reporting discounted prices as the "usual and customary" prices. Dkt. 195-7, at 8–9. They were not. And given the enormous stakes for Safeway, a jury could reasonably discount the executive's claims of innocent ignorance. For the twenty drugs with the highest overall revenues resulting from the differences between what cash customers actually paid and what Safeway told the government were its "usual and customary" prices, the percentage of discount sales shot up from 9 percent in 2006 to 49 percent in 2008. Dkt. 178-2, at 11 tbl.8, 53–54 tbl.30. Safeway continued to report the non-discounted prices as its "usual and customary" prices during this period. Price-matching continued until 2015. During its last five years, discount sales accounted for a substantial majority of sales—from 75 percent to 88 percent for the top twenty drugs, Dkt. 178-2, at 11 tbl.8, and from 56 percent to 66 percent of total cash sales, *id.* at 8 tbl.5. I have not yet seen a plausible definition of "usual and customary" prices that does not include the prices at which a *majority* of relevant sales are made.

Over the years, Safeway's pricing strategy shifted away from price-matching and toward the adoption of a "loyalty" program that Safeway used to conceal its actual "usual and customary" prices. The loyalty program began in 2008 under the label Matching Competitor Generic Program and was rebranded in 2010 as the Loyalty Membership Program in all but one division. The two programs were "functionally

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14—Coordination of Benefits, in Medicare Prescription Drug Benefit Manual 19 n.1 (2006), https://perma.cc/MW6A-H4P6.

identical," and members received the same cash price that Walmart charged for generic prescriptions. Ante at 6–7.

Both programs were designed to deceive the government by concealing the fact that the discounted prices were actually being offered to the general public, making those discounted prices the "usual and customary" prices. To join, a customer did not need to pay even a modest fee. The customer needed only to fill out an enrollment form that provided simple demographic information *that Safeway already had*. Ante at 6–7; see also Dkt. 195-10, at 18–19. A reasonable jury could infer that this membership device was merely a fig leaf to rationalize the failure to report the prices as "usual and customary."

Relator Proctor has offered evidence that that's just what Safeway was thinking at the time. Take the following exchange. In 2009, a divisional vice president asked about adopting a membership program. He observed: "it seems like to me this whole thing revolves @ the insurance angle — to get the $10 per item from them vs the $4 cash price … am I off?" Dkt. 190-33, at 2. A director told him he was exactly right but needed to be quiet about it:

> *Off the record that is exactly the angle* is getting the maximum we can from the insurance…. This is the reason why Walgreen's and CVS never launched this program is because the hit on the third party insurance would have crushed them (take the impact to us and multiply by 10).

Id. (emphasis added). By introducing this "stealth" membership program in bad faith, Safeway thought it could dodge that same "crushing" impact—an impact that should have

saved the federal and state governments tens of millions of dollars a year.

That kind of thinking remained central to Safeway's actions. When the company switched to the Loyalty Membership Program in 2010, it also replaced Safeway's limited $4 generics program. In some regions, Safeway had adopted Walmart's approach for a brief period. In those locations, every customer was eligible for the $4 price, and Safeway had been reporting honest "usual and customary" prices for those locations. Ante at 6. Then things changed.

Safeway replaced the generics program with the Loyalty Membership Program because it wanted to keep offering competitive prices to customers, but without continuing to pass those lower prices on to third parties like the federal and state governments. Relator's evidence illustrates this narrative. In 2009, a manager posed a "hypothetical" to the Director of Finance for Pharmacy: "We pull the $4 programs in Texas, Eastern, Genuardi's and Dominick's and offer the same program; however, as a membership (FREE but customers need to sign up) program …. What [are] the potential savings if we make this a membership program? *Thereby not affecting our insurance reimbursements*." Dkt. 190-38, at 3 (emphasis added). After discussing with others, the manager responded to his own email and estimated that it would save Safeway eight million dollars. *Id*. at 2.

Safeway moved forward with that deceptive strategy. In a message to participating stores, a director explained: "we will no longer have an automatic $4 generic program.… *The main reason for going to a membership program is to protect our Usual and Customary price which should have a positive impact on our gain*." Dkt. 190-10, at 2 (emphasis added). She emphasized the

need to keep that reason secret. The problem was that Safeway would need to convince customers who liked the discounts to join the new loyalty program to keep the discounts. How should Safeway explain the change? In a good example of Orwellian obfuscation of the stealth strategy, she wrote: "While we do not want to communicate the protection of Usual and Customary, we do want to communicate to our associates and the consumer that the reason we are doing this is to further enhance our offer so that we can offer them 'More.'" *Id.* at 3.

As this "stealth" membership program continued, Safeway received an additional notice that its position on "usual and customary" cash prices was dishonest. In 2011, a Safeway director forwarded to headquarters a message from Caremark regarding "usual and customary" prices: "Please see the announcement from Caremark. FEP is requiring that we provide our best price to them. This would [include] … the $4.00 program in Dominicks, Eastern, and Texas. I do not see a way around it." Dkt. 190-20, at 2.

Even though that particular writer was too honest to find "a way around it," others did. The evidence of the money Safeway took from the government by this deception is astonishing, going well beyond even the evidence in the *SuperValu* case. From 2011 to 2015 discount sales accounted for much more than a *majority* of Safeway's cash prescription sales. Yet Safeway continued to tell the government that its non-discounted prices were its "usual and customary" prices. Dkt. 178-2, at 8 tbl.5.

We can illustrate the point with one high-volume drug, lovastatin, which is used to reduce cholesterol levels. Between 2008 and 2012, Safeway sold 30-day supplies of lovastatin at

its $4 discount cash price 84 percent of the time. Dkt. 178-2, at 46 tbl.21. During those years, however, Safeway was claiming reimbursements from the government by reporting "usual and customary" prices between $27.14 and $65.99. *Id.* During those same years, Safeway sold 90-day supplies of lovastatin for $10 in 94 percent of its cash sales of the drug. *Id.* Yet Safeway claimed reimbursements from the government by reporting "usual and customary" prices between $81.42 and $108.99. *Id.* Safeway was claiming government reimbursements based on claimed prices *six to sixteen times higher* than its actual cash prices.

The cumulative effects of the deception were in the tens of millions of dollars per year. Focus on the twenty drugs where the government lost the most money: Safeway sold those drugs at discount cash prices far more than half the time from 2009 to 2015: 65 percent of the time in 2009, 74 percent of the time in 2010, 82 percent in 2011, 81 percent in 2012, 83 percent in 2013, 88 percent in 2014, and 75 percent in 2015. Dkt. 178-2, at 11 tbl.8. During those years, Safeway continued to claim its "usual and customary" prices were the prices used in the small fraction of cash sales that were not discounted.

In its defense, Safeway argues that everyone should ignore all of those cash sales in its loyalty program. The lawyers' theory is that those prices far below the reported "usual and customary" prices were offered only to members, not to the "general public." Recall, however, that to "join" the loyalty program, a customer simply had to fill out a form that provided Safeway with demographic information it already had, and, of course, agree to pay cash for prescriptions. Customers did not need to pay even the nominal $10 fee that we rejected in *Kmart*. See 824 F.3d at 643–45. Even the majority

acknowledges the point: "Safeway effectively used its enrollment forms as a fig leaf to disguise a Wal-Mart-style generics program without reporting those prices as U&C. The only thing separating club members from 'the general public' was the fact that they took an affirmative step to enroll." Ante at 16.

But the majority opinion then draws the wrong conclusion. It asserts that any "interpretation of U&C that excludes discounted prices available only to program participants 'is not inconsistent with the text of the U&C price definition.'" Ante at 16–17, quoting *SuperValu*, 9 F.4th at 469. The majority adds: "With the benefit of hindsight, it is easy to criticize Safeway's interpretation of U&C as applied to its discount clubs." Ante at 16.

In fact, however, relator's theory does not depend on hindsight. The contemporaneous evidence of Safeway's choices to hide what it was doing, and of its reasons for those choices, easily permits the inference that Safeway knew at the time that it was carrying out a fraud and needed to conceal it.

Remember some of the evidence quoted above: Safeway would match Walmart prices while maintaining on paper an "official company policy" of no price-matching, and "We cannot put any of this in writing to stores." We "need to keep a low profile" for our price matches. "My question is how the state of Nebraska will know that we offered to match any price out there." Asked whether the loyalty program was designed to address "the insurance angle," a Safeway executive answered: "Off the record that is exactly the angle is getting the maximum we can from the insurance." Safeway also knew it could not be candid about why it was shifting customers from a few honestly reported discount programs to

the new loyalty program: "While we do not want to communicate the protection of Usual and Customary…."

For these reasons, and the reasons explained in my dissent in *SuperValu*, we should not double down on our earlier mistake. We should instead overrule *SuperValu* and reverse summary judgment here.