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APPENDIX A

**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 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

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.

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

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

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

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

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

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

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).

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>.

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 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

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.

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

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 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).⁹ Before oral argument in this case, we asked the parties for supplemental briefing in response to *Schutte*.

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

⁹ 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.

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 SuperValu’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.¹⁰ As we explained in

¹⁰ 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 way to distinguish between “the general public” and program participants.

Schutte, 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.¹¹ PBMs and pharmacies are of course free

¹¹ 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 Colorado claims with prejudice after Colorado declined to intervene. Relator’s proffered guidance

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.*¹² *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.

With those principles in mind, we apply them to

from other state Medicaid programs is irrelevant because Relator is not bringing claims under those states’ parallel FCA statutes.

¹² 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).

the only relevant guidance relator has identified: the CMS Manual.¹³

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

¹³ 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.

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 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)).¹⁴

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.¹⁵

We also find it significant that the footnote went

¹⁴ *Accord 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).

¹⁵ 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.

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 price-matching nationwide.¹⁶ Relator has not explained why Safeway should be liable for claims submitted after the current version of the Manual went into effect.¹⁷ 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.¹⁸¹⁹ *See Purcell*,

¹⁶ *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).

¹⁷ 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).

¹⁸ 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*

807 F.3d 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

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 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.

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.

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 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

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

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 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.

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 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 medicaid 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

That executive testified in his deposition in this case that he assumed his employees were “doing the

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, *Chapter14—Coordination of Benefits*, in Medicare Prescription Drug Benefit Manual 19 n.1 (2006), <https://perma.cc/MW6A-H4P6>.

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 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.

APPENDIX B
IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF ILLINOIS
SPRINGFIELD DIVISION

United States of America, et al. ex rel. Thomas
Proctor,

Plaintiffs,

v.

Safeway Inc.,

Defendant.

Case No. 11-cv-3406

OPINION

RICHARD MILLS, United States District Judge:

Safeway, Inc. moves for summary judgment based on the U.S. Supreme Court's *Safeco*'s decision.

I. INTRODUCTION

Safeway's reporting of its usual and customary prices between 2006 and 2015 and whether it violated the False Claims Act ("FCA") is at issue in this case.¹

¹ The Relator's amended complaint also includes separate counts alleging Safeway violated ten state law and District of Columbia False Claims (or similarly titled) Acts. The claims asserted on behalf of the State of Maryland have since been dismissed with prejudice.

Safeway seeks summary judgment under *Safeco Insurance Co. of Am. v. Burr*, 551 U.S. 47 (2007), contending that the FCA imposes an “objective standard” for the knowledge element which Safeway claims the Relator is unable to meet. The Relator alleges *Safeco*, which addressed the Fair Credit Reporting Act, does not apply to the FCA and, even if it did, Safeway acted knowingly and thus is liable under the FCA.

The issue is whether the standard articulated in *Safeco* applies to the FCA and its scienter requirement, as some federal courts of appeal have held. In *United States ex rel. Garbe v. Kmart Corp.*, 824 F.3d 632 (7th Cir. 2016), the United States Court of Appeals for the Seventh Circuit held that a pharmacy’s “usual and customary prices” included its “discount” prices if the terms of the “discount programs” were offered to the general public and were the lowest prices for which the pharmacy’s drugs were “widely and consistently available.” *Id.* at 645. The court found that government programs such as Medicare and Medicaid are entitled to the same benefit. *See id.*

Garbe was decided almost one year after Safeway’s challenged programs were discontinued. Safeway claims that, between 2006 and 2015, its actions were objectively reasonable because there was no authoritative guidance as to how to define “usual and customary price” in conjunction with membership or discount programs. The Relator contends Safeway simply ignored the ample authority warning it away from its interpretation.

II. FACTUAL BACKGROUND

Safeway is a grocery retailer. Between October 1,

2006 and July 31, 2015, Safeway operated pharmacies located inside grocery stores in 20 states and the District of Columbia. Safeway's pharmacies served customers with prescription- drug benefits provided by both commercial plans and government programs, including Medicare Part D, TRICARE, the Federal Employees Health Benefits Plan, and state Medicaid programs.

Safeway alleges that for claims covered by third-party insurance, third-party payers typically reimbursed pharmacies based on a formula defined by contract between the payer and the pharmacy. The Relator disputes the information in the cited Stipulation supports that statement. Citing another Stipulation, the Relator alleges the contracts are irrelevant to the extent that "Safeway did not reference the pricing terms of specific contracts when setting its list prices that were reported as its U&C prices."

Safeway alleges that for many years before the relevant time period, and consistent with industry practice, "usual and customary price" was understood within the industry to mean the retail cash price that the pharmacy charged to the "general public" – *i.e.*, the price automatically charged to a majority of a pharmacy's cash-paying customers for a particular drug (specific to dose and quantity), on a particular day, and at a particular store, without the customer having taken any affirmative action to obtain the price. The Relator disputes that the industry understanding of usual and customary price involved or included "retail prices," and neither the cited deposition excerpts nor Defendant's expert Michael Jacobs' Report even contains the word

“retail.” Rather, Safeway’s expert accurately stated the “PBM [Pharmacy Benefit Manager] Industry Definition of U&C Price” is “generally understood to be the cash price charged to the general public.” Julie Spier (Safeway’s Division Manager/Director of Pharmacy Operations for the State of Texas) testified that her “personal definition” of usual and customary price includes the “cash price” or “price to customers without insurance.” Mr. Jacobs’ and Ms. Spier’s testimony is also consistent with Safeway Executive Michael Topf’s understanding that U&C is “a cash price.” Safeway claims that Ms. Spier’s “personal definition” is immaterial because Relator offers it as evidence of Safeway’s subjective state of mind, which is irrelevant under *Safeco*.

Government payers

The federal government provides beneficiaries of the Medicare Part D, TRICARE and FEP programs with prescription-drug benefits through relationships with “Sponsors,” which are private, state-licensed insurance companies. *See* 42 C.F.R. § 423.505. Sponsors, in turn, often contract with various PBMs that administer prescription-drug benefits provided by the specific Part D plan. *See* 42 U.S.C. § 1395w-112(b)(1). The PBMs then enter into contractual relationships with pharmacies, including Safeway.

Safeway alleges contracts between the PBMs and Safeway governed the terms by which Safeway was required to submit claims to the PBMs and, in turn, whether and how much the PBMs would pay Safeway for dispensing drugs to their beneficiaries. Federal regulations forbid the Centers for Medicare and Medicaid Services (“CMS”) from setting any of the terms in those contracts. 42 U.S.C. § 1395w-111(i).

The Relator disputes that the contracts between the PBMs and pharmacies were the only source of the terms by which Safeway was required to submit claims to the PBMs and, in turn, whether and how much the PBMs should pay Safeway for dispensing drugs to their beneficiaries. The Relator further disputes that the cited regulations forbid CMS from setting any of the terms in Medicare Part D contracts because the cited statute does not contain a blanket prohibition. Section 1395w-111(d)(2)(A) provides that the Secretary of HHS “has the authority to negotiate the terms and conditions of the proposed bid submitted and other terms and conditions of a proposed plan.”

Medicaid is an entitlement program that provides healthcare coverage to economically disadvantaged populations. State governments set their own benefits and eligibility, while the federal government (through CMS) provides and shares the outlays for the services.

States reimburse pharmacies that dispense prescription drugs to Medicaid beneficiaries based on reimbursement methodologies set through state statutes and regulations. Safeway claims that the particular methodologies vary, but generally dictate that Medicaid will pay the lowest of various prices, including a pharmacy’s usual and customary price, which Safeway says is the price charged to a majority of a specific pharmacy’s cash paying population. The Relator disputes Safeway’s characterization of usual and customary price, particularly that there is any majority requirement for usual and customary price.

PBM and pharmacy understanding of usual and customary

Safeway alleges during the relevant period, PBMs responsible for administering government healthcare programs through their contracts with pharmacies understood usual and customary to exclude discounts that are only available to customers who have taken affirmative action to become eligible for the reduced prices. The Relator disputes the assertion that PBMs understood usual and customary prices to exclude discounts. Moreover, the Relator disputes Safeway's use of the phrase "customers who have taken affirmative action."

Safeway alleges that PBM executives interpreted the phrase "usual and customary price" to exclude membership discounts or price matching programs like Safeway's. The Relator disputes Safeway's assertion, claiming that the declarations cited in support are attempts to reinterpret the contractual usual and customary provisions based on Defense Counsel's "misrepresentations" of Safeway's discount programs.

Safeway alleges that while concluding that the discounts would have no impact on usual and customary pricing, many pharmacies offered membership discount programs that required customer initiation and action to receive a discount. Large pharmacy chains including Walgreens, Kmart, CVS Health, SuperValu, Albertsons and Rite Aid offered these types of programs. The Relator claims it is immaterial that other previous or current False Claims Act defendants committed the same type of "fraud." The Relator also contends the undisputed contemporaneous evidence establishes that Safeway

knew its price matches would impact its usual and customary prices.

Walmart's and Safeway's \$4 generic programs

In September of 2006, Walmart attempted to disrupt the pharmacy industry by introducing low-priced generic drugs, pricing 30-day supplies of popular generic drugs at \$4. On September 21, 2006, certain Safeway employees received an email discussing the Walmart \$4 generic drug discount program. The same day, Safeway's Vice President of Pharmacy Dave Fong forwarded a news article to Chief Financial Officer Robert Edwards noting that Walmart's \$4 program was not good for the pharmacy business and drug store sector prices would be dropping. On September 25, 2006, Safeway's Senior Manager of Financial Planning and Analysis Michael Topf emailed other Safeway executives noting that the \$4 prices for generic prescriptions would lead to a "margin hit." Topf's email estimated an \$8.7 million annual margin hit on Safeway's cash business if Safeway lowered its price for drugs on Walmart's \$4 list to \$4. Other retail pharmacies such as Target, Kroger, HEB and Kmart offered competing versions of Walmart's \$4 discount generic drug programs. On October 26, 2006, Chuck Posterick, Safeway's Regional Pharmacy Manager, emailed Glen Davis, its Director of Pharmacy Operations, pertaining to "Wal-Mart and Coupon Discussion Points," which stated in part:

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.

Safeway alleges that because all Walmart customers received these lower prices without having to take any action, the \$4 prices became Walmart's usual and customary prices for its reimbursement submissions, as these prices were charged to everyone in the "general public." The Relator notes that Walmart properly reported its discounted prices as its usual and customary price to all Government Healthcare Programs because those prices were widely and consistently offered to the public. The "dilemma" posed by Walmart's \$4 program for Safeway was that if Safeway adopted a similar program, then \$4 would be the usual and customary price for those drugs, which Safeway would have to offer to third parties. On October 21, 2006, Glen Davis emailed his subordinates about "Price Matching" and explained, in part, "See the attached list of Generics Walmart is covering for the \$4/30 days supply. Our official company stance is we are not going to change our usual and customary price on these items. Cash customers on these items represent less th[an] 0.6% of our sales."

On October 11, 2006, CMS issued a Memorandum to all Part D Sponsors which answered

frequently asked questions relating to CMS's "Lower Cash Price Policy." A footnote in the Memorandum specifically referenced Walmart's program offering a reduced price for certain generics to its customers.

On December 15, 2006, CMS incorporated its Lower Cash Price Policy into the CMS Medicare Prescription Drug Benefit Manual Chapter 14, Section 50.4.2 at p. 19 n.1 (2006). Safeway claims this assertion is immaterial in that the cited footnote is not authoritative guidance, because it is consistent with Safeway's objectively reasonable interpretation of the law and because the Relator offers it as evidence of Safeway's subjective state of mind, which is irrelevant under *Safeco*.

On December 19, 2006, Ash Yerasi (Safeway's Director of Managed Care and Marketing) circulated CMS's Medicare Prescription Drug Benefit Manual Chapter 14 to Safeway pharmacy staff which stated in part: "Please keep abreast of those issues that impact your areas."

On October 27, 2006, a Medco representative sent an email to Safeway representatives regarding "Usual and Customary (U&C) pricing provision reminder." The email stated in part that by contract, a pharmacy's U&C "represents 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 included a "competitor's matched price," among other discounts. The email further provided "it is expected that" Medco member claims "will be submitted through TelePAID/POS by pharmacy submitting appropriate pharmacy U&C pricing." Yerasi circulated Medco's notice to Fong, Topf and other Safeway employees, while stating in part:

“I’m sure this has to do with the Walmart initiatives. There ‘are’ ramifications to normal 3rd party business. Language is pretty similar in all of our agreements ...”

On January 2, 2007, Coventry Health Care (a plan administered by PBM Caremark) sent Safeway a notice, dated December 29, 2006, that stated in part:

Generic Drug Discount Programs and Usual & Customary Charges

As Generic Drug Discount programs become more prevalent amongst retail pharmacies, we are reminding you that as a participating pharmacy for Coventry Health Care, Inc., you are required to bill either the Pharmacy Program Administrator or the Member the lowest possible price for the drug. Per our contract in Section I. “Definitions,” 1.24 “U&C” we define it as:

“Usual and Customary Charge” means the lowest price Pharmacy would charge to a particular customer if such customer were paying cash for an identical prescription on that particular day, exclusive of sales tax or other amounts claimed. This price must include any applicable discounts offered to attract customers.

Ash Yerasi circulated the email and memorandum to twelve people in the Safeway pharmacy department, including Dave Fong and his staff, and stated that the Coventry notice is, “Another Example 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 not[e] from Medco.”

In December 2006, Safeway received a notice from the State of Nebraska regarding usual and customary charges. The Nebraska notice provided in part:

Price Matching: When a pharmacy lowers its usual and customary price for a prescription (for example: to match a competitor’s price), all claims submitted to Medicaid for the same drug and quantity dispensed during that business day must also be billed at the lowered price.

On February 1, 2007, Oregon sent a proposed amendment to a Pharmacy Network Agreement with the State of Oregon, which stated in part:

“Usual and Customary Charge’ means the minimum retail price charged by Pharmacy for a Covered Drug in a cash transaction (in the quantity dispensed), on the date the prescribed drug is dispensed, as reported to PBA by the network pharmacy, including any discounts or special promotions offered on that date.”

A February 13, 2007 excerpt from the Caremark provider manual stated in relevant part:

The Caremark Provider Manual defines Usual and Customary as:

“Usual and Customary Price or U & C” means the lowest price Provider would charge to a particular customer if such customer were paying cash for an identical prescription on that particular day at that particular location. The price must include

any applicable discounts offered to attract customers.

Additionally, “Provider must submit all claims for Pharmacy Services related to Covered items for Eligible Persons electronically through the applicable claims system.”

In an email to a pharmacy manager dated February 14, 2007, Julie Spier stated, in part: “The deal is that as long as the [Third Parties] will pay at this level we want to leave it there so that we can make as much off of them for as long as possible. You can always price match as long as you do not go below cost.” A February 16, 2007 email from Glen Davis provided in part: “When I set prices I look at what third party plans pay[] us and then try to set the retail around the highest [Third Party] reimbursement rate. . . . The reason I do this is because 90% plus of our business is third party and we have the provisions of the plan’s price or the U&C which ever is lower.”

Starting in March 2008, Safeway introduced its own \$4 Generics Program, a pricing program for certain generic drugs, in certain divisions, including Texas, Dominick’s/Illinois, Eastern/Genuardi’s, some pharmacies in its Denver division, and Vons stores in the Las Vegas area. Under this program, Safeway created a list of generic drugs, known as a “formulary,” that would be part of the program, which changed over time as drugs were added or removed. Each drug on the \$4 Generics Program’s formulary was assigned a set list price of \$4 for a typical 30-day supply, \$8 for a typical 60-day

supply and \$12 for a typical 90-day supply.

According to Safeway Financial Planning & Analysis employee Lori Kennedy, the adoption of a \$4 price for the Walmart list of generic drugs nationwide would result in a \$65 million annual financial hit to Safeway's margin. However, Michael Topf testified that this estimate was a "[w]ild-ass guess." If business were to quadruple, moreover, Safeway's profits could have increased.

On April 4, 2008, Safeway's top executives met to discuss \$4 generic prescriptions and the meeting included a presentation titled "Generic Pricing Strategy & Response to Kroger." The presentation estimated that implementing a company-wide \$4 generic pricing program would cost \$46,879,230 and that doing nothing (i.e. not responding at all to grocery competition) "could result" in a loss of approximately \$75 million in profit based on grocery sales.

Safeway executives Jesse Talamantez (National Director of Pharmacy Supply Chain and Category Management Marketing & Advertising) and Steve Scalzo (Division Manager/Director of Pharmacy Operations for Dominick's (Illinois)) at times characterized Safeway's \$4 Generics Program offered in its Dominick's, Eastern and Texas divisions as a "true" \$4 program.

In April 2008, in Safeway divisions offering the \$4 Generics Program, the prices offered for drugs on Safeway's formulary were included in Safeway's reporting of the usual and customary price. "The \$4 pricing became the Safeway U&C for all program formulary drugs during that period." Starting in early 2008, Safeway also introduced its Matching

Competitor Generics Program in certain divisions that were not participating in the \$4 Generics Program, including in Phoenix, Denver, Portland, Seattle and Vons/Southern California divisions. According to Safeway, five pharmacies in the Denver division (but not the rest of the Denver division) instead participated in the \$4 Generics Program.

Safeway claims that no screening process or membership was required for the \$4 Generics Program. Because the discounted prices under the program were automatically charged to all customers, both cash-paying and those insured by third-party payers, Safeway states that it considered the discounted prices to be its retail cash prices to the “general public.” The Relator disputes these facts on the basis they misrepresent Safeway’s stipulation and the deposition excerpts on which they are allegedly based.

During the operation of its \$4 Generics Program, Safeway reported the discounted prices for drugs included on the program’s formulary as the usual and customary prices to all third-party payers. Safeway discontinued the \$4 Generics Program in 2010.

Ad hoc price matching and usual and customary price

The Relator asserts Safeway data shows that between October 1, 2006 and July 31, 2015, Safeway overrode the higher usual and customary prices it reported to Third Party payers (health insurers, including Government Healthcare Programs) in at least 5,626,027 cash transactions. Safeway disputes this allegation which is based on the report of the Relator’s expert, Ian Dew, claiming that Dew

incorrectly identifies, and vastly overstates, the number of price override transactions Safeway reported to third parties during this period.

The Relator alleges that from 2006 through July 15, 2015, Safeway pharmacies would give a price match to any customer who requested a price match to a lower competitor's price. Safeway disputes this assertion on the bases that price matching was available only if "based on a pharmacist's discretion" and if specific circumstances were present—such as to prevent the loss of a cash customer.

The Relator further asserts Safeway's price match cash prices were not reported as Safeway's usual and customary price to health insurers (including Government Healthcare Programs) that required the reporting of usual and customary prices. Safeway claims that, because it required customers to initiate a price-match transaction, it considered price matching to be a special, ad hoc pricing component that varied by drug and by location, which did not alter Safeway's list- pricing formulas or retail prices for the relevant drugs and therefore was not reported as Safeway's usual and customary price.

Safeway evaluated and monitored the impact of their competitors' \$4 discount programs, including the number of prescriptions that were being transferred from Safeway to Walmart, Target and Kmart. Safeway alleges that starting in 2006, some of its pharmacies received authority to match competitors' prices for certain drugs if specific circumstances were present. Specifically, pharmacists could honor a price- match request if: (1) the customer initiated the price match transaction, such as by requesting a price match or quoting a competitor's price to the

pharmacist; (2) the pharmacist verified the competitor's price; and (3) the customer paid for the drug in cash, without using any insurance benefits. The Relator disputes these alleged facts, claiming they misrepresent the language of and attempt to add limitations to Safeway's Stipulations ¶¶ 3-4, on which they are allegedly based.

The Matching Competitor Generics Program was a Safeway pharmacy discount program that required customers to pay cash and fill out an enrollment form to obtain \$4 generic and other discounted drugs. Because the club-membership prices were not Safeway's retail prices, Safeway did not report them to third-party payers as its U&C prices.

In April 2008, Texas Medicaid issued an Rx Update discussing discounted prices and U&C. Under "Pass Along Savings from Pharmacy Prescription Discount Plans," the Texas notice stated:

Based on requirements in the Texas Administrative Code, pharmacies that use a prescription discount plan (such as the Wal-Mart \$4 Rx Program) or who actively match the plan prices, should reflect the discounted prices in their Medicaid prescription claims. The discounted prices should be submitted in the Usual and Customary price for claims paid by Texas Medicaid, CHIP, CSHCN, and KHC. For plans that require membership, pharmacies are asked to enroll all of their Medicaid and other state program patients. Requiring a special identification card does not disqualify Medicaid clients from receiving the discounted pricing.

On April 7, 2008, a Safeway Pharmacy Manager

sent an email regarding “Matching Competitor Generic Pricing” to Safeway Pharmacy Division Director Joe Cooper stating, in pertinent part:

Hi Joe, I contacted our nebraska Medicaid program today, and they said by matching a price, it becomes our usual & customary and any prescription filled that day has to be priced as such. Otherwise it leaves a red flag which could encourage an audit. So, until our system is loaded with the updated, special priced generics we should refrain from any low-price matching.

The same day, Cooper forwarded that email to six Safeway executives with the messages, “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.”

On April 10, 2008, Safeway’s Group Director of Pharmacy Operations, Chris Gong, sent an email to Dave Fong, stating in part, “From Alan’s research on U & C on the five states, it is stated and implied that if you matcha [sic] price offer, that becomes your usual and customary for that day and that pricing needs to be extended to Medicaid on those drugs that are covered under medicaid.” Gong’s email further stated, in part:

If we advertise the price match—it is going to Alert the medicaid programs to start looking. As I have said in the beginning, Walmart, Kroger etc is okay because the \$4 is their U and C and is extended to Medicaid—need to keep a low profile.

On August 1, 2008, Dave Fong received an email

from Cathy Polley, a representative of the Food Marketing Institute, regarding the “Generic Discount Program and Billing to Medicare Part D,” which stated in part:

Given the expanding number of companies offering discount generic programs to their customers, I wanted to pass along a reminder from CMS regarding the proper handling of these prescriptions for Medicare Part D patients. Since the generic price is your “usual and customary” price, you must submit these claims to the Part D plan sponsor. This will ensure the patient record is complete, the prescription will count toward the TrOOP [true-out-of-pocket], step-therapy can be initialed, etc. 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.

Fong forwarded the email to subordinates, including Director of Compliance Mary Ward, in addition to Glen Davis, Merle Jarvill (Director of Managed Care at Safeway and President of its wholly-owned PBM, Avia Partners) with an instruction stating, “Please note and ensure we are in compliance. Thx[.]”

In September 2008, Colorado issued a Provider Bulletin regarding “Pharmacy Discount Programs,” which stated in part:

Pharmacies who offer prescription discount programs must use their discounted prices as the usual and customary charge on Medicaid claims. Pharmacies should not submit higher

prices on Medicaid claims than prices offered to the general public. As part of its ongoing compliance monitoring requirements, the Department's Pharmacy and Program Integrity Sections are coordinating claims reviews pharmacies offering listed drugs at the usual and customary price of \$4. Beginning October 1, 2008, pharmacy providers promoting the \$4 prescriptions will receive lists of claims paid at more than \$4 for those drugs.

A December 1, 2008 Walgreens Health Initiatives Manual defined "Usual and Customary" as follows: "The usual and customary price refers to the cash price including all applicable customer discounts, coupons or sale price which a cash-paying customer would pay at the pharmacy."

A January 1, 2009, Caremark Network Update included a "miscellaneous reminder" pointing to the definition of the U&C price in its February 13, 2007, Provider Manual that "Provider must submit all claims for Pharmacy Services related to Covered Items for Eligible Persons electronically through the applicable claims system," and that "Caremark is auditing for appropriate Usual and Customary pricing during several audit processes, including on-site visits."

A March 4, 2009 Catalyst Rx contract defined "Usual & Customary" as "the price at which a Pharmacy Service is available for sale to the public at the individual Network Pharmacy providing said Pharmacy Service."

Safeway used an Auto-Refill program for which individuals under a Medicare Part D Insurance plan

were eligible. When asked about the program Merle Jarvill explained, “The system would identify after a certain amount of time that a prescription was ready to be refilled and the pharmacies would refill it and let the member know that the prescription was ready for pickup.” Safeway claims its systems required customers to request a price match every time a prescription was filled regardless of whether the prescription was automatically scheduled to be filled as part of the auto-refill program.

Safeway alleges price-matched prescriptions amounted to, at most, just 1.4% of Safeway’s prescriptions during the relevant time period and only 17.6% of total cash sales during the relevant time period. The Relator disputes Safeway’s assertion on the basis that Safeway is comparing drugs that were routinely price-matched to drugs that were never price-matched and also is relying on incomplete or erroneous data.

Safeway alleges that because it required customers to initiate a price-match transaction, it considered price matching to be a one-time special price. A price match transaction did not alter Safeway’s list-price pricing formulas or retail prices for the other relevant drugs. The Relator disputes these facts because customers could obtain a price match without requesting one through Safeway’s auto refill program. That program automatically provided customers the same lower price they had received previously and did not require the customer to take any action other than paying the discounted prescription refill.

Safeway claims that, to document a price match, the pharmacist had to manually override the retail

price at the point of sale to reduce it to the competitor's price and the overridden price would be maintained in Safeway's online claims processing system. The Relator disputes this fact in that Safeway has misconstrued Safeway's Stipulation ¶ 4(a) on which it is allegedly based by substituting the word "retail" for "original" and inserting "Safeway's online claims processing system" for "the PDX system."

Safeway discontinued price matching in all stores by July 15, 2015.

Safeway's membership discount programs

Between early 2008 and July 2010, Safeway evaluated transitioning certain \$4 Generics stores to a membership or "opt-in" program. On March 4, 2009, Safeway's then-Corporate Pharmacy Category Manager Jose Alcaine sent an email with the Subject line "\$4 Generics" to Lori Kennedy, Michael Topf and Jesse Talamantez, stating in part:

"Hypothetical: 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:

1. What is the current cost of the \$4 program in the divisions mentioned above?
2. What is the potential savings if we make this a membership program? Thereby not affecting our reinsurance reimbursements.
3. Lastly, Mike. . . do you think if we change our program to a membership program and Walmart does not, do you think

we will lose scripts?

On March 4, 2009, Alcaine responded to his own email, calculating that the “Total cost= \$10 million,” and stating that “If we change the plan to a membership program, the assumption is that only 20% of the \$4 scripts are cash and these are the individuals who would sign up for the membership program. Based on this assumption the membership program would cost us \$2 million thereby potentially saving us \$8 million.”

Starting in March 2008, Safeway introduced a membership discount program transactions in certain divisions. From 2008 to 2010, the program was called the Matching Competitor Generic Program (“MCGP”) and in 2010 its name changed in most divisions to the Loyalty Membership Program (“LMP”) (except in one geographic division, where the MCGP branding remained in place).

Safeway alleges the total number of membership discount program transactions never approached a majority of Safeway’s cash transactions. According to the Relator’s expert, the discount program transactions amounted to at most 26.9% of total cash sales during the relevant time period and only 2% of total prescriptions Safeway filled. The Relator disputes that the total number of membership discount program transactions amounted to 2% of total prescription sales or 26.9% of total cash sales because Safeway is comparing drugs that were routinely discounted to drugs that were never discounted. Moreover, the Relator claims Safeway is relying on incomplete and suspect data.

Safeway alleges that for members of these membership special pricing programs, Safeway

created a list of generic drugs to be sold at \$4 for a 30-day supply, \$8 for a 60-day supply, and \$12 for a 90-day supply. The Relator disputes that Safeway's membership program prices were "special" because they were available to everyone. For drugs not on this list, Safeway provided members with discounts of 10% on brand prescriptions and 20% on generic prescriptions. Members of the programs could also obtain a price match to a local competitor's price upon customer request and pharmacist verification of that price. The Relator also disputes that price matches were only available upon customer request and pharmacist verification.

Safeway alleges that, to become a member of its programs, customers had to opt-in through affirmative actions: they had to decide to (1) fill out and submit an enrollment form agreeing to the program's terms and conditions, (2) provide their contact information (including address, email and phone number), and (3) pay in cash. Safeway claims that between 2006 and 2015, only 7.4% of Safeway's prescription drug claims were paid in cash, while the overwhelming majority (92.6%) were submitted to insurance companies. The Relator disputes those percentages and questions the accuracy of the data, claiming it has not undergone the canonicalization processes used by the Relator's expert to exclude anomalies from the analysis. Safeway also asserts that customers who did not decide to affirmatively enroll in the program—whether because they did not decide to affirmatively enroll in the program's terms and conditions, provide their contact information, or pay in cash—were not offered the program's special discounts, and instead had to pay the usual retail rate. The Relator claims there is no support in

Safeway's Stipulation for the assertion that, if customers did not decide to affirmatively enroll in the program, they "were not offered the program's special discounts, and instead had to pay the usual retail rate." The Relator alleges customers were still eligible to receive matched prices during the MCGP and LMP programs instead of paying the "usual retail rate." Moreover, it is immaterial under Seventh Circuit precedent because it does not matter whether or not the discounted prices were given through a club or price matching.

Safeway alleges that because the club membership discount prices were not Safeway's retail prices, Safeway did not report them to third-party payers as its usual and customary prices. The Relator disputes this assertion as not supported by Safeway's Stipulation ¶ 4.² Membership prescription drug sales were processed through Avia Partners (formerly known as SMCRX), a wholly owned subsidiary of Safeway.

On May 28, 2009, Safeway's then-Director of Finance for Pharmacy/Main Meals & Ingredients, Michael Topf, emailed Steve Scalzo (Division Manager/Director of Pharmacy Operations for Dominick's) stating, in part that: "In Phoenix where they already have a successful \$4 match program, at

² Safeway's Stipulation ¶ 4 provides in part, "To obtain the discounted prices offered under the program, the customer had to (a) pay cash; and (b) fill out a Prescription Membership Program Enrollment Form that spelled out the program's terms and conditions. The discounts provided through the [club membership] program were not reported to health insurers that required the reporting of U&C prices."

the most 20% of the customers eligible for \$4 generics actually take us up on it. Thus we are able to get the benefit of offering the program while only suffering 20% of the cost.” Steve Scalzo stated that this meant for the 80% of customers that did not take advantage of Safeway’s \$4 match, Safeway was getting some kind of higher reimbursement from third parties. However, Topf testified that a large percentage of customers would not opt in, stating “I’d say at least 80 percent of our cash customers were not taking advantage of the price match, even though it was offered.”

In a May 28, 2009 email, Topf stated in part, “The obvious downside is if we upset customers with the switch but with the right communication I hope we can minimize the lost customers since anyone who wants the \$4 generic price can still get it.”

In June of 2009, Safeway was again discussing a proposal to move its Illinois (Dominick’s) stores from a \$4 discount program to a “\$4 Membership” program. In an email to Michael Topf and others, then-Vice President of Finance for the Dominick’s Division, Brian Baer, stated in part:

[I]t 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?

Need to know a lot more about the -sign_up program . . . is there other parameters?

Topf responded to Baer’s June 17, 2009 email as follows:

Off the record that is exactly the angle getting the maximum we can from the

insurance (it may be more like 8-10/script). 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).

In July of 2010, Safeway introduced its LMP in all divisions other than NorCal. The MCGP and the LMP offered the exact same features and benefits to their respective members. As divisions introduced the LMP in July 2010, the \$4 Generics Program and the MCGP were discontinued in those divisions.

The discounts provided under the MCGP and the LMP were not reported to health insurers (including Government Healthcare Programs) that required the reporting of usual and customary prices. Safeway claims the discounts were not reported because club-membership discount prices were not Safeway's retail prices. In a June 17, 2010 email, Safeway's Division Manager/Director of Pharmacy Operations for the State of Texas Julie Spier wrote in part:

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. The majority of our contracts have a clause that they will reimburse us at the agreed contract price or our usual and customary whichever is cheaper.

Please let store operations know of this change and transition period in case they get any questions (Most likely this will not happen until after the launch). 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.”

Julie Spier provided the following instructions to Safeway’s Texas Division in conjunction with the July 17, 2010 transition from the \$4 Generics Program to the membership program (LMP):

This need is going to be magnified by the moving on July 17th from the automatic \$4 generic list to a membership program (in order for the patient to get a \$4 generic they will need to sign up for our new membership program). We are going to this membership program to try to protect some of our gain dollars. All of our plans reimburse using a contracted formula for reimbursement or our usual and customary whichever is less. If we have \$4 generics, we automatically have to give all the insurance companies the \$4 too.

With the implementation - for each of the previous \$4 generics the pharmacy will need the process first on the patients regular insurance to see what their copay is and if it is more than the \$4 generics – the pharmacy will need to reverse the claim and then move it over to the membership. This is very important so that we are able to put as much as we can back to the bottom line.

In an email dated April 12, 2011, Spier characterized Safeway’s programs as “going from \$4 generic to stealth Membership Program.”

A July 12, 2011 Caremark FEP Network Update defined U&C as follows:

“Usual and Customary Price” . . . means the lowest price Provider would charge to a particular customer if such customer were paying cash or utilizing a Promotional Pricing program for an identical prescription or on that particular location. For the purposes of this definition, “Promotional Pricing” means any discounts given or offered to the general public by Provider, including but not limited to:

- Discounts given or offered through membership, club, subscription programs;
- Cash rebates;
- Coupons; and
- Other promotional or price discounts including free medications.

On or about July 15, 2011, Merle Jarvill received Caremark’s July 12, 2011 Caremark Network Services FEP Notice that was sent to Safeway. On July 15, Jarvill emailed Jewel Hunt (Safeway Group Vice President, Pharmacy Health and Wellness), Alan Pope (Safeway internal counsel), and Brian Pavur (Group Director of Pharmacy Operations), the Caremark FEP notice and stated:

Please see the announcement from Caremark. FEP is requiring that we provide our best price to them. This would be 10% off [f] brands, 20% off generics, and the \$4.00 program in Dominicks, Eastern and Texas.

I do not see a way around it. Alan,[] what are your thoughts?

On May 2, 2012, Caremark sent Pharmacy Audit Tips to Safeway which stated in part:

Usual and Customary Amount U&C

Pharmacies shall provide the member with the pharmacy's Usual and Customary amount (U&C) in the event the U&C is less than member's copay amount. Pharmacies should continue to submit the claim to Caremark even if the member chooses to pay the U&C amount. Many health plans also require submitting an accurate U&C on all claims transactions.

A June 18, 2013 Prescription Solutions/Optum contract defined "Usual and Customary Charge" as "mean[ing] the price, that a cash paying customer pays Company for Drug Products, devices, products and/or supplies."

A November 12, 2012 Caremark-administered Health Net plan sent to Safeway stated as follows:

Recently Health Net has received numerous reports from members of pharmacy claims not being submitted for processing when members pay the Usual and Customary (U&C) amount for a prescription. All claims must be submitted to Health Net via the CVS Caremark claims processing system even when the member is paying the U&C amount.

Timely submission of all member claims, even when the U&C is lower than the member's copayment, provides Health Net

with a complete utilization record and keeps the member's prescription history up-to-date.

Submitting claims to Health Net/CVS

Caremark ensures:

- The member's true-out-of-pocket (TrOOP) amount is accurate. TrOOP amount accuracy is required by the Centers for Medicare and Medicaid Services (CMS) and allows members to maximize their benefit.
- The member pays the lowest amount available under their benefit – the lower of the copay or U&C.
- A complete prescription history for accurate case management. Without an accurate prescription history, it can appear that either the member is non-compliant or the physician is not managing their care according to national standards or guidelines.

The Relator alleges Safeway data shows that between January 1, 2008 and July 31, 2015, Safeway sold approximately 8.5 million prescriptions through its discount clubs at lower cash prices than the usual and customary prices it reported to Third Party payers (health care insurers). Safeway disputes the Relator's assertion. It specifically disputes that Relator's expert report provides the correct number of prescriptions Safeway sold through its discount programs between January 1, 2008 and July 31, 2015. Safeway claims Ian Dew overstates cash sales and special pricing arrangement sales. According to the corrected data, Safeway sold approximately 8.1 million

prescriptions through its discount programs during that period.

The Relator next alleges that between October 1, 2006 and July 31, 2015, Safeway sold approximately 14.2 million prescriptions through cash price overrides or discount clubs at lower cash prices than the U&C prices its reported to Third Party payers. Safeway disputes that Relator's expert report provides the correct number of prescriptions Safeway sold through cash price overrides or discount clubs during that period.

The National Council for Prescription Drug Programs' ("NCPDP") definition of "usual and customary charge" is, in part, the "Amount charged cash customers for the prescription exclusive of sales tax or other amounts claimed" which "represents the value that a pharmacist is willing to accept as their total reimbursement for dispensing the product/service to a cash-paying customer."

Price match transactions were cash sales where the Safeway pharmacist would manually override the original price at the point of sale (cash register) to reduce it to the competitor's price.

On November 29, 2018, Bretta Grinsteinner, Assistant Vice President for Network Management at PBM Prime Therapeutics, executed a Supplemental Declaration providing context for the original declaration she signed at the request of counsel for Safeway. Paragraph 2 of the Supplemental Declaration states as follows:

As stated in paragraph 21 of the Declaration, Defendant's counsel provided the factual descriptions contained in the Declaration

about Defendant's programs and practices. With respect to the statements in paragraphs 10 and 13-20 of the Declaration, I have no personal knowledge regarding the accuracy of any representations made by Defendant or Defendant's actual price matching practices and membership programs. Plaintiff's counsel has offered to provide information and documents regarding Defendant's price matching practices and membership programs. Prime did not conduct a review of Safeway's price matching practices or membership programs during the relevant time period and is not opining on Defendant's compliance with Usual & Customary (U&C) reporting regulations and requirements.

Accordingly, the Declaration should not be construed as a determination of the propriety of Defendant's U&C price reporting.

Safeway terminated all membership special pricing programs company-wide effective July 15, 2015.

III. DISCUSSION

Safeway alleges that under *Safeco*, it cannot be liable under the FCA because it reported usual and customary pricing in a way that was objectively reasonable and the FCA prohibits only knowing violations of clearly established law. Before the Seventh Circuit's decision in *Garbe*, the law on usual and customary pricing was not clearly established. Safeway asserts that its position is objectively reasonable and, because reasonable minds could differ on whether membership discount and price-

matching programs affect usual and customary prices and there was no authoritative guidance on that question, Safeway is entitled to summary judgment.

The Relator claims that *Safeco* is inapposite because the FCA already has a knowledge standard, which is different from the “willful” standard discussed in *Safeco*. Moreover, even assuming *Safeco* has any applicability, the Relator alleges binding precedent establishes it is far narrower than Safeway represents. Additionally, the Relator asserts that even if Safeway’s interpretation was objectively reasonable, there was authoritative guidance which warned it away from its discount program scheme.

Legal standard

Summary judgment is appropriate if the motion is properly supported and “there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” *See* Fed. R. Civ. P. 56(a). The Court views the evidence and construes all reasonable inferences in favor of the non-movant. *See Driveline Systems, LLC v. Arctic Cat, Inc.*, 936 F.3d 576, 579 (7th Cir. 2019). To create a genuine factual dispute, however, any such inference must be based on something more than “speculation or conjecture.” *See Harper v. C.R. England, Inc.*, 687 F.3d 297, 306 (7th Cir. 2012) (citation omitted). “The court does not assess the credibility of witnesses, choose between competing reasonable inferences, or balance the relative weight of conflicting evidence.” *Driveline Systems*, 36 F.3d at 579 (internal quotation marks omitted). Ultimately, there must be enough evidence in favor of the non-movant to permit a jury to return a verdict in its favor. *See Springer v. Durflinger*, 518 F.3d 479,

484 (7th Cir. 2008).

Safeco's application to this case

(1)

Safeway states that its motion raises a pure question of law under *Safeco*— whether Safeway violated the FCA by failing to treat its discount prices—provided to cash-paying customers through member-only discount programs and price-matching—as its usual and customary price for government programs.

The FCA provides for liability if a person “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.” 31 U.S.C. § 3729(a)(1)(B). A person acts “knowingly” for purposes of the FCA if he: “has actual knowledge of that information;” “acts in deliberate ignorance of the truth or falsity of the information;” or “acts in reckless disregard of the truth or falsity of the information.” 31 U.S.C. § 3729(b)(1)(A). No proof of specific intent to defraud is required. 31 U.S.C. § 3729(b)(1)(B).

In *Safeco*, the Supreme Court examined the scienter requirement of the Fair Credit Reporting Act (“FCRA”). The Court noted that “where willfulness is a statutory condition of civil liability, we have generally taken it to cover not only knowing violations of a standard, but reckless ones as well.” *Safeco*, 551 U.S. at 57.

The Court further observed that the common law has generally judged “recklessness” according to an objective standard and that Safeco’s conduct could not meet the statute’s scienter requirement absent an “objectively unreasonable” interpretation of the

statute's legal requirements. *See id.* at 58-60. The argument that "evidence of subjective bad faith can support a willfulness finding even when the company's reading of the statute is objectively reasonable" is unsound. *Id.* at 70 n.20. "Congress could not have intended" to make a defendant liable for knowing or reckless violations if the defendant "followed an interpretation that could reasonably have found support in the courts, whatever [its] subjective intent may have been." *Id.* Because "reckless disregard' . . . is the most capacious of the three" mental states, *see United States v. King-Vassel*, 728 F.3d 707, 712 (7th Cir. 2013), it follows that if a relator is unable to prove recklessness, he also would not be able to establish actual knowledge or deliberate indifference.

The Supreme Court in *Safeco* thought it significant that defendant did not have "the benefit of guidance from the courts of appeals or the Federal Trade Commission (FTC) that might have warned it away from the view it took." *Id.* at 70. No such guidance existed except for a letter "written by an FTC staff member to an insurance company lawyer." *Id.* at 70 n.19. Because of this lack of guidance, "Safeco's reading was not objectively unreasonable" and fell well short of constituting reckless disregard. *Id.* at 70.

The United States Court of Appeals for the Seventh Circuit has not addressed whether *Safeco's* standard with respect to the FCRA applies to the FCA and its scienter requirement. However, Safeway alleges every court of appeals to consider the issue has held that it does. *See U.S. ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 290 (D.C. Cir. 2015) (noting that under the FCA's knowledge element, the inquiry

involves the “objective reasonableness” of the defendant’s interpretation of an ambiguous term and whether the defendant was warned away from that interpretation); *U.S. ex rel. Streck v. Allergan Inc.*, 746 F. App’x 101, 106 (3d Cir. 2018) (quoting *Purcell* and stating that because of the “knowing” requirement, “the FCA does not reach an innocent, good-faith mistake about the meaning of an applicable rule or regulation. Nor does it reach those claims made based on reasonable but erroneous interpretations of a defendant’s legal obligations.”); *U.S. ex rel. McGrath v. Microsemi Corp.*, 690 F. App’x 551, 552 (9th Cir. 2017) (finding that scienter under the FCA could not be established because defendant’s good faith interpretation of a key term in the applicable regulation was reasonable); *U.S. ex rel. Donegan v. Anesthesia Associates of Kansas City, PC*, 833 F.3d 874, 879-80 (8th Cir. 2016) (concluding FCA scienter could not be established under *Safeco* barring evidence of government guidance warning a regulated defendant away from an otherwise reasonable interpretation of an ambiguous regulation). In *U.S. ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645 (5th Cir. 2017), the court cited *Safeco* with approval and found testimony supported the defendant’s assertion that a “reasonable interpretation of any ambiguity inherent in a regulation belies the scienter necessary” to violate the FCA. *Id.* at 657-58 & n.39.

Safeway contends that, as those courts of appeal have found, the Supreme Court’s analysis of the common-law definition of recklessness with respect to the FCRA in *Safeco* applies with equal force regarding the FCA. The Seventh Circuit has endorsed that principle, stating that “mere

differences in interpretation growing out of a disputed legal question” involving a contractual term cannot violate the FCA. *U.S. ex rel. Yannacopoulos v. General Dynamics*, 652 F.3d 818, 836 (7th Cir. 2011) (internal quotation marks). Because the FCA requires a knowingly false statement, 31 U.S.C. § 3729(a)(1)(B), a defendant lacks knowledge if “the particular false statements were the result of a difference in interpretation or even negligence.” *U.S. ex rel. Marshall v. Woodward, Inc.*, 812 F.3d 556, 561-62 (7th Cir. 2015).

Given that every court of appeals to address the issue has found that the Supreme Court’s analysis of the common-law definition of recklessness as to the FCRA in *Safeco* applies equally to the FCA and because the Seventh Circuit has approved the principle, the Court agrees with those circuit courts and finds that *Safeco*’s standard applies to the FCA and its scienter requirement.

(2)

Citing *U.S. ex rel. Berkowitz v. Automation Aids, Inc.*, 896 F.3d 834 (7th Cir. 2018), the Relator notes that scienter can be satisfied by showing that defendants acted with reckless disregard if “defendants had reason to know of facts that would lead a reasonable person to realize that the defendants were causing the submission of a false claim or that the defendants failed to make a reasonable and prudent inquiry into that possibility.” *Id.* at 842 (citation omitted). The relator in *Berkowitz* was president of a company that held a supplies contract with the General Service Administration (GSA). *See id.* at 838. The defendants were competitors who held similar contracts. *See id.* GSA

required that these vendors could “only offer and sell U.S.-made or other designated country end products to governmental agencies.” *Id.* The relator alleged defendants violated the FCA by making material false statements and presenting false claims to the United States regarding the selling of products from non-designated countries. *See id.* at 838-39. Although the relator presented evidence of GSA notices directing some defendants to remove non-compliant products from their inventories, the court found that relator had not sufficiently alleged that defendants acted with reckless disregard of the truth or falsity of the information provided to the government. *See id.* at 842-43. While acknowledging the difficulty for a relator to allege with accuracy what occurs inside the operations of a competitor, the Seventh Circuit stated that does not relieve the relator of “his obligation to adequately plead all of the elements of an FCA claim or to fully investigate his claim before filing a complaint.” *Id.* at 843. The Relator asserts *Berkowitz* and other Seventh Circuit cases establish that the FCA scienter standard is much broader than Safeway claims.

The Relator further asserts *Safeco* is about “willful” violations of the FCRA, while this case is about “reckless disregard,” “deliberate indifference” or “actual knowledge” of FCA violations. The statutory definitions of knowing and knowingly “set[] a fairly low standard, making it easier for the United States to prevail in FCA actions.” *U.S. ex rel. Chandler v. Cook, County, Ill.*, 277 F.3d 969, 976 (7th Cir. 2002). However, *Safeco* suggests that the same standard should be used whether the violation is alleged to be knowing or reckless. If “the statutory text and relevant court and agency guidance allow for

more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation as a knowing or reckless violator.” *See Safeco*, 551 U.S. at 70 n.20. Safeway states that the issue here is how to establish reckless disregard when the law is unsettled. *Safeco* has provided guidance in that regard.

“To establish liability under the FCA, the defendant must have acted with ‘actual knowledge,’ or with ‘deliberate indifference’ or ‘reckless disregard’ to the possibility that the submitted claim was false.” *King-Vassel*, 728 F.3d at 712.³ The Seventh Circuit stated it had previously defined “reckless disregard” as “innocent mistakes or negligence.” *Id.* The court noted other definitions of “reckless disregard” and found that plaintiff would need only show that defendant had reason to know of facts that would lead a reasonable person to realize he or she was causing the submission of a false claim (based on a *Black’s Law Dictionary* definition) or that defendant “failed to make a reasonable and prudent inquiry into that possibility” (per a Senate Report definition). *Id.* at

³ In *King-Vassel* the court determined that, based on factual determinations such as a mother’s testimony she had provided the doctor-defendant with the child’s Medicaid information, never paid out of pocket for the child’s appointments and based on the submission of paperwork suggesting the doctor- defendant had been compensated by Medicaid for the child’s prescriptions, a reasonable jury could find that plaintiff established the defendant recklessly disregarded the fact that the child had received Medicaid assistance. *See King-Vassel*, 728 F.3d at 713.

713. *King-Vassel* addresses facts that the actor knows or has reason to know, *see id.* at 713-14, not whether the applicable law is established as in *Safeco*.

As Safeway explains, if there is more than one reasonable interpretation of the applicable legal standard and no authoritative guidance, a party may think it knows what the law requires. Absent authoritative guidance on the issue, however, a party cannot know what is required or deliberately or recklessly ignore what is required. Accordingly, if a defendant adopts one of multiple reasonable interpretations, its “subjective intent” is legally irrelevant if there is “an interpretation that could reasonably have found support in the courts.” *Safeco*, 511 U.S. at 70 n.20.

The Relator alleges there is ample evidence of Safeway’s actual knowledge and evasion of its obligations. Between 2006 and 2015, Safeway received numerous notices from various PBMs and Medicaid programs referencing the contractual and regulatory expectations concerning Safeway’s reporting of usual and customary prices. In most cases, however, these notices are not authoritative guidance or are not inconsistent with Safeway’s interpretation of usual and customary price.

The Relator further asserts the record shows that Safeway executives were very aware of the ramifications of Walmart’s \$4 generic discount program on its business. They assessed those consequences in determining whether to match the program, initially deciding that Safeway would not change its “usual and customary price” for generic drugs. PBMs such as Medco and Coventry and state

Medicaid programs issued notices regarding definitions and/or explanations of usual and customary prices. Moreover, Safeway's Provider Manual in 2007 from Caremark defined usual and customary price to "include any applicable discounts offered to attract customers."

Safeway introduced its Matching Competitor Generics Program in certain divisions that did not adopt the \$4 Generics Program. Unlike with the \$4 Generics Program, those discounted prices were not reported to the Third Party health insurers. In April 2008, Safeway received notices from the States of Texas and Nebraska reminding Safeway that discounted prices should be submitted as its usual and customary price. The Relator contends that email records show that Safeway executives wanted to keep Safeway's manipulation of its usual and customary prices secret. Safeway received notices from PBMs and Medicaid programs advising it to comply with directions regarding its discount programs.

The Relator claims that in 2009, Safeway contemplated eliminating the \$4 Generics program in order to save money in pursuit of the highest possible profits. In June and July 2010, a Safeway executive stated that dropping the \$4 Generics program and going to a Loyalty Membership Program would have a positive economic impact.

The Relator asserts it was not reasonable for Safeway to ignore and deliberately circumvent the express notices it received warning of its obligation to report its actual usual and customary price. Although Safeway executives knew that its membership discounts and price-matching programs set its usual and customary prices, they chose to ignore that in

order to seek higher profits. Accordingly, the Relator contends *Safeco* does not affect Safeway's submission of false claims "knowingly."

If an objectively reasonable interpretation of the law supported its conduct, however, Safeway could not actually know it was violating a legal obligation. Otherwise, two actors could engage in the same conduct on the exact same facts and be subject to different liability under the FCA based on how they subjectively interpret the law. Such a result is not permitted under *Safeco*. This "[s]trict enforcement of the FCA's knowledge requirement" serves to prevent a party from becoming liable due to an innocent mistake, thereby "avoiding the potential due process problems posed by penalizing a private party for violating a rule without first providing adequate notice of the substance of the rule." *Purcell*, 807 F.3d at 287. The court in *Purcell* overturned a jury verdict finding FCA violations because the defendants "could reasonably have concluded" their conduct was permitted, even though defendants subjectively believed they were wrong and one witness "knew" they were wrong. *See id.* Subjective intent is "irrelevant" if a defendant has a reasonable interpretation. *See id.* at 290. In order for the conduct to be "knowingly" or "recklessly" illegal, therefore, an authoritative interpretation must exist stating that it is. Here, there does not appear to be any such authoritative interpretation.

(3)

The Relator next claims binding precedent establishes *Safeco* is considerably narrower than Safeway represents. Citing *Van Straaten v. Shell Oil Prods. Co.*, 678 F.3d 486 (7th Cir. 2012), the Relator

asserts *Safeco* is simply an analysis of “willfulness” under the FCRA. The Seventh Circuit stated the Supreme Court defined “willful” in *Safeco* and noted “only a reading that is ‘objectively unreasonable’ can be deemed a ‘willful violation.’” *Id.* at 489. The statutory standard in *Safeco* “concerns *objective* reasonableness, not anyone’s state of mind.” *Id.* at 491. In *Murray v. New Cingular Wireless Servs., Inc.*, 523 F.3d 719 (7th Cir. 2018), the Seventh Circuit applied *Safeco* in discussing “recklessness” under the FCRA. *See id.* at 726. The court in *Murray* found that, while “[i]t would be reckless *today*” to adopt the defendant’s position, “it was not reckless to act as [defendant] did in 2003” before *Safeco* provided authoritative guidance. *See id.* at 727.

Moreover, the Relator asserts that since *Safeco* was decided, the Seventh Circuit has never applied it in an FCA case and instead has articulated a different and broader knowledge standard. However, the Supreme Court did not limit *Safeco* to the FCRA, stating “that a common law term in a statute comes with a common law meaning, absent anything pointing another way.” *Safeco*, 551 U.S. at 58. The FCA does not point another way.

The Relator also cites a Court of Federal Claims case and two district court cases in noting some courts have rejected the application of *Safeco* in FCA cases. However, those cases are not persuasive given the appellate authority holding otherwise.

The Relator alleges Safeway overextends *Safeco*’s discussion of “recklessness” by arguing it is exempt from liability when there is any “objective” reasonable interpretation of a legal obligation offered at any time, even if Safeway did not adopt that

interpretation or actually knew it was violating a legal obligation. In *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923 (2016), a patent case, the Relator claims the Supreme Court rejected the broad application of *Safeco* advanced by Safeway in noting that “culpability is generally measured against the knowledge of the actor at the time of the challenged conduct.” *Id.* at 1933. The Court in *Halo* stated it had observed in *Safeco* that a person is reckless if he acts “knowing or having reason to know of facts which would lead a reasonable man to realize” his actions are unreasonably risky. *Id.* (quoting *Safeco*, 551 U.S. at 69). The Court in *Halo* noted that in *Safeco* it determined the defendant did not recklessly violate the FCRA because its interpretation had “a foundation in the statutory text” and the defendant lacked authoritative guidance that might have persuaded it to take a different view. *Id.* “Nothing in *Safeco* suggests that we should look to facts that the defendant neither knew nor had reason to know at the time he acted.” *Id.* The Relator contends the court of appeals cases relied on by Safeway for the proposition that *Safeco* provides the controlling scienter standard for cases brought under the FCA should be disregarded because the cases either pre-date *Halo* or do not address it, instead relying on *Safeco* and its progeny’s interpretation of “reckless disregard” without considering what *Halo* said about the issue.

As Safeway notes, the Supreme Court in *Halo* was considering § 284 of the Patent Act, which afforded district courts the discretion to “increase the damages” without specifying any “precise rule or formula” for doing so. *See Halo*, 136 S. Ct. at 1931-32. Unlike the FCA and FCRA, § 284 sets no scienter

standard for enhanced patent damages. The standard is left to the discretion of the courts, which over the years have established such damages should not “be meted out in a typical infringement case, but are instead designed as a ‘punitive’ or ‘vindictive’ sanction for egregious infringement behavior. . . . characteristic of a pirate.” *Id.* at 1932. The Patent Act’s subjective intent standard turns on the concept of “bad-faith infringement,” which the Court explained “is an independent basis for enhancing patent damages.” *See id.* at 1933 n.*. The Court instructed courts to apply sound legal principles and award enhanced damages under the Patent Act in “egregious cases typified by willful misconduct.” *Id.* at 1934. Accordingly, *Safeco* and *Halo* address different issues.

The Relator asserts Safeway’s reliance on the D.C. Circuit’s decision in *Purcell* should be rejected because *Purcell* relies heavily on footnote 20 in *Safeco* which the Relator claims the Supreme Court “walked back” in *Halo*. However, the Court did not walk back that footnote except as it applies to patent cases. In another footnote, the Court in *Halo* stated:

Respondents invoke a footnote in *Safeco* where we explained that in considering whether there had been a knowing or reckless violation of the Fair Credit Reporting Act, a showing of bad faith was not relevant absent a showing of objective recklessness. But our precedents make clear that “bad-faith infringement” is an independent basis for enhancing patent damages.

Halo, 136 S. Ct. at 1933* (internal citations and

citation omitted). The above passage from *Halo* does not walk back *Safeco's* objectively reasonable standard. The first sentence reaffirms the standard and notes that a bad faith showing is not necessary with respect to the FCRA unless there is objective recklessness. The second sentence notes that “bad-faith infringement” is a consideration in determining damages under the Patent Act.

Additionally, the statement in *Halo* regarding whether courts “should look to facts that the defendant neither knew nor had reason to know,” *id.*, does not affect *Safeco's* holding as to objectively reasonable interpretations of the law.

The Relator further claims Safeway's cases citing *Purcell* are distinguishable because those cases interpreted only the “reckless disregard” prong of the FCA's scienter standard or otherwise did not consider the other two prongs that provide alternative ways of establishing scienter. The Relator contends the circuit court cases cited by Safeway conflict with the Seventh Circuit cases interpreting “knowing” violations of the FCA and ignore more recent Supreme Court precedent. The Relator notes that *Safeco* concerns “willfully” failing to comply with the FCRA, not a knowing violation of the FCA. Even if *Safeco* was applicable to “reckless disregard” in this FCA case (one of three independent ways a defendant can act knowingly), the Supreme Court's decision in *Halo* makes clear that *Safeco* does not mean what Safeway claims it does.

As Safeway notes, however, three courts of appeals in cases that post-date *Halo* have applied *Safeco* to the FCA without invoking *Halo*. These

include the Third Circuit in *Streck*, the Eighth Circuit in *Donegan* and the Ninth Circuit in *McGrath*. Accordingly, the Court concludes that *Halo* is limited to the patent context. *Halo* did not apply *Safeco* and does not alter *Safeco*'s objectively reasonable standard.

Based on the foregoing, this Court agrees with those courts of appeal that have found that the Supreme Court's analysis of the common law definition of recklessness as to the FCRA in *Safeco* applies equally to the FCA.

Safeway and the *Safeco* standard

The Relator next contends Safeway cannot even meet the standard that it advocates. And that Safeway misrepresents the case law and relies on "guidance" that has nothing to do with the "usual and customary" price for pharmacy claims. The Relator alleges Safeway misrepresents Relator's counsels' prior statements concerning guidance in attempting to manufacture confusion over the meaning of usual and customary price before the Seventh Circuit's decision in *Garbe*. Moreover, Safeway relies on facially irrelevant hospital and ambulance resources that are taken out of context to manufacture support for its "objectively reasonable" interpretation. The Relator further alleges the district court cases relied on by Safeway are inapposite.

Safeway contends the Relator is simply attempting to avoid *Safeco*'s objectively reasonable standard because summary judgment is required based on what it claims was Safeway's objectively reasonable position at the time. Moreover, the cases Safeway cites are not offered as the only or best interpretation of the law, but to confirm at the time of

the alleged conduct that “[t]he statutory text and relevant court and agency guidance allow[ed] for more than one reasonable interpretation.” *Safeco*, 551 U.S. at 70. This Court in *U.S. ex. rel. Schutte v. SuperValu, Inc.*, 2019 WL 3558483, (C.D. Ill. Aug. 5, 2019) implicitly recognized there was no court of appeals guidance on the meaning of usual and customary price until May 2016, when the Seventh Circuit issued its decision in *Garbe*.⁴ In determining whether a price-match program required inclusion in usual and customary pricing, this Court relied on *Garbe*, explaining that it “cannot disregard applicable Seventh Circuit precedent,” and holding that “*Garbe* makes clear that Medicare Part D and Medicaid are entitled to the benefit of the [U&C] price regularly offered by a pharmacy to its cash customers.” *Schutte*, 2019 WL 3558483, at *6.

Safeway alleges *Garbe* came too late for it to be warned from its reasonable, contrary interpretation. Safeway stopped all of the challenged programs no later than July 2015, almost one year before *Garbe* was decided. Therefore, the guidance from *Garbe* came after Safeway submitted all of the allegedly false claims in this case and thus has no bearing on

⁴ The first sentence of the relators’ motion for partial summary judgment in *Schutte* also suggests that prior to *Garbe*, the way to determine usual and customary pricing with respect to a price match program was not settled: “The Seventh Circuit opinion in *United States ex rel. James Garbe* definitively addressed, as a matter of law, how usual and customary (“U&C”) prescription drug pricing is to be determined and why the Medicare Part D and Medicaid programs are entitled to the benefit of discounted cash prices.” Case No. 11-3290, D/E 164, at 1.

whether Safeway violated the FCA.

Safeway asserts that in pleadings in this case and *Schutte*, the Relator's counsel has alleged *Garbe* "clearly established" the meaning of usual and customary pricing as it relates to price matching. The Relator characterized Safeway's pre- *Garbe* authority as "consist[ing] of random, facially irrelevant, non-binding OIG materials (a letter, an advisory opinion and proposed non-final rules)" that, "[u]nlike the controlling opinion issued by the Seventh Circuit in *Garbe* . . . do not even address U&C pricing for prescription drugs and instead consider a different provision of the U.S. Code not at issue here." *Schutte*, D/E 315, at 5. Safeway claims it is undisputed that no court of appeals had spoken on the issue at the time of the conduct at issue.

The Relator claims Safeway misrepresents Relator's counsel's statements regarding guidance as to the meaning of usual and customary prices pre-*Garbe*. Moreover, the Relator alleges the "irrelevant, nonbinding OIG materials" relied on by SuperValu in *Schutte* and Safeway here are not pertinent with respect to the pharmacy transactions in this case.

Safeway alleges *Garbe* confirms this was an unsettled legal question at the time. The district court in *Garbe* had held that U&C means "cash price to the general public," and that "members of Kmart's generic discount programs are part of the 'general public.'" *U.S. ex. Rel. Garbe v. Kmart Corp.*, 73 F. Supp.2d 1002, 1014, 1017 (S.D. Ill. 2014). The district court certified three questions for interlocutory appeal under 28 U.S.C. § 1292(b) and the Seventh Circuit "added the question whether the district court correctly identified the "usual and

customary” price. *Garbe*, 824 F.3d at 637. Based on the standard under § 1292(b) that district judges are directed to employ, Safeway claims the issue was one “as to which there is substantial ground for difference of opinion.” 28 U.S.C. § 1292(b).

For these reasons, Safeway claims the Relator cannot, as a matter of law, point to “sufficient record evidence that there was ‘guidance from the court of appeals’ or relevant agency ‘that might have warned [Safeway] away from the view it took.’” *Purcell*, 807 F.3d at 289 (quoting *Safeco*, 551 U.S. at 70).

Objective reasonableness of Safeway’s position

Safeway claims that, regardless of the current legal status after *Garbe*, its position was objectively reasonable between 2006 and 2015. Prevailing industry understanding considered the “usual and customary price” to be the undiscounted retail price for cash-paying customers. Safeway’s usual and customary prices did not include exceptions to those same prices through either (1) membership programs that discounted prices only for customers who took affirmative steps to enroll, or (2) customer-initiated and pharmacist-verified price matches of a local competitor’s price. Safeway contends that, even if its interpretation of governing law was wrong, it was still objectively reasonable under *Safeco*, which warrants summary judgment in its favor.

(1)

Safeway further states that before, while and after its allegedly fraudulent conduct took place, numerous courts have issued rulings either adopting Safeway’s position or acknowledging that the phrase “usual and customary” is susceptible to multiple

interpretations. Safeway cites a number of district court decisions both from within and outside the Seventh Circuit showing how different courts have interpreted the phrase. *See Madison v. Mississippi Medicaid Comm'n*, 86 F.R.D. 178, 188 n.*** (N.D. Miss. 1980) (stating discount prices offered to a portion of customers “would be excluded from the usual and customary calculations unless the patients receiving the favorable prices represent more than 50 percent of the store’s prescription volume”); *U.S. ex rel. Garbe v. Kmart Corp.*, 73 F. Supp.3d 1002, 1015 (S.D. Ill. 2014) (stating “with respect to government programs . . . U&C is defined by the relevant contract and/or payer sheet of the PBMs [and] [w]ith respect to state Medicaid programs, U&C is defined by statute or regulation”); *Corcoran v. CVS Health*, 2017 WL 3873709, at *14 (N.D. Ca. Sept. 5, 2017) (finding that specific terms of each PBM contract controlled whether defendants were “required to submit the [discount] program prices as U&C” and concluding none did), *rev’d*, 779 F. App’x 431, 433 (9th Cir. June 12, 2019) (finding there were genuine issues of material fact concerning the meaning of U&C which required the reversal of summary judgment); *Klaczak v. Consolidated Medical Transport*, 458 F. Supp.2d 622, 679-80 (N.D. Ill. 2006) (crediting testimony that “there is generally no requirement that a discount be offered to Medicare” and “there’s no absolute guidelines that I’m aware of for setting that standard”); *U.S. ex rel. Gathings v. Bruno’s, Inc.*, 54 F. Supp.2d 1252, 1257 (M.D. Ala. 1999) (“This court agrees that, in the context of the federal and Alabama regulations, ‘usual and customary charge to the general public’ refers to customers paying the prevailing retail price.”).

Based on those authorities showing there was more than one reasonable interpretation of “usual and customary price,” Safeway alleges it cannot be treated as a “knowing or reckless violator.” *See Safeco*, 551 U.S. at 70 n.20. “Congress could not have intended such a result for those who followed an interpretation that could reasonably have found support in the courts.” *Id.* Based on the aforementioned district court cases and the lack of any controlling authority at the time, it would be difficult to describe Safeway’s pre-*Garbe* position as objectively unreasonable.

Safeway claims that other entities shared its view. It states that the Academy of Managed Care Pharmacy, a leading nonprofit professional organization of pharmacists, defined “usual and customary” as the “undiscounted price that individuals without drug coverage would pay at retail.” The Relator asserts Safeway has mischaracterized one sentence out of an Academy of Managed Care Pharmacy discussion of usual and customary price and presented it out of context, in failing to explain that the “discount” clearly refers to contractual discounts, as opposed to the cash price paid by someone without a negotiated discount. The “Glossary” in the full version of the Academy of Managed Care Pharmacy document defines “usual and customary price” as “The price for a given drug or service that a pharmacy would charge a cash paying customer without the benefit of insurance provided through a payer or intermediary with a contract with the pharmacy.”

Safeway notes the record includes affirmations from PBMs and other leading pharmacies reaching

the same conclusion. See *Schutte*, 2019 WL 3558483, at *1 (describing SuperValu and Albertsons' price-match program); *Garbe*, 824 F.3d at 636 (describing Kmart's discount program); *Forth v. Walgreen Co.*, 2018 WL 1235015, at *5 (N.D. Ill. Mar. 9, 2018) (noting Walgreen's assertion that "because cash-paying customers need to opt in to the [discount program] and pay a yearly membership fee to access [discount] prices, such prices cannot qualify as U&C prices"); *Garbe*, Case No. 15-1502, D/E 17 at 10 (stating Rite Aid's position that U&C "does not include reduced prices offered to members of drug-discount- programs, because those reduced prices are available only to those individuals who actually enroll in the program—not to the 'general public'").

Safeway also points to the Expert Report of Leslie Norwalk, an attorney and former Acting Administrator for CMS who drafted some of the applicable regulations, and states that "by submitting its own regular cash price as its U&C price," Safeway did not "cause[] any damage to the Medicare Part D. program." Moreover James Kevin Gorospe, a private consultant and former Chief of Pharmacy Policy for California's Medicaid program, notes that during the relevant time period for its litigation, Safeway operated pharmacies in 22 states and participated in the Medicaid programs of each state. Gorospe described the approaches of the 22 states as follows: (1) states that clearly could not or did not enforce U&C definitions that attempted to include individualized competitor price matching or membership-club pricing; (2) states in which "U&C reporting did not require Safeway to report the prices charged to patients pursuant to competitor price

matching,” based on the definition of U&C;⁵ and (3) “states that had State Plans, statutes, and/or regulations that could be interpreted as requiring pharmacies engaged in a competitor price matching program to report those matched prices to state Medicaid programs, at least for some portion of the relevant time period.”

Safeway claims the agency guidance that did exist affirmatively supported its view that membership-only and price-matching programs did not control usual and customary prices. Instead of suggesting discounted prices are usual and customary prices, CMS regulations have distinguished between the two. Safeway further asserts other Medicare guidance documents show that discounts offered by a pharmacy may fall below the cost of a prescription obtained under a Medicare prescription drug plan. That could not happen if the mere offer of membership discount programs or price matching supplanted the existing U&C price.

The Relator contends Safeway wrongly claims that CMS treated “discount prices” and usual and customary price as mutually exclusive. However, CMS stated that even discounts which are obtained through a “discount card” are considered “usual and customary prices” when they are offered throughout the benefit year. *See Garbe*, 824 F.3d at 644 (quoting CENTERS FOR MEDICARE & MEDICAID SERVS., *Chapter 14—Coordination of Benefits*, in MEDICARE PRESCRIPTION DRUG

⁵ This second group includes 19 of the 22 states in which Safeway did business.

BENEFIT MANUAL 19 n.1 (2006),
<https://perma.cc/MW6A-H4P6>).

Safeway's contracts with PBMs are clear on this point and often defined usual and customary price as including "applicable discounts," though the Relator asserts Safeway ignores them here because they contradict its litigation position. Safeway was aware of its PBM contracts and CMS's position on its discount programs at the time it engaged in its FCA violations. The Relator further claims there is no evidence that Safeway ever saw or considered the unrelated and inapplicable "guidance" cited by its counsel in the instant motion.

Safeway claims enforcement guidance from the Department of Health & Human Services Office of Inspector General ("HHS-OIG") likewise instructed that "usual" charges need not include "free or substantially reduced charges to (i) uninsured patients or (ii) underinsured patients who are self-paying," such as cash customers like those using Safeway's membership programs.

The Relator asserts Safeway's reliance on hospital discounts is misplaced because Safeway is not a hospital and its discount programs were offered to everyone regardless of insurance status or any other distinguishing criteria. From 2011 to 2015, Safeway sold prescriptions at "discount" cash prices more often than it sold them at its reported usual and customary price and in 2010 Safeway "discounted" close to half of its cash prescription sales. Safeway notes it is irrelevant whether the guidance concerned a pharmacy or a hospital, Medicare Part D or a state Medicaid regulation, private pharmacy sales or sales to Medicare beneficiaries, or a discovery order or a

motion for summary judgment. The significance of any case or other authority concerns its definition of usual and customary pricing and/or whether the phrase is susceptible to multiple interpretations.

Safeway states the Government Accountability Office (“GAO”), in an official report to Congress, explains that “usual and customary price” means the “undiscounted price individuals without drug coverage would pay.” Safeway claims GAO’s guidance excludes far more from usual and customary pricing than Safeway’s more conservative interpretation, in that the government interpreted the U&C to exclude all discounts while Safeway only excluded discounts through programs that require affirmative enrollment.

The Relator claim Safeway’s reliance on a letter transmitting a GAO report on usual and customary price trends that refers to U&C price as the “undiscounted price individuals without drug coverage would pay” is misplaced. According to the Relator, Safeway’s assertion that “[t]he government interpreted U&C to exclude *all* discounts” is not a reasonable conclusion to draw from the cover letter.

The Relator states that the Court should disregard Safeway’s *post hoc* interpretation of usual and customary price. The regulations, longstanding guidance, industry understanding of usual and customary price and Safeway’s contracts establish its routinely available lower cash discount program prices should have been submitted as its usual and customary price.

The record does contain evidence that Safeway executives had concerns about how to properly determine its usual and customary price. These

individuals were particularly worried about Safeway's potential financial losses depending upon how usual and customary price was defined and how many entities received the benefit of that price. Some executives expressed views that questioned whether Safeway could legally avoid reporting discount or price-match programs prices as its usual and customary prices. However, these subjective views are not enough for the conduct to be "knowingly" or "recklessly" illegal under the FCA. *See Purcell*, 807 F.3d at 287, 290.

Certainly, various Government Healthcare Programs and other third parties expressed views regarding "usual and customary price" that conflicted with Safeway's interpretation. However, none of these emails or other documents expressing other views constitute authoritative guidance. Moreover, they do not address the objective reasonableness of Safeway's position.

Before *Garbe*, there was guidance from CMS, HHS-OIG and the GAO in the form of regulations, memoranda, manuals, enforcement, guidance official reports to Congress supporting Safeway's interpretation. In many cases, these materials distinguished between discount and U&C prices. There was also authority that supported the Relator's interpretation that was eventually recognized in *Garbe*. To establish an FCA violation, the Relator must show there was a clear rule forbidding Safeway's position at the time of the conduct. *See, e.g., Yannacopoulos*, 652 F.3d at 836 (noting that "mere differences in interpretation growing out of a disputed legal question" do not violate the FCA). Guidance documents alone would not be sufficiently

authoritative. If there are competing interpretations that are supported by court decisions or other authority, then Safeway's conduct would not be objectively unreasonable under *Safeco*.

(2)

The Relator claims that, even if Safeway's interpretation was objectively reasonable, there existed controlling authority of which Safeway was aware in 2006 that directly warned Safeway away from its discount program scheme. Moreover, Safeway misrepresents that it was not until *Garbe* that the definition of usual and customary price was established. The Relator asserts the parties in *Garbe* agreed what usual and customary price meant—they simply argued what the “general public” was and the Seventh Circuit rejected Kmart's attempt to hide its true cash price. *See Garbe*, 824 F.3d at 643 (noting “Kmart argues that the ordinary meaning of ‘general public’ excludes customers who join a discount program” and finding “[o]ur reading of ‘general public’ is consistent with the regulatory structure that gave rise to the ‘usual and customary’ price.”). Safeway disputes the Relator's assertion that any authoritative guidance—in the form of appellate court cases or agency regulations—warned it away from its objectively reasonable interpretation of usual and customary.

The Relator further claims neither the Seventh Circuit in *Garbe* nor this Court in *SuperValu* originated the understanding of usual and customary price as the “cash price offered to the general public,” even though the Relator claims Safeway acts as if it was. In seeking partial summary judgment in *SuperValu*, the relators stated *Garbe* “was no

innovation.” See Case No. 11-3290, D/E 164, at 10. The Court’s Opinion granting the Relator’s motion quotes *Garbe* discussing regulations and cases interpreting usual and customary price. The Relator contends these authorities have indicated for decades that usual and customary price is the cash price offered to the general public. Safeway simply ignored the preexisting requirement that it not charge the Government any more than the cash price offered to the general public.

Safeway alleges the understanding of “cash price offered to the general public” begs the question of what, precisely, “cash price offered to the general public” is and must it include membership club prices or price matches? This Court in *Schutte* based its decision on *Garbe*, “apply[ing] the law that was so clearly established by the Seventh Circuit,” as the relators in *Schutte* alleged in their motion for partial summary judgment. *Schutte*, D/E 164, at 2; see also 2019 WL 3558483, at *6 (“*Garbe* makes clear that Medicare Part D and Medicaid are entitled to the benefit of the usual and customary price regularly offered by a pharmacy to its cash customers.”). By adding “whether the district court correctly identified the ‘usual and customary’ price” to the issues certified by the district court in *Garbe*, see *Garbe*, 824 F.3d at 637, the Seventh Circuit appeared to determine the issue was sufficiently debatable to be addressed.

This Court’s prior Opinion in *Schutte* on the relators’ motion for partial summary judgment under *Garbe* noted the Seventh Circuit had considered certain non-authoritative guidance documents bearing on the meaning of U&C and its application to the meaning of discount programs. See *Schutte*, 2019

WL 3558483, at *5-6.

Safeway alleges CMS's informal guidance documents also supported its interpretation. CMS in 2006 issued a non-binding Memorandum to Part D Sponsors addressing Walmart's \$4 generic program. Safeway claims that, consistent with its own understanding and practice, CMS explained that Walmart's low prices on specific generics were the U&C prices for those drugs. Safeway says that is why when it offered a \$4 Generics program of its own to all customers, it reported those prices as its U&C. The logical extension of this is that discount programs unlike Walmart's—that offered "special" prices unavailable to the usual customer and not adjudicated through the Plan's systems—did not affect U&C. Safeway asserts that although an informal guidance document like this would not have been sufficiently "authoritative" to warn Safeway away from its interpretation, the fact that it actually supported Safeway's view bolsters its entitlement to summary judgment. *See Safeco*, 551 U.S. at 70 & n.19.

The Relator claims that Safeway, like SuperValu before, ignores undeniably authoritative instructions from CMS that directly addressed Safeway's conduct and warned it away from the path it chose. The Seventh Circuit and this Court noted, "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,' even where the cash purchaser uses a discount card." *Garbe*, 824 F.3d at 644 (quoting CENTERS FOR MEDICARE & MEDICAID SERVS., *Chapter*

14—*Coordination of Benefits, in* MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL 19 n.1 (2006), <https://perma.cc/MW6A-H4P6>); *Schutte*, 2019 WL 3558483, at *6 (C.D. Ill. Aug. 15, 2019) (same).

The Relator claims Safeway simply chose not to follow the authoritative guidance that its discount programs were “considered the ‘usual and customary’ price rather than a ‘one-time “lower cash price.”” The court in *Garbe* stated, “The ‘usual and customary’ price requirement should not be frustrated by so flimsy a device as Kmart’s ‘discount programs.’” *Garbe*, 824 F.3d at 645.

However, the CMS Manual does not constitute “authoritative guidance” under *Safeco*, which provides that authoritative guidance documents must be “binding on” an agency. *Safeco*, 561 U.S. at 70 & n.19 (noting that guidance documents “not binding on” the agency are not sufficiently authoritative to warn defendants away). Courts have noted that documents such as the CMS Manual, which did not go through notice and comment, are not binding as a matter of law. *See e.g., Clarian Health West, LLC v. Hargan*, 878 F.3d 346, 356 (D.C. Cir. 2017) (“the [Medicare Claims Processing Manual] instructions bind neither CMS nor the Board in adjudications”); *see also Hoctor v. U.S. Dep’t. of Agric.*, (7th Cir. 1996) (agency rules “intended to bind” must go through notice and comment); *Baylor Cty. Hosp. Dist. v. Price*, 850 F.3d 257, 261-64 (5th Cir. 2017) (finding CMS State Operations Manual persuasive but not having the force of law). Because the CMS Manual is not binding, it does not constitute authoritative guidance.

The Relator claims that even if “reckless

disregard” is the only way to establish knowledge under the FCA, Safeway’s motion should still be rejected because its price-match and discount programs were not an “objectively reasonable” attempt to circumvent existing usual and customary price requirements, especially given the contrary CMS directives and based on Safeway’s actual knowledge it was doing something wrong.

However, the CMS “directives” are not really directives—they were guidance documents but not authoritative guidance. As the Court earlier noted, *Safeco*’s interpretation of “willfulness” encompasses both “knowing” and “reckless” violations of a statute. *See Safeco*, 551 U.S. at 57. Thus, *Safeco*’s holding applies to recklessness and higher levels of intent. Safeway did not violate the FCA by “act[ing] in reckless disregard of the truth or falsity of the information,” *see* 31 U.S.C. § 3729(b)(1)(A), unless there was authoritative guidance at the time that its interpretation of “usual and customary price” was incorrect.

Safeway could not recklessly or knowingly violate the law between 2006 and 2015 when the law relating to the impact of membership discount and price matching programs on usual and customary prices was not clear. Because there was no authoritative guidance warning Safeway away from its interpretation of the law before *Garbe*, the Court finds that Safeway’s position at that time was objectively reasonable. Accordingly, Safeway is entitled to summary judgment under *Safeco*.

IV. CONCLUSION

For the reasons stated herein, this Court finds persuasive the decisions of the Third, Eighth, Ninth

and D.C. Circuits, which held that *Safeco's* objective scienter standard applies to the FCA. Between 2006 and 2015, there was some authority in support of both parties on the issue of how membership discount and price matching programs affect usual and customary prices. The Seventh Circuit in *Garbe* added “the question whether the district court correctly identified the ‘usual and customary’ price” to the three issues certified by the district court. *Garbe*, 824 F.3d at 637. *Garbe* definitively answered the question as to the impact of discount and price matching programs on usual and customary price.

Before *Garbe*, however, there was not authoritative guidance that warned Safeway away from what was an objectively reasonable position. Although Safeway’s internal communications show it was concerned about whether membership discount/price matching programs resulted in those prices becoming the usual and customary price, there was no guidance from the courts of appeals or binding authority from the applicable agency. Accordingly, the Relator cannot meet *Safeco's* objective scienter standard and thus cannot establish the FCA’s “knowing” element as a matter of law. Safeway is entitled to summary judgment.

Ergo, the motion of Defendant Safeway, Inc. for summary judgment under the Supreme Court’s *Safeco* decision [d/e 176] is GRANTED.

The False Claims Act claims asserted in Count I are Dismissed with Prejudice.

Pursuant to 28 U.S.C. § 1367(c)(3), the Court declines to exercise supplemental

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jurisdiction over the remaining state law claims.

The state law claims are Dismissed without Prejudice.

The Clerk will terminate the Defendant's motion for case management procedures regarding related *Safeco* motions for summary judgment [d/e 180].

The Clerk will enter Judgment.

ENTER: June 12, 2020

FOR THE COURT:

/s/ Richard Mills

Richard Mills

United States District Judge

APPENDIX C
UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF ILLINOIS

United States of America, State of California, State of Colorado, State of Delaware, State of Hawaii, State of Illinois, State of Maryland, State of Montana, State of New Jersey, State of New Mexico, State of Nevada, State of Virginia, District of Columbia,

Plaintiffs,

and

Thomas Proctor,

Relator,

vs.

Safeway Inc.,

Defendant.

Case Number: 11-3406

JUDGMENT IN A CIVIL CASE

JURY VERDICT. This action came before the Court for a trial by jury. The issues have been tried and the jury has rendered its verdict.

DECISION BY THE COURT. This action came before the Court, and a decision has been rendered.

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IT IS ORDERED AND ADJUDGED that the Relator's and Plaintiffs' False Claims Act claims are DISMISSED and the Court relinquishes jurisdiction over the remaining state law claims pursuant to 28 U.S.C. Section 1367(c)(3).

Dated: June 15, 2020

s/Shig Yasunaga

Shig Yasunaga
Clerk U.S. District Court

APPENDIX D

31 U.S.C. § 3729 provides in relevant part:

§ 3729(a) Liability for certain acts.—

(1) In general.—Subject to paragraph (2), any person who—

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

(D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;

(E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit

money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-4101), plus 3 times the amount of damages which the Government sustains because of the act of that person.

* * *

(b) Definitions.—For purposes of this section—

(1) the terms “knowing” and “knowingly” —

(A) mean that a person, with respect to information—

(i) has actual knowledge of the information;

(ii) acts in deliberate ignorance of the truth or falsity of the information; or

(iii) acts in reckless disregard of the truth or falsity of the information; and

(B) require no proof of specific intent to defraud;