No. 20-3425

UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

UNITED STATES OF AMERICA, et al.,
ex rel. THOMAS PROCTOR,

Plaintiffs-Appellants

v.

SAFEWAY, INC.,

Defendant-Appellee

Appeal From The United States District Court
For the Central District of Illinois,
Case No. 3:11-CV-03406-RM-TSH
The Honorable Richard Mills

BRIEF AND REQUIRED SHORT APPENDIX OF PLAINTIFF-APPELLANT THOMAS PROCTOR

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CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Pursuant to Circuit Rule 26.1, Relator Thomas Proctor discloses as follows:

1. The full name of every party that the attorney represents in the case:

Thomas Proctor, Relator

2. The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

Dale J. Aschemann, John Timothy Keller (Aschemann Keller LLC); Paul B. Martins, Julie W. Popham, James A. Tate (Helmer, Martins, Rice & Popham Co., LPA); Jason M. Idell (Idell PLLC); Rand J. Riklin (Goode, Casseb, Jones, Riklin, Choate & Watson); Gary M. Grossenbacher; Glenn Grossenbacher (Law Office of Glenn Grossenbacher); C. Jarrett Anderson (Anderson LLC); and Gaylon Hayes (Hayes Legal Group, P.C.).

3. If the party or amicus is a corporation:

N/A

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page No.**

Cases Page No.

Cases **Page No.**

Statutes and Regulations **Page No.**

Statutes and Regulations **Page No.**

Legislative History **Page No.**

Other **Page No.**

JURISDICTIONAL STATEMENT

1. The district court had subject matter jurisdiction of this action under 28 U.S.C. §§ 1331 and 1345; 31 U.S.C. §§ 3730(b) and 3732(a); and supplemental jurisdiction over the state law claims under 28 U.S.C. § 1367(a) and 31 U.S.C. § 3732(b).

2. This Court has jurisdiction under 28 U.S.C. § 1291.

3. On June 15, 2020, the district court entered judgment for Safeway, dismissing Plaintiffs' and Relator's federal False Claims Act (FCA) claims and relinquishing jurisdiction over the remaining state law claims. Short Appendix (SA)-66.

4. Relator's Motion to Alter Judgment and for Leave to Supplement the Record was filed July 10, 2020 and was denied November 13, 2020. District Court Record (R)-204, R-211.

5. Relator's Notice of Appeal from the final judgment disposing of all parties' claims was filed December 11, 2020. R-212.

STATEMENT OF THE ISSUES

1. Did the district court err when it adopted Safeway's argument that "Before the Seventh Circuit's decision in *Garbe*, the law on usual and customary pricing was not clearly established," SA-31, 63-64, and based on this, applied the analysis of willful violations of ambiguous obligations set out in *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47 (2007)?

2. Did the district court err in its application of *Safeco* when it determined that: usual and customary (U&C) price was ambiguous; Safeway articulated an "objectively reasonable interpretation" that its free discount program cash prices offered to the general public were not its U&C price; and, Safeway was not "warned away" from this incorrect interpretation of U&C requirements because the warnings it received were not "binding," and therefore did not constitute authoritative guidance?

3. Did the district court err when it determined that the term "recklessly" as applied in *Safeco* supplanted the FCA's scienter standard and precluded analysis of evidence of subjective knowledge or subjective intent?

STATEMENT OF THE CASE

This is a False Claims Act (FCA) case brought by pharmacist-Relator Thomas Proctor alleging that Safeway submitted false claims when it failed to report its true "usual and customary" (U&C) cash prices to third party payers of pharmacy claims like Medicare Part D, Medicaid, TRICARE, and the Federal Employee Health Benefits Program (FEP) (collectively, Government Healthcare Programs or GHPs).[1] *See generally* R-50, First Amended Complaint. Instead of reporting its lower cash U&C prices to GHPs, Safeway adopted price matching and a free membership club to conceal its true cash prices. Safeway knowingly reported higher U&C prices and obtained higher reimbursements from third parties (that capped payment at the U&C price) while offering lower cash prices to customers so it could remain competitive with other pharmacies. Factual History, *infra*. This Court considered a similar scheme and confirmed such conduct violates the FCA. *U.S. ex rel. Garbe v. Kmart Corp.*, 824 F.3d 632 (7th Cir. 2016), *cert. denied*, 137 S. Ct. 627 (2017).

[1] In *Garbe*, this Court observed that "[u]nless state regulations provide otherwise, the 'usual and customary' price is defined as the 'cash price offered to the general public.'" *Garbe*, 824 F.3d at 643.

I. Factual History

A. Walmart's $4 Generics Program Generated Competition Over the Cash Price of Prescription Drugs

The Medicare Part D drug benefit program began on January 1, 2006. R-73, Safeway's Answer, ¶65.

Within months of the introduction of Part D, on September 21, 2006, Walmart, the country's largest retailer, introduced a $4 generic drug discount program. SA-7; *see also* R-195-6, Topf Depo. 28:21-29:25. Walmart reported these $4 generic sales as its U&C price to GHPs. *See*, *e.g.*, R-190-31, 4/9-10/2008 Email at SW-Proctor-TARN-00019085.1 (noting that Walmart's $4 price is extended to Medicaid); SA-8-9.

On the same day that Walmart introduced its program, Safeway Senior VP of Pharmacy Dave Fong forwarded a news article, *Wal-Mart to sell drugs for $4*, to Safeway CFO Robert Edwards, stating: "FYI-drug store sector stock prices are tanking. . . . this is not good for the business of Pharmacy[.]" R-190-23, at SW-Proctor-TARN-00074706.1; SA-7.

Four days later, on September 25, Safeway Executive Michael Topf (then-Senior Manager Financial Planning and Analysis) emailed

"Walmart data" to Senior VP of Pharmacy Fong and Group Director of Pharmacy Services Phil Cadero, stating: "Although we are still making money on the majority of these drugs at $4, we have such a high mark up presently, that the $4/script would force us to take a huge margin hit." R-190-24; SA-7-8. Mr. Topf estimated a loss of $8.7 million annually if Safeway adopted Walmart's program, and noted that this preliminary analysis of "cash" prescriptions "does not take into account any issues we may have with U&C." *Id.*; SA-8.

Other retail pharmacies like Target, Kroger, HEB, and Kmart responded with competing versions of Walmart's $4 discount generic drug program. R-190-26, 10-23-2006 Email; R-195-6 Topf Depo. 32:17-33:1; SA-8. Safeway monitored and evaluated the impact of its competitors' $4 discount programs, including the number of Safeway prescriptions that were being transferred to its competitors. R-190-26; SA-16. Safeway eventually settled on the Kmart approach of using price matching and a membership program to separate its discount cash prices from the U&C price it reported to third parties.

B. Safeway's Price Matching and Membership Discount Programs

Safeway implemented its discount programs at different times in different divisions. These are discussed below, and summarized in **Addendum A**, Safeway Programs by Division over Time. *See* 30(b) Appendix at 1.

1. Safeway's Price Matching

Safeway stipulated that from 2006 through July 15, 2015, its pharmacies price matched lower competitor prices for any customer who (according to Safeway) requested such a price match. R-195-4, Stipulations, ¶4(a). Price match transactions were cash sales where Safeway pharmacists manually overrode the original price and replaced it with a lower cash price. *Id.* at ¶¶4(a), 7; SA-30. Safeway ignored these lower cash matched prices in setting its U&C prices and instead reported "what third party plans pays us and then try to set the retail around the highest [Third Party] reimbursement rate." R-190-8, 2/14-16/2007 Email at SW-Proctor-261036. Safeway did this because over 90% of its pharmacy business was paid for by third party insurers. *Id.*; SA-12.

Between October 1, 2006 and July 31, 2015, Safeway routinely sold cash prescriptions at lower matched prices. *See* R-178-2, Dew Report at 7 & Table 5. During that time, Safeway overrode the higher U&C prices it reported to third party payers, including GHPs, in at least 5.6 million cash price match transactions. *Id.* at Table 5 (identifying 5,626,027 override sales as well as an additional 8,584,801 club sales during this time period, totaling 14,210,828 total discount cash sales). Safeway did not report these price match overrides as its U&C price to GHPs. R-195-4, ¶4(a).

Safeway authorized its pharmacists to override prices to avoid losing cash customers. R-190-8, 2/14-16/2007 Email at SW-PROCTOR-261036. In a February 14, 2007 email to a pharmacy manager, Julie Spier (Safeway's Division Manager/Director of Pharmacy Operations for Texas) explained: "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 . . . ." *Id.*; SA-12.

In January 2008, Safeway estimated that adopting a $4 price for the Walmart list of generic drugs nationwide would result in a $65 million

annual margin loss. R-195-6, Topf Depo. 63:16-64:11 & 66:22-67:20; R-190-29, 1/17-27/2008 Email.

On April 4, 2008, "very top level executives" including the CEO, CFO, and Vice Presidents met concerning Safeway's "Pharmacy Generic Pricing Strategy & Response to Kroger." R-195-7, Fong Depo. 150:5-151:22; R-195-30, 4/4/2008 Email with attachment; SA-13. At the time, Safeway's average charged price for the generic drugs sold by competitors like Walmart for $4 was $10.04, while Safeway's average cost for those same drugs was $0.90. R-190-30, at SW-PROCTOR-TARN-00028406.7. Safeway estimated an annual profit margin loss of $46,879,230 if it sold these generic drugs for $4 and reported $4 as its U&C price. *Id.* Safeway also estimated losing an additional $75 million in annual profits based on associated lost grocery sales by losing pharmacy customers to competitors' $4 programs. *Id.* at SW-PROCTOR-TARN-00028406.2; SA-13.

2. Safeway's $4 Generics Program

From March 2008 to July 2010, Safeway offered a $4 Generics Program in several of its divisions. R-195-4, ¶¶3(b), 4(b); **Addendum A**; SA-12-13.

Safeway's Generics Program consisted of a formulary (list) of generic drugs that Safeway sold at $4 for a 30-day supply, $8 for a 60-day supply, or $12 for a 90-day supply. R-195-4, ¶4(b); SA-13. The $4 Generics Program did not require membership enrollment. R-73, Safeway's Answer, ¶¶116, 121; R-195-4, ¶4(b). Divisions offering the $4 Generics Program properly reported these offered cash prices to GHPs as Safeway's U&C price. R-73, ¶¶116, 121; R-195-4, ¶4(b); SA-14-15. "The $4 pricing became the Safeway U&C for all program formulary drugs during that period." R-195-4, ¶4(b); SA-14-15. Executives characterized Safeway's $4 Generics Program as a "true" $4 Program. R-195-10, Scalzo Depo., 123:15-124:9; R-190-40, 4/28-30/2009 Email at SW-PROCTOR-TARN-00373213.1; SA-13-14.

3. Safeway's Membership Programs: Matching Competitor Generics Program / Loyalty Membership Program

Also starting in early 2008, Safeway introduced its Matching Competitor Generics Program (MCGP) club in certain divisions that were not participating in the $4 Generics Program. R-195-4, ¶¶3(b)-(c); **Addendum A**. The MCGP was a free pharmacy discount program that required customers to fill out an enrollment form (with basic demographic data that Safeway already had in its computer system)

and pay cash to obtain $4 generic and other discounted drugs. R-195-4 at ¶4(c); R-195-10, Scalzo Depo. 178:10-179:1. All customers, including GHP beneficiaries, were eligible to join the MCGP. *Id.* Unlike Safeway divisions offering the $4 Generics Program, the MCGP discounted prices for generic drugs were not reported to GHPs and other insurers. R-195-4, ¶4(c).

Safeway used the same "base" drug list for the MCGP that it used for the $4 Generics Program. *See* R-190-37, 3/31/2010 Email at SW-PROCTOR-143771-72; *see also* R-195-10, Scalzo Depo. 175:8-177:19. Safeway "processed" MCGP claims through its wholly-owned subsidiary, Avia Partners. R-195-4, ¶¶25(a), (d). Safeway set the pricing rules for its membership program. *Id.* ¶25(d). Avia did not pay any portion of membership drug purchases, did not transmit the sales information to any member's insurer or Pharmacy Benefit Manager (PBM), and did not conduct a Drug Utilization Review. *Id.*

Safeway also implemented an Auto-Refill program for Medicare Part D patients in November 2008 where the pharmacy would automatically refill prescriptions without the customer asking. R-190-19, Corporate

Pharmacy Alert re: Auto Refill Program Update; R-195-8, Jarvill Depo. 93:15-23.

In the Spring of 2009, Safeway discussed converting its "true" $4 Generics Program into a free membership program like the MCGP to keep its lower cash prices from third parties. R-190-38, at SW-Proctor-TARN-00000145.2; SA-21. On March 4, 2009, Safeway's then-Corporate Pharmacy Category Manager, Jose Alcaine, posed a "Hypothetical" to other Safeway executives: "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" and asked, "What is the potential savings if we make this a membership program? Thereby not affecting our insurance reimbursements." *Id.*

That same day Mr. Alcaine responded to his own email, calculating that the "Total cost [of the current program] =$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." *Id.*; SA-22.

On May 28, 2009, Safeway's then-Director of Finance for Pharmacy, Michael Topf, reported to Steve Scalzo (Division Manager/Director of Pharmacy Operations for Dominick's) that: "In Phoenix where they already have a successful $4 match program, at 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." R-190-32; SA-25. By keeping the prices and drugs the same but having cash customers join a free membership program, Mr. Topf "hope[d] we can minimize the lost customers [due to a transition from a $4 generic program to more of an 'opt-in' program] since anyone who wants the $4 generic price can still get it along (sic)." *Id.*

In June 2009, executives overseeing Safeway's Illinois (Dominick's) stores continued debating moving from a $4 discount program to a "$4 Membership" program. R-195-6, Topf Depo. 183:18-184:5; SA-25. Then-Vice President of Finance for the Dominick's Division, Brian Baer, said about the $4 membership program in a June 17, 2009 email:

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

R-190-33, at SW-Proctor-TARN-00091064.1; SA-25-26.

Mr. Topf responded stating:

> Off the record that is exactly the angle is 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)

R-190-33, at SW-Proctor-TARN-00091064.1; SA-26.

In July 2010, Safeway replaced the MCGP and $4 Generics programs (in all divisions other than NorCal) with the Loyalty Membership Program (LMP). R-195-4, ¶¶3(d), 4(b), 4(d); **Addendum A**; SA-26. The MCGP and the LMP programs offered identical features and benefits. R-195-4, *compare* ¶4(c) *with* ¶4(d); SA-26. The new LMP membership program also offered the same drugs at the same prices as the $4 Generics Program. R-195-10, Scalzo Depo. 176:1-25, 177:15-19. The discounts provided under the MCGP and its LMP successor were not reported to insurers, including GHPs. R-195-4, ¶¶4(a), (c)-(d); SA-26.

In a June 17, 2010 email, Safeway's Division Manager/Director of Pharmacy Operations for Texas, Julie Spier, wrote: "The main reason for going to a membership program is to protect our [U&C] price" in order to protect insurance reimbursement gains. R-190-10, at SW-Proctor-TARN-0095518.1; SA-26. Ms. Spier explained the reasoning for

Safeway's transition from the $4 Generics Program to a membership program that would become the LMP:

> 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 to 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.

R-190-11, 7/12/2010 Email at SW-PROCTOR-261108; SA-27. Ms. Spier later characterized this as "going from $4 generic to stealth Membership Program." R-190-1, 4/12/2011 Email at SW-PROCTOR-261114; SA-27.

C. Safeway Frequently Charged Lower Cash Prices Through Its Price Match and Discount Club Programs

Between October 1, 2006 and July 31, 2015, Safeway sold approximately 14.2 million prescriptions through price overrides or discount clubs at lower cash prices than the U&C prices it reported to third party payers like GHPs. *See* R-178-2 at 5, 7 & Table 5. From 2011 to 2015 Safeway's discount cash sales were a majority of *all* Safeway's

cash prescriptions, while Safeway reported the higher U&C prices it charged in the minority of its cash sales to insurers. *See id.* at 7, Table 5; R-195-4, ¶¶4(a), (c)-(d).

High volume maintenance drugs were sold most frequently at lower price match and club cash prices. Of the Top-20 drugs identified by the Relator based on overpayments, Safeway sold them at "discount" cash prices (instead of the reported U&C price) 65% of the time in 2009, 74% in 2010, 82% in 2011, 81% in 2012, 83% in 2013, 88% in 2014, and 75% in 2015. R-178-2 at 10, Table 8. (Between 2006 and 2008, the percentage of discount sales went from 9% to 49% of all cash sales. *Id.*)

Safeway also charged the most common discount prices far more often than the U&C prices it reported for frequently discounted drugs. For example, between 2008 and 2012, Safeway sold Lovastatin (NDC 001850074) at its $4 (30-day supply) discount cash price 84% of the time, but reported to GHPs that U&C cash price was between $27.14 and $65.99. *Id.* at 45, Table 21. Safeway sold 90-day supplies of Lovastatin for $10 cash 94% of the time, while telling third parties that its cash price was between $81.42 and $108.99. *Id.*

D. Safeway Knew that if It Lowered Its Cash Prices to Compete with Walmart, Third Party Payers Would Consider that Lower Price to be Safeway's U&C Price

While Safeway was charging lower cash prices through its discount programs but reporting higher cash prices for these same drugs as its U&C price, it received many official communications from the Centers for Medicare and Medicaid Services (CMS), PBMs, and state Medicaid programs reminding Safeway that it was obligated to report discounts to its cash price as its U&C price. (See 30(b) Appendix at 2, **Addendum B** for a complete list of communications referenced by the district court.)

On October 11, 2006, CMS issued its "Lower Cash Price Policy" Memorandum stating that CMS considered Walmart's offered $4 generic prices to be its U&C price: "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." R-195-21, at PROCTOR-00000001 n.1; SA-9.

On October 26, 2006, Chuck Posterick (Regional Pharmacy Manager) emailed Glen Davis (Safeway's Director of Pharmacy Operations) recapping their discussion regarding "Wal-Mart and Coupon Discussion Points." R-190-6; SA-8. Mr. Posterick confirmed that "The official

company policy is that we DO NOT match . . .” but acknowledged that if a regular customer asks for a price match, “the answer is YES . . . .” and that Safeway pharmacists should “Fill the Rx as cash - Do not bill to the third party.” *Id.* (emphasis in original). He further stated: “We cannot put any of this in writing to stores because our official policy is we do not match.” *Id.* Director of Pharmacy Operations Davis confirmed that this was Safeway’s approach. *Id.*

The next day, one of Safeway’s largest PBMs, Medco, sent Safeway a U&C pricing provision reminder that, “by contract,” a pharmacy’s U&C price is “the lowest net price a cash patient would have paid on the day that the prescription was dispensed inclusive of all applicable discounts. These discounts include . . . competitor’s matched price, or other discounts offered customers.” R-190-7; SA-10. Ash Yerasi (Safeway’s Director of Managed Care and Marketing) circulated Medco’s notice among Safeway pharmacy and financial executives, writing “I’m sure this has to do with the Wal-Mart initiatives. There ‘are’ ramifications to normal 3rd party business. [Medco’s] Language is pretty similar in all of our agreements.” *Id.*

The Medco notice was only the first of many notices Safeway received that affirmed its obligation to include discounts in U&C. The authority identified in **Addendum B** and throughout the district court's recitation of the facts (SA-9-12, 17-19, 27-29) is replete with guidance from CMS, PBMs, and Medicaid programs pointing out that U&C includes discounts.

On December 15, 2006, CMS incorporated its Lower Cash Price Policy into the CMS Medicare Prescription Drug Benefit Manual at Chapter 14, Section 50.4.2, at 19 n.1 (2006). R-190-34 (12/19/2006 Email attaching CMS's 12/15/2006 Medicare Prescription Drug Benefit Manual, Chapter 14); SA-9. Four days later Director of Managed Care and Marketing Yerasi circulated this CMS Manual to pharmacy staff stating: "Please keep abreast of those issues that impact your areas." R-190-34; SA-10.

A January 2, 2007, Coventry Health Care (a plan administered by PBM Caremark) notice addressing "Generic Drug Discount Programs and Usual & Customary Charges" explained that Safeway was required, by contract, to include "any applicable discounts" in U&C. R-190-28; SA-10-11.

Mr. Yerasi circulated that Coventry Notice to twelve colleagues in the Safeway pharmacy department, noting that it was:

> 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.

Id.

A February 1, 2007 Oregon Medicaid contract amendment likewise specified that Safeway's U&C must include discounts. R-190-16, Oregon Medicaid Contract Amendment at SW-PROCTOR-108654; SA-11. Caremark's February 13, 2007 provider manual similarly defined U&C as including discounts, and stated that all claims must be submitted to Caremark. R-190-36; SA-12.

Texas Medicaid's April 2008 "Rx Update" also required reporting discounted prices as the U&C price, whether in the form of a membership program or price matching. R-190-9, at SW-PROCTOR-261386; SA-17.

On April 7, 2008, a Safeway Pharmacy Manager sent an email to his Pharmacy Division Director, Joe Cooper, stating:

> 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.

R-190-18, 4/5-8/2008 Email at SW-PROCTOR-108469; SA-17. That same day Mr. Cooper forwarded the email to six Safeway executives including Chris Gong (Group Director Pharmacy Operations) asking "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.*

On April 10, 2008, Mr. Gong sent an email to his boss Dave Fong (Senior VP of Pharmacy) reporting that "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." R-190-31, at SW-Proctor-TARN-00019085.1; SA-17-18.

Mr. Gong's email further stated:

> If we advertise this 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.

Id.

On August 1, 2008, Mr. Fong received an email from the Food Marketing Institute (FMI), an industry group Safeway belonged to, concerning the requirements of the Lower Cash Price Policy in CMS's Medicare Prescription Drug Benefit Manual. FMI reminded its members that Chapter 14, Section 50.4.2 required pharmacies to report discount program prices as their U&C price:

> 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, step-therapy can be initiated, 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.

R-190-17, at SW-PROCTOR-005249; SA-18. FMI's directive to "Specifically pay attention to the foot note at the end" refers to the Lower Cash Price Policy footnote in the December 15, 2006 CMS Manual, R-190-34. *See* 190-17.

Senior VP of Pharmacy Fong forwarded FMI's email to subordinates, including Mary Ward (Director of Compliance), Mr. Davis (who was responsible for setting U&C), and Merle Jarvill (Director of Managed

Care and President of Safeway's wholly-owned subsidiary, Avia Partners) with an instruction stating, "[p]lease note and ensure we are in compliance. Thx[.]" R-190-17, 8/1/2008 Email; R-195-7, Fong Depo. 70:5-11; SA-18.

Pharmacy chief Mr. Fong testified that he assumed his subordinates "were doing the right thing" and that it would be a problem if they were not reporting price match discounts as the U&C price to third parties. R-195-7, Fong Depo. 71:7-72:9; 90:7-91:21. He did not recall attempting to confirm that price match discounts were being sent to third parties. *Id.* 90:18-23.

In September 2008 Colorado issued a Provider Bulletin on "Pharmacy Discount Programs" stating that discount program prices must be reported as U&C, and that "Pharmacies should not submit higher prices on Medicaid claims than prices offered to the general public." R-195-36, at 2; SA-18-19.

Likewise, a Walgreens December 1, 2008 Health Initiative PBM Manual defined U&C as including all applicable discounts. R-190-2, at SW-PROCTOR-TARN-00563447.22; SA-19. Caremark's July 12, 2011 FEP Network Update defined U&C similarly. R-190-12; SA-27-28.

On July 15, 2011, Director of Managed Care and Avia President Jarvill forwarded the Caremark FEP notice to Jewel Hunt (Group Vice President, Pharmacy Health and Wellness), Alan Pope (Safeway internal legal counsel), and Brian Pavur (Group Director of Pharmacy Operations) stating:

> Please see the announcement from Caremark. FEP is requiring that we provide our best price to them. This would be 10% of[f] brands, 20% off generics, and the $4.00 program in Dominick's, Eastern, and Texas.
>
> I do not see a way around it. Alan,, what are your thoughts?

R-190-20; SA-28.

Notwithstanding these notices and directives, Safeway continued reporting higher cash U&C prices that did not disclose the lower cash discount prices it charged customers through price matching and its free membership clubs. R-195-4, ¶¶4(a), (c)-(d); SA-26.

E. Procedural History

Relator's *qui tam* FCA complaint was filed under seal on November 7, 2011 on behalf of the United States, the District of Columbia, and the States of California, Colorado, Delaware, Hawaii, Illinois, Montana, Nevada, New Jersey, New Mexico, and Virginia. R-1. The government

declined to intervene on August 24, 2015, allowing Relator to proceed on its behalf pursuant to 31 U.S.C. § 3730(b)(4)(B) and (e)(3). R-23.

Colorado and Maryland declined to intervene and were dismissed in accord with the provisions of their respective State False Claims Acts. R-71, Order on Motion to Dismiss at 7-8.

On December 1, 2016, the district court denied Safeway's motion to dismiss, finding in relevant part:

> Because of Safeway's actions, virtually all drugs sold by Safeway were offered at everyday deep discounted prices nationwide and across all of Safeway's brands.

R-71, at 18-19.

> Government health program reimbursement rules and regulations prohibit pharmacy providers from being reimbursed at amounts greater than what they otherwise charge members of the general public and government health program prescription drug reimbursement rules require that discounts offered to the general public at the point of sale must also be provided to government health program beneficiaries.

Id. at 19.

> Safeway characterized its discount drug programs as point of sale discounts, not insurance.

Id. at 22.

> Safeway's internal communications show that its directors understood the alleged scheme as a means to manipulate the usual and customary price and charge government health

> programs more than the general public, in violation of the FCA.

Id. at 40.

After discovery concluded, Safeway repeatedly sought and obtained extensions of the dispositive motion deadline asserting that judicial efficiency would be served by delaying summary judgment briefing until the district court ruled on pending dispositive motions in an earlier-developed case involving similar legal issues before the same court, *U.S. ex rel. Schutte v. SuperValu, Inc.*, No. 11-3290 (C.D. Ill.). *See*, R-204, Rule 59(e) Motion to Alter Judgment and for Leave to Supplement the Record at 7-8.

On November 22, 2019, Safeway filed its *Safeco* summary judgment motion while contemporaneously seeking to delay the filing of all other dispositive motions. R-180, Motion for Case Management Procedures Regarding Related *Safeco* Motions for Summary Judgment. Four days later, the court extended the dispositive motion deadline to January 15, 2020. Nov. 26, 2019 Text Order. In a series of subsequent Text Orders issued at the request of the parties, the district court extended the dispositive motion deadline—eventually settling on July 1, 2020. 1/10/2020 Text Order; 3/5/2020 Text Order; 4/24/2020 Text Order.

On June 12, 2020, the district court granted Safeway's *Safeco* motion for summary judgment and made the following findings:

> • Because reckless disregard is "the most capacious" of the three FCA scienter standards, "it follows that if a relator is unable to prove recklessness, he also would not be able to establish actual knowledge or deliberate ignorance." SA-34 (quoting *United States v. King-Vassel*, 728 F.3d 707, 712 (7th Cir. 2013)).
>
> • PBM and Medicaid program notices referencing contractual and regulatory U&C reporting requirements "are not authoritative guidance or are not inconsistent with Safeway's interpretation of U&C price." *Id.* at 40.
>
> • The Supreme Court's statement that "[n]othing in *Safeco* suggests that we should look to facts that the defendant neither knew nor had reason to know at the time he acted" is "limited to" patent cases. *Id.* at 44, 46-47 (quoting *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1933 (2016)).
>
> • The CMS Manual does not constitute "authoritative guidance" under *Safeco* because it did not go through notice and comment and, consequently, is not "binding" as a matter of law. "CMS 'directives' are not really directives — they were guidance documents but not authoritative guidance." *Id.* at 62-63.
>
> • "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 the time was objectively reasonable." *Id.* at 63-64.

Judgment was entered in Safeway's favor on June 15, 2020. SA-66.

Pursuant to Civil Rule 59(e), Relator moved the district court to reconsider its decision and also requested leave to supplement the

record with a summary of the applicable PBM contract terms defining U&C price. R-204. Relator had not provided this information earlier due to the bifurcated dispositive motion procedure adopted by the court. R-204, at 6-8; *see also* R-206-1, Summary Chart of PBM Contract Terms, Exhibit A at 1-5. On November 13, 2020, the district court denied Relator's Civil Rule 59(e) Motion and denied Relator leave to supplement the record with additional PBM contract terms. R-211.

Relator timely filed this appeal on December 11, 2020.

SUMMARY OF THE ARGUMENT

The district court's summary judgment order should be reversed for three independent reasons.

First, the court erred in determining that *U.S. ex rel. Garbe v. Kmart Corp.*, 824 F.3d 632 (7th Cir. 2016), redefined "usual and customary" price. Argument I, *infra*. *Garbe* did not redefine U&C price, it merely stated what the rule always was and applied a common-sense analysis to Kmart's "flimsy" attempt to circumvent that rule. Here, Safeway made a similar attempt that was even flimsier than Kmart's. Accordingly, the court should have never embarked on its *Safeco* analysis.

Second, the court erred in its application of *Safeco*. Argument II, *infra*. U&C price, as applied to Safeway's conduct, is unambiguous; the *post hoc* re-interpretation of U&C offered by Safeway's counsel is objectively unreasonable; and, authoritative guidance warned Safeway away from this interpretation many times. *Safeco* requires satisfaction of all these elements. Safeway fails each one.

Finally, the court erred in determining the "reckless disregard" scienter standard supplanted the defined term "knowing" in the FCA.

Argument III, *infra*. "Actual knowledge" and "deliberate ignorance" are not statutory surplusage. The court was wrong to treat them as such, and to disregard all evidence of Safeway's subjective knowledge and subjective intent.

For each of these reasons, this Court should reverse the district court's summary judgment order and remand the cause for trial.

STANDARD OF REVIEW

Review of a district court's interpretation of statutes and regulations is *de novo*. *Storie v. Randy's Auto Sales, LLC*, 589 F.3d 873, 876 (7th Cir. 2009) (citation omitted); *U.S. v. Wisconsin Power & Light Co.*, 38 F.3d 329, 332 (7th Cir. 1994). A district court's decision to grant summary judgment is also reviewed *de novo*. *Id.*

ARGUMENT

I. The District Court's Summary Judgment Decision Is Based upon a Misinterpretation of *U.S. ex rel. Garbe v. Kmart*

The district court's summary judgment order begins from a fundamentally flawed premise, adopting Safeway's argument that "the law on usual and customary pricing was not clearly established" before this Court's decision in *Garbe*, 824 F.3d 632. SA-31, 63-64. This

misreads *Garbe*, and that misreading—which was the predicate for the court's *Safeco* analysis—is fatal to the district court's decision.

A. The Meaning of "Usual and Customary" Price Was Not Disputed in *Garbe*

"Usual and customary" price was well-established long before *Garbe*, where its definition was never at issue. This Court observed without citation that: "Unless state regulations provide otherwise, the 'usual and customary' price is defined as the 'cash price offered to the general public.'" *Garbe*, 824 F.3d at 643. Regulations discussed by the Court refer to "'usual and customary charges to the general public.'" *Id.* at 644 (citation omitted).[2] Kmart also acknowledged that "usual and customary price . . . is understood in the industry to be the pharmacy's 'cash price to the general public.'" *See* Brief of Appellant Kmart Corporation at 9, *Garbe*, 824 F.3d 632 (7th Cir. 2016) (No. 15-1502), ECF No. 14 (Kmart Brief).

[2] The National Council for Prescription Drug Programs (NCPDP) has also long noted that "usual and customary charge . . . represents the value that a pharmacist is willing to accept as their total reimbursement for dispensing the product/service to a cash-paying customer . . . ." R-190-39, at SW-PROCTOR-TARN-00056968.2; R-195-11, Harris Depo. 186:15-189:25 (discussing same); SA-30; *see also* R-195-18, Excerpt of NCPDP Data Dictionary at 71 (Sept. 1999).

Safeway's witnesses offered the same established definition of U&C price: "The U&C price is generally understood to be the cash price charged to the general public," R-176-4, at 15 (Safeway Expert Jacobs Report); U&C "would be that the patient is paying cash for it, and that there is no third party," R-176-2, Spier Depo. 110:5-110:15; U&C is "a cash price offered to a customer." R-176-3, Topf Depo. 26:7-12.

Garbe did not change the longstanding, well-understood definition of U&C price. Though this Court added the question "whether the district court correctly identified the 'usual and customary' price," *Garbe*, 824 F.3d at 637, this does not mean there was a "substantial ground for difference of opinion" about what "usual and customary" price meant. The parties in *Garbe* agreed on its definition and did not seek review of the U&C price question. *See* Kmart Brief at 4, n.1. Rather, the Seventh Circuit simply exercised its discretion to identify a relevant question because "an appeal under § 1292(b) brings up the whole certified order, . . . rather than just the legal issue that led to certification." *United Airlines, Inc. v. Mesa Airlines, Inc.*, 219 F.3d 605, 609 (7th Cir. 2000) (citation omitted). The district court erred when it decided that this meant "usual and customary" price was unclear before *Garbe*, and

therefore Safeway could not have submitted its false claims "knowingly" before that case was decided.

The real issue in *Garbe* was not the undisputed definition of U&C price (cash price to the general public); it was "(4) whether Kmart's 'discount' prices were offered to the 'general public.'" *Garbe*, 824 F.3d at 635. To answer this question, the Court relied on dictionary definitions of "'general public'": *e.g.*, "'ordinary people in society, rather than people who are considered to be important or who belong to a particular group.'" *Garbe*, 824 F.3d at 643 (citation omitted). There was not a "substantial ground for difference of opinion" about what "usual and customary" price meant. *See* 28 U.S.C. § 1292(b).

B. *Garbe* Rejected Kmart's "Flimsy" Attempt to Separate Participants in Its Discount Programs from the "General Public"

The dispositive question in *Garbe* was whether Kmart made its discount cash prices available to "ordinary people in society." *Garbe*, 824 F.3d at 643.[3] Kmart argued that customers who opted-in to its club

[3] As Kmart put it: "The question before the Court is whether the enrollment requirements of Kmart's discount programs [paying a fee

and paid a membership fee were part of a "particular group" segregated from the "general public." *Id.* at 643. This Court disagreed, finding that because there was no "meaningful selectivity for the people who joined Kmart's programs," they could not be "distinguished in any way from the 'general public.'" *Id.* The evidence showed that "the barriers to joining the Kmart 'programs' were almost nonexistent, to the extent they were enforced at all." *Id.*

This was a straightforward application of the plain meaning of "general public" to the facts. This Court then confirmed that "[o]ur reading of 'general public' is consistent with the regulatory structure that gave rise to the 'usual and customary' price term," by surveying regulations, laws, and cases going back decades. *Id.* at 644.

Ultimately, this Court rejected Kmart's attempt to "artificially divid[e] its customer base," finding:

> The "usual and customary" price requirement should not be frustrated by so flimsy a device as Kmart's "discount programs." Because Kmart offered the terms of its "discount programs" to the general public and made them the lowest prices for which its drugs were widely and consistently

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and filling out a form] remove members of those programs from the 'general public' as that phrase is used in contracts and regulations that govern usual and customary price for pharmacy services." Kmart Brief at 40.

> available, the Kmart "discount" prices at issue represented the "usual and customary" charges for the drugs.

Garbe, 824 F.3d at 645.

Pharmacies like Safeway have always been required to identify the cash prices they offer or charge to "ordinary people" as their "usual and customary" price. *Garbe* simply rejected Kmart's "flimsy"—and therefore unreasonable—attempt to frustrate the clear purpose of the U&C price requirement, capping reimbursement at the cash price available to the general public. *See id.* at 644-45.

C. Safeway's Attempt to Separate Its Cash Discount Programs from the "General Public" Was even Flimsier than Kmart's

In *Garbe*, Kmart routinely used price matching and clubs to hide its actual cash prices from third parties. *See Garbe*, 824 F.3d at 636. Kmart experimented with different discount programs, beginning with the "Kmart Maintenance Program" (KMP) offering 90-day prescriptions at discount prices. *Id.* at 635. Kmart later renamed the KMP the "Retail Maintenance Program" (RMP) "[i]n order to put it at as 'long a[s] possible arms length from [Kmart's] U&C pricing,'" and in 2008 "expanded RMP to include additional drugs and expanded its discount programs to many 30- and 60-day prescriptions." *Id.* at 636. Kmart used a third-party processor, Agelity, to administer the RMP in an effort "[t]o

strengthen Kmart's 'firewall' between RMP and its 'usual and customary' prices," but Kmart still dictated "the RMP formulary, the prices for those drugs, and which customers were eligible for those prices." *Id.*

"Kmart's programs typically offered its 'discounts' in return for nothing more than assent, demographic data the pharmacy already needed to fill a prescription, and a nominal fee. . . . The program's most robust version allowed customers to obtain its 'benefits' immediately for ten dollars." *Id.* at 643.

Safeway followed a nearly identical path to Kmart in *Garbe*, but its "firewall" was less robust.

Like Kmart, Safeway started out routinely matching competitor prices, and all customers were eligible for matched prices as long as they paid cash. R-195-4, ¶4(a). From March 2008 to July 2010, Safeway experimented with other methods for discounting its cash price. In some divisions, Safeway ran a $4 Generics Program and reported its lower cash prices as its U&C price. R-195-4, ¶¶3(b), 4(b). In other divisions, Safeway introduced a club-based Matching Competitor Generics Program (MCGP) and did not report its lower cash prices as its U&C

price. R-195-4, ¶¶3(c), 4(c). Safeway used the same "base" drug formulary list for both programs. *See* R-190-37, at SW-PROCTOR-143771-72; R-195-10, Scalzo Dep. 175:8-177:19. Safeway offered the MCGP to all customers and, unlike Kmart, did not charge a membership fee. R-195-4, ¶4(c). To participate in the free MCGP club, Safeway customers only had to fill out an enrollment form seeking "basic demographic information" that was generally already in Safeway's computer system. R-195-4, ¶4(c); R-195-10, Scalzo Depo. 178:10-179:1.

In order to conceal its actual cash prices from third party payers, Safeway transmitted club transactions to Avia Partners, its wholly-owned subsidiary. R-195-4, ¶¶25(a), (d). Safeway created the formulary, prices, and program terms and dictated them to Avia. R-195-4, ¶25(d). Avia simply returned Safeway's cash price as the amount the patient owed. R-195-10, Scalzo Depo. 160:20-161:23. The only reason for Avia's participation in this process was to disguise Safeway's discount program cash transactions as third party transactions.

In July 2010, Safeway discontinued its $4 Generics Program and the MCGP, and switched its cash discounts to a renamed prescription club,

the Loyalty Membership Program (LMP). R-195-4, ¶¶ 3(c), 4(b); **Addendum A**. The LMP was identical to the MCGP except it had a broader geographic scope. R-195-4, ¶¶4(c), (d). With the introduction of the LMP, Safeway separated all the low cash prices it offered to the general public from the inflated U&C price it reported for reimbursement purposes, hiding its true cash prices from GHPs and other third parties. *See id.*

Safeway sold approximately 14.2 million prescriptions at lower cash prices through undisclosed price matches or discount clubs between October 1, 2006 and July 31, 2015, while reporting higher U&C prices for the same dosages of the same drugs to insurers, including GHPs. *See* R-178-2, at 7 & Table 5 (identifying 5,626,027 override sales and 8,584,801 discount club sales during this time period, totaling 14,210,828 discount sales). Even considering *all* of Safeway's cash transactions—including drugs that were never part of Safeway's discount programs—from 2011 to 2015 Safeway sold prescriptions at these unreported "discount" cash prices more often than it sold them at its reported U&C price. *Id.* at 7, Table 5.

Cash sales for drugs that were part of Safeway's price matching and club programs were dominated by these unreported lower cash prices. Safeway sold the 20 drugs that resulted in the highest overpayments from its false U&C reports at "discount" cash prices between 65% and 88% of the time between 2009 and 2015. *See* Factual History, Part I.C, *supra*. Safeway also charged the most common $4 (30 day) or $10 (90 day) discount cash price much more often than its reported U&C cash price. *See id.*

The parallels between Safeway's conduct here and Kmart's conduct in *Garbe* are undeniable. Safeway offered its discounts to everyone for free (Kmart charged a membership fee), and the "PBM" Safeway used to launder club transactions was its own captive subsidiary (Kmart used an outside PBM). Safeway's knowing and deliberate attempts to evade its obligation to report its true U&C price and deny GHPs the benefit of its true cash prices were even more unreasonable than Kmart's.

This Court's straightforward, common-sense application of the undisputed definition of U&C price to Kmart's discount programs did not create new obligations or write new laws governing U&C price. U&C price had a settled meaning long before *Garbe*, which simply

confirmed—rather than revealed—the obvious application of U&C price to conduct almost identical to Safeway's. Accordingly, the district court erred in embarking on its *Safeco* analysis.

II. Misapplication of the *Safeco* Standard: The District Court Erred in Concluding that U&C Price Was Ambiguous, that Safeway Held an Objectively Reasonable Interpretation, and that there Was No Contrary Authoritative Guidance

In *Safeco*, the Supreme Court outlined a standard for (statutorily undefined) "willful" violations of the Fair Credit Reporting Act that the D.C. Circuit applied to FCA "reckless disregard" through a three-step analysis in *Purcell*. *Safeco*, 551 U.S. at 68-70; *U.S. ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 287-88 (D.C. Cir. 2015).

The district court misapplied *Safeco*'s three-pronged "reckless disregard" analysis in three ways. First, U&C price unambiguously applies to the routine price matching and free cash discount programs that Safeway offered to the general public over multiple benefit years. *See* Argument II.A, *infra*. Second, the district court erred in treating *Safeco*'s discussion of objective reasonableness as an abstraction, divorced from the facts and indifferent to whether Safeway's conduct was reasonable at the time rather than based on *post hoc* rationalizations. *See* Argument II.B, *infra*. Finally, the district court

improperly limited its analysis to "binding" guidance that might have warned Safeway away from submitting false claims, while also ignoring guidance that was authoritative *and* binding. Argument II.C, *infra*.

A. There is No Ambiguity Concerning What U&C Price Means

The district court never identified what aspect of the "cash price offered to the general public" was ambiguous. The court simply declared that before *Garbe* "the law relating to the impact of membership discount and price matching programs on usual and customary prices was not clear," and therefore "Safeway could not recklessly or knowingly violate the law between 2006 and 2015." SA-63. This conclusion is difficult to reconcile with an earlier finding in the district court's December 1, 2016 order denying Safeway's Motion to Dismiss:

> Safeway's internal communications show that its directors understood the alleged scheme as a means to manipulate the usual and customary price and charge government health programs more than the general public, in violation of the FCA.

R-71 at 40.

Ambiguity is a context-specific issue that can only be addressed when the rule in question is applied to the facts in this case. As the district court and Safeway's directors acknowledged, it was always clear that Safeway's schemes were designed to charge GHPs more than

Safeway's cash price to the "general public." U&C price has always been defined and understood as the "cash price to the general public," including by Safeway. *See* discussion *supra,* Argument I.A. Medicaid regulations in effect throughout the relevant time share this common definition, capping Medicaid reimbursement for prescription drugs at the lower of acquisition cost plus a dispensing fee, or the providers' "usual and customary charges to the general public." 42 C.F.R. § 447.331(b) (2006) (re-codified at 42 C.F.R. § 447.512(b) (from 2007 to the present)).

The established understanding of U&C price is reinforced by its "clear" purpose, articulated by this Court after conducting a comprehensive survey of the applicable contracts, regulations, case law, and industry understanding of U&C price from the 1980s to 2016:

> "[t]he purpose of these regulations is clear: state agencies are not to pay more for prescribed drugs than the prevailing retail market price." *United States v. Bruno's, Inc.,* 54 F. Supp. 2d 1252, 1257 (M.D. Ala. 1999) (interpreting 42 C.F.R. § 447.512(b), then numbered 42 C.F.R. § 447.331(b)). Regulations 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. See generally *Arkansas Pharmacists Ass'n v. Harris*, 627 F.2d 867, 869 n.4 (8th Cir. 1980) . . . .

Garbe, 824 F.3d at 644. The CMS Manual too 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.

Id. (quoting CMS Manual, at 19 n.1 (2006)).

U&C price has had an unambiguous, well-understood meaning and purpose in the context of prescription drug reimbursement for decades. This Court did not rewrite the rules in *Garbe*. But as *Garbe* plainly demonstrated, there is no reasonable dispute that participants in free discount programs open to everyone are members of the "general public." Without ambiguity, this Court need go no further in its *Safeco* analysis. *See Purcell*, 807 F.3d at 288.

B. Safeway's Disregard of Approximately 14.2 Million Cash Price Match and Club Discounts in Setting Its U&C Price Was Not Objectively Reasonable

The second *Safeco* question is whether Safeway's failure to report its true cash prices as its U&C price was "objectively unreasonable," and therefore reckless. This analysis looks to what a reasonable person in Safeway's position would have done, given the same circumstances that Safeway was in. *See U.S. v. King-Vassel*, 728 F.3d 707, 713 (7th Cir. 2013) ("a person acts with reckless disregard 'when the actor knows or

has reason to know of facts that would lead a reasonable person to realize' that harm is the likely result of the relevant act.") (quoting Black's Law Dictionary 540-41 (9th ed. 2009)); *cf. Dunn v. Menard, Inc.*, 880 F.3d 899, 908 (7th Cir. 2018) ("[T]he operative focus is not on *plaintiff* himself, but on a *reasonable person* with plaintiff's knowledge of the situation . . . .") (emphasis in original).

This "objective reasonableness" inquiry is not an abstraction, divorced from the facts in this case. Rather, it requires an evaluation of what Safeway actually did, knowing what Safeway actually knew or should have known at the time. A reasonable pharmacy in Safeway's position would have reported the ubiquitous, freely-available discount prices that dominated cash sales of discounted drugs (and in many years were the majority of *all* cash sales) as its U&C price. Instead, Safeway knowingly implemented stealthy programs to segregate and hide its 14.2 million cash price match and club discounts from GHPs and deny them the lower cash prices it charged to the general public.

1. Whether Safeway Acted Reasonably Depends on what Safeway Knew and Did at the Time It Acted, not Its *Post Hoc* Rationalizations

Safeway acted unreasonably, and recklessly, if it knew or should have known facts that would have led a reasonable pharmacy to realize that it was submitting false claims. *See King-Vassel*, 728 F.3d at 713. *Safeco* does not change this focus on whether it was reasonable for Safeway to submit false claims when it submitted them. "[C]ulpability is generally measured against the knowledge of the actor at the time of the challenged conduct." *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1933 (2016).

The Supreme Court's rejection of *post hoc* rationalizations is apparent in *Safeco* and reinforced by *Halo*. In *Safeco*, the Court observed that a defendant who "followed" a reasonable interpretation (rather than one manufactured *post hoc*) could not simultaneously "knowingly or recklessly" violate that law. *See Safeco*, 551 U.S. at 70 n.20. As the *Halo* Court further explained: "in *Safeco* . . . we stated 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." 136 S. Ct. at 1933 (quoting *Safeco*, 551 U.S. at 69)

(emphasis added in *Halo*). "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.*

Consistent with *Halo*, other courts have held that a defendant's contemporaneous understanding is what matters in establishing FCA scienter:

> under the district court's legal interpretation, a defendant could avoid liability by relying on a "reasonable" interpretation of an ambiguous regulation manufactured *post hoc*, despite having actual knowledge of a different authoritative interpretation. However, scienter is not determined by the ambiguity of a regulation, and can exist even if a defendant's interpretation is reasonable.

U.S. ex rel. Phalp v. Lincare Holdings Inc., 857 F.3d 1148, 1155 (11th Cir. 2017); *see Minn. Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1053 (8th Cir. 2002) ("If the Association shows the defendants certified compliance with the regulation knowing that the [government] interpreted the regulations in a certain way and that their actions did not satisfy the requirements of the regulation as the [government] interpreted it, any possible ambiguity of the regulations is water under the bridge"); *U.S. ex rel. Bahnsen v. Bos. Sci. Neuromodulation Corp.*, No. 11-1210, 2017 U.S. Dist. LEXIS 206512,

*22 (D.N.J. Dec. 15, 2017) (citation omitted) ("the timing of a defendant's reasonable interpretation is critical . . . a claimant cannot avoid liability by manufacturing an after-the-fact reasonable interpretation of an ambiguous provision.").

Courts are understandably "uncomfortable with the notion that an FCA defendant can escape liability by identifying any reasonable interpretation of the statute at issue, regardless of whether the defendant followed that interpretation or believed it to be correct." *U.S. ex rel. Suarez v. AbbVie, Inc.,* No. 15 C 8928, 2020 U.S. Dist. LEXIS 222468, at *51-52 (N.D. Ill. Nov. 30, 2020). This is why courts look to whether "'the actor knows or has reason to know of facts that would lead a reasonable person to realize' that harm is the likely result of the relevant act," (*King-Vassel*, 728 F.3d at 713), not to justifications constructed by counsel after the fact.

2. A Reasonable Pharmacy, Knowing what Safeway Knew at the Time, Would have Realized that It Was Submitting False Claims

The record is clear that when Safeway submitted claims for payment falsely reporting inflated U&C cash prices, it knew that GHPs considered discount program cash prices like Safeway's to be a

pharmacy's U&C price. A reasonable pharmacy with this knowledge would have reported its lower cash prices to GHPs, or at the very least would have inquired into its obligation to do so.

Beginning in October 2006, Safeway started receiving notices reminding it that, for example: a pharmacy's U&C price is "'the lowest net price a cash patient would have paid on the day that the prescription was dispensed inclusive of all applicable discounts.' These discounts include . . . competitor's matched price, or other discounts offered customers." R-190-7; SA-10. A Safeway Director shared this with other executives and noted that "[Medco's] Language is pretty similar in all of our agreements. . . ." *Id.*

In December 2006 Safeway knew CMS's Medicare Manual stated that "where a pharmacy offers a lower price to its customers throughout a benefit year" it was the pharmacy's U&C price, not a "one-time special price." R-190-34, at SW-PROCTOR-006697; SA-9.

In January 2007, Coventry Health Care reminded Safeway that "'Usual and Customary Charge' . . . must include any applicable discounts offered to attract customers." R-190-28; SA-10-11. A Safeway executive told his colleagues that this was "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." *Id.*

Over the next two years Safeway received similar notices from Nebraska Medicaid, Oregon Medicaid, Caremark, Texas Medicaid, the Food Marketing Institute, Colorado Medicaid, and Walgreens Health Initiative. *See* Factual History, Part I.D, *supra*. These notices reminded Safeway that U&C price included price matching, applicable discounts, membership clubs, discount programs, and sale prices. *See* R-190-15 (Nebraska); R-190-16 (Oregon); R-190-36 (Caremark); R-190-9 (Texas); R-190-17 (FMI); R-195-36 (Colorado); R-190-2 (WHI); SA-11-12, 17-19.

The Court is not blinded to these facts when determining whether a reasonable person would have interpreted U&C price as encompassing Safeway's ubiquitous cash discount programs. To the contrary, whether the interpretation Safeway now advances in litigation is reasonable must be considered in light of those facts—would a reasonable pharmacy, having received these same notices and knowing what Safeway knew, realize that it was likely submitting false claims by omitting the most commonly charged cash discount prices that it made

available to all of its customers? Plainly a reasonable pharmacy would have, and Safeway's failure to do so was reckless.

Safeco and its progeny do not permit Safeway to ignore the facts and manufacture a *post hoc* reinterpretation of its clear obligation to report cash discount prices charged in millions of transactions as its U&C price—regardless of whether that *post hoc* incorrect interpretation is "objectively reasonable." (Though here, Safeway's *post hoc* rationalization is unreasonable too.) By accepting Safeway's *post hoc* justifications, the district court gave undue credit to Safeway's misguided argument, and misapplied *Safeco*.

3. Safeway Failed to Advance any Objectively Reasonable Interpretation, *Post Hoc* or Otherwise, that Justified Its Failure to Report Price Match and Club Discount Cash Prices as Its U&C Price

The district court accepted, without analysis, that "guidance" proffered by Safeway in litigation supported Safeway's position. SA-58. But Safeway never offered an "objectively reasonable" interpretation of U&C price that fit its conduct in this case.

First, the case law recited by the district court, SA-51-53, does not support Safeway's conduct. The court relied on *Madison v. Mississippi Medicaid Comm'n*, 86 F.R.D. 178 (N.D. Miss. 1980) for the proposition

that for Mississippi Medicaid in 1980 "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.'" SA-51 (citation omitted). Of course, Safeway's discounts were offered to all customers and were *actually charged* more than half the time for years. *See* Factual History, Part I.C at 14-15, *supra*. Moreover, 40-year-old Mississippi Medicaid regulations are not at issue in this case and, even accepting Safeway's interpretation, this case simply reinforces *Garbe*'s recognition that U&C price is the "'cash price offered to the general public" "[u]nless state regulations provide otherwise." *Garbe*, 824 F.3d at 643.

The district court's reliance on *U.S. ex rel. Garbe v. Kmart Corp.*, 73 F. Supp. 3d 1002 (S.D. Ill. 2014) and the overruled case *Corcoran v. CVS Health*, No. 15-cv-03504-YGR, 2017 U.S. Dist. LEXIS 143327 (N.D. Ca. Sept. 5, 2017), *rev'd* 779 F. App'x 431 (9th Cir. 2019), simply reinforces that PBMs and state Medicaid programs define U&C price—they do not say U&C price is something other than the cash price to the general public. *See* SA-51. Additionally, *Corcoran* was a private class

action dealing with a fee-based club, not fraud against GHPs involving free discounts offered to everyone. *See Corcoran*, 2017 LEXIS 143327 at *8 & n.2. Likewise, the district court mistakenly relied on *Klaczak v. Consol. Med. Transp.*, 458 F. Supp. 2d 622 (N.D. Ill. 2006). *See* SA-51-52. *Klaczak* is irrelevant as it addresses allowable rates for ambulance transports under Medicare Parts A and B which have nothing to do with determining the U&C price of prescription drugs under Medicare Part D. *Klaczak*, 458 F. Supp. 2d at 679-80.

The district court also recited and appears to have credited several statements that Safeway picked from inapposite or inaccurately-presented sources that it identified in a *post hoc* attempt to justify its past conduct:

- **Academy of Managed Care Pharmacy:** Safeway excerpts a quote related to contractual discounts and U&C as the "undiscounted price" out of context, SA-52-53, and ignores the Glossary definition of U&C in the same AMCP document, which defines U&C price as the "price" that "a pharmacy would charge a cash-paying customer" without reference to undiscounted prices. AMCP Guide at 57 (October 2007) (*available at* https://www.amcp.org/sites/default/files/2019-03/AMCP%20Guide%2C%202007%20Comprehensive%20Edition.pdf). *United States ex rel. Garbe v. Kmart Corp.*, 73 F. Supp. 3d 1002, 1015 (S.D. Ill. 2014) relied on this same Glossary definition of U&C.
- **HHS-OIG Enforcement Guidance:** Safeway relies on guidance

stating that "usual" charges need not include "free or substantially reduced charges to (i) uninsured patients or (ii) underinsured patients who are self-paying." SA-55-56. But this applies to discounts for Medicare Part A *hospital services* provided to *indigent patients*, not to discounted pharmaceuticals offered to all patients under the completely different billing system of Medicare Part D.

- **Cover Letter to a GAO Report:** Safeway exaggerates a cover letter that made passing reference to U&C as an "undiscounted" price. SA-56-57. This 2004 cover letter is not a GAO report, it predates Medicare Part D and pertains to pharmaceutical assistance programs for the elderly in New York and Pennsylvania. Moreover, in the unlikely event it is making a substantive statement about U&C price, an offhand reference to "undiscounted" price in a cover letter does not justify Safeway ignoring the cash prices it offered to everyone when it reported its cash price to the general public.

There is no evidence that Safeway ever mistakenly relied on any of these purported contrary authorities at the time it acted. Moreover, none of the cases or authorities that Safeway presented to the district court changes the common understanding—shared by Safeway—that usual and customary price is the cash price offered to the general public. And there is no interpretation that can be taken from these sources that makes Safeway's conduct in this case objectively reasonable. They do not support Safeway failing to report as its U&C the lower cash prices that it made available for free to everyone (and charged more often than its reported U&C cash price).

C. Authoritative Guidance Warned Safeway Away from Its Decision to Hide Program Prices from GHPs

1. A Question of Fact: Whether Authoritative Guidance Warned Safeway Away from Its Conduct

Safeco also recognized that a defendant's "objectively reasonable" interpretation of an "ambiguous" regulation could still be "reckless" if there was sufficient evidence to warn it away from its interpretation. *See Purcell*, 807 F.3d 281, 288-89. This is a question of fact that precludes summary judgment. *Id.* at 289.

2. The District Court's Rejection of Authoritative Guidance Warning Safeway Away from Its Conduct Was Error

In concluding that "there was no authoritative guidance warning Safeway away from its interpretation of the law before *Garbe*," SA-63-64, the district court rejected authoritative federal regulations, CMS instructions, and contract specifications requiring compliance with those regulations and instructions. The court also took an overly narrow view of the type of guidance that might satisfy *Safeco*, limiting its analysis to sources it considered to be "binding" rather than simply "authoritative." SA-62-63. *See contra Safeco*, 551 U.S. at 70 (discussing "authoritative guidance" which "might have warned [defendant] away from the view it took").

As this Court noted in *Garbe*, the regulatory structure surrounding U&C price has been in place since at least 2006, and consists of federal and state regulations, CMS instructions, and contracts incorporating those federal regulations. *Garbe*, 824 F.3d at 644; 42 C.F.R. § 423.1(b) ("Scope. This part . . . establishes standards and sets forth requirements, limitations, procedures and payments for organizations participating in the Voluntary Prescription Drug Program."); 42 C.F.R. § 423.505(i)(4)(iv) (2006) ("All contracts or written arrangements must specify that the related entity, contractor, or subcontractor must comply with all applicable Federal laws, regulations, and CMS instructions").

These regulations and the Government-mandated contract specifications incorporating them require Part D contractors such as Safeway to comply with U&C contract definitions and CMS instructions.[4]

[4] Safeway's violations of these Government contract terms are more than simple contract breaches. The failures to report the true U&C prices are FCA violations because they were made "knowingly" (31 U.S.C. § 3729(b)(1)) and were "material" to Safeway's receipt of Government funds (31 U.S.C. § 3729(b)(4)).

a. Contractually Binding, Authoritative CMS Guidance Warned Safeway Away from Its Conduct

On October 11, 2006, CMS issued a Memorandum to all Part D sponsors notifying them of a "Lower Cash Price Policy." R-195-21; SA-9. In December 2006 this Policy was incorporated into Chapter 14 of the CMS Medicare Prescription Drug Benefit Manual in Section 50.4.2 at 19 n.1 (2006) (CMS Manual), https://perma.cc/MW6AH4P6; SA-9. Safeway knew of this Policy and its incorporation into CMS's Manual. R-190-34; SA-10. As this Court observed in *Garbe*:

> 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.

824 F.3d at 644 (quoting CMS Manual at 19 n.1 (2006)).

As mandated by 42 C.F.R. § 423.505(i)(4)(iv), (a regulation adopted after notice-and-comment) Medicare Part D contracts required Safeway to "comply with all applicable Federal laws, regulations, and CMS instructions," including this CMS instruction providing that where Safeway offers a "lower [cash] price to its customers throughout a benefit year" (like its free, programmatic price matching and discount clubs) the offered lower price is the U&C price. *See* R-190-4, at SW-

Proctor-TARN-00262921.40 (PBM Optum contract implementing 42 C.F.R. § 423.505(i)(4)(iv) at 2.10 by defining "Medicare Laws and Regulations" as including "(iii) any and all guidelines, bulletins, manuals, instructions, requirements, policies, standards or directives adopted and issued from time to time by CMS.")

Notwithstanding the inherently "authoritative" nature of a final manual stating CMS's official position on U&C reporting requirements and the Government mandated contractual specifications requiring compliance with CMS instructions like those in the CMS Manual, the district court concluded that "the CMS Manual does not constitute 'authoritative guidance' under *Safeco*, which provides that authoritative guidance documents must be 'binding on' an agency." SA-62. But *Safeco* did not hold that agency instructions and directives had to be "binding" notice-and-comment rulemaking to constitute authoritative "guidance." *Safeco*, 551 U.S. at 70 n.19. Instead, *Safeco* observed that a letter by an individual agency staff member "explicitly indicated that it was merely 'an informal staff opinion . . . not binding on the Commission.'" *Id.* Similarly, in *Purcell,* the court found testimony about what a Government representative said to a defendant representative was not

"authoritative." *Purcell*, 807 F.3d at 289-90. The CMS Manual, however, is very different from the informal opinions of individual agency staff members.

If the Supreme Court had meant to limit "authoritative guidance" to "binding authorities" it would have said so, but instead it used the term "guidance." Contrary to the district court's conclusion, an agency's interpretation of its own rules has been recognized as the type of "guidance" specified in *Safeco*. *See Donegan*, 833 F.3d 874, 879-80 (8th Cir. 2016) (recognizing that the Medicare agency memorandum at issue in a prior case was evidence of government guidance that was sufficient to warn a defendant away from an otherwise reasonable interpretation of an ambiguous regulation); *U.S. ex rel. Streck v. Bristol-Myers Squibb Co.*, 370 F. Supp. 3d 491, 497 (E.D. Pa. 2019) (Third Circuit refused to find as "insufficiently 'authoritative'" administrative guidance that included a proposed CMS rule, CMS Manufacturer Releases, and an HHS report).

Indeed, this Court has determined that the very provision of the CMS Manual at issue here is authoritative: "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 (discussing CMS Manual, at 19 n.1 (2006)) (citations omitted).

The published CMS Manual at issue here is not an informal opinion from a single staff member or an informal conversation about purported industry custom. The Medicare Prescription Drug Benefit Manual provisions are formal instructions drafted, vetted, and published by the regulating agency as official agency policy and, through 42 C.F.R. § 423.505(i)(4)(iv), are expressly incorporated into all of Safeway's Part D contracts. *See* Medicare Prescription Drug Benefit Manual, Introduction, Ch. 1, Sec. 10 ("Pub. 100-18 sets forth consolidated policy and operational guidance based on the current Part D program regulations.") (effective Sept. 26, 2008) *available at* https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/memopdbmanualchap1_10.16.08_6.pdf.

Accordingly, the CMS Manual was inherently and contractually binding authoritative guidance warning Safeway away from routinely offering lower cash price match and club discount prices to the general public throughout multiple benefit years while reporting inflated U&C prices.

b. Authoritative U&C Definitions Warned Safeway Away from Its Conduct

At the outset of Safeway's response to Walmart's $4 program, the PBM Medco alerted Safeway that, "by contract," the definition of U&C included "all applicable discounts" including "competitor's matched price":

> [W]e wanted your organization to be reminded of the Usual and Customary pricing provision in all Medco pharmacy network agreements.
>
> Pharmacy is required, by contract, to: "Submit Pharmacy's Usual and Customary ("U&C") price, which 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 include, but are not limited to . . . competitor's matched price, or other discounts offered customers.

R-190-7, 10/27/2006 Medco Notice.

Medco's email was circulated by Mr. Yerasi that same day among various Safeway pharmacy and financial executives. *Id.*. Mr. Yerasi stated, "I'm sure this has to do with the Wal-Mart initiatives. There 'are' ramifications to normal 3rd party business. [Medco's] Language is pretty similar in all of our agreements. . . ." *Id.* The Medco contract

definition of U&C is authoritative and, as Mr. Yerasi noted, all of Safeway's other contracts were "pretty similar." *Id.*

As detailed in the first 30 pages of the district court's decision, throughout the nine-year existence of Safeway's price match and membership cash discount programs, Safeway received numerous notices from PBMs warning it that U&C contract definitions required reporting discount cash prices offered to the general public as the U&C price. SA-9-12, 17-19, 27-29; *See* Factual History, Part I.D, *supra*. Safeway was notified that U&C price includes discounts on at least ten separate occasions by PBMs and Medicaid programs (in addition to the CMS guidance discussed in Argument II.C.2.a, *supra*). *See* SA-10 (Medco, Coventry), SA-11 (Nebraska, Oregon), SA-12 (Caremark), SA-17 (Texas), SA-18-19 (Colorado, Walgreens, Caremark again), and SA-27-28 (Caremark once again).

These warnings that U&C includes discount cash prices were "authoritative guidance" that warned Safeway away from its unreasonable conduct. The court's failure to consider these additional warnings is reversible error.

c. Authoritative Guidance from State Medicaid Programs Warned Safeway Away from Its Conduct

In concluding that "there was no authoritative guidance warning Safeway away from its interpretation of the law before *Garbe*," SA-63-64, the district court also ignored authoritative state and federal guidance—and binding regulations—that made clear Safeway's obligation to report to Medicaid its price match and club discount cash prices offered to the general public. *See* 42 C.F.R. § 447.331(b) (2006) (re-codified at 42 C.F.R. § 447.512(b) (from 2007 to the present) (limiting Medicaid reimbursement to "usual and customary charges to the general public"). The district court disregarded multiple state Medicaid program notices directing Safeway to report as its U&C price the discounted cash prices. *See* SA-39-40.

For example, in 2006, Safeway received a notice from the State of Nebraska warning that price matching set U&C price:

> 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.

R-190-15, 12/29/2006 Nebraska Notice at SW-PROCTOR-108650; SA-11.

On February 1, 2007, Oregon sent a Medicaid contract amendment to Safeway warning that U&C price included discounted retail prices and special promotions:

> "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 [Pharmacy Benefits Administrator] by the network pharmacy, including any discounts or special promotions offered on that date.

R-190-16 at SW-PROCTOR-108654; SA-11.

In April 2008, Texas Medicaid warned Safeway that discount prices set U&C price, and that Texas Medicaid beneficiaries should be enrolled in any membership programs:

> Based on requirements in the Texas Administrative Code, pharmacies that use a prescription discount plan (such as the Walmart $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.

R-190-9, at SW-PROCTOR-261386; SA-17.

In September 2008, Colorado issued a Provider Bulletin warning Safeway that it was required to report its discount prices as U&C:

> Pharmacy Discount Programs: 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.

R-195-36, at 3; SA-18-19.

State Agencies repeatedly warned Safeway that Medicaid caps reimbursement at the U&C charge to the general public. The district court erred when it failed to consider this authoritative guidance.

III. The Decision that Safeway Did Not Act with Reckless Disregard Erroneously Ignored Undisputed Evidence of Safeway's Actual Knowledge and Deliberate Ignorance

Finally, the district court erred in categorically rejecting any evidence of subjective knowledge or subjective intent to establish a "knowing" violation of the FCA. Instead, the court concluded that the "objective scienter standard" in *Safeco* absorbs the subjective "deliberate [ignorance]" and "actual knowledge" prongs of FCA knowledge, SA-34 & 64-65, rendering subjective knowledge or intent irrelevant in determining scienter if the defendant conceives of a reasonable interpretation—regardless of its actual conduct. SA-42 ("Subjective intent is 'irrelevant' if a defendant has a reasonable interpretation") (citing *Purcell*, 807 F.3d at 290).

This wholesale rejection of any subjective evidence is contrary to the express language of the FCA which imposes liability based on objective *or* subjective states of mind. A "knowing" FCA violation can be established if a claimant requests payment despite "actual knowledge" that a requirement was not met; *or*, "acts in deliberate ignorance" of whether a requirement was met; *or*, "acts in reckless disregard" of whether a requirement was met. 31 U.S.C. § 3729(b)(1)(A); *King-Vassel*, 728 F.3d at 712. This definition of knowledge was adopted by Congress to expand the culpable mental states in the FCA, not cabin them within reckless disregard. *See* H.R. Rep. No. 99-660 at 20-21 (1986) ("This definition, therefore, enables the Government not only to effectively prosecute those persons who have actual knowledge, but also those who play 'ostrich.' . . . There is no doubt that actual knowledge of a claim's falsity will confer liability under the statute.").

The FCA has an objective scienter standard, "reckless disregard"—though this does not mean that all facts are irrelevant, *see* Argument II.B, *supra*—which was described by this Court six years after *Safeco* as an "'extreme version of ordinary negligence,'" "'an extension of gross negligence,'" or knowing or having reason to know of facts that would

lead a "'reasonable person to realize'" that harm is likely to result. *King-Vassel*, 728 F.3d at 713 (quoting *U.S. v. Krizek*, 111 F.3d 934, 942 (D.C. Cir. 1997) and Black's Law Dictionary 540-41 (9th ed. 2009)). As the Supreme Court explicitly recognized in *Safeco*: "'recklessness' . . . has [been] generally understood . . . in the sphere of civil liability as conduct violating an objective standard." 551 U.S. at 68 (citation omitted); *see also van Straaten v. Shell Oil Prods. Co.*, 678 F.3d 486, 491 (7th Cir. 2012) ("the statutory standard [at issue in *Safeco*] concerns *objective* reasonableness, not anyone's state of mind") (emphasis in original).

But "actual knowledge" and "deliberate ignorance" both concern the defendant's *subjective* mental state. *See, e.g.*, *U.S. v. Speqtrum, Inc.*, 113 F. Supp. 3d 238, 249 (D.D.C. 2015) (citation omitted) ("Actual knowledge looks at 'subjective knowledge,' while deliberate ignorance 'seeks out the kind of willful blindness from which subjective intent can be inferred.'"). Because the FCA explicitly recognizes two *subjective* mental states that permit the imposition of liability, the *objective* reasonableness of a defendant's actions is not dispositive. *Accord Safeco*, 551 U.S. at 60 ("action falling within the knowing subcategory does not simultaneously fall within the reckless alternative"); *Halo*, 136 S. Ct. at

1933 (recognizing that subjective willfulness that is intentional or knowing may warrant enhanced damages (and therefore exist) without regard to whether the conduct was objectively reckless).

Nevertheless, the district court erroneously concluded that objective recklessness was the beginning *and* end of the inquiry, holding that a Relator who is unable to prove recklessness would necessarily be unable to establish actual knowledge or "deliberate [ignorance]." SA-34 (citing *King-Vassel*). This conclusion is based on a faulty premise.

Though this Court has recognized that reckless disregard is "the most capacious of the three" FCA scienter standards, *King-Vassel*, 728 F.3d at 712, it has never held that recklessness subsumes deliberate ignorance and actual knowledge, rendering them surplusage in the statute. On the contrary, these are independent ways to establish liability:

> If the reckless disregard standard of section 3729(b)(3) [now 3729(b)(1)(A)(iii)] served merely as a substitute for willful misconduct—to prevent the defendant from "deliberately blinding himself to the consequences of his tortious action"—section (b)(3) would be redundant since section (b)(2) [deliberate ignorance] already covers such struthious conduct. *See Kungys v. United States,* 485 U.S. 759, 778, 99 L. Ed. 2d 839, 108 S. Ct. 1537 (1988) (citing the "cardinal rule of statutory interpretation that no provision should be construed to be entirely redundant"). Moreover, as the statute explicitly

> states that specific intent is not required, it is logical to conclude that reckless disregard in this context is not a "lesser form of intent," *see Steadman,* 967 F.2d at 641-42, but an extreme version of ordinary negligence.

U.S. v. Krizek, 111 F.3d 934, 942 (D.C. Cir. 1997).

Even if Safeway did not act with reckless disregard pursuant to *Safeco* (it did), this is but one of three ways to establish scienter under the FCA. *U.S. ex. rel. Colquitt v. Abbott Labs.*, No. 3:06-cv-1769-M, 2016 U.S. Dist. LEXIS 92450, at *7 (N.D. Tex. Mar. 8, 2016) ("To the extent the Supreme Court's decision in *Safeco* applies to any question presented by this case, the Court determines its reach is limited to the issue of whether Defendants' reliance on a reasonable interpretation of an ambiguous requirement precludes a finding of 'reckless disregard' under 31 U.S.C. § 3729(b)[(1)(A)(iii)]") (citations omitted); *see also Krizek*, 111 F.3d at 942 ("reckless disregard" does not subsume "deliberate ignorance").

Accordingly, though subjective intent (which is distinct from what Safeway knew or should have known) may be irrelevant to an *objective* standard like reckless disregard, it is certainly relevant to the FCA's *subjective* mental states.

A. The Record Shows that Safeway Acted with Actual Knowledge and Deliberate Ignorance when It Submitted False Claims

Safeway actually knew it was obligated to submit price match and discount program cash prices as its U&C price and was concerned with putting any of its plans in writing. *See, e.g.*, Factual History Part I.D (discussing evidence). Safeway was aware of its obligations as early as October 2006, when it was warned by CMS that discounted cash prices offered to the general public throughout the benefit year are to be reported as U&C prices. R-195-21, at PROCTOR-00000001 n.1; (incorporated into the CMS Manual in December 2006); SA-9-10.

In October 2006, Medco also reminded Safeway that U&C price includes "all applicable discounts" like "competitor's matched price, or other discounts offered customers," and Safeway's Director of Managed Care and Marketing reminded his colleagues that this language was "pretty similar in all of our agreements." R-190-7; SA-10.

Shortly after receiving this Medco notice, Coventry Health Care, another PBM, reminded Safeway that U&C "price must include any applicable discounts offered to attract customers." R-190-28; SA-10-11. The same Safeway Director then circulated this to fellow executives,

stating that it was "Another Example of how plans are reacting, ie, any modified price needs to be offered to the 3rd party if meets U&C definition." *Id.*

In April 2008 a Safeway Division Director emailed Safeway's Group Director of Pharmacy Operations and told him a subordinate reported that Nebraska Medicaid "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." R-190-18 at SW-PROCTOR-108469; SA-17. This Division Director's response, uncontested by his superiors, was "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.*

Despite Safeway's actual knowledge of its obligation to report price match and club discounts as its U&C price, two days after this Nebraska email the same Group Director Pharmacy Operations cautioned Safeway's Senior VP Pharmacy that advertising price matching would alert Medicaid programs, so Safeway should "keep a

low profile." R-190-31, SW-Proctor-TARN-00019085.1 (citing his understanding of a memo determining "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"); SA-17-18.

A few months later, Safeway's Senior VP Pharmacy was likewise told by the Food Marketing Institute, an industry group, that the CMS Manual required pharmacies to report discount program prices as U&C. R-190-17; SA-18.

And in July 2011, Safeway's Director of Managed Care and President of its wholly-owned subsidiary, Avia Partners, forwarded a Caremark FEP Network Update to other executives and internal counsel which defined U&C as "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," stating: "FEP is requiring that we provide our best price to them. This would be 10% off brands, 20% off generics, and the $4.00

program in Dominick's, Eastern, and Texas. I do not see a way around it." R-190-20; SA-27-28.

Safeway was not merely "warned away" from its conduct under the reasonable person standard of reckless disregard, it actually knew it was required to submit its price match and discount program cash prices as its U&C price. Its continuous failure to do so for nearly a decade was a "knowing" FCA violation.

"Deliberate ignorance" is also a "knowing" FCA violation, and Safeway deliberately ignored numerous warnings from CMS, States, and PBMs. Rather than disclosing to the third party payers its discount cash prices and inquiring whether they must be reported as its U&C, Safeway sought to "keep a low profile" to hide its price matching and adopted what its Division Manager/Director of Pharmacy Operations for Texas characterized as "stealth Membership Program" (R-190-1, SW-PROCTOR-261114; SA-27) to conceal discount cash prices from third party payers, including GHPs. *See also* R-190-6, 10/26/2006 email ("We cannot put any of this in writing to stores because our official policy is we do not match."); SA-8.

The district court's order granting summary judgment on the basis that Safeway did not act recklessly and therefore could not act with deliberate ignorance or actual knowledge rewrites the FCA and cannot be squared with the undisputed facts.

IV. Conclusion

The meaning of usual and customary pricing was well-established long before Medicare Part D launched in 2006 and long before *Garbe* was decided ten years later: Medicaid and Medicare are to pay no more for prescription drugs than the cash prices that pharmacies offer to the general public. CMS, PBMs, and Medicaid programs repeatedly reminded Safeway that U&C price included the very type of discount programs Safeway adopted. But Safeway disregarded these reminders and actively concealed the true cash price it offered to everyone else through price matching and free membership programs and accepted lower cash prices for prescriptions drugs more than 14 million times. Safeway knowingly submitted false claims by reporting inflated "usual and customary" cash prices to GHPs that ignored these lower prices.

The district court's summary judgment order was in error and should be reversed and remanded for trial for three independent reasons.

First, the court erred in determining that *Garbe* redefined "usual and customary" price. The issues before this Court are predicated on the mistaken premise that *Garbe* changed the rules with respect to reporting U&C, and thus created new law. *Garbe* created no new law or obligation.

Second, the court erred in its application of *Safeco*. *Safeco* stands for the proposition that a party should not be held liable for innocent mistakes. The record is replete with material facts demonstrating that Safeway is not innocent and its scheme to defraud the government was no mistake. A reasonable pharmacy, knowing what Safeway knew or should have known, would not have submitted claims for payment that omitted the lowest cash prices it offered to the general public.

Third, the court erred in determining that the objective "reckless disregard" scienter standard supplanted the statutorily defined FCA term "knowing," and erred in treating evidence of subjective knowledge and subjective intent as irrelevant.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH FED. R. APP. P. RULE 32(a)(7) AND CIRCUIT RULE 32(c)

The undersigned, counsel of record for Plaintiff-Appellant Thomas Proctor, furnishes the following in compliance with Fed. R. App. P. Rule 32(a)(7), Circuit Rule 32(c), and Fed. R. App. P. Rule 32(g):

I hereby certify that this brief conforms to the type-volume limitations contained in Fed. R. App. P. Rule 32(a)(7)(B)(i) as modified by Circuit Rule 32(c) for a brief with a proportionally spaced font. Excluding the parts of this brief exempted by Fed. R. App. P. 32(f), this brief contains 13,994 words.

Dated: February 8, 2021

s/ James A. Tate
James A. Tate

Counsel for Plaintiff-Appellant Thomas Proctor

CERTIFICATE OF SERVICE

I hereby certify that on February 8, 2021, I electronically filed the foregoing Brief and Required Short Appendix of Plaintiff-Appellant with the Clerk of the Court for the Seventh Circuit Court of Appeals via the Court's Case Management/Electronic Case Filing (CM/ECF) system pursuant to Circuit Rule 25(a). Participants in the case who are registered CM/ECF users—which include counsel of record for Defendant-Appellee—were served electronically at the time of filing.

Dated: February 8, 2021

s/ James A. Tate
James A. Tate

Counsel for Plaintiff-Appellant
Thomas Proctor

CERTIFICATE OF COMPLIANCE REQUIRED BY CIRCUIT RULE 30(d)

Pursuant to Circuit Rule 30(d), I hereby certify that all documents required by Circuit Rule 30(a) are included in this Required Short Appendix. The documents required by Circuit Rule 30(b) are included in a separate Appendix.

Dated: February 8, 2021

s/ James A. Tate
James A. Tate

Counsel for Plaintiff-Appellant
Thomas Proctor

No. 20-3425

UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

UNITED STATES OF AMERICA, et al.,
ex rel. THOMAS PROCTOR,

Plaintiffs-Appellants

v.

SAFEWAY, INC.,

Defendant-Appellee

Appeal From The United States District Court
For the Central District of Illinois,
Case No. 3:11-CV-03406-RM-TSH
The Honorable Richard Mills

REQUIRED SHORT APPENDIX OF PLAINTIFF-APPELLANT THOMAS PROCTOR

TABLE OF CONTENTS

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

UNITED STATES OF AMERICA, and The STATES OF CALIFORNIA, COLORADO, DELAWARE, HAWAII, ILLINOIS, MARYLAND, MONTANA, NEW JERSEY, NEW MEXICO, NEVADA, VIRGINIA, and The DISTRICT OF COLUMBIA, *ex rel.* THOMAS PROCTOR,	)	
Plaintiffs,	)	
v.	)	Case No. 11-cv-3406
SAFEWAY INC.,	)	
Defendant.	)	

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] Safeway seeks summary judgment under *Safeco Insurance Co. of Am. v. Burr*, 551

[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.

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 clams 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.

[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."

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 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 contact 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% of[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 choses 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

[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

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 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

that plaintiff established the defendant recklessly disregarded the fact that the child had received Medicaid assistance. *See King-Vassel*, 728 F.3d at 713.

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 whether Safeway violated the FCA.

[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.

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 it 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

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

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 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*, s*ee 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 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

E-FILED
Monday, 15 June, 2020 04:16:11 PM
Clerk, U.S. District Court, ILCD

UNITED STATES DISTRICT COURT

for the
Central District of Illinois

United States of America, State of 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.	)	**Case Number: 11-3406**
Safeway Inc,	)	
Defendant.	)	

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.

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