Nos. 21-1326 and 22-111

IN THE

Supreme Court of the United States

UNITED STATES EX REL. TRACY SCHUTTE, ET AL.,
Petitioners,
v.
SUPERVALU INC., ET AL.,
Respondents.

UNITED STATES EX REL. THOMAS PROCTOR,
Petitioner,
v.
SAFEWAY, INC.,
Respondent.

ON WRITS OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

BRIEF OF NATIONAL ASSOCIATION OF CHAIN DRUG STORES AS AMICUS CURIAE IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICUS CURIAE*[1]

The National Association of Chain Drug Stores ("NACDS") is a non-profit, tax-exempt organization that represents over 80 members, including traditional drug stores, supermarkets, and mass merchants. NACDS members operate more than 40,000 pharmacies across the country, employ nearly three million individuals, and fill over three billion prescriptions annually. They also help patients use medicines correctly and safely, while offering innovative services that improve patient health and health care affordability. NACDS members and their pharmacies are providers to beneficiaries of Medicaid and Medicare, filling more than a billion prescriptions for this patient population annually. Since the COVID-19 pandemic, NACDS members have been responsible for more than 300 million vaccinations and helped prevent more than 1 million deaths, 8 million hospitalizations, and $450 million in health care costs.

Amicus and its members have a strong interest in this case. Retail pharmacies play a critical role in the provision of medication and services across the country, and do so in a highly complex regulatory environment. Processing millions of claims daily, pharmacies must decipher the competing mandates set out by fifty-two Medicaid

[1] Pursuant to this Court's Rule 37.6, NACDS states that this brief was not authored in whole or in part by counsel for any party. No person, other than *amicus curiae*, its members, or its counsel, contributed money that was intended to fund preparing or submitting this brief.

jurisdictions, the Centers for Medicare and Medicaid Services ("CMS"), and the Part D sponsors responsible for administering Medicare Part D—and they must do so in real time on a claim by claim basis while also complying with myriad regulations unrelated to payments. While navigating this complexity, pharmacies *must* be able to perform their functions without fear that they will be subject to the steep per claim penalties of the False Claims Act for adhering to an objectively reasonable interpretation of an ambiguous regulation that is later declared wrong.

SUMMARY OF ARGUMENT

In the United States, the burden to establish the contours of complex regulations lies with the regulator, not the regulated. This bedrock principle of due process is essential to the retail pharmacy industry, where pharmacies operating with razor-thin margins must navigate labyrinthine requirements, often with a less than clear road map, in order to provide critical public services. In this environment, pharmacies must be able to make reasonable decisions in the face of regulatory ambiguity without risk of being subject to the severe penalties of the False Claims Act ("FCA")—including treble damages, civil penalties on a per claim basis, and attorney's fees. This Court should make clear that they can.

Here, the specific ambiguity at issue concerns the meaning of "usual and customary," an ambiguous term used in a patchwork of federal and state regulations. For years, the entire industry operated on the understanding that, in the absence of a specific contractual provision or regulation instructing otherwise, "usual and customary"

meant the prices provided to a cash-paying member of the general public and did not include prices that required affirmative action by the patient, such as a patient-initiated request for price matching or enrollment into a pharmacy's discount club membership program.

That all changed with the Seventh Circuit's controversial decision in *Garbe*. *See United States ex rel. Garbe v. Kmart Corp.*, 824 F.3d 632, 645 (7th Cir. 2016). In *Garbe*, the Seventh Circuit erroneously held that all Medicaid jurisdictions, as well as Medicare Part D, operate under a single, uniform definition of "usual and customary" that requires members of enrollment based, discount savings programs to be treated as "the general public" for purposes of determining a pharmacy's "usual and customary" price. *Id.*

Garbe constituted a sea change in the law, and its flawed analysis remains controversial. Even so, it serves as the foundation of the FCA claims against the Respondents in this case. Both Safeway and SuperValu are accused of submitting "false" claims to the government not because of some factual error or clear obligation of law that was ignored—but rather due to a subsequent Seventh Circuit decision that shocked the industry. This backdrop is important. Petitioners and the Government are asking this Court to adopt a construction of the FCA under which Respondents and other retail pharmacies could be deemed liable for failing to predict a change in law that no one saw coming. The harsh penalties of fraud should not be imposed so lightly.

The FCA punishes only "knowing" violations. Under the FCA, "knowing" can be shown through "actual knowledge," "deliberate ignorance," or "reckless disregard" of the falsity of the information presented to the government. 31 U.S.C. § 3729(b). This consolidated appeal raises the critical question whether a pharmacy acts "knowingly" under the FCA when it presents a factually accurate claim under an objectively reasonable interpretation of the law later declared wrong. The answer is no.

The Court's analysis in *Safeco Insurance Co. of Am. v. Burr*, 551 U.S. 47 (2007), provides the proper approach. In *Safeco*, the Court recognized that only "conduct violating an objective standard" qualified as the kind of "reckless disregard" that gave rise to a willful violation of the Fair Credit Reporting Act ("FCRA"). 551 U.S. at 48. And under that standard, if a defendant's proffered reading of the statute was "objectively reasonable," it could not be liable for a "knowing" or "reckless" violation, "whatever [its] subjective intent may have been." *Id.* at 70 n.20.

The Seventh Circuit, like the other circuits to consider the issue, correctly applied *Safeco*'s "objectively reasonable" framework to determine whether an FCA defendant acted with scienter as to the falsity of information. When a regulated entity submits a factually accurate claim under an objectively reasonable interpretation of the law, and there is no authoritative guidance warning the entity away from its view, that entity has not "knowingly" submitted a false claim just because the government disagrees with the interpretation. *United States v. Supervalu Inc.*, 9 F.4th 455, 468 (7th Cir. 2021);

see also Safeco, 551 U.S. at 70 n.20. As in *Safeco*, subjective intent is irrelevant to that threshold inquiry. *Id*.

Beyond the predictability and consistency offered by the *Safeco* approach, the objective scienter standard also aligns with the historical understanding of fraud and principles of due process. FCA liability carries severe consequences. An objective standard protects regulated entities from unfair, post-hoc application of the FCA when they fail to divine the government's preferred meaning of an ambiguous regulation. This is especially critical for retail pharmacies, which by virtue of the sheer volume of low-margin claims they submit to the government, face outsized, potentially devastating exposure under the FCA's per claim, treble damages regime.

Here, the Respondents acted consistently with objectively reasonable interpretations of "usual and customary"—an industry term used in federal and state pharmacy regulations—when submitting claims to the government. Those interpretations reflected the prevailing industry view at the time, and did not conflict with any applicable regulatory guidance. Indeed, as the Seventh Circuit recognized below, the term "usual and customary" was subject to multiple reasonable interpretations before *Garbe* and there was no official, authoritative guidance on point. Following one of those objectively reasonable interpretations should not be deemed fraud.

Rejecting the *Safeco* approach will create undue regulatory risk that stifles innovation and may lead to increases in prescription drug prices. If guessing incorrectly regarding what an unclear regulation means triggers the FCA's punitive measures, retail pharmacies

may be left paralyzed, unable to provide health services and affordable prescription drugs to their patients. Indeed, these cases exemplify that risk. Both the price-matching and club member programs challenged in these cases began as creative attempts to deliver low prices to underinsured and uninsured patients consistent with applicable regulations. That all changed with *Garbe*, which forced pharmacies to determine if they needed to scale back or terminate these innovative programs, eliminating cost savings for many patients, and created hesitation to develop similar programs moving forward.

The *Garbe* decision was also plainly wrong. It is beyond dispute that there is no uniform definition of "usual and customary" applicable to all fifty-two Medicaid jurisdictions, much less a top-down, federally mandated definition of the term under Medicare Part D. Moreover, the *Garbe* court ignored a multitude of evidence from both the industry and governmental sources to reach the conclusion that "usual and customary" encompassed enrollment based, discount club prices. And although the correctness of the *Garbe* decision is not squarely presented in this appeal, the errors throughout that opinion remain relevant because they demonstrate the convoluted regulatory environment that pharmacies face and the reasonableness of Respondents' pre-*Garbe* interpretations of "usual and customary."

ARGUMENT

I. The *Safeco* Objective Standard Applies to the FCA's Scienter Requirement.

The FCA carries a "rigorous" scienter requirement. A defendant is liable under the act only if it submits a claim for payment with actual knowledge, deliberate ignorance, or reckless disregard that the information submitted is false. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016); 31 U.S.C. § 3729(b)(1)(A). These standards do not permit liability against a defendant who submits a factually accurate claim for payment that becomes legally "false" as a result of regulatory ambiguity later resolved against the defendant.

A. The Text of the FCA Supports an Objective Scienter Standard with Respect to a Company's Knowledge of Its Legal Obligations.

While the FCA includes a three part definition for its knowledge requirement, the "loosest" standard provided for a "knowing" violation is "reckless disregard." *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 288 (D.C. Cir. 2015) (citing 31 U.S.C. § 3729(b)(1)(A)). To examine the meaning of "knowing" and, in particular, "reckless disregard," *Safeco* is instructive.

The FCRA, like the FCA, uses "reckless disregard" as the floor for a "knowing" violation of the law. *Safeco*, 551 U.S. at 59. When evaluating the term's meaning, the Court observed "the general rule that a common law term in a statute comes with a common law meaning" and the "interpretive assumption that Congress knows how [the

Supreme Court] construes statutes and expects us to run true to form." *Id.* at 48; *see also Escobar*, 136 S. Ct. at 1999 ("It is a settled principle of interpretation that, absent other indication, Congress intends to incorporate the well-settled meaning of the common-law terms it uses"). The result was unequivocal: "the common law has generally understood ['recklessness'] in the sphere of civil liability as conduct violating an objective standard." 551 U.S. at 48. Thus, under *Safeco*, when a defendant follows an objectively reasonable interpretation of the law and no authoritative guidance exists to warn it away from its view, that defendant cannot act with knowing or reckless disregard of the law—"whatever their subjective intent may have been." *Id.* at 70, n.20.

These interpretive principles apply with equal force to a defendant's knowledge of its legal obligations under the FCA. The FCA's scienter requirement applies specifically to a defendant's knowledge of falsity "with respect to information." 31 U.S.C. § 3729(b)(1)(A). The emphasis on "information" is important because it aligns with the common law understanding of fraud as a misrepresentation of *fact*—not an erroneous interpretation of the law. *See Safeco,* 551 U.S. at 70 (explaining that "it would defy history and current thinking to treat a defendant who merely adopts one [reasonable but incorrect] interpretation as a knowing or reckless violator").

That distinction makes sense under the FCA. A pharmacist can act with actual knowledge, deliberate ignorance, or reckless disregard as to the falsity of factual claims, such as the number of prescriptions filled in a given

period. But a pharmacist cannot know or ignore the falsity of his legal interpretation of an ambiguous regulation. In that circumstance, the scienter analysis hinges on whether the pharmacist's conduct was objectively reasonable. If not, then he can be said to have knowingly, deliberately, or recklessly disregarded the falsity of his claim. But if the interpretation was objectively reasonable, he cannot be liable.

In light of this critical distinction, it comes as no surprise that every circuit court that has considered the question has applied *Safeco* to the FCA and required an objectively clear legal obligation as a prerequisite to liability.[2] In the proceedings below, the Seventh Circuit joined that chorus and properly recognized that "*Safeco* covers all three of the scienter standards listed in § 3729." *SuperValu,* 9 F.4th at 468.

B. An Objective Scienter Standard Respects Due Process.

As a "fundamental principle" of due process, regulations "must give fair notice of conduct that is forbidden or required." *F.C.C. v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012); *see Wis. Res. Prot. Council v. Flambeau Min. Co.*, 727 F.3d 700, 707 (7th Cir. 2013) (identifying "fair

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[2] *Purcell*, 807 F.3d at 290; *United States ex rel. Streck v. Allergan Inc.*, 746 F. Appx. 101, 106 (3d Cir. 2018); *United States ex rel. Donegan v. Anesthesia Assocs. of Kan. City, PC*, 833 F.3d 874, 879–80 (8th Cir. 2016); *United States ex rel. McGrath v. Microsemi Corp.*, 690 F. Appx. 551, 552 (9th Cir. 2017); *see also United States ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645, 657–58, n.39 (5th Cir. 2017) (citing *Safeco* and defendant's application thereof to the FCA claim).

warning" as "a cardinal rule of administrative law"). The fair-notice requirement is especially important under the FCA where the consequences for violations are "essentially punitive in nature." *Escobar*, 136 S. Ct. at 1996 (internal quotation marks omitted).

Put simply, if the government expects regulated entities to adhere to a particular interpretation of a regulation, then it must first make that interpretation clear. *See Purcell*, 807 F.3d at 291 ("Had the government wanted to avoid such consequences, it could have defined its regulatory term to preclude them."). Indeed, a regulation "cannot be construed to mean what an agency intended but did not adequately express . . ." *Gates & Fox Co., Inc. v. OSHRC*, 790 F.2d 154, 156 (D.C. Cir. 1986) (Scalia, J.) (citation omitted). In the absence of such adequate expression, due process precludes liability against an entity that adopts a reasonable path forward.

These same principles of fair notice have guided this Court's jurisprudence in other areas of law, including the limits of deference afforded to an agency's interpretation of its own ambiguous regulations. For years, the strength of *Auer* deference, a rule of judicial deference applying to agencies' reasonable interpretations of such regulations, has been in question. *See, e.g.*, *Exelon Generation Co., LLC v. Local 15, Int'l. Bhd. of Elec. Workers, AFL-CIO*, 676 F.3d 566, 576 n.5 (7th Cir. 2012), *as amended* (May 9, 2012) ("Justice Scalia is willing to 'reconsider' *Auer–Seminole Rock* deference, . . . and the Court may soon have an opportunity to do so." (internal citations omitted)). Among other criticisms, Justice Scalia explained that "deferring to an agency's interpretation of its own rule encourages the

agency to enact vague rules which give it the power, in future adjudications, to do what it pleases." *Talk Am., Inc. v. Mich. Bell Tel. Co.*, 564 U.S. 50, 69 (2011) (Scalia, J., concurring). As he further noted, "This frustrates the notice and predictability purposes of rulemaking, and promotes arbitrary government." *Id.*

This trend recently culminated in *Kisor v. Wilkie*, in which this Court established that *Auer* deference is only appropriate where an interpretation is the agency's "authoritative or official position," is not merely a "convenient litigating position" or a "*post hoc* rationalization[s]," and is not "a new interpretation . . . that creates unfair surprise to regulated parties." 139 S. Ct. 2400, 2418, 2430 (2019) (internal quotation marks omitted). Applying *Safeco* to the FCA is consistent with *Kisor*. If an agency is not given deference for its interpretation of an ambiguous regulation where there would be "unfair surprise," it would be equally inappropriate to hold a private party liable for following a reasonable interpretation not previously and officially foreclosed by the agency. *See General Electric Co. v. U.S. E.P.A.*, 53 F.3d 1324, 1329, 1334 (D.C. Cir. 1995) (recognizing that agencies cannot retroactively apply new regulatory interpretations without fair notice).

C. An Objective Knowledge Standard Protects the Retail Pharmacy Industry from Excessive and Unfair False Claims Act Actions.

The importance of an objective scienter standard is especially critical to the retail pharmacy industry. Retail pharmacies operate at high volumes on low margins in a

highly complex regulatory space, which makes them uniquely vulnerable to overaggressive application of the FCA. Medicaid requirements differ across fifty-two jurisdictions and the requirements of Medicare Part D vary across each privately negotiated contract, all of which contain their own pricing formulas and directives. In turn, each contract or individual regulation presents its own complicated structure, typically consisting of a "lesser than" methodology under which reimbursement is defined as the lowest price available under a series of pricing sources or formulas, the majority of which are not maintained or controlled in any way by the pharmacy. *See, e.g.,* Wash. Admin. Code § 388-530-7000 (2007) (instructing that reimbursement "must not exceed the lowest of" six options, including the drug's "estimated acquisition cost," "maximum allowable cost," "federal upper limit," "actual acquisition cost," "automated maximum allowable cost," or the "the provider's usual and customary charge to the non-Medicaid population"). Together, the result is that individual pharmacies often may face different legal obligations from patient to patient even within the same state and concerning the same drug.

Indeed, even the concept of "same drug" is complicated. Drugs are identified and reported using a unique, three-segment number called a National Drug Code, or NDC. But the "same drug" can have many different NDCs based on its manufacturer, dosage, strength, and packaging. For example, Lipitor—a medication widely used to lower cholesterol levels—has more than 35 different NDCs.[3]

[3] *See, e.g.,* https://www.findacode.com/ndc/drugs/Lipitor.

Each one of these NDCs may carry different acquisition costs, be subject to different limits, and thus be reimbursed differently depending on the plan or regulation in question—even if the pharmacy's usual and customary price is constant. Retail pharmacies must calculate all of these variables in real time on a claim by claim basis, all while also complying with the many other regulations unrelated to payments.

The FCA exposure created by this regulatory maze is exacerbated by the fact that retail pharmacies process a high number of government claims. NACDS members alone accounted for more than a billion prescriptions to the government in 2018. This high volume, when paired with the FCA's threat of treble damages on a per claim basis, can create extreme liability scenarios. Retail pharmacies thus disregard regulatory compliance at their peril. In cases of genuine fraud, the severe penalties of the FCA may be appropriate. But if pharmacies adhering to objectively reasonable interpretations of ambiguous regulations are subjected to those same penalties, there is a real risk that the FCA will smother the industry.

Such undue legal risk comes at a high cost for retail pharmacies and the communities they serve because uncertainty stifles innovation. As the federal government has long recognized, rising prices of prescription drugs is a significant societal problem. A recently passed federal law, the Know the Lowest Price Act of 2018, acknowledges that pharmacies have long sought to address this problem in creative ways that, at times, leads to lower prices being available to uninsured or underinsured patients compared to those available under any given health coverage plan.

Enacted nearly two years after *Garbe* became final, the Know the Lowest Price Act makes clear that, to achieve lower pricing, pharmacies are allowed to inform enrollees in Medicare Part D plans of any difference between the price to the enrollees under their plan and the price the enrollees would pay if they did not use any health insurance coverage. *See* Pub. L. No. 115–262, § 2(a), 132 Stat. 3670 (2018). In other words, the law presupposes that pharmacies can and do provide lower prices to certain patients compared to those reported to Medicare Part D contractors, and that such practices are not only permissible, but encouraged.

Price matching and discount savings programs are just two examples of customer-friendly initiatives that were developed as creative means to keep prescription drug costs low for underinsured patients. And, unfortunately, post-*Garbe*, the spectre of FCA liability has chilled the adoption of such initiatives—even outside the Seventh Circuit, where *Garbe* does not control. This is to the detriment of patients, especially those who struggle most to afford their medications. In short, while Congress has taken steps to encourage the industry to develop new strategies to help patients combat the rise in prescription costs, such as the Know the Lowest Price Act, the looming shadow of potential FCA exposure for even objectively reasonable conduct can force pharmacies to scrap price-savings initiatives before they even get started.

Applying an objective knowledge standard to the FCA provides the regulatory confidence needed to continue innovation. It affirms that retail pharmacies may continue to interpret the law reasonably to meet patient demands

without fearing ruinous liability under a statute aimed at preventing *knowing* fraud. And it properly places the burden of clarifying ambiguous regulations on those with the power to do so. The *Safeco* objective knowledge standard is properly applied to FCA cases.

II. Using the *Safeco* Standard, this Court Should Affirm.

Under the *Safeco* standard, the Seventh Circuit correctly determined that it was objectively reasonable for Appellees to interpret the term "usual and customary" to exclude the prices offered under their respective price-matching and discount savings programs. At all relevant times, the scope of "usual and customary" was genuinely ambiguous, and no authoritative guidance existed warning Safeway or SuperValu away from their respective understandings. Thus, under the *Safeco* standard, Respondents did not act in reckless disregard of the falsity of their claims.

A. Respondents' Conduct Was Objectively Reasonable.

The first step under the *Safeco* analysis asks whether the regulated party's asserted reasonable interpretation "has a foundation in the statutory text," *Safeco*, 551 U.S. at 50, and is otherwise "facially reasonable." *See Purcell*, 807 F.3d at 288 (using textual interpretation techniques to conclude that defendant's interpretation was reasonable); *Allergan*, 746 F. Appx. at 108 (same). An interpretation is not rendered unreasonable by a different, better interpretation. *Purcell*, 807 F.3d at 289.

The regulatory ambiguity in this case concerns whether, under the numerous relevant state Medicaid regulations and contractual provisions with Medicare Part D sponsors, Respondents were required to report customer-initiated, price-matched prices and the discounted prices offered in club membership programs as a pharmacy's "usual and customary" price for a given drug. Consistent with the prevailing industry view at the time, Respondents did not report those prices as usual and customary.

Respondents' interpretation of their regulatory obligations was objectively reasonable, with respect to both price matching and club membership pricing. First, it was "facially" reasonable for retail pharmacies to treat price-matched prices as separate from their own "usual" or "customary" price. Competitive price matching is generally customer-initiated and ad hoc, as not every patient will request, let alone receive, a price match and a pharmacy cannot predict which drugs could be subject to a price match. On its face, such a practice is a far cry from a "usual and customary" price. Likewise, Respondent Safeway reasonably determined that "usual and customary" did not encompass prices available only to patients who chose to affirmatively enroll in its discount savings program designed to lower costs for uninsured and underinsured patients, because such persons—having affirmatively opted in to the program—were not considered members of the "general public."

Nor did the regulatory scheme or case law at the time suggest these practices were unlawful. For example, Centers for Medicare and Medicaid Services ("CMS") regulations merely reference the phrase "Providers' usual and customary charges to the general public" without defining it. 42 C.F.R. § 447.512. And although many of the fifty-two Medicaid jurisdictions have adopted their own competing definitions of the phrase "usual and customary," the vast majority were equally ambiguous. *See* Respondents' Brief, Appendix A (listing regulations). The Seventh Circuit expressly acknowledged this in the proceedings below, observing that the term "usual and customary" was "open to multiple interpretations" during the time Respondents operated their respective programs. 9 F.4th at 469.

The objectively reasonable nature of Respondents' interpretation is further supported by the multitude of materials issued by the government during the relevant time period that *supported* Respondents' interpretation. For example, in 2004, the Department of Health and Human Services ("HHS") issued enforcement guidance confirming that "when calculating their 'usual charges' . . . entities do not need to consider free or substantially reduced charges to (i) uninsured patients or (ii) underinsured patients who are self-paying . . . ." This guidance supports the interpretation that price matching and club prices need not be considered in determining the "usual and customary" price.

Additional examples abound. The 2006 version of the CMS Medicare Prescription Drug Benefit Manual (the "CMS MPDB Manual") maintained a distinction between a

"'special' price or other discount" and the pharmacy's "usual and customary" price. Foreshadowing the Know the Lowest Price Act, which would arrive from Congress more than a decade later, CMS also expressly acknowledged in the CMS MPDB Manual that individuals may "receive a better cash price for a covered Part D drug at a network pharmacy than the plan offers via its negotiated price," including in situations where the "pharmacy is offering a 'special' price or other discount for all customers, or if the beneficiary is using a discount card[.]" 2006 CMS MPDB Manual, Ch. 14 § 50.4.2.

Various Government Accountability Office ("GAO") and HHS Office of Inspector General ("OIG") reports from the time period also squarely contradicted any suggestion that "usual and customary" encompassed club membership or price-matched prices. *See, e.g.*, GAO, Report to Congress on Trends in Usual and Customary Prices for Drugs Frequently Used by Medicare and Non-Medicare Enrollees at 1 (Oct. 6, 2004) ("The usual and customary price is the undiscounted price individuals without drug coverage would pay."); GAO, Overview of Approaches to Control Prescription Drug Spending in Federal Programs (June 24, 2009) ("The usual and customary charge for a drug is the full retail price that individuals without prescription drug coverage pay when purchasing drugs at a retail pharmacy."); HHS OIG, A Comparison of Medicaid Federal Upper Limit Amounts to Acquisition Costs, Medicare Payment Amounts, and Retail Prices at 7 n.26 (Aug. 2009) ("If the pharmacy charges a fee to join their discount generic program, CMS does not have a stated policy as to whether the prices charged under that program would

meet the definition of a usual and customary charge to the public."); GAO, Medicaid Prescription Drugs (Dec. 2013) ("The usual and customary charge for a drug is the full retail price that individuals without prescription drug coverage pay when purchasing drugs at a retail pharmacy.").

Each of these sources supported Respondents' understanding of their regulatory obligations during the relevant time period and confirm that their interpretation of "usual and customary" was objectively reasonable.

B. No Authoritative Guidance Existed to Warn Respondents Away from Their Interpretation.

The second step of the *Safeco* analysis considers whether, notwithstanding regulatory ambiguity, authoritative guidance should have "warn[ed]" a defendant away from its otherwise objectively reasonable legal interpretation. 551 U.S. at 70, n.19. This step makes clear that *Safeco* is far from the blanket invitation to "plunder" statutory ambiguities that Petitioners portray. Pet. Br. at 51. To the contrary, the second step places the burden to clarify ambiguities where it belongs—with regulators who can end regulatory uncertainty by providing specific, authoritative guidance on the subject. *Safeco* shields parties from FCA liability only when regulators abdicate that role and remain silent.

That is what happened here. For years, a portion of the retail pharmacy industry operated discount savings programs and allowed ad hoc price matching in full view of state and federal regulators. Those regulators and lawmakers could have enacted amendments or engaged in

rulemaking to clarify the relationship between a pharmacy's "usual and customary" price, its club membership prices, and the price-matched prices of its competitors. But they did not. The most Petitioners can point to is a later-removed footnote in the CMS MPDB Manual finding "usual and customary" charges in Wal-Mart's $4 generic savings program, under which *all* patients automatically received lower prices. Pet. Br. at 51-52.[4] As the Seventh Circuit correctly reasoned, this non-binding and buried "guidance" was insufficiently "authoritative" to warn Safeway and SuperValu away from their interpretations of "usual and customary." *Supervalu*, 9 F.4th at 472; *Safeway*, 30 F.4th at 662.

Petitioners complain that the Seventh Circuit "made up" its requirements for specificity and authoritativeness, Pet. Br. at 51, but those elements spring directly from *Safeco*. This Court embraced those limitations by describing decisions from the courts of appeals or "authoritative" guidance from the applicable agency as the kind of circumstances that could "warn away" an otherwise reasonable interpretation, while also rejecting the relevance of a "non-binding" letter from an agency. *Safeco*, 551 U.S. at 70. Similarly, specificity and authoritativeness are well known principles in the context of qualified immunity for officials sued under § 1983. In that arena, it is well-settled that the otherwise ambiguous contours of a legal right will be deemed "clearly established" only if there existed controlling authority, or at least a "robust

[4] The footnote was removed in 2013, during the time period in which Respondents operated their programs. Petitioners are silent as to how that removal should be interpreted.

consensus of cases of persuasive authority," to warn officers away from their challenged conduct with a "high degree of specificity." *D.C. v. Wesby*, 138 S. Ct. 577, 589-90 (2018); *see also Ashcroft v. al-Kidd*, 563 U.S. 731, 741 (2011) ("[E]xisting precedent must have placed the statutory or constitutional question beyond debate.").

This appeal illustrates why a similar rule requiring guidance to be authoritative and binding is needed in the context of the FCA. As discussed in the preceding sections, a voluminous amount of non-binding guidance *supported* Respondents' interpretation of "usual and customary." *See supra,* Part II(A). It is simply unrealistic to hold defendants to a single contrary non-binding authority under such circumstances, as Petitioners suggest. Moreover, such guidance can be propounded or rescinded at will and without warning or explanation—as the CMS MPDB footnote was in this case. *See Safeway,* 30 F.4th at 662 (observing that "the footnote was removed in 2013—two years before Safeway ended its discount programs and price-matching nationwide"). Requiring retail pharmacies to adjust instantaneously to such fleeting and contradictory instructions is neither realistic nor fair, and calling a failure to do so as fraud is indefensible.[5]

[5] The actions of Texas in recent years represent the danger of the rule proposed by Petitioners and the Government. For years, the state of Texas has defined "usual and customary" to mean "the price the provider most frequently charges the general public for the same drug." 1 Tex. Admin. Code § 355.8544. This ambiguous regulation did not provide pharmacies fair notice that "discount savings club" prices had to be treated as the "usual and customary" price, and there is ample evidence that Texas understood as much. Nevertheless, Texas has

For all these reasons, a defendant's objectively reasonable interpretation of an ambiguous law should protect it from FCA liability unless specific, authoritative guidance—in the form of binding appellant precedent from an applicable court or notice and comment rulemaking from the relevant agency—warns that defendant away from its interpretation.

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never amended its definition officially. Instead, it has purported to change the meaning of its definition over time through non-binding edits to its Texas Vendor Drug Program Pharmacy Provider Procedure Manual—and sued pharmacies that failed to predict those changes for fraud. *See, e.g., State of Texas ex rel. Winkelman, et al. v. CVS Health Corp., et al.*, No. D-1-GV-14000388 (126th Judicial District, Travis Cnty., Tex. 2017).

Separately, in May 2020, as retail pharmacies were scrambling to help this country manage the onset of the COVID-19 pandemic, Texas purported to announce additional sweeping changes to the meaning of "usual and customary" through additional edits to its Provider Manual. In direct contradiction to the actual regulation still in effect, these changes included, but were not limited to: (1) requiring pharmacies to "automatically" submit their club membership pricing as their "usual and customary" charge, without respect to the frequency of the charge; (2) declaring that "advertised" prices count as prices "charged" to the public even if no patient ever paid them; and (3) requiring pharmacies to adopt the prices obtained under third-party discount cards (over which pharmacies exercise no control) as the pharmacy's own "usual and customary" price. No new legislation or notice and comment rulemaking accompanied these changes. Nevertheless, under the rule proposed by Petitioners and the Government, every pharmacy operating in Texas may be at risk of being accused of fraud for failing to anticipate them.

Here, it is undisputed that such specific authoritative guidance did not exist during the time that Respondents operated their respective discount club and price-matching programs. Indeed, the first authoritative guidance from an appellate court became final only after Respondents *ended* their challenged programs. *See Garbe*, 824 F.3d 632 (certiorari denied January 9, 2017). But even as the *Garbe* court held that discount club programs should be considered in determining a "usual and customary" price, the paucity of authority cited in support of that proposition reinforced the lack of binding government guidance. *Id*. at 643.[6]

C. The Erroneous Analysis of *Garbe* Reinforces the Need for an Objective Scienter Standard.

No other federal court of appeals has weighed in on the meaning of "usual and customary" since *Garbe*. Even though the question of *Garbe* is not squarely presented, the validity and reasoning of *Garbe* directly bears on the reasonableness of Respondents' prior interpretations of their legal obligations in this case. Rather than showing an obvious meaning of "usual and customary," *Garbe*'s errant analysis only highlights the convoluted regulatory environment facing pharmacies and the reasonableness of Respondents' conduct in this case.

Further, the analysis in *Garbe* is unmistakably flawed. Medicaid jurisdictions across the country define "usual and

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[6] Even the procedural posture of *Garbe*—an interlocutory appeal under 28 U.S.C. § 1292(b) granted in light of "substantial ground for difference of opinion"—suggested the lack of authoritative guidance. *See* 824 F.3d at 635.

customary" differently and their definitions reflect widely diverging approaches to reimbursement. *Cf.* Conn. Agencies Regs. § 17-2-95 (directing pharmacies to exclude third-party payors when determining "usual and customary" price) *with* Mass. State Plan Amendment #06-005, 4.19-B, p. 1b (eff. July 1, 2006) (directing pharmacies to look at only third party/insured payors in determining "usual and customary" price). Indeed, as the federal government once recognized, not only do "States define the usual and customary charge differently," the fact that "usual and customary charges are based on the prices the individual pharmacy charges" means that a pharmacy chain's usual and customary price for a given drug "can vary among pharmacies within the same State." *See* HHS OIG, Variation in State Medicaid Drug Prices (Sept. 2004) at 19-20 (recognizing that "States define the usual and customary charge differently"). Notwithstanding this widely recognized fact, the entire evaluation of "usual and customary" in *Garbe* rests on the unfounded premise that the term has a single definition across all fifty-two Medicaid jurisdictions which, despite complete silence on the subject, required pharmacies to treat members of enrollment-based discount clubs as members of the "general public." 824 F.3d at 644-45.

The *Garbe* decision likewise reflects a fundamental misunderstanding of Medicare Part D. The opinion cited three unrelated regulations as establishing a top-down, federal definition of "usual and customary" under the Part D program. 824 F.3d at 644-45. But the only case cited for that conclusion was a district court decision from 1999—four years before the Part D program was created. *Id.* at

644 (citing *United States v. Brunos, Inc.*, 54 F.Supp.2d 1252, 1257 (M.D. Ala. 1999)). In truth, the meaning of "usual and customary" and all other pricing issues are a matter of contract between pharmacies and the private PBMs who serve as plan sponsors under the Part D program. CMS not only plays no role in these contractual negotiations, it is *forbidden* by law from interfering with them. *See* 42 U.S.C. § 1395w-111(i) ("Noninterference").

At bottom, *Garbe* and its flaws illustrate the challenging regulatory complexities faced by pharmacies. Retail pharmacies adjudicate millions of claims every day that are subject to a myriad of regulations that can apply different meanings to the same terms. Moreover, the infirmity of *Garbe*'s analysis underscores the reasonableness of Respondents' interpretations of "usual and customary." And, properly understood through the *Safeco* analysis, those reasonable interpretations preclude a finding that Respondents knowingly submitted false claims.

CONCLUSION

The judgments below should be affirmed.

Respectfully submitted,

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