# SUPREME COURT ISSUES DECISION REGARDING FALSE CLAIMS ACT'S SCIENTER ELEMENT

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**US Health Care and FDA Alert**

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*The United States Supreme Court recently held that a defendant's subjective belief is always relevant to the False Claims Act's scienter element, regardless of what an objectively reasonable person may have believed. This means that an objectively reasonable interpretation of a requirement can still result in False Claims Act liability if accompanied by evidence that a defendant thought the claim was inaccurate at the time of submission. In practice, the holding means that it will be increasingly difficult for defendants to prevail in False Claims Act litigation as to scienter at the motion to dismiss stage. Instead, any fight regarding scienter will need to be made with discovery, in motions for summary judgment, and at trial. For health care providers and government contractors, the holding also confirms entities should carefully consider (1) carefully and contemporaneously documenting their interpretations of ambiguous provisions and should consider (2) whether adopting a more conservative interpretation of an ambiguous provision and/or inquiring with the relevant agency as to the "correct" interpretation is the safest course of action given potential reduction in enforcement risk.*

## INTRODUCTION

On 1 June 2023, the United States Supreme Court in the case of *United States ex rel. Schutte v. SuperValu* issued one of the most anticipated decisions in federal False Claims Act (FCA) jurisprudence in years. In a unanimous opinion drafted by Justice Clarence Thomas, the Supreme Court addressed what constitutes a "knowing" violation of the FCA. Focusing on the "usual and customary" price requirement for reimbursement under Medicare and Medicaid, the court held that the FCA's scienter element "refers to the respondents' knowledge and subjective beliefs—not to what an objectively reasonable person may have known or believed."[1]

## BACKGROUND & PROCEDURAL HISTORY

The narrow question before the court was "whether respondents could have the requisite scienter under the FCA if they correctly understood that standard and thought their claims were inaccurate."[2] In other words, did the FCA's scienter element ignore the respondents' subjective belief where their actions fell within an objectively reasonable interpretation?

Before the court were two consolidated FCA cases from the Seventh Circuit, *United States ex rel. Schutte v. SuperValu*[3] and *United States ex rel. Proctor v. Safeway*.[4] *SuperValu* concerned a large retail pharmacy, which billed Medicare Part D (the prescription drug arm of Medicare) and Medicaid from 2006 to 2016.[5] Under the relevant Medicare and Medicaid programs, the reimbursement for certain drugs is often capped at the providers' "usual and customary" charge for the drug.[6] Relators alleged that during that decade, SuperValu created a price-

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match program whereby, upon a customer's request, it would match a competitor's lower prescription drug price.[7] Once the customer asked for the price match, SuperValu would then automatically apply the price-matched value to all of the customer's refills.[8] SuperValu, however, would then bill Medicare and Medicaid its standard higher retail price, rather than the discounted, price-matched amount it accepted from customers.[9] Based on those allegations, in 2011, relators filed an FCA complaint alleging that SuperValu "price-matched to avoid losing customers to competitors with lower drug prices . . . and made up the difference by charging the government healthcare programs its higher retail price."[10]

The district court granted partial summary judgment against SuperValu on the falsity prong of the FCA.[11] The district court found that the discounted prices were the "usual and customary" prices and that in not reporting the discounted prices—but rather billing Medicare and Medicaid for the higher retail price—SuperValu submitted false claims. In applying the holding in *Safeco Insurance Co. of America v. Burr*[12] —a Supreme Court case regarding the Fair Credit Reporting Act (FCRA)—however, the district court ultimately entered summary judgment in favor of SuperValu on the scienter prong of the FCA,[13] which requires that the defendant act "knowingly" in order for FCA liability to attach.[14] The district court held that, under *Safeco*, SuperValu's understanding of the "usual and customary" price, while ultimately incorrect, was objectively reasonable at the time the defendant relied upon it.[15] Consequently, the district court entered summary judgment in favor of SuperValu on all FCA claims.[16]

On appeal, the Seventh Circuit Court of Appeals affirmed, finding that an FCA "defendant who acted under an incorrect interpretation of the relevant statute or regulation did not act with reckless disregard if (1) the interpretation was objectively reasonable and (2) no authoritative guidance cautioned defendants against it."[17] The Seventh Circuit held that "companies could not have acted 'knowingly' if their actions were consistent with an objectively reasonable interpretation of the phrase 'usual and customary.'"[18] Importantly, the Seventh Circuit held that this was so even where—as relators alleged—the defendant subjectively did not believe its interpretation was correct.[19]

The other case before the Supreme Court was *Safeway*, in which the defendant, also a retail pharmacy, was accused by a relator of failing to account for various types of discounts in reporting its "usual and customary" price to Medicare and Medicaid.[20] As in *SuperValu*, the district court in *Safeway* relied on the *Safeco* opinion to grant summary judgment to the defendant based on scienter.[21] On appeal, the Seventh Circuit affirmed the district court's opinion, nothing that, "[i]n doing so, [it] joined every other circuit to address the issue."[22]

On 13 January 2023, the Supreme Court granted certiorari in both *SuperValu*[23] and in *Safeway*,[24] consolidating the actions. Oral arguments took place on 8 April 2023.[25] Foreshadowing the unanimous opinion, justices across the political spectrum seemed to agree that *SuperValu* presented a fairly straightforward and simple question of whether subjective belief is ever relevant to the FCA scienter inquiry. With their opinion, the Supreme Court confirmed the answer to be an emphatic "Yes".

## THE OPINION

In its unanimous opinion in *SuperValu*, the Supreme Court held that "[w]hat matters for an FCA case is whether the defendant knew the claim was false. Thus, if respondents correctly interpreted the relevant phrase and believed their claims were false, then they could have known their claims were false."[26] The court made clear throughout its opinion that the decision was based squarely in the text of the FCA and the FCA's roots in common-law fraud.[27] Justice Thomas walked through the three mental states of scienter under the FCA—actual

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knowledge, deliberate ignorance, and reckless disregard—noting that this "three-part test largely tracks the traditional common-law scienter requirement for claims of fraud."[28] Before even addressing respondents' arguments, the opinion made clear that "the FCA's standards focus primarily on what respondents thought and believed."[29] Likewise, Justice Thomas maintained that "[b]oth the text and the common law also point to what the defendant thought when submitting the false claim—not what the defendant may have thought after submitting it."[30] In this manner, the court addressed a major theme of the case—that the Seventh Circuit's holdings in *SuperValu* and *Safeway* would create "a safe harbor for fraudsters" where lawyers could conjure up "an innocent explanation" or post hoc justification that might render their claims accurate.[31]

The balance of the opinion laid out respondents' three main arguments and explained why the court found none to be persuasive. First, respondents had argued that the "inherent ambiguity" of the terms "usual and customary" meant that the respondents could not have acted with the requisite scienter.[32] While acknowledging the possible ambiguity, the court held that "ambiguity does not preclude respondents from having learned [the terms'] correct meaning—or, at least, becoming aware of a substantial likelihood of the terms' correct meaning."[33] The alleged facts in this case reflect that the respondents received notices that made them aware of the correct meaning of the phrase "usual and customary." The court noted that both respondents allegedly "received a notice in 2006 from a pharmacy benefit manager stating that the phrase 'usual and customary' refers to discounted prices" and that Safeway "apparently received the same message from state Medicaid agencies."[34] Additionally, in support of its holding, the court laid out an illustrative analogy of a driver who sees a sign reading, "Drive Only Reasonable Speeds." The court reasoned that, while the term "reasonable" may be ambiguous, the driver could learn what constitutes an unreasonable speed from police or from the speed of surrounding vehicles.[35] That analogy aside, the court made clear that the "facial ambiguity" of a statute, regulation, or other relevant language "does not by itself preclude a finding of scienter under the FCA."[36]

Second, the court addressed *Safeco*, which had been relied on by both the Seventh Circuit and respondents in briefing before the Supreme Court. Respondents had argued that, because the FCA and FCRA contain the same common-law terms, *Safeco*'s interpretations of "knowing" and "reckless" should be applied in the FCA context.[37] The Supreme Court distinguished *Safeco* given that it interpreted a different statute, FCRA, which had a different mens rea standard of "willfully." The court held that "[t]o take *Safeco* as establishing categorical rules for [knowingly and reckless] would accordingly 'abandon the care we have traditionally taken to construe such words in their particular statutory context.'"[38] Citing to a previous decision of the court—which had declined to apply *Safeco* in the patent infringement context—the court noted, "'[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.'"[39]

Finally, respondents had argued that at common law, respondents' claims would not be fraudulent given they were mere misrepresentations of law rather than misrepresentations of fact.[40] The court noted that it "assume[d] without deciding that the FCA incorporates some version of this rule" that mere misrepresentations of law are not actionable.[41] But, the court noted that, where a statement implies something about "facts that justify" a speaker's statement, it may constitute a misrepresentation of fact.[42] Here, the court found that respondents had essentially said, "'this is what our usual and customary prices are,'" which carried with it an implied statement of facts.[43]

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## THE IMPACT

The fallout from the decision will be seen in the years to come as district courts grapple with how to apply *SuperValu*. There is a possibility that courts will apply *SuperValu* narrowly and, as a result, the impact could be somewhat minimal. As the court emphasized, the question presented was a very limited one: "If respondents' claims were false and they actually thought they were false . . . then would they have 'knowingly' submitted a false claim within the FCA's meaning?"[44] District courts will be left to determine how subjective belief and objective reasonableness interact in the face of ambiguous language where a defendant does not actually think their claims were false and an objectively reasonable interpretation exists.

Some impacts of the decision are more concrete, however. The decision made clear that a defendant facing FCA liability cannot prevail solely by pointing to an unidentified/hypothetical "reasonable person" who might have interpreted the provision in a different way than the defendant. Rather, the defendant's subjective belief is critical to the scienter analysis. On a practical level, the relevance of a defendant's subjective belief means that defendants no longer have an opportunity for a knockout blow in the early stages of a case, particularly at the motion to dismiss stage, on scienter-related grounds. Instead, the battleground on scienter will likely have to be fought in discovery, in motions for summary judgment, and at trial.

While the true impacts of *SuperValu* will likely take years to fully develop, the uncertainties it has created are more apparent. In clarifying scienter, the court may have inadvertently created uncertainty as to the "deliberate ignorance" and "reckless disregard" standards for scienter under the FCA. In discussing "deliberate ignorance," the court cited to a nineteenth century English case, *Derry v. Peek*, stating that in "capturing the FCA's use of the term 'deliberate ignorance,' that decision noted that an action for fraud would lie if 'a person making a false statement had shut his eyes to the facts, *or purposely abstained from inquiring into them*.'"[45] Later in the conclusion, the court explained that a petitioner may establish "deliberate ignorance" by showing that the respondents "were aware of a substantial risk that their higher, retail prices were not their 'usual and customary' prices and intentionally avoided learning whether their reports were accurate[.]"[46] Thus, it appears from the court's explanation that, if there is an ambiguous regulation and a "substantial risk" that the preferred interpretation could be incorrect, then a duty exists to inquire or take further actions to determine the "correct" interpretation of the language in question. This could mean that, in a situation where an entity is unsure as to meaning of a term or phrase, the entity should either adopt the more conservative interpretation or make a good faith attempt to inquire with the relevant agency as to the "correct" interpretation.

Additionally, the court's discussion of "reckless disregard" in *SuperValu* was vague and void of clear guidance. The court stated that reckless disregard "captures defendants who are conscious of a substantial and unjustifiable risk that their claims are false, but submit the claims anyway."[47] As a large portion of FCA cases involve reckless disregard, the court's failure to define what it considers to be a "substantial and unjustifiable risk" is likely to create future litigation. As with the uncertainty surrounding "deliberate ignorance," a potential course of action is to inquire with the relevant agency as to the "correct" interpretation of the term or phrase. That course of action, however, could quickly be used against a party in establishing the party's subjective belief at the time the claim is submitted.

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## TAKEAWAYS

The court made one thing certain—a defendant's subjective belief at the time a claim is submitted is critical to the scienter analysis. Careful and contemporaneous documentation of a party's belief at the time of claim submission will be an ever more heavily scrutinized component in defending an FCA case after *SuperValu*. This will likely involve thorough tracking of a party's interpretation of an ambiguous provision and the reason behind such an interpretation. To do so, providers and contractors will also need to ensure that they keep abreast of regulatory and sub-regulatory guidance.

Additionally, and as noted above, where a provider or contractor is unsure as to meaning of a term or phrase, *SuperValu* suggests that the safest course of action is to either adopt the more conservative interpretation or make a good faith attempt to inquire with the relevant agency as to the "correct" interpretation. Such an approach could help to mitigate enforcement risk given the relevance of subjective intent and the present lack of clarity on how courts will view subjective intent's interplay with ambiguous terms or phrases. If the government does not respond to an inquiry, the provider or contractor should document both the attempt to seek guidance and its interpretation in light of the government's failure to respond.

Relatedly, *SuperValu* has reinforced the need for providers and contractors to proactively seek legal advice in order to effectively show their subjective belief where ambiguity may exist. K&L Gates' health care fraud and enforcement team will continue to closely monitor how the FCA's scienter standard develops in the lower courts following the *SuperValu* decision.

## FOOTNOTES

[1] *United States ex rel. Schutte v. SuperValu, Inc.*, 598 U.S. ___ (June 1, 2023).

[2] *Id*. at 2.

[3] *United States ex rel. Schutte v. SuperValu, Inc.*, 9 F.4th 455 (7th Cir. Aug. 12. 2021), *cert. granted*, 143 S.Ct. 644 (Jan. 13, 2023).

[4] *United States ex rel. Proctor v. Safeway, Inc.*, 30 F.4th 649 (7th Cir. Apr. 5, 2022), *cert. granted*, 143 S.Ct. 643 (Jan. 13, 2023).

[5] *SuperValu*, 9 F.4th at 461.

[6] *SuperValu*, note 2, at 1.

[7] *Id*.

[8] *SuperValu*, note 2, at 4.

[9] *SuperValu*, 9 F.4th at 461–62.

[10] *Id*. at 462.

[11] *Id*.

[12] 551 U.S. 47 (2007).

[13] *SuperValu*, 9 F.4th at 462.

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[14] 31 U.S.C. § 3729(a)(1)(A).

[15] *SuperValu*, 9 F.4th at 462–63.

[16] *Id*. at 463.

[17] *Id*. at 464.

[18] *SuperValu*, note 2, at 2.

[19] *SuperValu*, 9 F.4th at 466 ("In the absence of textual indicia in the FCA supporting that subjective intent matters here, we apply Supreme Court precedent to interpret the same common law terms addressed in Safeco.").

[20] *Id*. at 654–57.

[21] *Id*. at 657.

[22] *Id*. at 657–58 (citing *United States ex rel. Streck v. Allergan*, 746 F. App'x 101, 106 (3d Cir. 2018); *United States ex rel. McGrath v. Microsemi Corp.*, 690 F. App'x 551, 552 (9th Cir. 2017); *United States ex rel. Donegan v. Anesthesia Assocs. of Kan. City, PC*, 833 F.3d 874, 879–80 (8th Cir. 2016); *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 284 (D.C. Cir. 2015); *United States ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340, 344 (4th Cir. 2022)).

[23] 143 S.Ct. at 644.

[24] 143 S.Ct. at 643.

[25] *See United States ex rel. Schutte v. SuperValu, Inc.*, No. 21-1326, Dkt No. 108 (S.Ct. Apr. 18, 2023).

[26] *SuperValu*, note 2, at 2.

[27] *See* id. at 2, 8–17.

[28] *Id*. at 9.

[29] *Id*. at 10.

[30] *Id*. at 11 (emphasis in original).

[31] *SuperValu*, 9 F.4th at 476 (Hamilton, J., dissenting).

[32] *SuperValu*, note 2, at 12.

[33] *Id*.

[34] *Id*. at 5.

[35] *Id*.

[36] *Id*. at 13.

[37] *Id*.

[38] *Id*. (quoting *Jerman v. Carlisle, McNellie, Rini, Kramer & Ulrich, L.P.A.*, 559 U.S. 573, 585 (2010)).

[39] *Id*. at 14 (quoting *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 579 U.S. 93, 106 (2016)).

[40] *Id*. at 14–15.

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[41] *Id*. at 15.

[42] *Id*. at 15–16.

[43] *Id*. at 16.

[44] *Id*. at 7.

[45] *Id*. at 9 (quoting *Derry v. Peek*, [1889] 14 App. Cas. (emphasis added)).

[46] *SuperValu*, note 2, at 16.

[47] *Id*. at 2.

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