Portfolio Media. Inc. | 230 Park Avenue, 7th Floor | New York, NY 10169 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Checking In On How SuperValu Has Altered FCA Litigation

By **Elena Quattrone and Olivia Plinio** (September 25, 2023, 5:19 PM EDT)

Elena Quattrone

Olivia Plinio

On June 1, in the case of U.S. ex rel. Schutte v. SuperValu Inc.[1] and its companion case, U.S. ex rel. Proctor v. Safeway Inc., the U.S. Supreme Court, in a decision authored by Justice Clarence Thomas, **unanimously settled** a long-standing dispute over a subjective versus objective standard for scienter under the False Claims Act, holding that a defendant's own subjective belief is relevant to scienter, rather than what an objectively reasonable person may have known or believed.

In its wake, the SuperValu decision spawned reaction and analysis from across both the plaintiffs and defense bars, with attorneys opining on the impact of the SuperValu decision, its clear win for relators and the limitations on, or opportunities it presents to, defendants responding to allegations of FCA violations.

Though much can be speculated about the impact of SuperValu and the significance of the Supreme Court's decision, its reach may be more limited than initially anticipated. In this article, we examine the impact of SuperValu and subsequent interpretations of the holding, now almost four months after the decision, and what can be expected going forward when facing FCA liability.

Background on SuperValu and the Legal Standard

SuperValu, which was consolidated from two lower court decisions, involved allegations that the defendants, two retail pharmacy chains, overcharged the government for prescription drugs in violation of the FCA when it reported the full retail price of prescription drugs as their usual and customary price, when it was actually providing those drugs to patients at a significant discount.

The relators alleged that the pharmacies were overcharging Medicaid and Medicare for prescription drugs in violation of the FCA by submitting amounts as their usual and customary prices that did not reflect the significantly discounted prices that their retail customers often actually paid.

Pursuant to the FCA, a defendant may be held liable for an FCA violation if the defendant "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval."

"Knowingly" is defined as acting with (1) actual knowledge of the falsity, (2) deliberate ignorance of the truth, or (3) reckless disregard of the truth.[2] In the context of SuperValu, the usual and customary standard set forth by the Centers for Medicare & Medicaid Services is susceptible to multiple interpretations in connection with prescription drugs, making it more of a challenge to prove the defendant had the requisite scienter if the defendant's actions were consistent with one of the objectively reasonable interpretations of the standard.

The Supreme Court agreed to hear the case after the U.S. Court of Appeals for the Seventh Circuit held in favor of the defendants in August 2021, finding that when a defendant's interpretation is considered objectively reasonable, the defendant's subjective intent is irrelevant to the scienter inquiry under the FCA.[3]

Resoundingly rejecting the Seventh Circuit's interpretation, and resolving a long-standing circuit split, the Supreme Court emphasized that in regard to FCA cases, the defendant's subjective knowledge of the falsity of the claim is what is determinative.

Under the SuperValu standard, the Supreme Court's decision expanded the FCA scienter standard, essentially holding that the FCA may now reach defendants who knew that the claims they submitted were fraudulent, even if such defendants subsequently offered an objectively reasonable interpretation of a requirement material to the government's payment decision.

The Supreme Court further clarified that what defendants actually thought and believed at the time of claims submission, as opposed to what the defendants may have thought after submitting claims or any post-submission interpretations that might have rendered such claims accurate, is what is controlling.

The court defined the "reckless disregard" standard as "captur[ing] defendants who are conscious of a substantial and unjustifiable risk that their claims are false, but submit the claims anyway," arguably an expansion of the objective standard previously adopted by a number of circuits.[4]

Benefits for the Defense Bar

Despite the Supreme Court's expansion of the scienter standard, Justice Thomas' opinion offers several consolation prizes for FCA defendants. Such prizes can be viewed as potential tools for defending similar FCA cases following SuperValu — some of which have already been relied on since June 1.

For instance, Justice Thomas opined in the SuperValu decision that one potential avenue for a defense to FCA liability based on knowledge is a good faith, even if mistaken, interpretation of the terms of a requirement material to the decision to pay.

Justice Thomas further remarked that even some objectively unreasonable interpretations may avoid liability if a defendant believes such interpretations to be accurate, stating "[t]he FCA's scienter element refers to respondents' knowledge and subjective beliefs — not to what an objectively reasonable person may have known or believed."

In this regard, the focus on what a defendant actually believed or knew at the time of the submission of a claim, rather than what an objectively reasonable person would have understood, could very well end up benefiting future unwitting defendants in their defense of FCA suits.

Impact of SuperValu on Future FCA Litigation — 90 Days After and Beyond

Reliance on the SuperValu Standard

Whether looked at as a benefit or detriment to defendants, the decision in SuperValu effectively prevents defendants from citing to hypothetical reasonable interpretations of submitted claims to avoid liability.

In the short time since the decision in SuperValu, the FCA defense bar has attempted to confront these challenges on behalf of defendant companies facing government investigations under the FCA, homing in on the precise meaning of "recklessness" as it relates to a defendant's scienter under the FCA in a series of test cases, described further below.

For example, in its brief in support of a motion to dismiss, filed in the U.S. District Court for the Western District of Virginia on June 23 in the case U.S. ex rel. Miller v. Reckitt Benckiser Group PLC, a pharmaceutical company defendant, Indivior, argued that SuperValu established a three-part test for reckless disregard, covering defendants who are "[1] conscious of a [2] substantial and [3] unjustifiable risk," that the billing is not in line with compliance duties, and plaintiffs must show each element to meet their pleading burden.[5]

This defense-friendly standard advocated for by the defendant inspired the U.S. Department of Justice to file a statement of interest response brief in the matter.

In its brief, the DOJ argued that SuperValu "clearly did not intend to place new limitations" on what constitutes scienter under the FCA, nor were the justices attempting to place additional pleading hurdles on whistleblowers and government intervenors. Rather, they were "simply drawing from and reaffirming existing standards for proving knowledge, and not establishing new and restrictive criteria."[6]

In another test case out of the U.S. Court of Appeals for the Ninth Circuit — designated as such due to it testing the impact and reach of SuperValu — involving the FCA's role in customs fraud, Sigma Industries, a supplier of water and wastewater infrastructure products, is alleged to have submitted false statements to U.S. Customs and Border Protection to avoid paying anti-dumping duties on pipe fittings imported from China.[7]

Sigma argued that it had not acted knowingly under the FCA, as its interpretation of the anti-dumping order in question was objectively reasonable. The case was stayed pending SuperValu, after which the Ninth Circuit requested the parties submit supplemental briefs addressing the effect of SuperValu on the case.

The Ninth Circuit has not yet commented on these briefs, but the case is being monitored to see how the SuperValu decision will affect this FCA case, especially in a non-health care setting.

Defense attorneys will have even more attempts to assess the impact of SuperValu as previously paused FCA cases are remanded in light of the SuperValu decision, including cases against Allergan and Abbott Laboratories in the U.S. Courts of Appeal for the Fourth and Eleventh Circuits.

In both cases, the defendants' motions to dismiss were granted by district courts in November 2020 and August 2020, respectively, citing the plaintiffs' failure to meet the scienter standard, and each decision was upheld at the appellate level. Now, the whistleblowers in both cases have another chance to argue scienter in the wake of the Supreme Court's decision should they decide to pursue this option.

Creative Arguments Involving Dicta From SuperValu

SuperValu's impact extends even beyond its scienter holding, with ambitious litigants parsing through the dicta of the decision to extend the case's impact as far as possible.

In a recent example from June 2023, in a case against Teva Pharmaceuticals in the U.S. District Court for the District of Massachusetts, U.S. v. Teva Pharmaceuticals USA et al., the DOJ relied on SuperValu's holding in an attempt to resolve a circuit split between the U.S. Courts of Appeal for the Third and Eighth Circuits relating to interpretation of causation under the Anti-Kickback Statute.

In its brief to the court, the DOJ cited to SuperValu, which, in dicta, stressed the importance of construing words in their particular statutory context. The DOJ cited to the SuperValu dicta as support that the court should not consider the causation standard established by the Controlled Substances Act when attempting to parse the causation standard of the AKS.

The district court ultimately denied Teva's motion for summary judgment and granted the government's partial summary judgment motion on July 14, declining to apply the causation standard established by the CSA, arguably giving weight to the DOJ's arguments regarding the importance of statutory context established in SuperValu.

Following the summary judgment rulings, Teva petitioned the district court to certify an interlocutory appeal to the U.S. Court of Appeals for the First Circuit on the causation standard question. Such petition has been fully briefed, and both parties are awaiting a ruling by the First Circuit.

Procedural Impact and Hurdles for Future Litigants

The shift in perspective established by SuperValu suggests that defendants will have hurdles to overcome when litigating against allegations of FCA violations.

For example, efforts by defendants to obtain early dismissal of FCA cases on the basis of lack of

scienter may become more challenging in future cases, as questions of intent will be highly fact-sensitive, requiring close review of defendant communications and documentation, as well as extensive deposition testimony.

Qui tam relators will bear the brunt of this additional discovery, but it is the defendants who will likely suffer the fallout of exhaustive inquiries.

In addition, the shift from an objective to a subjective standard means that defendants may find it more difficult to avoid liability under the new FCA standard as the focus shifts from hypothetical reasonable interpretations to measures of belief indicated by defendants' actual words and conduct.

On the other hand, the newly established standard will not protect those defendants who are on notice that their "subjectively reasonable" beliefs are not in line with established law. A defendant may subjectively believe that their interpretation of a statute is reasonable, but if they are on notice that such interpretation is improper, they will not be saved by their belief under the SuperValu standard.

For companies facing potential FCA liability, the decision in SuperValu creates even more uncertainty around compliance with ambiguous laws and regulations that are so common in the heavily regulated industry of health care, and beyond.

Best Practices for Compliance and Avoidance of Potential FCA Liability

Ultimately, the SuperValu decision will have a widespread impact on future FCA cases. Those operating in the health care space, and those contracting with the government in general, should take preemptive steps to protect against future FCA suits.

Best practices should include making good faith efforts to reasonably interpret and comply with all relevant legal and contractual provisions related to the government's decision to pay claims, and documenting such interpretations at the time of claim submission.

Additionally, effective compliance programs may help to stem the risk of future FCA liability by identifying areas of risk before they rise to the level of an FCA suit.

Those operating in the health care space, especially those at risk of FCA suits, should be prepared to make arguments for the element of scienter.

In addition, as FCA cases continue to move through the lower courts in the wake of SuperValu, litigants and would-be future litigants would do well to keep an ear to the ground on future impactful decisions relying upon SuperValu that may shape the FCA litigation.

Elena M. Quattrone is senior counsel and Olivia Plinio is an associate at Epstein Becker Green.

[1] https://www.supremecourt.gov/opinions/22pdf/21-1326_6jfl.pdf.

[2] 31 U.S.C. § 3729.

[3] https://casetext.com/case/united-states-ex-rel-schutte-v-supervalu-inc-12.

[4] United States ex rel. Schutte v. SuperValu Inc., 143 S.Ct. 1391, 1401 (2023).

[5] United States ex rel. Miller v. Reckitt Benckiser Group PLC, 1:15-cv-00017, Dkt. No. 149 at 10-11 (W.D. Va. July 7, 2023) (quoting United States ex rel. Schutte v. SuperValu Inc., 143 S.Ct. 1391 (2023)).

[6] (United States ex rel. Miller v. Reckitt Benckiser Group PLC,1:15-cv-00017, Dkt. No. 150 at 3 (W.D. Va. July 7, 2023). The Court has yet to issue a ruling on Invidor's motion.

[7] United States of America ex rel. Island Industries, Inc., v. Sigma Corporation .