



Health Law Diagnosis

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[Unanimous Supreme Court Endorses Subjective Belief Standard for False Claims Liability](#)

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On June 1, 2023, the U.S. Supreme Court [issued](#) a unanimous opinion in the highest-profile False Claims Act (FCA) case for many years, concluding that a party's subjective belief as to whether it overcharged Medicare and Medicaid is a factor in determining liability under the False Claims Act.

In *U.S. ex rel. Schutte v. Supervalu Inc.*, the Court held that for purposes of establishing scienter (knowledge) under the FCA, "it is enough if [defendants] believed that their claims were not accurate" [because] "what matters for an FCA case is whether the defendant knew the claim was false." The Court declined to uphold a proposed objective scienter standard under the FCA, and accordingly vacated the underlying Seventh Circuit judgment.

This decision arises from two consolidated qui tam FCA suits against operators of retail drug pharmacies. The suits claimed that the pharmacies violated the FCA by submitting claims to federal health care programs for covered prescription drugs with reported prices that exceeded the "usual and customary" charges for the drugs to the general public. These practices were claimed to violate Medicare and Medicaid regulations that limit pharmacy reimbursement based on a formula that, in part, looks to the pharmacy's "usual and customary charge" to the public as a cap on the amount Medicare or Medicaid may reimburse for the drug. The alleged FCA violations specifically related to discount drug programs offered by these retail pharmacies, and whistleblower claims that (i) the wide prevalence of the discounts on drugs meant that the discounted rate offered to customers became the respective pharmacy's "usual and customary" rate (not the higher non-discounted rate reported by the pharmacies to Medicare and Medicaid), and (ii) the defendants were notified that the discounted prices were the "usual and customary" prices but submitted claims anyway and sought to shield that information from regulators.

The Seventh Circuit upheld judgments in favor of the pharmacies on the basis that they did not knowingly violate the FCA because they acted consistent with an objectively reasonable interpretation of the relevant law (the "usual and customary" requirement), even though it may not have been a correct interpretation. In other words, Seventh Circuit held that the pharmacies' subjective beliefs did not matter because "someone else, standing in the [defendants'] shoes, may have reasonably thought that" their interpretation was accurate.

The Supreme Court rejected the Seventh Circuit's approach, and instead instructed that the answer "is straightforward: The FCA's scienter element refers to [the defendants'] knowledge and subjective beliefs—not to what an objectively reasonable person may have known or believed." To reach this conclusion, the Court observed that the "facial ambiguity" of the phrase "usual and customary" does not by itself preclude a finding of scienter under the FCA. The Court further refused to recognize an "objective safe harbor" against FCA liability proposed by the defendants, and stated that the Court will not "look to legal interpretations that [defendants] did not believe or have reason to believe" when submitting claims to absolve those claims from FCA liability. Pursuant to the decision, scienter may be established in one of three ways: (1) actual knowledge of the falsity of claims; (2) awareness of the substantial risk of the falsity of claims and intentional avoidance of learning whether the claims were accurate; or (3) submission of claims despite an awareness of a substantial and justifiable risk that they are false.

The Court's decision underscores the importance of evidence concerning the actual knowledge and beliefs of health care providers and other organizations that may be subject to FCA liability, including notices from regulators and internal deliberations concerning often-ambiguous or vague regulatory requirements. Interestingly, the decision was authored by Justice Thomas, who also authored the opinion on behalf of a unanimous Supreme Court in the last high-profile FCA case before the Court – the seminal decision in *Universal Health Services v. U.S. ex rel. Escobar*, 136 S. Ct. 1989 (2016) addressing the FCA's materiality standard.

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