2 Recent Decisions Highlight Ambiguity As FCA Defense

By **Elisha Kobre** (February 4, 2022)

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The past year has seen substantial activity by the federal courts in guarding against government overreach in False Claims Act cases. One of the principal areas courts have focused on is the FCA's knowledge requirement — i.e., FCA liability can only be imposed where a person violates the act knowingly.

Two recent decisions, from the U.S. Court of Appeals for the Seventh Circuit and the U.S. Court of Appeals for the Fourth Circuit, clarify the FCA's knowledge requirement in a way that should make it easier for defendants to obtain a dismissal at the early stages of an FCA case and that provide a tool to potentially limit costly discovery for cases that are not dismissed.

In substance, the rule is now established that, absent authoritative guidance otherwise, FCA liability cannot be imposed unless no objectively reasonable reading of the relevant statute or regulation supports the alleged fraudulent claims or relevant representations made to the government. Put another way, the subjective intent of the defendant is irrelevant, and the existence of an objectively reasonable reading of the statute or regulation is a defense to FCA liability.

While several courts of appeal in recent years, either implicitly or in nonpublished opinions, applied this standard, the Seventh Circuit's August 2021 decision in U.S. ex rel. Schutte v. SuperValu Inc., and the Fourth Circuit's decision last month in U.S. ex rel. Sheldon v. Allergan Sales LLC solidified this objective framework as fundamental and clearly established law.

These cases make for a strong defense to FCA claims — particularly those involving the complex statutory or regulatory schemes that abound in the healthcare sector and government contracting.

Both of the recent decisions involve whistleblower claims alleging fraud by pharmaceutical manufacturers or retailers relating to drug pricing in the Medicare and Medicaid programs, undisputedly a complex regulatory scheme.

In Schutte, the relator alleged that the defendant grocery store chain knowingly filed false reports of its pharmacies' usual and customary drug prices when it sought reimbursement under the federal programs. The defendant listed its retail cash prices rather than the lower, price-matched amounts that it charged qualifying customers under its discount program, thereby denying the government the lower prices.

In Sheldon, the relator alleged that the pharmaceutical manufacturer Allergan failed to properly aggregate discounts given to separate customers in the supply chain for purposes of reporting its so-called best price to the government, and thereby likewise denied the government the benefit of the true discounted price.

Applying an objective standard to the FCA's knowledge requirement, the Sheldon court affirmed the dismissal of the complaint and the Schutte court affirmed summary judgment in favor of the defendant.

Both cases reached their results by interpreting the FCA's knowledge requirement in accordance with the U.S. Supreme Court's 2007 decision in Safeco Insurance Co. of America v. Burr, a case interpreting the Fair Credit Reporting Act, a different statute containing a similar knowledge requirement.

Sheldon and Schutte first held that, like the statute at issue in Safeco, the FCA's "reckless disregard" standard must be understood as conduct violating a purely objective standard and set forth a two-step analysis as to reckless disregard: (1) whether the defendant's interpretation was objectively reasonable; and (2) whether "authoritative guidance might have warned defendant away from that reading."

The cases went on to hold that the same two-part test applies to preclude even a finding of actual knowledge, the logic being that the defendant could not have truly known it was acting wrongfully where its conduct was supported by an objectively reasonable interpretation.

The practical import of applying the Safeco framework to the FCA is substantial.

First, the Safeco framework eliminates consideration of an FCA defendant's subjective intent as to its understanding of the relevant statutes or regulations. Because a determination of subjective intent often requires substantial factual development, elimination of the subjective inquiry should make it easier to obtain a dismissal at the initial stages of a case. In other words, the only relevant interpretation of the statutes or regulations are objective ones that can be made by the court on a motion to dismiss.

Second, many regulatory schemes contain inherent ambiguity necessarily lending themselves to more than one objectively reasonable interpretation. Indeed, in some cases, regulatory agencies and will employ what the Fourth Circuit referred to as "strategic ambiguity" to intentionally expand potential liability for regulated entities. Whether intentional or not, this ambiguity often leaves room for multiple objectively reasonable understandings of the regulatory requirements, providing a powerful defense to FCA liability.

Third, because subjective intent is no longer an issue, FCA defendants have a strong argument to preclude or substantially limit discovery as to internal deliberations relating to compliance with regulatory requirements. Such discovery often imposes a substantial and intrusive burden on FCA defendants.

Fourth, most courts have interpreted Safeco's second element — i.e., whether the defendant was warned off of its otherwise objectively reasonable reading by authoritative guidance — to apply only where such guidance has been provided by either (1) the federal courts of appeals; or (2) the relevant agency itself. The complexity and nuance inherent in many areas make this a difficult burden for the government to meet. The guidance must also be sufficiently specific on the point of ambiguity.

The Safeco framework, while undoubtedly favorable to the defense, is nonetheless unlikely to eliminate FCA liability in the mine run of cases.

For one thing, the framework is irrelevant to what the Fourth Circuit terms "factually false claims" — i.e., the paradigmatic FCA action in which someone has submitted an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided. In such cases, the law is clear, there is no ambiguity, and the

Safeco framework made applicable to the FCA in Sheldon and Schutte will not apply.

In addition, Safeco's "objectively reasonable" requirement makes efforts to construct a post hoc strained or questionable reading risky. And, of course, as issues arise, agencies and the courts are likely to issue sufficiently specific guidance to make even an objectively reasonable interpretation unsupportable.

It is also worth noting that both decisions were the subject of lengthy, reasoned and vigorous dissents, and it is certainly possible that they ultimately wind up before the U.S. Supreme Court. This is particularly true given the vast amounts of money at stake for the government in FCA cases.

But for now Sheldon and Schutte provide significant safeguards against government overreach in the FCA context, empower the courts to determine the merits of at least some FCA claims at the dismissal stage, and limit potentially burdensome discovery should an FCA case move forward.

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