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Legal Sidebar

Supreme Court to Consider the Meaning of "Knowingly" Under the False Claims Act

April 13, 2023

On April 18, 2023, the Supreme Court is scheduled to hear arguments in a pair of False Claims Act (FCA) cases involving allegations that retail pharmacies charged the government inflated prices for prescription drugs under Medicare and Medicaid. The FCA is a *qui tam* statute that authorizes private individuals—called *relators*—to sue to recover money on behalf of the government from any person who knowingly submitted false claims to the government for payment. These relators, who are often whistleblowers, are awarded a portion of the proceeds in a successful action or settlement. The cases before the Supreme Court, consolidated as *United States ex rel. Schutte v. SuperValu, Inc.*, concern the scienter, or mental state, element of an FCA violation. Specifically, the Court will consider whether a defendant "knowingly" violates the FCA if it is aware of a substantial risk that its payment submissions might violate a legal requirement but the submissions are also consistent with an objectively reasonable (but wrong) interpretation of that requirement. Stated another way, does the defendant's subjective intent at the time of submission matter if its incorrect interpretation of the legal requirement was objectively reasonable? Resolution of this issue is important not only for guidance in FCA cases—where circuit courts are divided—but potentially also for a variety of federal laws whose civil penalties turn on whether the defendant acted knowingly.

The FCA's Knowledge Standard and the Allegations in *Schutte*

A person is liable for a civil penalty and triple damages under the FCA if the person "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." The FCA defines this scienter requirement, stating that a person acts "knowingly" when, "with respect to information," the person (1) "has actual knowledge of the information," (2) "acts in deliberate ignorance of the truth or falsity of the information," or (3) "acts in reckless disregard of the truth or falsity of the information." Knowledge can be established without "proof of specific intent to defraud."

The *Schutte* case involves two *qui tam* actions on behalf of the federal government and several states. The relators allege that the defendants, operators of hundreds of retail pharmacies, violated the FCA by knowingly reporting a false price for certain prescription drugs in seeking government reimbursement. Specifically, the relators allege that the defendants reported their higher, *retail* prices instead of the lower, *discounted* prices offered to many consumers through price-match and membership programs. This

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LSB10948

practice, according to relators, violated federal and state laws requiring pharmacies to report their "usual and customary" prices (U&C prices) when submitting reimbursement claims through Medicare Part D and Medicaid. Although the federal government has a right to intervene in FCA cases, it did not do so in this litigation. The district court in *Schutte* held, and the defendants did not contest on appeal, that they submitted *false* claims. Instead, the defendants argue that they did not do so *knowingly*.

The Seventh Circuit's Decisions Below

In each of the decisions below, a divided three-judge panel of the Seventh Circuit held that the defendants did not act "knowingly" and thus did not violate the FCA. The court based its reasoning on the Supreme Court's 2007 decision in *Safeco Insurance Co. v. Burr*.

In *Safeco*, the Court interpreted the "willfully" standard in a different federal statute, the Fair Credit Reporting Act (FCRA), to encompass both knowing and reckless mental states. The Court held that the defendant in that case did not act recklessly because its interpretation of the law, though incorrect, was objectively reasonable in light of the "less-than-pellucid" statutory text and the lack of "guidance" from federal appellate courts or regulators. In a footnote that has become central to the *Schutte* case, the *Safeco* Court declined to consider evidence of the defendant's "subjective bad faith." The *Safeco* Court opined that where "the statutory text and relevant court and agency guidance allow for more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation as a knowing or reckless violator."

The Seventh Circuit in *Schutte* applied *Safeco*'s rule because of the similar scienter elements in the FCA and FCRA. The court asked whether the pharmacy defendants' interpretation of the U&C price as excluding certain discounted prices was objectively reasonable, holding that it was. The court concluded that the references to U&C prices in Medicare and Medicaid regulations were susceptible to "multiple interpretations." The court also concluded that no "authoritative guidance" called the defendants' interpretation into question, holding that only "binding precedent" from federal courts of appeals or "sufficiently specific" guidance from the relevant federal agency would qualify as authoritative for purposes of this analysis. Accordingly, the court declined to consider U&C price definitions in state Medicaid programs or contracts with pharmacy benefit managers (private companies that serve as intermediaries between pharmacies and Medicare Part D plan sponsors) as evidence that defendants' interpretation was unreasonable. Although the relators identified an agency manual from the Centers for Medicare and Medicaid Services (CMS) advising pharmacies to treat certain discounted prices as their U&C price, the court did not consider that information authoritative because it appeared in a single footnote and was subject to revision at any time. Ultimately, the court opined that even if the defendants believed they were reporting incorrect U&C prices at the time they submitted their claims, their subjective beliefs could not establish scienter under the FCA because the knowledge "inquiry is an objective one." The court considered its decisions to be consistent with that of four other circuits that applied *Safeco* in evaluating the FCA's scienter element, citing the decisions of the D.C. and Eighth Circuits, and the unpublished, nonprecedential opinions of the Third and Ninth Circuits.

One judge on the Seventh Circuit panels dissented, arguing that a jury could reasonably find, based on internal company documents or circumstantial evidence of price disparities, that the defendants actually knew or deliberately ignored that the prices they reported to the government were not their U&C prices, thus satisfying either of the first two prongs of the FCA's definition of "knowingly." The dissenting judge also found the majority's reasoning inconsistent with the Eleventh Circuit's approach in another FCA case.

Arguments Before the Supreme Court

In their briefing to the Supreme Court, the relators (the petitioners in *Schutte*) and the federal government (participating as amicus curiae) argue that the Seventh Circuit's interpretation of the FCA's scienter requirement is inconsistent with the statute's text, common-law background, and legislative history. They argue that subjective intent is an integral part of both the "actual knowledge" and "deliberate ignorance" prongs of the FCA's definition of "knowingly." According to their reading of the statute's legislative history, Congress added the statutory definition in 1986 to extend liability to government contractors who suspected their claims were false and failed to verify the truth of those claims. The relators and the United States also maintain that the Seventh Circuit erred in relying on *Safeco* because the Supreme Court has explained that courts must evaluate scienter on a statute-by-statute basis. In their view, the FCRA is an inapt comparison to the FCA, because the FCRA incorporates common-law standards of tort liability for reckless conduct, rather than the common-law standards of fraud that underlie the FCA's more capacious definition of knowledge.

The relators and the federal government additionally argue that under Supreme Court precedent, parties who contract with the government have a duty to seek clarification of ambiguous legal requirements in order to present true and accurate claims for reimbursement. The United States posits that the Seventh Circuit's rulings diminish contractors' incentives to seek clarification of their legal obligations, by allowing them to "escape FCA liability simply by identifying wrong-but-reasonable post hoc justifications for their conduct if and when litigation occurs." Both the relators and the government ask the Court to remand the Seventh Circuit's decisions for application of the "appropriate" scienter standard. The relators ask the Court, in the alternative, to hold that a reasonable jury could find that the defendants acted knowingly within the meaning of the FCA, and to remand the cases to the district court for trial.

The pharmacy defendants (the respondents in *Schutte*) argue that "[w]hen the government fails to speak clearly, a regulated party cannot 'know' what the law requires." They maintain that Congress and the regulatory agencies could have, but chose not to, specify how contractors should calculate prescription-drug reimbursement rates under Medicare and Medicaid, or to define U&C prices in a consistent way. They also point out that the government audited them "literally *thousands* of times" while the defendants offered their "well-known" price-matching and membership programs, without ever raising concerns about the defendants' reported reimbursement rates. The defendants advocate for the *Safeco* standard applied by the Seventh Circuit, which, in their view, is consistent with the approach taken by the majority of circuits. According to the defendants, the *Safeco* rule also comports with Supreme Court precedent construing the FCA's scienter requirement strictly in order to provide FCA defendants "fair notice" of prohibited conduct.

Considerations for Congress

A Supreme Court decision in this case could clarify the application of the FCA's scienter element in cases involving disputed legal requirements. If Congress were to disagree with the Court's interpretation of the FCA's scienter standard, it might have the option to amend the statute in accordance with Congress's policy choice. A possible limit on Congress's ability to respond through lawmaking is if the Court grounds its reasoning in the constitutional, due process principle of "fair notice" that the defendants invoke. A decision in *Schutte* might also inform future interpretations of other federal statutes that authorize civil penalties based on "knowing" violations. For example, the Civil Monetary Penalties Law (CMPL) allows the Department of Health and Human Services (HHS) to recover civil penalties from persons who "knowingly" present Medicare claims that the person "knows or should know" contain false information. CMPL regulations define "knowingly" consistently with the FCA's three-prong definition, except that the CMPL definition describes a mental state with respect to *acts*, such as submitting a claim, rather than with respect to *information*. The CMPL's statutory definition of "should know"—which

applies with respect to information—tracks the "deliberate ignorance" and "reckless disregard" prongs of the FCA definition. Additionally, CMPL regulations list "actual knowledge" as an aggravating factor for purposes of determining penalty amounts. If the Court were to hold in *Schutte* that subjective intent at the time of claim submission is irrelevant for FCA liability where the inaccurate part of the claim is consistent with an objectively reasonable interpretation of the applicable legal requirement, that holding could inform how HHS or courts construe the scienter elements in the CMPL or how HHS measures culpability for purposes of assessing penalties under that statute.

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