Published on *The National Law Review* https://natlawreview.com

"Objectively Reasonable" Interpretation Defeats FCA Knowledge in 4th Circuit

Article By:

Lisa M. Noller

Katy E. Koski

Michael J. Tuteur

The Fourth Circuit Court of Appeals is now the latest in a growing number of courts holding that an objectively reasonable interpretation of governing law defeats the requisite element of intent or "scienter" under the False Claims Act (FCA). Since FCA violations must be knowing, the holding is very helpful to defendants seeking to dismiss complaints or win summary judgment.

In United States ex rel. Sheldon v. Allergan Sales, LLC, the Fourth Circuit — like all five other circuits that have considered the issue — found the scienter framework originally set forth by the Supreme Court with respect to the Fair Credit Reporting Act (FCRA) also applies to the FCA. 24 F.4th 340 (4th Cir. 2022), applying *Safeco Insurance Co. of America v. Burr*, 551 U.S. 47 (2007). Under this standard, a defendant cannot be found liable under the FCA if (1) its reading of applicable statutory or regulatory requirements was objectively reasonable and (2) no authoritative guidance warned it away from that interpretation.

The *Sheldon* relator claimed the defendant manufacturer had engaged in an allegedly fraudulent price reporting scheme under the Medicaid Drug Rebate Statute. Under the Rebate Statute, drug manufacturers seeking to have their drugs covered by Medicaid must enter into rebate agreements by which they provide quarterly rebates to states on Medicaid sales of covered drugs. The manufacturer reports the "Average Manufacturer Price" (AMP) and the "Best Price" for covered drugs to the Center for Medicare & Medicaid Services (CMS), and CMS then calculates the rebate amount based on the greater of (1) the statutory minimum rebate percentage or (2) the difference between the AMP and the Best Price. In *Sheldon*, the relator alleged the defendant had failed to aggregate discounts given to separate customers for purposes of reporting the "Best Price" for use in drug rebate calculations and appealed following the district court's dismissal of his complaint. 24 F.4th at 345-46.

While the district court dismissed the relator's complaint for failure to plead both falsity and scienter, the Fourth Circuit addressed only scienter. At the outset, the Court noted its obligation to strictly enforce the FCA's "rigorous" scienter requirement under *Escobar*, as well as the Seventh Circuit's

recent adoption of the objective reasonableness *Safeco* standard in *United States ex rel. Schutte*. *Id.* at 344 (citing *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2002 (2016); *Schutte v. Supervalu Inc.*, 9 F.4th 455 (7th Cir. 2021)). The Fourth Circuit took the same approach as "each and every circuit" considering the applicability of the *Safeco* standard to the FCA, holding there was no reason why the *Safeco* scienter standard for FCRA violations committed knowingly or with reckless disregard should not to apply to the same common law terms used in the FCA. *Id.* at 348.

The *Sheldon* court then held that under the FCA, a defendant cannot act "knowingly" if its actions are based on an objectively reasonable interpretation of a relevant statute or regulation when it has not been warned away from that interpretation by authoritative guidance. *Id.* The court further held the drug manufacturer defendant's interpretation of the Rebate Statute was not only objectively reasonable but the most natural reading of the law — since the statute defined "Best Price" as the "lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity[,]" the plain language indicated that the "Best Price" was one offered to a single entity. *Id.* at 345 (citing 42 U.S.C. § 1396r-8(c)(1)(C)(i)). In addition, no authoritative guidance — either circuit court precedent or guidance from the relevant agency — had warned the defendant away from its interpretation of this language, i.e., CMS never clearly stated that discount aggregation to different entities was required. *Id.* at 353-54.

The Court did specify that this scienter standard does not apply to factually false claims, where the law is clear; rather, the objective reasonableness defense is "narrowly cabined to legally false claims" involve contested statutory and regulatory requirements. *Id.* at 350. This, however, is still a boon to FCA defendants struggling with the seemingly impossible task of navigating complex regulatory landscapes. *Id*. ("If the government wants to hold people liable for violating labyrinthine reporting requirements, it at least needs to indicate a way through the maze.") (internal citation omitted). So, too, is the Fourth Circuit's holding that to function as a warning, authoritative guidance requires "both the right source and sufficient specificity." *Id.* at 353. Not only must guidance issue from circuit court precedent or a relevant agency, but it also must canvass the issue with sufficient specificity to function as a warning. A putative relator cannot simply point to vague or conflicting regulations to establish her FCA case.

Key Takeaways

The *Sheldon* decision is notable as the latest in a trend where defendants in six circuits have defeated the scienter element of an FCA claim by demonstrating their interpretation of the law (whether correct or not) was objectively reasonable. Given its impact on FCA claims, it would be unsurprising if the applicability of the objective reasonableness standard is taken up by additional circuit courts. Even though all circuits currently are in agreement, it remains to be seen whether any other circuits will take a different approach, which then would potentially require review by the Supreme Court.

National Law Review, Volume XII, Number 67