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Dear FBA Health Law Section Members:

As we each look forward to (or, perhaps, brace ourselves for?) the opportunities and challenges that 2023 will bring to our legal practices, I invite us to remember that a noble and effective practice is always oriented towards the service of others. Towards clients? Yes, certainly, first and foremost. But also towards our fellow lawyers—our colleagues in the office, whether seasoned or green; opposing counsel; judges; clerks; and mediators.

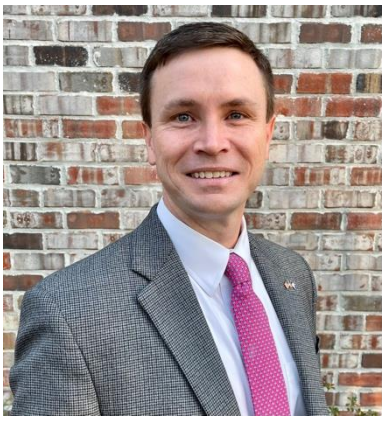
Each of us carries a weight, often unseen, that can feel overwhelming at times. However, we each have the ability to lessen someone else's weight by a kind word, a professional courtesy extended, a commitment to mentoring, a willingness to take on some of the grunt work…the list is endless. Let us resolve this year to see and undertake the (often) small acts of service that make a big difference to those with whom we work.

The Board of the FBA Health Law Section hopes this newsletter offers practical assistance to you in your practice. We welcome your feedback (tschneidau@cityofslidell.org) and would love for you to consider assisting us in our continued efforts to advance the practice of health law.

With kind regards,

Thomas S. Schneidau

Chair, FBA Health Law Section



Scienter to Become Front and Center: Developments in the FCA's Objectively Reasonable Interpretation Defense

By G. Norman Acker, III, Melissa M. Yates, and Michael H. Phillips, K&L Gates LLP

The Significance of the False Claims Act's Scienter Requirement

A direct False Claims Act (FCA) action requires a showing of "(1) a false statement or fraudulent course of conduct, (2) made with scienter [or knowledge], (3) that was material, (4) causing the government to pay out money or forfeit moneys due."[1] In recent years, there has been growing debate surrounding a potential defense to the scienter element—the "objectively reasonable interpretation" defense. That defense asserts that where a hospital or other health care provider has an objectively reasonable interpretation of an ambiguous statute or regulation, that provider should not be held liable under the FCA for following that objectively reasonable interpretation, even if that interpretation ultimately proves to be wrong. Over the last several years, many courts have begun to apply this common sense defense in FCA cases brought in their jurisdictions. However, the United States Department of Justice and relators' counsel in *qui tam* (or "whistleblower") cases have been pushing back on this defense, and the ultimate parameters of this defense remain in doubt.

History of the Objectively Reasonable Interpretation Defense

In 2007, in the case of *Safeco Ins. Co. of Am. v. Burr*, the U.S. Supreme Court set out the parameters of the "objectively reasonable interpretation" defense.[2] *Safeco* was not an FCA case, but rather interpreted what "reckless disregard" meant in the context of the Fair Credit Reporting Act (FCRA). The Court set up a two-step test to determine whether a defendant acted in "reckless disregard" of the meaning of a statute: (1) did the defendant have a "reading of the statute, albeit erroneous, [that] was not objectively unreasonable" and, if so, (2) did the defendant lack "the benefit of guidance from the court of appeals or [the relevant agency] that might have warned it away from the view it took[?]"[3] Therefore, under *Safeco*, if these two steps are met, a defendant will not have a reckless disregard for the meaning of the statute and will not face FCRA liability.

Eight years after the *Safeco* decision, the *Safeco* "reckless disregard" standard was extended by the Court of Appeals for the D.C. Circuit in *U.S. ex rel. Purcell v. MWI Corp.*, where it was applied to the FCA context for the first time.[4] The D.C. Circuit held that "[u]nder the FCA's knowledge element, then, the court's focus is on the objective reasonableness of the defendant's interpretation of an ambiguous term and whether there is any evidence that the agency warned the defendant away from that interpretation."[5] However, the D.C. Circuit articulated a three-step test (instead of a two-step test) for this defense, adding a requirement that the statute or regulation must actually be ambiguous.[6]

Following the D.C. Circuit's decision in *Purcell*, the Third, Seventh, Ninth, and Eleventh Circuit Courts of Appeal have also utilized *Safeco*'s test (with some slight modifications and variations) in the FCA context and explicitly approved the "objectively reasonable interpretation" defense.[7]

A particularly relevant case is the Seventh Circuit's *United States ex rel. Schutte v. SuperValu Inc.*[8] Although *SuperValu* cited to *Purcell,* it explicitly adopted *Safeco*'s two-step test, rather than *Purcell*'s three-step test. The court held that (1) the defendant's interpretation of Medicare and Medicaid's "'usual and customary price' was objectively reasonable [although ultimately erroneous] under *Safeco*" and (2) there was no "authoritative guidance" from the Centers for Medicare and Medicaid Services that "warned defendants away from their erroneous interpretation[,]" which precluded the defendant from acting "knowingly" as prescribed by the FCA.[9] Although *SuperValu* delineates a slightly different test than some of the other cases cited above, the most important elements of this defense—a defendant's objectively reasonable, though erroneous, interpretation and a lack of authoritative guidance to notify the defendant of the erroneous interpretation—are uniform in all of the circuit courts that have expressly considered the defense.

On 25 January 2022, the Fourth Circuit in *United States ex rel. Sheldon v. Allergan Sales* adopted *Safeco's* two-step test and decided (1) the

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defendant's interpretation of the Medicaid Drug Rebate Statute['s 'Best Price'] "was at the very least objectively reasonable" even if erroneous and since (2) the defendant "was not warned away from that [interpretation] by authoritative guidance," the defendant could not have acted "knowingly" as outlined by the FCA.[10] The court declared that it could not "accept the idea that a defendant acts 'knowingly' when its reading of a statute is both objectively reasonable and in fact the best interpretation; when the agency's regulation mirrors, rather than repudiates, that interpretation; when the agency resists attempts to get it to clarify its view; and when the agency explicitly invites regulated parties to make reasonable assumptions."[11] Importantly, however, on 23 September 2022, after rehearing the case *en banc*, the Fourth Circuit issued an order stating that the court was equally divided on whether to uphold the panel's decision, which resulted in the panel decision being vacated, and the district court's ruling thereby reinstated.[12] Since the district court had ruled in favor of the defendant and had applied the *Safeco* standard for the "objectively reasonable test," the case remained dismissed, but the *Sheldon* case has absolutely no precedential authority.[13] Most importantly, there is absolutely no indication from the Fourth Circuit as to whether the *Safeco* "objectively reasonable test" is good law or not in the FCA context, so health care providers and other regulated industries in the Fourth Circuit have no way of knowing whether or not this defense will apply.

An Ongoing Issue to Keep an Eye On: What Constitutes "Authoritative Guidance"?

One issue that courts have continued to struggle with in applying this defense is determining what constitutes "authoritative guidance" that would warn a provider away from its objectively reasonable interpretation. Specifically, can sub-regulatory guidance constitute "authoritative guidance?" In *Azar v. Allina Health Servs*., the Supreme Court indicated that under certain circumstances the government must go through official "notice and comment" procedures in order for guidance to be authoritative.[14] However, it is still unclear what, if any, sub-regulatory guidance is sufficient to "warn away" a provider from an incorrect interpretation of a statute or regulation sufficiently to deny the provider the benefits of the "objectively reasonable interpretation" defense.

Supreme Court to Potentially Address the Objectively Reasonable Interpretation Defense

On 1 April 2022, the relator in *SuperValu* filed a petition for *certiorari* to the U.S. Supreme Court, asking the Supreme Court to take up the question of the applicability of the "objectively reasonable interpretation" defense, and the exact parameters of the defense.[15] The relator argued that there is a circuit split on this issue, while the defendant claimed that there is not.[16] No court of appeals that has directly considered the issue has rejected the defense, although, as previously noted, there are slight differences in the exact application of the defense.[17] However, given the Fourth Circuit's inability in *Sheldon* to reach a majority view on whether the defense applies, there may be a sufficient circuit split for the Supreme Court to take up the issue.[18] Significantly, on 22 August 2022, the Supreme Court took the step of inviting the solicitor general to file a "brief in this case expressing the views of the United States."[19] On 6 December 2022, the solicitor general filed a brief asserting that the Supreme Court should grant *certiorari* given that "the question presented has generated disagreement in the courts of appeals and is important to efforts to fight fraud involving the public fisc."[20]

Conclusion and Practical Guidance

In light of the potential circuit split and uncertainties regarding the applicability and parameters of the "objectively reasonable defense," how can a health care provider (or government contractor) protect itself as much as possible from being sued under the FCA? The best practices for healthcare providers are to: (1) ensure that they keep abreast of both regulatory and sub-regulatory guidance; (2) document their rationale for interpreting ambiguous regulations to make clear they are acting in good faith; (3) seriously consider following all administrative guidance and sub-regulatory guidance to minimize the risk of an FCA suit, even if such sub-regulatory guidance is not "authoritative," and (4) if the provider determines that the sub-regulatory guidance is not authoritative and decides to not follow it, consider explaining to the Medicare Administrative Contractor (MAC) why the provider does not believe the guidance is authoritative, and why the provider is interpreting the regulation the way it is. If a provider is up-front with the MAC about any issues regarding regulatory interpretation, this could go a long way in rebutting any allegation of fraud or bad faith.

Clarita I. Sullivan, a Summer Associate in the Firm's Research Triangle Park office, also contributed to this article.

Disclaimer: This publication is for informational purposes and does not contain or convey legal advice. The information herein should not be used or relied upon in regard to any particular facts or circumstances without first consulting a lawyer.

[1] *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 899 (9th Cir. 2017).
[2] 551 U.S. 47 (2007).
[3] *Id.* at 69–70.
[4] 807 F.3d 281, 290 (D.C. Cir. 2015).
[5] *Id.*
[6] *Id.* at 288.
[7] *United States ex rel. Schutte v. SuperValu Inc.*, 9 F.4th 455, 459 (7th Cir. 2021); *United States ex rel. Streck v. Allergan, Inc.*, 746 F. App'x 101, 106 (3d Cir. 2018) (unpublished, but cited by the Seventh Circuit in *U.S. ex rel. Schutte v. SuperValu Inc*., 9 F.4th 455 (7th Cir. 2021)); *United States ex rel. McGrath v. Microsemi Corp*., 690 F. App'x 551, 552 (9th Cir. 2017); *United States ex rel. Donegan v. Anesthesia Assocs. of Kansas City*, PC, 833 F.3d 874, 879–80 (8th Cir. 2016).
[8] 9 F.4th 455.
[9] *Id*. at 468, 471.
[10] *United States ex rel. Sheldon v. Allergan Sales*, 24 F.4th 340, 343–44 (4th Cir 2022) [hereinafter, "*Sheldon I*"], rehearing *en banc* granted, No. 20-2330, 2022 WL 1467710 (4th Cir. May 10, 2022), and opinion vacated upon an even split upon rehearing *en banc*, 49 F.4th 873 (4th Cir. Sept. 23, 2022).
[11] *Id*. at 356.
[12] *United States ex rel. Sheldon v. Allergan Sales*, LLC, 49 F.4th 873, 874 (4th Cir. 2022) [hereinafter, "*Sheldon II*"].
[13] *Id*.; *see also*, *Sheldon I*, 24 F.4th at 343–44.
[14] 139 S.Ct. 1804, 1817 (2019)*; see also Polansky v. Exec. Health Res., Inc.,* 422 F. Supp. 3d 916, 931–36 (E.D. Pa. 2019) (analyzing the *Allina* decision in the context of the FCA and finding that "[t]he core of the *Allina* decision as it relates to this case is that because the reimbursement standard applicable to the . . . claims [here] was contained in agency manuals that had not been promulgated pursuant to notice and comment, as required by the Medicare Act, [d]efendant could not have violated the FCA.").
[15] *United States ex rel. Schutte v. SuperValu Inc.,* Case No. 21-1326, (Apr. 1, 2022) (currently on *Petition for a Writ of Certiorari* before the U.S. Supreme Court).
[16] *United States ex rel. Schutte v. SuperValu Inc.,* Case No. 21-1326, *Petition for Writ of Certiorari*, (Apr. 1, 2022) at 13; *United States ex rel. Schutte v. SuperValu Inc.,* Case No. 21-1326, *Brief in Opposition*, (Jun. 21, 2022) at 2, 15–26.
[17] *See e.g.*, *SuperValu*, 9 F.4th at 459; *Streck*, 746 F. App'x at 106; *McGrath*, 690 F. App'x at 552; *Donegan*, 833 F.3d at 879–80.
[18] *See generally Sheldon II*.
[19] *United States ex rel. Schutte v. SuperValu Inc.,* Case No. 21-1326, Docket ("[t]he Solicitor General is invited to file a brief in this case expressing the views of the United States.").
[20] *United States ex rel. Schutte v. SuperValu Inc.,* Case No. 21-1326, *Brief for the United States as Amicus Curiae*, (Dec. 6, 2022) at 18–19.