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2022 Key Developments For The Federal False Claims Act

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The federal False Claims Act (FCA) remained in flux in 2022, marked by significant activity at the appellate level. DOJ's enforcement of the FCA remained robust, headlined by a $900 million settlement with Biogen, Inc. arising out of an Anti-Kickback Statute violation in which Biogen paid outsized "speaker honoraria, speaker training fees, consulting fees and meals" to physicians as an inducement to prescribe Biogen pharmaceuticals to patients. Below are some of the year's most significant legal developments for practitioners, government contractors, and other parties with potential False Claims Act exposure due to their receipt of government monies.

Justices Signal Support for Government's Right to Seek Dismissal of Declined FCA Cases

In United States ex rel. Polansky v. Executive Health Resources, Inc., the Supreme Court heard oral argument on the Government's right to seek dismissal, over a relator's objection, of an FCA action in which the Government declined to intervene at the outset. The issues before the Court are: (1) whether the Government may seek dismissal of the action under the statutory provision in the FCA where it declines to intervene at the outset of the case; (2) whether the Government must intervene to seek dismissal; and (3) the substantive standard the Government must meet to dismiss a case over a relator's objection. Though the Court did not clearly signal the exact mechanics of the Government's right to dismiss, all Justices appeared to support the Government's authority to dismiss a declined case over a relator's objection, and all Justices appeared to contemplate that the Government's burden to articulate a basis for its dismissal would be a minimal one.

The dispute arises out of the statutory text of the FCA, which provides the Government with a clear right of dismissal but is not specific on when that right arises or the standard for courts to apply. The Act requires the Government to determine at the outset of the case—with allowance for a period of investigation—whether it will "proceed with the action" or "decline[] to take over the action." If the latter, "the [relator] shall have the right to conduct the action." If the former, the Government assumes "primary responsibility for prosecuting the action" and is not bound by the actions of the relator, who nevertheless has "the right to continue as a party to the action, subject to the limitations set forth in paragraph (2)." Paragraph (2) provides the Government with various mechanisms to curtail the relator's participation in the action, including moving to "dismiss the action notwithstanding

the objections of the [relator] if the [relator] has been notified by the Government of the filing of the motion and the court has provided the [relator] with an opportunity for a hearing on the motion."

The Relator-Petitioner argued that "the limitations set forth in paragraph (2)" are available only where the Government elects to "proceed with the action" at the outset. Relator-Petitioner argued that Paragraph (3) guides that later intervention by the Government is allowed only to intervene for "good cause" and "without limiting the status and rights of the [relator]," and dismissing the action would remove the property right vested in relators by the FCA. The Government and the Defendant-Respondent argued that the Government always has the right to supervise the Relator's conduct of the action regardless of whether the Government takes "primary responsibility" for the litigation at the outset. The Government also argued that it need not first intervene using the mechanism presented Paragraph (3), and that because the dismissal provision does not provide a substantive legal standard, only the baseline Fifth Amendment protection for stripping a property right from the Relator would apply. The Defendant-Respondent described the differences in the mechanisms adopted by various courts as "academic," but argued that the Courts of Appeals are uniformly "highly deferential to the Government's dismissal decisions" in declined cases.

All Justices' questioning at argument focused primarily on the standard governing dismissal, largely ignoring Relator's threshold question of whether the Government has dismissal authority in declined cases. The Justices did not signal unanimous support for a standard, but multiple Justices' questions appeared to make the point that both a baseline Fifth Amendment analysis and rational basis review would result in dismissal where the Government provides virtually any non-discriminatory basis rooted in fact.

Our takeaway is that the ability of the Government to dismiss declined FCA actions is likely to remain intact, particularly in circumstances where the Government believes a relator may make bad law, the prosecution of the action will interfere with ongoing investigations and/or administrative actions, or the litigation of the action (and particularly discovery in the action) would burden the Government's administrative resources.

Fourth Circuit Splits 7-7 on Whether False Claims Act Carries Objective or Subjective Scienter Standard

In September, an evenly divided Fourth Circuit released a three-line decision vacating an earlier panel decision regarding the applicable FCA standard for "legally false"—as opposed to "factually false"—claims, but nevertheless affirming the lower court's dismissal of the underlying action. The case, United States ex rel. Sheldon v. Allergan Sales, LLC, involved an allegation that the defendant's failure to "stack" all theoretically available rebates and discounts in its statutory "best price" calculation for Medicaid caused the Centers for Medicare and Medicaid Services (CMS) to overpay the defendant for prescribed pharmaceuticals. The case examined whether a defendant acted with the requisite scienter where its actions were consistent with an "objectively reasonable" interpretation of an ambiguous statute, rule, or regulation and was not "warned away" by clarifying administrative action. This "objectively reasonable" interpretation of scienter derives from the Supreme Court's articulation of the "reckless disregard" scienter standard under another federal Statute—the Fair Credit Reporting Act—in Safeco Ins. Co. of Am. v. Burr.

Both the Relator and the Government argued for a subjective interpretation of scienter—in other words, an FCA defendant may not avoid suit through post hoc rationalization if it did not hold that interpretation at the time of the action. An earlier panel of the Fourth Circuit rejected this argument in a 2-1 decision. The panel found the argument advanced by the Relator and the Government to be

contrary to the decisions of the Third, Seventh, Eighth, Ninth, and D.C. Circuits, all of whom had adopted the Safeco standard. The panel then found that it did not need to address any allegations of subjective intent, because objective scienter is a lesser standard that was not met. The panel also reasoned that the rule advocated by the Relator and the Government was contrary to the Supreme Court's directive to the lower courts in Universal Health Services, Inc. v. United States ex rel. Escobar to undertake a "rigorous" examination of scienter (and materiality) under the False Claims Act from the outset of the case. The subjective standard advocated by the Relator and the Government would require a more probing factual inquiry into a defendant's actual rationale for undertaking its actions, and thus may not be amenable to resolution on a motion to dismiss.

The complex web of statutory and regulatory requirements underlying Sheldon undoubtedly complicated the Court's analysis, as the majority and dissent appeared to disagree on both the law and the facts. The majority held that the defendant's failure to "stack" was an objectively reasonable interpretation not expressly warned away by CMS. Indeed, a group of pharmaceutical manufacturers, including the predecessor of the Defendant, responded to CMS's proposed rulemaking that failed to address the meaning of "best price" by "ask[ing] CMS to 'clarify' or confirm'" that the "best price" would "continue" to mean "the single lowest price available to a particular consumer." CMS did not respond. Thus, the majority held it was not necessary to examine the actual rationale for the Defendant's "best price" methodology, because the Defendant used a reasonable interpretation that was not "warned away." The dissent, on the other hand, found that CMS's failure to respond to the Defendant's comment supported an inference on a motion to dismiss that the Defendant's interpretation was incorrect and that the rule did not require clarification. The dissent also downplayed the Safeco standard as dictum from a "footnote buried at the end of a Supreme Court opinion on credit reporting" and interpreted the facts relayed by the complaint as sufficient to allege actual knowledge of wrongdoing, a standard not examined by the majority because it was a higher bar than the one the Relator failed.

These same divides were equally apparent during the en banc oral argument. There, the Government and the Relator walked a fine line, acknowledging that the Safeco standard may govern pure reckless disregard, but should not lead a court to ignore pleaded indicia of "actual knowledge" or "deliberate ignorance" of falsity where a complaint contains such allegations. The Government stated that the only other case to make such a holding was the Seventh Circuit's decision in United States ex rel. Schutte v. SuperValu, Inc., where the Government and the Relator are currently seeking certiorari from the Supreme Court, and Senator Grassley (who sponsored the 1986 amendments to the False Claims Act) has filed an amicus brief in support of the Government's position. Ultimately, the Court could not reconcile these differences in approach, evenly splitting 7-7 and affirming the result while vacating the panel's written opinion.

Because the Fourth Circuit ultimately vacated the previous panel decision, there still is not a true circuit split on whether Safeco applies to the False Claims Act or whether the failure to meet Safeco prevents consideration of indicia of subjective intent. Nevertheless, the appropriate standard for scienter remains an unsettled area of law in more than half the Circuits.

Supreme Court Declines to Review Rule 9(b) Pleading Standard for FCA Cases

Earlier this fall, the Supreme Court, without a written order, declined the opportunity to clarify whether Federal Rule of Civil Procedure 9(b) requires an FCA complaint to plead specific instances of submitted false invoices, sufficiently representative of the larger body of submitted false claims, where it otherwise pleads specific facts regarding a fraudulent scheme.

The Court's failure to grant any of the three pending certiorari petitions before it may reflect the fact that the differences among the courts are largely in degree, rather than kind. The Sixth Circuit recognized that "[e]very circuit that has applied a heightened standard, save ours, has retreated from" a strict requirement to identify a specific false claim where "other detailed factual allegations support a strong inference that claims were submitted." The Solicitor General echoed this sentiment in its recommendation that the Court deny certiorari, arguing that courts have "largely converged on an approach" and that differences in outcomes or articulation of the rule reflect an appropriate "fact-intensive" inquiry under Rule 9(b).

The majority rule remains that at least some detailed factual allegations of a defendant's billing practices, whether by reference to normal billing practices or to specific false claims, are necessary to satisfy the heightened standard imposed by Rule 9(b), and parties should be attuned to this issue when filing or responding to an FCA complaint.

False Claims Amendments Act of 2021 Receives CBO Scoring but No Vote

The False Claims Amendments Act of 2021 has reached the end of the legislative session without a vote. The bill, first introduced in July 2021 and reported to the Senate by the Judiciary Committee in November 2021, received its Congressional Budget Office scoring in July of this year but has not been brought to a vote. If passed, the bill would have two major effects. First, it would clarify that the Government's decision to continue paying a defendant after their discovery of the false claims would not be dispositive of a lack of materiality "if other reasons exist for the decision of the Government with respect to such refund or payment." This amendment responds to the Supreme Court's statement in Universal Health Services, Inc. v. United States ex rel. Escobar that the Government's continued decision to pay is "very strong evidence" of immateriality. Second, it would clarify that in the hearing to address a relator's objection to the Government's decision to dismiss the case, "the Government shall identify a valid government purpose and a rational relation between dismissal and accomplishment of the purpose, and the person initiating the action shall have the burden of demonstrating that the dismissal is fraudulent, arbitrary and capricious, or illegal." The Senate will likely wait until the Court renders decision in Polansky, and thus will have the benefit of that decision in determining whether and how it wishes to modify the FCA.

FOOTNOTES

[1] https://www.justice.gov/usao-ma/pr/biogen-inc-agrees-pay-900-million-settle-false-claims-act-allegations-related-improper**.**

[2] 31 U.S.C. § 3730(b)(4).

[3] Id

[4] 31 U.S.C. § 3730(c)(1).

[5] 31 U.S.C. § 3730(c)(2)(A).

[6] https://www.ca4.uscourts.gov/opinions/202330R1.P.pdf.

[7] Whereas a "factually false" claim involves an inaccurate description of goods provided or services rendered (to the extent any goods or services were provided at all), a "legally false" claim involves the false certification of the adherence to a legal requirement imposed on the submitter of the claim.

[8] Under the False Claims Act, a defendant has violated the act only where it acts “knowingly,” which the Act further splits into three prongs: “actual knowledge”; “deliberate ignorance”; or “reckless disregard.” 31 U.S.C. § 3729(b)(1).

[9] 551 U.S. 47 (2006).

[10] https://www.ca4.uscourts.gov/opinions/202330.P.pdf.

[11] 579 U.S. 176 (2016).

[12] Id. at 192.

[13] https://www.ca4.uscourts.gov/opinions/202330.P.pdf at 23.

[14] Id. at 31.

[15] United States ex rel. Prather v. Brookdale Senior Living Communities, Inc., 838 F.3d 750, 772 (6th Cir. 2016). In that opinion, the Sixth Circuit itself retreated from a strict interpretation, recognizing that certain facts may not demand the identification of specific false claims.

[16] https://www.supremecourt.gov/DocketPDF/21/21-462/226201/20220524193203503_No.%2021-462%20Johnson%20v.%20Bethany%20Hospice%20U.S.%20CVSG%20Brief%20Final.pdf.

[17] See https://www.congress.gov/bill/117th-congress/senate-bill/2428/text.

[18] 579 U.S. at 195.

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