Tenth Circuit Reverses Dismissal of Complaint Alleging False Claims Act Liability for Unnecessary Surgical Procedures

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On July 9, 2018, in *United States ex rel. Polukoff v. St. Mark's Hosp.*,[1] the Tenth Circuit Court of Appeals added to the debate over the role of the False Claims Act in policing medical necessity. The court held that "[i]t is possible for a medical judgment to be 'false or fraudulent' as proscribed by the FCA."[2] Thus, the court reversed the district court's dismissal of the **qui tam** relator's complaint, holding that the "specific factual allegations" contained in the complaint were sufficient "to state a claim as a matter of law and survive Rule 12(b)(6) dismissal."[3]

A number of recent cases at the district court level have held that FCA liability may not be premised upon a difference of clinical opinion alone.[4] *Polukoff* did not address or expressly reject those opinions or their reasoning, though it did reach a different conclusion. Whether *Polukoff* should best be read as an *implicit* rejection of the reasoning of these other recent cases, or whether the decision is simply reflective of the unique specific facts and procedural posture that were before the *Polukoff* court, is a bit unclear. However, as discussed below, there are good reasons to believe the *Polukoff* decision is limited to its specific facts and procedural context and is not a rejection of these other decisions.

I. Medical Necessity and the FCA

In any FCA lawsuit, the plaintiff (whether the government or a private whistleblower) must establish all elements of an FCA claim, including scienter (*i.e.*, knowledge) and materiality; however, the crux of a viable FCA complaint is the falsity of the claim presented to the government for reimbursement.[5] To that end, for purposes of proving falsity, courts have distinguished between objective falsity and subjective differences of opinion, requiring proof of the former in order to hold the defendant liable.[6] As the Tenth Circuit had explained, objective falsity under the FCA "does not mean 'scientifically untrue'; it means 'a lie.'"[7] Stated differently, "liability under the FCA must be predicated on an objectively verifiable fact" rather than a subjective opinion that the claim is false.[8] In FCA cases based upon allegedly incorrect clinical judgments by a physician or other provider,

1 895 F.3d 730 (10th Cir. 2018).
2 *Id.* at 743.
3 *Id.*
4 *See United States v. AseraCare Inc*, 176 F. Supp. 3d 1282, 1285 (N.D. Ala. 2016) ("When two or more medical experts look at the same medical records and reach different conclusions about whether those medical records support the certifying physicians' COTI [Certificate of Terminal Illness], all that exists is a difference of opinion. This difference of opinion among experts regarding the patients' hospice eligibility alone is not enough to prove falsity, and the Government has failed to point the court to any objective evidence of falsity."); *U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, No. 3:07-cv-00604, 2016 WL 3449833, at *3 (N.D. Tex. June 20, 2016) ("A testifying physician's disagreement with a certifying physician's prediction of life expectancy is not enough to show falsity."); *U.S. ex rel. George v. Fresenius Med. Care Holdings, Inc.,* No. 2:12-CV-00877-AKK, 2016 WL 5361666, at *16 (N.D. Ala. Sept. 26, 2016) ("[T]he court declines to find that a difference in medical judgment—in absence of evidence that a doctor's independent judgment was compromised, for instance, through the writing of inefficient prescriptions—constitutes a false claim.").
5 *See, e.g., Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1052 (11th Cir. 2015) ("[T]he '*sine qua non of a False Claims Act violation*' is the submission of a false claim to the government.") (citing Corsello v. Lincare, Inc., 428 F.3d 1008, 1012 (11th Cir. 2005)).
6 *See United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 376 (5th Cir. 2004) ("[E]xpressions of opinion or scientific judgments about which reasonable minds may differ cannot be 'false'."); *United States v. Prabhu*, 442 F.Supp.2d 1008, 1026 (D.Nev.2006) ("[C]laims are not 'false' under the FCA when reasonable persons can disagree regarding whether the service was properly billed to the Government.").
7 *U.S. ex rel. Morton v. A Plus Benefits, Inc.*, 139 Fed. Appx. 980, 982 (10th Cir. 2005) (unpublished) (quoting *Wang v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir. 1992)).
8 *Id.* at 983.

several courts have held that "[e]xpressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false."[9] Thus, in the healthcare context, courts have held that despite the Medicare Act's requirement that "no payment may be made . . . for any expenses incurred for items or services" that "are not *reasonable and necessary* for the diagnosis or treatment of illness or injury,"[10] criticisms of a provider's judgment regarding a specific course of treatment may not be sufficient to provide the basis for an action under the FCA.[11]

II. The Polukoff Decision

a. The Plaintiff's Complaint

On December 6, 2012, *qui tam* relator Dr. Gerald Polukoff filed an FCA action against defendants Dr. Sherman Sorensen, his medical practice (Sorensen Cardiovascular Group), and two hospitals where Dr. Sorensen had privileges and performed heart surgeries, Intermountain Healthcare, Inc. (Intermountain) and St. Mark's Hospital (St. Mark's).[12] Dr. Polukoff's complaint alleged that "Dr. Sorensen performed thousands of unnecessary heart surgeries and received reimbursement through the Medicare Act by fraudulently certifying that the surgeries were medically necessary."[13] The complaint further alleged that Intermountain and St. Mark's "were complicit in and profited from Dr. Sorensen's fraud."[14]

Specifically, Dr. Polukoff (who practiced alongside Dr. Sorensen at Intermountain and St. Mark's, and began working directly for Dr. Sorensen in 2011) contended that Dr. Sorensen performed medically unnecessary atrial septal defect (ASD) and patent foramen ovale (PFO) closures (collectively, "PFO closures"), an alternative to open heart surgery whereby a physician inserts a thin tube into the patient's blood vessel to access the heart.[15] According to Dr. Polukoff, citing to guidelines published by the American Heart Association and American Stroke Association (the "AHA/ASA Guidelines"), "[t]here has long been general agreement in the medical community that PFO closure is not medically necessary, except in the limited circumstances where there is a confirmed diagnosis of a recurrent cryptogenic stroke or TIA [transient ischemic attack]."[16] Despite these Guidelines, Dr. Polukoff alleged, Dr. Sorensen performed hundreds of unnecessary PFO closures due to his "medically unsupported belief that PFO closures would cure migraine headaches or prevent strokes." [17] Importantly, the complaint alleged that, because Dr. Sorensen was aware that Medicare and Medicaid would not reimburse PFO closures performed to treat migraines, "he chose to represent that the procedures had been performed based upon indications set forth in the AH[A]/ASA stroke guidelines—the existence of confirmed recurrent cryptogenic stroke."[18]

Eventually, after several physicians at Intermountain complained about Dr. Sorensen's approach to PFO closures, Intermountain suspended Dr. Sorensen's cardiac privileges, citing violations of its internal guidelines.[19] Upon his return, however, Dr. Sorensen continued violating the hospital's policies and resigned in September 2011 after the hospital moved to permanently suspend him.[20] According to the complaint, St. Mark's solicited Dr. Sorensen to move his entire practice there, despite the hospital's knowledge of Dr. Sorensen's suspension from Intermountain.[21] Dr. Sorensen continued practicing at St. Mark's until he retired from medicine a few months later, in December 2011.[22]

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9 *Id.* (quoting *U.S. ex rel. Roby v. Boeing Co.*, 100 F.Supp.2d 619, 625 (S.D. Ohio 2000)); *see also*, *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1026 (D. Nev. 2006) ("[C]laims are not 'false' under the FCA when reasonable persons can disagree regarding whether the service was properly billed to the Government.").
10 42 U.S.C. § 1395y(a)(1)(A) (emphasis added).
11 *See U.S. ex rel. Phillips v. Permian Residential Care Ctr.*, 386 F. Supp. 2d 879, 884 (W.D. Tex. 2005) ("[T]his Court holds that the False Claims Act should not be used to call into question a health care provider's judgment regarding a specific course of treatment.").
12 *Polukoff*, 895 F.3d at 738. The initial complaint included a fifth defendant, for-profit hospital system HCA, Inc. (corporate owner of St. Mark's Hospital), and was originally filed in the Middle District of Tennessee; however, the court dismissed the claims against HCA and concluded that, without HCA, the Middle District of Tennessee was no longer the proper venue. Accordingly, the case was transferred to the District Court for the District of Utah. *Id.* at 739.
13 *Id.* at 734.
14 *Id.*
15 *Id.* at 736.
16 *Id.* at 737.
17 *Id.*
18 *Id.*
19 *Id.* at 738.
20 *Id.*
21 *Id.*
22 *Id.*

b. The Lower Court's Decision

Two and a half years after Dr. Polukoff filed his complaint, the Department of Justice (DOJ) filed notice of its decision to not intervene in the case.[23] Thereafter, the district court unsealed the complaint and all defendants filed a motion to dismiss.[24] In granting the defendants' motions to dismiss, the lower court determined that "Dr. Polukoff must show that the defendants knowingly made an objectively false representation to the government that caused the government to remit payment."[25] Yet, said the court, the representations made by Dr. Polukoff (*i.e.*, that the PFO closures *were* medically reasonable and necessary) "cannot be proven to be objectively false."[26] Relying on language from an unpublished Tenth Circuit opinion, *United States ex rel. Morton v. A Plus Benefits, Inc.*,[27] the lower court further held that "[o]pinions, medical judgments, and 'conclusions about which reasonable minds may differ cannot be false' for the purposes of an FCA claim." [28] Thus, the district court held that Dr. Polukoff's allegations pertaining to the medical unreasonableness of Dr. Sorensen's PFO closures "are based on subjective medical opinions that cannot be proven to be objectively false."[29]

The lower court admonished Dr. Polukoff for creating a "false equivalence" between the AHA/ASA guidelines relating to the medical necessity of PFO closures and the standard imposed by the Medicare Act. The court held that "Medicare does not require compliance with an industry standard as a prerequisite to payment. Thus, requesting payment for [medical procedures] that allegedly did not comply with a particular standard of care does not amount to a 'fraudulent scheme' actionable under the FCA."[30] The court therefore held that even if Dr. Sorensen did fail to comply with the relevant AHA/ASA guidelines, such noncompliance would not support Dr. Polukoff's claim that Dr. Sorensen's certification of medical necessity was objectively false.[31] Thus, the lower court held that Dr. Polukoff's complaint failed to state a claim under the FCA.

c. The Tenth Circuit's Holding

In reversing and remanding the district court's opinion, the Tenth Circuit first noted that the court's opinion in *Morton* "did not create a bright-line rule that medical judgments can never serve as the basis for an FCA claim."[32] The court determined that at least three reasons exist for the possibility that a medical judgment could be considered "false or fraudulent" within the ambit of the FCA: (1) the court reads the FCA broadly; (2) that an allegedly false statement constitutes the speaker's opinion does not necessarily disqualify it from forming the basis of a viable FCA claim; and (3) "claims for medically unnecessary treatment are actionable under the FCA."[33]

The Tenth Circuit further determined that "[a] Medicare claim is false if it is not reimbursable, and a Medicare claim is not reimbursable if the services provided were not medically necessary."[34] And, "[f]or a claim to be reimbursable, it must meet the government's definition of 'reasonable and necessary,' as found in the Medicare Program Integrity Manual."[35] Thus, the court held, "a doctor's certification to the government that a procedure is 'reasonable and necessary' is 'false' under the FCA if the procedure was not reasonable and necessary under the government's definition of the phrase."[36] The court acknowledged "the concerns that a broad definition of 'false and fraudulent' might expose doctors to more liability under the FCA," but determined that these concerns were addressed by the Supreme Court's decision in Escobar to cabin broad FCA liability through rigorous enforcement of materiality and scienter requirements.[37]

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23 *Id.* at 739
24 *Id.*
25 *United States v. St. Mark's Hosp.*, No. 216CV00304JNPEJF, 2017 WL 237615, at *9 (D. Utah Jan. 19, 2017).
26 *Id.*
27 139 F. App'x 980 (10th Cir. 2005).
28 *St. Marks*, No. 216CV00304JNPEJF, 2017 WL 237615, at *9.
29 *Id.*
30 *Id.* (quoting *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 468 (6th Cir. 2011); *accord Mikes v. Straus*, 274 F.3d 687, 698 (2d Cir. 2001) abrogated on other grounds by Universal Health Servs., Inc. v. United States, 136 S. Ct. 1989, 1999–2001 (2016)).
31 *Id.*
32 *Polukoff*, 895 F.3d at 742.
33 *Id. (citing United States ex rel. Riley v. St. Luke's Episcopal Hosp.,* 355 F.3d 370, 376 (5th Cir. 2004)).
34 *Id.*
35 *Id.* (emphasis added).
36 *Id.* at 743 (emphasis added).
37 *Id.* at 743 (citing *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 2002 (2016)).

The court concluded that the following "specific factual allegations" in Dr. Polukoff's complaint were sufficient "to state a claim as a matter of law and survive Rule 12(b)(6) dismissal against Dr. Sorensen":[38]

1. "Dr. Sorensen performed an unusually large number of PFO closures";
2. "[T]hese procedures violated both industry guidelines and hospital guidelines";
3. "[O]ther physicians objected to Dr. Sorensen's practice";
4. "Intermountain eventually audited Dr. Sorensen's practice and concluded that its 'guidelines had been violated in many of the 47 cases reviewed'"; and
5. "Dr. Sorensen knew that Medicare and Medicaid would not pay for PFO closures to treat migraines, so he chose to represent that the procedures had been performed based upon indications set forth in the AH[A]/ASA stroke guidelines—the existence of confirmed recurrent cryptogenic stroke."

Moreover, with respect to Intermountain and St. Mark's, the court held that by submitting their required Hospital Cost Reports—which require hospitals to certify that the services identified therein were provided in compliance with the applicable laws and regulations—Dr. Polukoff had sufficiently alleged that both hospitals had submitted false claims for reimbursement.[39] The court further held that Dr. Polukoff's complaint adequately alleged, at a minimum, that the two hospitals "acted with reckless disregard as to whether the PFO closures Dr. Sorensen was performing were medically necessary."[40]

III. Conclusion

The impact of the Tenth Circuit's *Polukoff* decision in the ongoing debate over the role of the FCA in policing claims of "medical necessity" remains to be seen. But there are reasons to doubt that *Polukoff* represents a significant departure from existing case law on the subject.

- Perhaps most notably, *Polukoff* does not cite or expressly disagree with recent cases where courts have held that the FCA was not the proper vehicle for policing claims of medical necessity. This may indicate that the *Polukoff* decision is reflective of differences in the specific procedural posture and allegations that were before the court (see below) rather than a sharp difference of opinion as to the viability of FCA claims premised on allegations of faulty clinical judgment.
- The *Polukoff* decision, unlike many other recent FCA medical necessity decisions, involved motions to dismiss under Rule 12(b)(6), which meant that the court was required to assume that all allegations in Dr. Polukoff's complaint were true, including that the surgeries were unnecessary, the Dr. Sorensen knew they were unnecessary, and that Dr. Sorensen falsified diagnoses to make them appear necessary. It also meant that the defendants had no opportunity to present evidence that might contradict these allegations.
- The decision makes clear the Tenth Circuit's view that there is no "bright-line rule that a medical judgment can *never* serve as the basis for an FCA claim."[41] However, the Tenth Circuit stopped far short of holding that allegations of defective medical judgment can always serve as the basis for an FCA claim. In fact, the decision held that the specific complaint at issue could survive a Rule 12(b)(6) motion to dismiss in light of five "specific allegations," one of which was that the defendant physician knew that the surgeries at issue would not have been covered and recorded false diagnoses to hide the true reasons for the surgeries and to obtain coverage.[42] That allegation (which the court was required to assume as true in the context of a motion to dismiss) indicates that the *Polukoff* case involves more than just an allegation of poor medical judgment in deciding whether a surgery was reasonable and necessary.
- To the extent that the sufficiency of the *Polukoff* complaint rests on the falsity of the assertion of the "existence of confirmed recurrent cryptogenic stroke,"[43] such a retrospective fact (whether a confirmed recurrent cryptogenic stroke *exists*) would seem far more capable of truth or falsity than a prospective prognosis (for example, in

38 *Id.*
39 *Id.* at 743-44
40 *Id.* at 744.
41 *Id.* at 742 (emphasis added).
42 *Id.* at 743.
43 *Id.*

the hospice context, “a medical prognosis that the individual’s life expectancy is 6 months or less”[44]). Thus, it is unclear whether, or to what extent, the reasoning of *Polukoff* would be applicable to FCA claims premised upon a “false” *prognosis*, as opposed to claims premised upon a “false” *diagnosis*.

44 42 U.S.C. § 1395x(dd)(3)(A).

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