**UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT**

SUMMARY ORDER

RULINGS BY SUMMARY ORDER DO NOT HAVE PRECEDENTIAL EFFECT. CITATION TO A SUMMARY ORDER FILED ON OR AFTER JANUARY 1, 2007 IS PERMITTED AND IS GOVERNED BY FEDERAL RULE OF APPELLATE PROCEDURE 32.1 AND THIS COURT'S LOCAL RULE 32.1.1. WHEN CITING A SUMMARY ORDER IN A DOCUMENT FILED WITH THIS COURT, A PARTY MUST CITE EITHER THE FEDERAL APPENDIX OR AN ELECTRONIC DATABASE (WITH THE NOTATION "SUMMARY ORDER"). A PARTY CITING TO A SUMMARY ORDER MUST SERVE A COPY OF IT ON ANY PARTY NOT REPRESENTED BY COUNSEL.

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York, on the 18th day of March, two thousand twenty.

PRESENT:

JOHN M. WALKER, JR.,
BARRINGTON D. PARKER,
SUSAN L. CARNEY,
Circuit Judges.

SUSAN VIERCZHALEK, M.D.,

Plaintiff-Appellant,

v. No. 19-0093

MEDIMMUNE INC.,

Intervenor-Defendant-Appellee.*

FOR PLAINTIFF-APPELLANT: BARBARA J. HART, (David C. Harrison, Scott V. Papp, *on the brief*), Lowey Dannenberg P.C., White Plains, NY; Kenneth A. Wexler, Wexler Wallace LLP, Chicago IL.

FOR DEFENDANT-APPELLEE: JOHN C. DODDS, (James D. Nelson, David B. Salmons, Matthew J.D. Hogan Sr., Natalie M. Georges), *on the brief*,

* The Clerk of Court is directed to amend the caption as set forth above.

Morgan Lewis, & Bockius LLP,
Washington, DC; Philadelphia, PA.

Appeal from a judgment and orders of the United States District Court for the Southern District of New York.

UPON DUE CONSIDERATION WHEREOF, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that the judgment entered on March 11, 2019, the decision and order dated September 28, 2018, and the order orally issued on December 6, 2018, are **AFFIRMED**.

Plaintiff-Appellant Susan Vierczhalek ("Vierczhalek") appeals from an order of the United States District Court for the Southern District of New York (Sullivan, *J.*) granting Defendant-Appellee MedImmune, Inc.'s ("MedImmune") motion to dismiss Vierczhalek's claims brought under the False Claims Act ("FCA"), 31 U.S.C. § 3729. Vierczhlaek also appeals from the District Court's (Batts, *J.*) subsequent denial of her motion to amend her complaint. We assume the parties' familiarity with the underlying facts, the procedural history of the case, and the issues on appeal, to which we refer only as necessary to explain our decision to affirm the District Court's judgment and orders.

The following statement of facts is taken from the undisputed portions of the parties' filings. In 2009, Vierczhalek, a medical doctor acting as a relator, brought a *qui tam* action (the "Original Complaint") in the District Court against MedImmune, the manufacturer of a drug called Synagis, which is prescribed to prevent lung infections in premature infants. The action also named as defendants two health care service providers, Trinity Homecare LLC ("Trinity") and OptionCare. Vierczhalek alleged that these entities violated the FCA by promoting the "off-label" use of Synagis—that is a, use for which the drug had not been specifically approved by the Food and Drug Administration.

Vierczhalek's suit was stayed for several years as the United States and various States weighed whether to intervene. In 2013, the United States notified the District Court that it declined to intervene in the suit. In 2015, the State of New York (the "State") intervened as to claims stated against Trinity and OptionCare. The State ultimately settled the claims made

against those entities for $22.4 million dollars, and all claims stated in the suit against Trinity and OptionCare were thereafter dismissed. Vierczhalek received $4,040,808.84 as part of the settlement.

The State also continued its investigation of MedImmune, however, and in March 2017, it filed a complaint-in-intervention against the company. Instead of focusing on the off-label promotion of Synagis as had the Original Complaint, however, the State now alleged that MedImmune had engaged in an unlawful scheme with Trinity. It charged that MedImmune had made a practice of gaining access to protected health information ("PHI") of hospitalized infants who might be candidates for a Synagis prescription and passed this information along to Trinity. Trinity used the PHI to identify possible patients for its services in administering the drug, with the goal of increasing sales of Synagis-related services.

In November 2017, Vierczhalek filed an Amended Complaint in the action, designating herself a relator on behalf of the United States and the States other than New York. She now also alleged that MedImmune engaged in an unlawful kickback scheme with Trinity and thereby violated the FCA and the States' FCA analogs. Her Amended Complaint did not reprise her off-label claims.

The District Court dismissed Vierczhalek's Amended Complaint, finding that (1) the Amended Complaint was substantially similar to New York State's complaint-in intervention, and (2) she was not an "original source" of the allegations in the Amended Complaint, and thus was precluded by the FCA's public disclosure bar from acting as a relator. The District Court subsequently denied Vierczhalek's motion for leave to amend her Amended Complaint on the ground that amendment would be futile. Vierczhalek now appeals both orders, which were encompassed by a March 2019 judgment.

I. Motion to Dismiss

We review *de novo* a district court's grant of a motion to dismiss a *qui tam* action. *United States v. Quest Diagnostics Inc.*, 734 F.3d 154, 163 (2d Cir. 2013). We affirm the judgment of the District Court dismissing the Amended Complaint for substantially the same reasons

as are stated in its comprehensive opinion. The parties do not dispute that the New York Attorney General's ("NYAG") Complaint is a "public disclosure" for purposes of 31 U.S.C. § 3730(e)(4)(B). Vierczhalek therefore cannot maintain this *qui tam* action unless she is an "original source" of the allegations made in the NYAG complaint. Vierczhalek's Amended Complaint failed to allege that she was the original source of those allegations. In particular, the NYAG's allegations explain that it discovered MedImmune's conduct only after it expanded its original investigation.

In response, Vierczhalek argues that the information she disclosed to the NYAG with respect to off-label use of Synagis should be considered "core information" under this Court's decision in *United States ex rel. Kreindler & Kreindler v. United Technologies Corp.*, 985 F.2d 1148, 1159 (2d Cir. 1993), and is therefore sufficient to make her an original source of the MedImmune-kickback allegations as well, Appellant's Br. at 39-40. A relator cannot qualify as an original source, however, merely by providing *some* core information. Rather, she must provide information regarding "the essential elements of the alleged fraud." *See United States ex rel. Kirk v. Schindler Elevator Corp.,* 437 F. App'x 13, 17 (2d Cir. 2011). Vierczhalek has not so alleged here.

Vierczhalek also counters that the public disclosure rule should not bar her Amended Complaint's allegations about MedImmune's unlawful scheme *outside* of New York, citing 31 U.S.C. § 3730(e)(4)(A). She urges that these latter claims are not "allegations or transactions" that are substantially similar to the NYAG's allegations. *Id.* But, as the District Court correctly observed, descriptions of the scheme that the NYAG first alleged pervade the Amended Complaint, and indeed Vierczhalek's Amended Complaint intermittently uses the NYAG Complaint's phrasing. *See* Joint App'x at 188. The additional details that Vierczhalek uncovered about similar unlawful activity in states other than New York do no more than support closely related claims about the unlawful scheme. They therefore do not free her of the public disclosure rule.

Finally, Vierczhalek contends that her allegations in the Amended Complaint regarding similar activities pursued by MedImmune in states other than New York are "independent of and materially add[]" to the State's complaint, thus qualifying her as an

"original source" under the FCA. *See* 31 U.S.C. § 3730(e)(4)(B) (internal quotation marks omitted). For the following reasons, we are not persuaded.

First, Vierczhalek's allegations of similar conduct in other states and with one other pharmacy are not "independent of" the activities charged in the NYAG Complaint. She admits that she "investigated further [in other States] *after* New York elected to pursue only a local Trinity-centric kickback theory." Appellant's Br. at 55 (emphasis added). Vierczhalek's own recitation leaves no doubt that her investigation into kickback activity outside of New York arose from the NYAG's kickback allegations, not vice-versa. *See U.S. ex rel. Schumann v. AstraZeneca Pharm. L.P.*, 769 F.3d 837, 845 (3d Cir. 2014) ("The independent knowledge requirement means that 'knowledge of the fraud cannot be merely dependent on a public disclosure.'"). A relator who simply "conducted some collateral research and investigations" in response to public allegations, and paired the results of that research with her background information, does not qualify as an original source. *See Kreindler*, 985 F.2d at 1159.

Second, for new allegations to "materially add" to public disclosures, they must "substantially" or "considerably" add to information that is already public. *U.S. ex rel. Paulos v. Stryker Corp.*, 762 F.3d 688, 694-95 (8th Cir. 2014). We discern no error in the District Court's conclusion that Vierczhalek at most augmented the "where" of the kickback allegations against MedImmune, and did not contribute "an iota to the 'who,' the 'what,' or the 'how' of the scheme." *United States ex rel. Vierczhalek v. MedImmune, Inc.*, 345 F. Supp. 3d 456, 465 (S.D.N.Y. 2018).

Thus, Vierczhalek's Amended Complaint does not adequately allege that she is an original source for purposes of avoiding the FCA's public disclosure bar. The District Court properly dismissed the Amended Complaint.

II. Motion to Amend

We generally review a district court's denial of leave to amend a complaint for abuse of discretion, *see Grabcheski v. Am. Int'l Grp., Inc.*, 687 F. App'x 84, 88 (2d Cir. 2017), but if the denial is based on "futility," we review it *de novo*, *Panther Partners Inc. v. Ikanos Cmmc'ns, Inc.*, 681 F.3d 114, 119 (2d Cir. 2012). We are unpersuaded that the District Court erred in

denying Vierczhalek's motion for leave to amend her Amended Complaint with respect to her original source allegations.

A proposed amendment is futile, and need not be allowed, when it would fail to cure the deficiencies identified in the prior complaint. The proposed Second Amended Complaint did not cure the deficiencies in Vierczhalek's Amended Complaint that we have just described, namely, that she failed to plausibly allege that she was an "original source" of the unlawful scheme against MedImmune. Vierczhalek urges that the allegations made in her Second Amended Complaint "support[] an *inference* that Trinity and MedImmune shared the NICU lists to market Synagis," and that this is new. Appellant's Br. at 22 (emphasis added). But the District Court already correctly rejected the notion that this inference made Vierczhalek an original source of the operative allegations. For this reason, we conclude that the District Court did not err in denying Vierczhalek's motion to amend.

* * *

We have considered Vierczhalek's remaining arguments and conclude that they are without merit. Accordingly, the judgment and orders of the District Court are **AFFIRMED**.

FOR THE COURT:
Catherine O'Hagan Wolfe, Clerk of Court