17-1522-cv
Daniel Coyne v. Amgen, Inc.

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 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 December, two thousand seventeen.

PRESENT: DENNIS JACOBS,
GUIDO CALABRESI,
DENNY CHIN,
Circuit Judges.

- -X
Daniel Coyne, MD,
Relator-Appellant,

-v.- **17-1522-cv**

Amgen, Inc.,
Defendant-Appellee.
- -X

FOR APPELLANT: Lori Siler Restaino, John M. Restaino, Jr., The Restaino Law Firm, Denver, Colorado.

Kenneth J. Brennan, Tyler J. Schneider, TorHoerman Law LLC, Edwardsville, Illinois.

FOR APPELLEES: David S. Rosenbloom, McDermott Will & Emery LLP, Chicago, Illinois.

Eric O. Corngold, Friedman Kaplan Seiler & Adelman LLP, New York, New York.

Appeal from a judgment of the United States District Court for the Eastern District of New York (Azrack, J.).

UPON DUE CONSIDERATION, IT IS HEREBY ORDERED, ADJUDGED AND DECREED that the judgment of the district court be **AFFIRMED**.

Dr. Daniel Coyne, serving as *qui tam* relator, appeals from the judgment of the United States District Court for the Eastern District of New York granting the motion to dismiss his False Claims Act ("FCA") suit against Amgen, Inc. ("Amgen"). Coyne, a former paid speaker for Amgen, alleges that from 1996 to at least 2010, the pharmaceutical company caused the Government to make unreasonable or unnecessary reimbursements of prescriptions for the kidney disease drug Epogen. We assume the parties' familiarity with the underlying facts, the procedural history, and the issues presented for review.

Coyne's allegations center on representations made by Amgen on the packaging and marketing materials for Epogen, a drug used to treat anemia by stimulating red blood cell production. In 1994, the Food and Drug Administration ("FDA") approved Epogen to treat chronic kidney disease by raising hemoglobin levels to the target level of 10-12 grams per deciliter (g/dL). The packaging for Epogen contained two discrete sections: (1) "Indications and Usage," which provides the intended treatment and dosage information as approved by the FDA; and (2) "Clinical Experience," which describes ancillary quality of life benefits and attributes. The pre-2007 packaging for Epogen stated in the Clinical Experience section that once a patient reached target hemoglobin levels, "statistically significant improvements were demonstrated for most quality of life parameters...." J. App'x at 83. The packaging statement did not mention any potential differences in

quality of life metrics that may arise within the 10-12 g/dL range.

Beginning in 1993, Amgen conducted the "Normal Hematocrit Trial" ("NHT"), which randomly assigned dialysis patients to one of two groups: the "low arm," which maintained participant hemoglobin levels of 9-11 g/dL; and the "high arm," which maintained participant hemoglobin levels of 13-15 g/dL. After patients in the "high arm" began to experience an elevated number of heart attacks and deaths, Amgen halted the study and reported the NHT and underlying data to the FDA in 1996. According to Coyne's interpretation, the NHT data "established that the [quality of life] scores reach their apex and then plateau at or before the 9-11 g/dL target range," suggesting (in his view) that taking Epogen beyond the 11 g/dL level confers no discernible quality of life benefit. J. App'x at 19. Coyne therefore asserts that Amgen knew as of 1996 that raising hemoglobin levels above 11 g/dL would not necessarily increase quality of life, but nonetheless continued to market Epogen as approved for usage up to 12 g/dL without separately noting its limitations in "Clinical Experience."

The FCA extends liability to "any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A); see also 31 U.S.C. § 3729(b)(2)(defining "claim" as "any request or demand, whether under a contract or otherwise, for money or property ... that is presented to an officer, employee, or agent of the United States"). Coyne proceeds on a theory of implied certification; according to this theory, "when a defendant submits [or causes to be submitted] a claim, it impliedly certifies compliance with all conditions of payment." Universal Health Servs. v. United States ex rel. Escobar, 136 S. Ct. 1989, 1995 (2016). Coyne's contention is that between 1996 and 2011, Amgen's misrepresentations on Epogen's packaging and marketing materials about quality of life caused the submission of false claims for prescription reimbursement to the Centers for Medicare and Medicaid Services ("CMS"), because each patient's payment claim to CMS impliedly certified Epogen's compliance with the agency's requirement that medication be "reasonable and necessary" under 42

U.S.C. § 1395y(a)(1)(A). The district court ruled that the FCA's public disclosure bar precluded the claims against Amgen and dismissed the suit.[1] See 31 U.S.C. § 3730(e)(4)(A).

"We review the district court's grant of a motion to dismiss *de novo*, but may affirm on any basis supported by the record." Coulter v. Morgan Stanley & Co., Inc., 753 F.3d 361, 366 (2d Cir. 2014) (per curiam). To state a claim under 31 U.S.C. § 3729(a)(1), the plaintiff must show "the defendants (1) made a claim, (2) to the United States Government, (3) that is false or fraudulent, (4) knowing of its falsity, and (5) seeking payment from the federal treasury." United States ex rel. Kirk v. Schindler Elevator Corp., 601 F.3d 94, 113 (2d Cir. 2010), rev'd on other grounds, 563 U.S. 401 (2011). An alleged "misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable" under the FCA. Universal Health Servs., 136 S. Ct. at 2002. "The materiality standard is demanding" and materiality "cannot be found where noncompliance is minor or insubstantial." Id. at 2003. Specifically, to be material the government must have made the payment "as a result of the defendant's alleged misconduct." United States ex rel. Ge v. Takeda Pharm. Co. Ltd., 737 F.3d 116, 124 (1st Cir. 2013).

Coyne cannot satisfy these requirements because he does not connect his allegations to the submissions of false claims. Even adopting *arguendo* Coyne's interpretation of the NHT data, he fails to plausibly allege that any

[1] Since the NHT data was "publicly disclosed" to the Government in 1996, Coyne cannot evade the public disclosure bar unless he was an "original source" for the information about Epogen's quality of life benefits. See 31 U.S.C. § 3730(e)(4)(A). The definition of original source was amended in 2010. See Pub. L. 111-148, 124 Stat. 119 (2010). Because we are affirming the dismissal of the action on other grounds, we need not consider whether Coyne is an original source or whether the revised definition applies.

misrepresentation by Amgen materially impacted CMS's payment determination.[2] The amended complaint relies on a conclusory assertion that Amgen's failure to disclose the NHT study to CMS was material to, or in effect caused, payment. But it is not "sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance," Universal Health Servs., 136 S. Ct. at 2003: the complaint must present concrete allegations from which the court may draw the reasonable inference that the misrepresentations on Epogen's packaging and marketing materials caused the Government to make the reimbursement decision. See United States ex rel. Chorches v. Am. Med. Response, Inc., 865 F.3d 71, 78 (2d Cir. 2017)(citing Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)). Coyne offers none.

Any claims about quality of life improvements contained on the Clinical Experience portion of the label would be unlikely to impact CMS reimbursement. That is because FDA approval for Indications and Usage of a medication makes it presumptively "reasonable and necessary" for the purposes of CMS reimbursement, and only the Indications and Usage section of the drug label relates to FDA approval. See 21 C.F.R. § 201.56-57; Bayer Schera Pharma AG v. Sandoz, Inc., 741 F. Supp. 2d 541, 547-48 (S.D.N.Y. 2010). On the facts of this case, given that Epogen was prescribed consistent with its FDA-approved indication, reimbursement is appropriate. See Mut. Pharma Co. v. Bartlett, 133 S. Ct. 2466, 2471 (2013); United States ex rel. Polansky v. Pfizer, Inc., 822 F.3d 613, 616, 618-19 (2d Cir. 2016).

Amgen's introduction of new labeling for Epogen in 2007 confirms the lack of materiality. Following changes to FDA policy, Amgen added information to the "Clinical Experience" section of Epogen's label in place of the language challenged by Coyne:

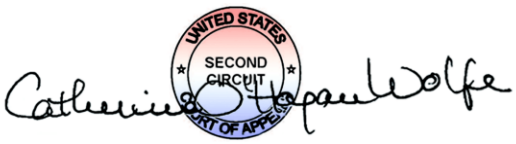
[2] Coyne also brings claims under 31 U.S.C. §§ 3729(a)(1)(B) and (a)(1)(G), both of which contain materiality requirements. Claims brought under these sections fail for the same lack of materiality.

> In a 26-week double-blind, placebo-controlled trial, 118 anemic dialysis patients with an average hemoglobin of approximately 7 g/dL were randomized to either Epogen or placebo. By the end of the study, average hemoglobin increased to approximately 11 g/dL in the Epogen-treated patients and remained unchanged in patients receiving placebo. Epogen-treated patients experienced improvements in exercise tolerance and patient-reported physical functioning at month 2 that was maintained throughout the study.

Supp. App. at 164. Amgen's brief explains that the company added this new information in the "Clinical Experience" section of the label without making any change to the "Indications and Usage" section. The new language—limiting certain benefits to hemoglobin levels of approximately 11 g/dL—is what Coyne claims should have been disclosed on the Epogen label since 1996. Yet armed with this information, CMS did not alter its reimbursement practices with respect to Epogen or exercise any independent discretion from the presumption of FDA approval. The mechanics of the CMS reimbursement scheme and its operation in practice show that any concealment of the NHT data from CMS was immaterial to its payment decisions.

For the foregoing reasons, and finding no merit in Coyne's other arguments, we hereby **AFFIRM** the judgment of the district court.

FOR THE COURT:
CATHERINE O'HAGAN WOLFE, CLERK



United States Court of Appeals for the Second Circuit
Thurgood Marshall U.S. Courthouse
40 Foley Square
New York, NY 10007

ROBERT A. KATZMANN
CHIEF JUDGE

CATHERINE O'HAGAN WOLFE
CLERK OF COURT

Date: December 18, 2017
Docket #: 17-1522cv
Short Title: United States of America v. Amgen, Inc.

DC Docket #: 12-cv-3881
DC Court: EDNY (CENTRAL ISLIP)
DC Judge: Shields
DC Judge: Azrack

BILL OF COSTS INSTRUCTIONS

The requirements for filing a bill of costs are set forth in FRAP 39. A form for filing a bill of costs is on the Court's website.

The bill of costs must:
* be filed within 14 days after the entry of judgment;
* be verified;
* be served on all adversaries;
* not include charges for postage, delivery, service, overtime and the filers edits;
* identify the number of copies which comprise the printer's unit;
* include the printer's bills, which must state the minimum charge per printer's unit for a page, a cover, foot lines by the line, and an index and table of cases by the page;
* state only the number of necessary copies inserted in enclosed form;
* state actual costs at rates not higher than those generally charged for printing services in New York, New York; excessive charges are subject to reduction;
* be filed via CM/ECF or if counsel is exempted with the original and two copies.