UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

August Term, 2015

(Argued: December 7, 2015 Decided: May 17, 2016)

Docket No. 14-4774

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UNITED STATES OF AMERICA,
ex rel. DR. JESSE POLANSKY,

Plaintiff-Appellant,

- v.-

PFIZER, INC.,

Defendant-Appellee.

- -x

Before: JACOBS, LIVINGSTON, and LYNCH, Circuit Judges.

Dr. Jesse Polansky appeals from a partial final judgment of the United States District Court for the Eastern District of New York (Cogan, J.), dismissing his False Claims Act ("FCA") and state analog causes of action. Polansky alleges

that: his former employer, defendant Pfizer, Inc. ("Pfizer"), improperly marketed Lipitor, a popular statin, as appropriate for patients whose risk factors and cholesterol levels fall outside the National Cholesterol Education Program Guidelines ("NCEP Guidelines" or "Guidelines"); that the Guidelines are incorporated into and made mandatory by the drug's label; and that Pfizer thus induced doctors to prescribe the drug, pharmacists to fill the prescriptions, and federal and state health care programs to pay for "off-label" prescriptions. Judge Cogan dismissed the claims on the ground that the FDA's approval of Lipitor was not dependent upon compliance with the Guidelines. We affirm.

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MARC S. CHEFFO, Quinn Emanuel Urquhart & Sullivan, LLP, New York, New York (Hayden A. Coleman, on the brief), for Appellee.

DENNIS JACOBS, Circuit Judge:

Dr. Jesse Polansky appeals from a partial final judgment of the United States District Court for the Eastern District of New York (Cogan, J.), dismissing

his False Claims Act ("FCA") and state analog causes of action. We have appellate jurisdiction by virtue of certification. Polansky alleges that in and after 2002: his former employer, defendant Pfizer, Inc. ("Pfizer"), improperly marketed Lipitor, a popular statin, as appropriate for patients whose risk factors and cholesterol levels fall outside the National Cholesterol Education Program Guidelines ("NCEP Guidelines" or "Guidelines"); that the Guidelines are incorporated into and made mandatory by the drug's label; and that Pfizer thus induced doctors to prescribe the drug, pharmacists to fill the prescriptions, and federal and state health care programs to pay for "off-label" prescriptions. Judge Cogan dismissed the claims because he determined that the FDA's approval of Lipitor was not dependent upon compliance with the Guidelines.[1] We affirm.

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[1] Polansky also challenges Pfizer's termination of his employment as motivated by unlawful retaliation under a number of federal and state laws. This panel dismissed Polansky's prior appeal for lack of appellate jurisdiction because we could not determine whether the district court had meant to dismiss all of Polansky's claims or only those brought under the FCA and analogous state laws. United States ex rel. Polansky v. Pfizer, Inc., 762 F.3d 160, 164-65 (2d Cir. 2014) ("Polansky III"). On remand, the district court clarified that it had only dismissed Polansky's fraud-based claims, certified those claims for appeal under Federal Rule of Civil Procedure 54(b), and entered partial final judgment. As we had instructed, the appeal returned to this panel. Polansky's employment-based claims, which have not been dismissed, remain before the district court.

BACKGROUND

A

The Food, Drug and Cosmetic Act ("FDCA") forbids pharmaceutical manufacturers from marketing or selling a drug until the Food and Drug Administration ("FDA") has approved it as safe and effective for its intended use or uses (the drug's "indications"). See 21 U.S.C. § 355(a), (d); United States v. Caronia, 703 F.3d 149, 152-53 (2d Cir. 2012); see also 21 U.S.C. § 393(b)(2)(B). The exact wording of the drug's "label" must be approved by the FDA, and thereafter generally cannot be altered without further approval. Wyeth v. Levine, 555 U.S. 555, 568 (2009); see 21 U.S.C. § 355(b)(1)(F), (d); 21 C.F.R. §§ 314.105(b), 601.12. The label (which can be quite lengthy) must include, inter alia, the drug's indications, contra-indications, limitations of use, use by specific populations, and dosage instructions. 21 C.F.R. § 201.57.

"Once FDA-approved, prescription drugs can be prescribed by doctors for both FDA-approved and -unapproved uses; the FDA generally does not regulate how physicians use approved drugs." Caronia, 703 F.3d at 153; see also 21 U.S.C. § 396 (principle of non-interference with the practice of medicine). "Indeed, courts and the FDA have recognized the propriety and potential public value of

unapproved or off-label drug use." Caronia, 703 F.3d at 153 (citing cases and FDA draft guidance). However, pharmaceutical manufacturers are generally prohibited from promoting off-label uses of their products if the off-label marketing is false or misleading, or if it evidences that a drug is intended for such off-label use and is therefore "misbranded."[2]

Polansky contends that prescriptions written for off-label uses are generally not reimbursable by federal and state health care programs. Federal reimbursement for prescription drugs under Medicare and Medicaid is generally limited to drugs prescribed for FDA-approved (on-label) uses or for certain purposes included in any of three drug compendia. See 42 U.S.C. § 1396r-8(k)(2),

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[2] A drug is misbranded if its labeling lacks "adequate directions" for safe use by a layperson "for the purposes for which it is intended." 21 U.S.C. § 352(f)(1); 21 C.F.R. § 201.5; see also 21 C.F.R. § 201.128 (definition of "intended uses"). In Caronia, this Court construed the FDCA not to prohibit or criminalize "the simple promotion of a drug's off-label use" where that off-label use is not prohibited and where the promotional speech is not false or misleading, to avoid First Amendment concerns. 703 F.3d at 160, 165 & n.10, 168-69. Caronia left open the government's ability to prove misbranding on a theory that promotional speech provides evidence that a drug is intended for a use that is not included on the drug's FDA-approved label. See id. at 162; see also 21 C.F.R. § 201.128 ("[I]f a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.").

(3), (6); id. § 1395w-102(e)(1), (4). State Medicaid programs "may exclude or otherwise restrict coverage" if a drug is prescribed off-label unless included in any of those compendia. Id. § 1396r-8(d)(1)(B)(i).

B

Lipitor (atorvastatin calcium) is a popular statin, a drug that lowers cholesterol levels by blocking enzymes essential to cholesterol production. Broadly speaking, Lipitor is approved for treatment of elevated cholesterol, and for prevention of cardiovascular disease. During the time period relevant to this case, Lipitor was approved for five "indications" relating to treatment of elevated cholesterol.[3]

Polansky alleges that Lipitor's approved use is more narrow than these specific indications: that it is approved only when the patient's risk factors and cholesterol levels fall within a framework outlined in the NCEP Guidelines, and that any use by a patient outside that framework is unapproved and off-label. He further alleges that Pfizer widely marketed Lipitor for outside-Guidelines

[3] Beginning in July 2004, Lipitor has also had several "indications" relating to prevention or reduction of risk of various cardiovascular diseases.

use,[4] causing physicians to write Lipitor prescriptions for patients whose risk factors and cholesterol levels fell outside the Guidelines framework, and causing those prescriptions to be submitted for reimbursement by federal and state health care programs. Because government health care programs generally do not reimburse prescriptions for off-label use, see supra, he contends that these requests for reimbursement impliedly certified (falsely) that the prescription was for an on-label use, and thus constituted false claims under the FCA and state laws.

The Guidelines were promulgated in 2001 by the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, under the aegis of the National Heart, Lung, and Blood Institute of the National Institutes of Health.[5] The Guidelines were "recommendations for cholesterol testing and management," J.A. 32, and cautioned that they were advisory only:

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[4] Polansky was employed by Pfizer as Medical Director for a committee that reviewed the company's marketing strategies for certain drugs, including Lipitor.

[5] The NCEP Guidelines were updated in 2004; and in 2013 they were replaced by further updated guidelines issued by the American College of Cardiology and the American Heart Association.

> This evidence-based report should not be viewed as a standard of practice. Evidence derived from empirical data can lead to generalities for guiding practice, but such guidance need not hold for individual patients. Clinical judgment applied to individuals can always take precedence over general management principles. Recommendations . . . thus represent general guidance that can assist in shaping clinical decisions, but they should not override a clinician's considered judgment in the management of individuals.

J.A. 33. The full Guidelines report is nearly 300 pages long.

The Guidelines recommended a focus on lowering LDL (low-density lipoprotein) cholesterol. Patients were grouped on the basis of their risk for coronary heart disease events. Each of the three risk categories was accorded (1) an LDL cholesterol therapeutic "goal"; (2) an LDL level at which to initiate therapeutic lifestyle changes; and (3) an LDL "cutpoint" at which to consider drug therapy. (The particulars are in the margin.[6])

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[6] For patients in the highest risk category, the Guidelines recommended an LDL cholesterol goal of below 100 milligrams per deciliter (mg/dL); initiation of lifestyle changes at 100 mg/dL or above; and drug therapy at 130 mg/dL or above--but they also advised physicians to "[c]onsider drug options" between 100 and 129 mg/dL, noting differing preferences among authorities and the need for "[c]linical judgment." J.A. 119. For patients in the middle risk category, the Guidelines recommended an LDL goal of below 130 mg/dL; initiation of lifestyle changes at 130 mg/dL or above; and drug therapy at either [i] 130 mg/dL or above (for patients with a ten-to-twenty percent risk of a coronary heart disease event within ten years) or [ii] 160 mg/dL or above (for patients with a below ten percent risk of a coronary heart disease event within ten years). For patients in the lowest risk category, they recommended an LDL goal of below 160 mg/dL;

The Lipitor label changed somewhat during the time between the Guidelines' promulgation in 2001 and the filing of the operative complaint in 2010; but the only difference material to the outcome of this case is one made in June 2009. Pre-2009 Lipitor labels included a table summarizing the recommendations of the NCEP Guidelines (see footnote 6); but this table does not appear anywhere in the 2009 label. Notwithstanding that change, the 2009 label is *substantively the same* as its pre-2009 iteration[7]: any substantive modifications had to be specifically disclosed in the new, 2009 label, see 21 C.F.R. § 201.57(a)(5); no such modifications were listed in the 2009 label, which was submitted to and approved by the FDA; and it was agreed by the parties during district court proceedings that the 2009 label did not effect any substantive changes.[8]

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initiation of lifestyle changes at 160 mg/dL or above; and drug therapy at 190 mg/dL or above--but they also stated that drug therapy was "optional depending on clinical judgment" between 160 and 190 mg/dL. J.A. 121.

[7] The 2009 label was promulgated pursuant to the FDA's Physician Labeling Rule, which revised the FDA's requirements for label content and formatting with the intent of making pharmaceutical labels easier for physicians to read and use. See Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006) (codified at 21 C.F.R. § 201.56).

[8] Polansky now argues half-heartedly that this is a question of fact, but he also acknowledges that the removal of the Guidelines table "does not appear to have

Pre-2009 labels referred to the NCEP Guidelines in two sections: "Indications and Usage" and "Dosage and Administration." The "Indications and Usage" section enumerated the drug's five indications relating to treatment of elevated cholesterol, and then added:

> Therapy with lipid-altering agents should be a component of multiple-risk-factor intervention in individuals at increased risk for atherosclerotic vascular disease due to hypercholesterolemia. Lipid-altering agents should be used in addition to a diet restricted in saturated fat and cholesterol only when the response to diet and other nonpharmacological measures has been inadequate (see *National Cholesterol Education Program (NCEP) Guidelines*, summarized in Table [below]).

E.g., J.A. 718-19 (2005 label). The Guidelines summary table followed.

The "Dosage and Administration" section of pre-2009 labels contained four-to-six patient subcategories (depending on the date); in one of these patient subcategories, the labels referenced the Guidelines: "The starting dose and maintenance doses of LIPITOR should be individualized according to patient characteristics such as goal of therapy and response (see *NCEP Guidelines*, summarized in Table [above])." E.g., J.A. 729 (2005 label).

In the 2009 label, the summary table does not appear. The Guidelines are

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been considered a substantive change." Br. of Appellant at 48.

not mentioned at all in the "Indications and Usage" section (even though that section includes a restriction based on LDL level for patients between the ages of ten and seventeen, as did pre-2009 labels). The "Dosage and Administration" section retains the same parenthetical reference to the Guidelines as did earlier labels. The Guidelines appear nowhere else in that label.

C

The FCA is an anti-fraud statute; accordingly, Polansky must plead fraud with particularity pursuant to Federal Rule of Civil Procedure 9(b). See Gold v. Morrison-Knudsen Co., 68 F.3d 1475, 1476 (2d Cir. 1995) (per curiam). Judge Korman, to whom this case was originally assigned, reviewed the previous version of the complaint, and dismissed the FCA and state analog claims for failure to satisfy Rule 9(b)'s requirements. United States ex rel. Polansky v. Pfizer, Inc., 04-CV-0704 (ERK), 2009 WL 1456582, at *5-10 (E.D.N.Y. May 22, 2009) ("Polansky I").

Polansky then filed the operative complaint, seeking to cure the defects Judge Korman had identified. Judge Cogan, to whom the case was reassigned, again dismissed these claims, but on the different ground that Pfizer had not engaged in off-label marketing as a matter of law and therefore could not have

caused false claims to be submitted. United States ex rel. Polansky v. Pfizer, Inc., 914 F. Supp. 2d 259, 266 (E.D.N.Y. 2012) ("Polansky II"). Judge Cogan determined that the premise underlying Polansky's FCA claims--that the label required compliance with the Guidelines--was implausible. See Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007) (complaint must provide "enough facts to state a claim to relief that is plausible on its face" to survive motion to dismiss).

DISCUSSION

As relevant here, the FCA imposes liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the U.S. government; or who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)-(b). Polansky's theory of FCA liability necessarily rests on the contentions that (1) the NCEP Guidelines were incorporated into Lipitor's FDA-approved label and made mandatory, and (2) requests for reimbursement of Lipitor prescriptions impliedly certified (falsely) that the

prescription was for an on-label use.[9]

Pfizer urges that we can affirm on any of several alternative grounds: that the Guidelines are not incorporated into the Lipitor label, as held by Judge Cogan in Polansky II; that the operative complaint failed to cure the Rule 9(b) particularity defect identified by Judge Korman in Polansky I; or that no false claims have been alleged because the complaint fails to plausibly allege that requests for reimbursement impliedly certified on-label use. We expressly endorse and adopt Judge Cogan's carefully considered and thorough analysis, and affirm on that basis.

As Judge Cogan explained, "guidelines" usually provide advice and (unsurprisingly) guidance, "not mandatory limitation." Polansky II, 914 F. Supp. 2d at 262. The NCEP Guidelines themselves expressly disclaimed prescriptive force: Their "general guidance" "need not hold for individual patients" and "should not override" a physician's clinical judgment about appropriate

[9] A claim submitted to the government "is legally false only where a party certifies compliance with a statute or regulation as a condition to governmental payment." Mikes v. Straus, 274 F.3d 687, 697 (2d Cir. 2001). Such certification may be either express or implied. In the medical provider context, "implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies expressly states the provider must comply in order to be paid." Id. at 700 (emphasis omitted).

treatment of a particular patient. J.A. 33.

The district court drew the proper inferences. "Once the doctor's clinical judgment is introduced as the determinative factor in the decision making process, it must be apparent that this data serves as a recommendation, not a limitation or prohibition." Polansky II, 914 F. Supp. 2d at 264-65. We "cannot accept plaintiff's theory that what scientists at the National Cholesterol Education Program clearly intended to be advisory guidance is transformed into a legal restriction simply because the FDA has determined to pass along that advice through the label." Id. at 265.

Where the label imposes cholesterol-level restrictions, it does so only for pediatric patients. This express restriction makes "more conspicuous" the absence of a similar restriction for adults, id. at 263, and shows how easily the FDA could have mandated compliance with the NCEP Guidelines with respect to all patients if it wanted to do so.

This conclusion is reinforced by the 2009 label. Notwithstanding that it is substantively identical to the prior version (as a matter of administrative procedure), it omits the Guidelines table, makes no more than fleeting reference to the Guidelines, and fails to mention them at all in the "Indications and Usage"

section of the label, which is where a limitation on approved "usage" would be expected to appear. "A person reading the 'Indications and Usage' section of the 2009 label must come away with one clear meaning; the drug is to be used if a physician believes his patient should lower his cholesterol. That is the drug's essential purpose as defined by the label--to lower cholesterol." Id. For further particulars of the analysis, the reader is referred to Judge Cogan's opinion, which we adopt.

Because we affirm on that basis, we need not wade into the circuit split regarding whether, to satisfy Rule 9(b), an FCA relator alleging a fraudulent scheme must provide the details of specific examples of actual false claims presented to the government (which Polansky does not do). (That split is detailed in the margin.[10]) Nor need we decide whether Polansky has adequately

[10] Compare, e.g., United States ex rel. Bledsoe v. Cmty. Health Sys., Inc., 501 F.3d 493, 504 (6th Cir. 2007) ("We hold that pleading an actual false claim with particularity is an indispensable element of a complaint that alleges a FCA violation in compliance with Rule 9(b)."), and United States ex rel. Nathan v. Takeda Pharms. N. Am., Inc., 707 F.3d 451, 457-58 (4th Cir. 2013) ("[W]hen a defendant's actions, as alleged and as reasonably inferred from the allegations, *could* have led, but *need not necessarily* have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government for payment. To the extent that other cases apply a more relaxed construction of Rule 9(b) in such circumstances, we disagree with that approach."), with United States ex rel. Grubbs v. Kanneganti, 565 F.3d 180,

alleged that a request for prescription-drug reimbursement is an implied certification of on-label use.

We are skeptical, however, that even under Polansky's theory of the case, anyone could be identified who actually submitted a false claim. "[T]he FDA does not prohibit physicians, who are free to do so, from prescribing Lipitor for patients with normal cholesterol." Polansky I, 2009 WL 1456582, at *10. Accordingly, it is unclear just whom Pfizer could have caused to submit a "false or fraudulent" claim: The physician is permitted to issue off-label prescriptions; the patient follows the physician's advice, and likely does not know whether the use is off-label; and the script does not inform the pharmacy at which the prescription will be filled whether the use is on-label or off. We do not decide the case on this ground, but we are dubious of Polansky's assumption that any one of these participants in the relevant transactions would have knowingly, impliedly certified that any prescription for Lipitor was for an on-label use. Cf.

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190 (5th Cir. 2009) ("[A] relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted."), and Foglia v. Renal Ventures Mgmt., LLC, 754 F.3d 153, 156-57 (3d Cir. 2014) (adopting same approach, and discussing circuit split).

id. at *7 ("[B]ecause the FDA has expressly advised physicians that, 'unlabeled uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature,' and because physicians 'commonly exercise professional medical judgment and prescribe drugs for uses not within the indications articulated by the FDA,' the entities to which reimbursement claims are made could hardly be understood to have operated on the assumption that the physician writing the prescription was certifying implicitly that he was prescribing Lipitor in a manner consistent with the Guidelines." (citations omitted)).

"The False Claims Act, even in its broadest application, was never intended to be used as a back-door regulatory regime to restrict practices that the relevant federal and state agencies have chosen not to prohibit through their regulatory authority." Polansky II, 914 F. Supp. 2d at 266. It is the FDA's role to decide what ought to go into a label, and to say what the label means, and to regulate compliance. We agree with Judge Cogan that there is an important distinction between marketing a drug for a purpose obviously not contemplated by the label (such as, with respect to Lipitor, "to promote hair growth or cure

cancer") and marketing a drug for its FDA-approved purpose to a patient population that is neither specified nor excluded in the label. Id. at 265. An FCA relator alleging off-label marketing might be able to satisfy Rule 9(b) and surmount the impediment of implied certification in a case in which it would be obvious to anyone that the use promoted is one that is not approved; but this is emphatically not such a case.

For these reasons, the partial judgment is **AFFIRMED.**