12-5008-cv

United States Court of Appeals

for the

Second Circuit

UNITED STATES OF AMERICA, EX REL DR. JESSE POLANSKY,

Plaintiff-Appellant,

– v. –

PFIZER, INC.,

Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

PAGE PROOF BRIEF FOR DEFENDANT-APPELLEE

MARK S. CHEFFO
HAYDEN A. COLEMAN
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
Attorneys for Defendant-Appellee
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7000

CORPORATE DISCLOSURE STATEMENT

No parent corporation or publicly held corporation owns 10% or more of Pfizer Inc.'s stock.

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TABLE OF ABBREVIATIONS

CHD ..... Coronary Heart Disease
EEOC ..... Equal Employment Opportunity Commission
FAC ..... Fifth Amended Complaint
FCA ..... False Claims Act
FDA ..... Food and Drug Administration
HDL ..... High-density lipoprotein
LDL ..... Low-density lipoprotein
NCEP ..... National Cholesterol Education Program
NDA ..... New Drug Application
NHANES ..... National Health and Nutrition Examination Survey
PLR ..... Physician Labeling Rule

PRELIMINARY STATEMENT

Defendant-Appellee Pfizer Inc. ("Pfizer") manufactures the prescription medicine Lipitor, which the Food and Drug Administration ("FDA") has approved to treat elevated cholesterol levels and to reduce the risk of heart attack, stroke, and certain kinds of heart surgeries in patients with multiple risk factors for coronary heart disease. Appellant-Relator Dr. Jesse Polansky claims that Pfizer has caused the United States Government to pay false claims by marketing Lipitor for unapproved or "off-label" uses. Relator's false claim counts are premised entirely on his contention that *recommendations* issued by the National Cholesterol Education Program ("NCEP") were transformed into *mandatory restrictions* when those recommendations were referenced in earlier versions of the FDA-approved prescribing information, or "label," for Lipitor.

The district court properly concluded that Relator's theory of liability conflicts with the plain language of the Lipitor labels at issue. *See United States ex rel. Polansky v. Pfizer, Inc.*, No. 04-cv-0704, 2012 WL 5595933, at *7 (E.D.N.Y. Nov. 15, 2012) (Cogan, J.) ("Everything about the two labels at issue in this case suggests that the NCEP Guidelines, as a matter [of] plain language, fall well within the usual, non-compulsory definition of the word guidelines."). As the district court explained, Polansky's theory of False Claims Act ("FCA") liability relies entirely on a reference to the NCEP Guidelines that appeared in the "Indications

and Usage" section of the 2005 Lipitor label. *See Polansky II*, 2012 WL 559533, at *2-3. However, in June 2009, the FDA approved several *non-substantive* revisions to the Lipitor label, which were made pursuant to an FDA rule designed to enhance the ability of healthcare practitioners to access, read, and use prescription drug labeling. Crucially, these revisions did *not* alter the meaning of the label or broaden the approved "indications," or uses, for Lipitor.

One of the revisions to the 2009 Lipitor label was to *remove* completely the reference to the NCEP Guidelines and the accompanying summary table on which Polansky bases his false claims counts. In other words, the reference that Polansky alleges imposed a "mandatory" restriction on Lipitor use no longer exists in the label, confirming both that no liability could be based on the 2009 label and that Polansky's assertion that the 2005 label and other pre-2009 versions were circumscribed by the NCEP Guidelines was untenable. *Id.* at *7.

This Court, however, should not reach this question or other issues concerning the merits of Polansky's claims because the district court did not issue a final judgment resolving all claims advanced by Polansky. In addition to suing Pfizer for violating the FCA, 31 U.S.C. §§ 3729-3733, and related state law causes of action, Polansky also sued Pfizer for wrongfully terminating him. The district court never adjudicated these claims. Instead, as Polansky acknowledges, after the case was transferred to a new judge and Pfizer filed a motion to dismiss Polansky's

false claims counts, but *not* his employment counts, the district court "simply overlooked the employment claims" in dismissing the entire case. (Appellant Br. at 61.) As other circuits have recognized, in that situation, there is no final judgment resolving all the claims in the case and, thus, no appellate jurisdiction.

Pfizer therefore respectfully requests that this appeal be dismissed for lack of jurisdiction, and the case remanded to the district court. If the Court finds that it has appellate jurisdiction, the district court's dismissal of Relator's FCA claims and related state law claims should be affirmed, and this case should be remanded to the district court for consideration of Relator's employment claims.

STATEMENT OF JURISDICTION

This Court lacks appellate jurisdiction over the district court's November 15, 2012 Order because, as explained below in Section I of the Argument, the order does not resolve Relator's employment claims and, thus, does not provide the basis for a final judgment.

ISSUES PRESENTED FOR REVIEW

1. Whether the district court's November 15, 2012 Order provides the basis for a final judgment when Defendant did not move to dismiss Relator's employment claims, the district court did not address those claims, and Relator acknowledges that the district court simply overlooked those claims in entering judgment.

2. Whether guidelines promulgated by the National Cholesterol Education Program constituted a mandatory restriction on the approved use of Lipitor for treatment of elevated cholesterol.

3. Whether Relator has stated valid False Claims Act and related state law claims based on alleged off-label promotion of Lipitor even though he has not identified any false claims made to the Government.

4. Whether Relator has stated valid False Claims Act and related state law claims based on violations of the NCEP Guidelines even though he has not alleged that compliance with those Guidelines was a condition or prerequisite for any payments by the Government.

STATEMENT OF THE CASE

In February 2004, Relator Polansky filed a *qui tam* Complaint under seal on behalf of the United States, alleging FCA violations and related state law claims. Polansky also alleged violations of the FCA's retaliation provision, 31 U.S.C. § 3730(h), and the New York Whistleblower Statute, New York Labor Law § 740. In June 2005, Polansky filed an amended complaint, adding employment discrimination claims under Title VII, 42 U.S.C. § 2000E *et seq.*, and the New York State Human Rights Law, New York Executive Law § 290. In August 2007, the United States Department of Justice declined to intervene. Polansky then amended his complaint three more times.

Pfizer subsequently moved to dismiss the false claims counts and most of the employment counts in the Fourth Amended Complaint. On May 22, 2009, the district court (Korman, J.) dismissed the false claim counts with leave to replead. *See United States ex rel. Polansky v. Pfizer, Inc.*, No. 04-cv-0704, 2009 WL 1456582, at *11 (E.D.N.Y. May 22, 2009) (Korman, J.) ("*Polansky I*" or the "May 2009 Order"). By separate opinion filed the same day, the district court denied Pfizer's motion to dismiss Polansky's claims under the FCA's retaliation provision and the New York Whistleblower Statute. (May 22, 2009 Order on Employment Claims, ECF No. 61 at 1.)

In February 2010, Relator filed a Fifth Amended Complaint (the "FAC"). (ECF No. 77.) Pfizer again moved to dismiss the false claims counts, but Pfizer did ***not*** move to dismiss any of the employment claims. (ECF Nos. 90, 91, 92.) In December 2011, the case was reassigned to Judge Brian M. Cogan. The district court then granted Pfizer's motion to dismiss the false claims counts pursuant to Rule 12(b)(6). *See United States ex rel. Polansky v. Pfizer, Inc.*, No. 04-cv-0704, 2012 WL 5595933, at *7 (E.D.N.Y. Nov. 15, 2012) (Cogan, J.) ("*Polanksy II*" or the "November 2012 Order"). Although Pfizer's motion to dismiss did not address Polansky's employment claims, the district court directed the Clerk to enter judgment in favor of Pfizer, which the Clerk did.

Polansky subsequently filed a notice of appeal. Although Pfizer's counsel told Polansky's counsel that jurisdiction was lacking and that Pfizer would not oppose a motion to dismiss the appeal and return to the district court for proceedings on the employment claims, Polansky declined and pursued this appeal.

STATEMENT OF FACTS

A. The Lipitor Label and Its Approved Uses

Lipitor (also known as atorvastatin calcium) is a synthetic lipid lowering agent manufactured and sold by Pfizer. Approved by the FDA in 1996, it is one of a class of medicines commonly known as statins, which are prescribed by physicians to regulate blood cholesterol. Among other FDA-approved uses – or approved "indications" – Lipitor is approved to treat elevated cholesterol and to reduce the risk of heart attack, stroke, and certain kinds of heart surgeries in patients with multiple risk factors for coronary heart disease.

After the FDA has approved a prescription medicine for an indication, a manufacturer can market the product for use for that indication. *See, e.g.*, 21 U.S.C. § 355(a); *cf. U.S. v. Caronia*, 703 F.3d 149, 152-55 (2d Cir. 2012) (describing regulatory scheme governing the sale and promotion of prescription medicines). In other words, if a use is included in the indications of an FDA-approved label, it is a "labeled" use, and promotion of that use is permitted. *See Polansky I*, 2009 WL 1456582, at *6.

At the time that Polansky filed his Fourth Amended Complaint, Lipitor had five FDA-approved indications involving the treatment of elevated cholesterol. The first approved use was:

> As an adjunct to diet to reduce elevated total-C, LDL-C, apo B, and TG levels and to increase HDL-C in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (Fredrickson Types IIa and IIb)[.]

2005 Lipitor Label (ECF No. 77-10 at 11.) In layman's terms, "hypercholesterolemia" or "hyperlipidemia" is the presence of high cholesterol levels in the blood, or simply high cholesterol. Thus, Lipitor was primarily approved, or indicated, to *lower cholesterol in patients with high cholesterol*.

As the language quoted above demonstrates, in approving Lipitor as an adjunct to diet to reduce, *inter alia*, elevated low-density lipoprotein cholesterol ("LDL-cholesterol," often known as "bad" cholesterol) in adult patients, the FDA did not identify a numerical LDL-cholesterol threshold below which Lipitor is not indicated. By contrast, in approving Lipitor for use in *children* ages 10 to 17, the FDA *did* impose a numerical LDL-cholesterol threshold below which Lipitor is not indicated. Specifically, the same label provided that Lipitor is approved:

> As an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present:

a. LDL-C remains ≥ 190 mg/dL or

b. LDL-C remains ≥ 160 mg/dL and:

- there is a positive family history of premature cardiovascular disease or
- two or more other CVD risk factors are present in the pediatric patient

(ECF No. 77-10 at 12.)

Before the label changed in 2009, the Lipitor label referenced and included a summary chart from the NCEP Guidelines, which contain "[r]ecommendations . . . [that] represent general guidance that can assist in shaping clinical decisions [respecting the treatment of high cholesterol], but . . . [that] should not override a clinician's considered judgment in the management of individuals." (ECF No. 45-3 at I-2.) The NCEP Guidelines were promulgated under the auspices of the National Heart, Lung and Blood Institute in 2001 and updated in 2004. The primary focus of the Guidelines is the prevention of coronary heart disease ("CHD"). (ECF No. 45-3 at I-1.) The basic principle of cholesterol-lowering therapy under the Guidelines is that the need for such therapy corresponds to the relative risk of a CHD-event (*e.g.*, a heart attack) over a ten-year period. (ECF No. 45-3 at IV-1.) Using an algorithm to assess a patient's "degree of risk" for a CHD event, the Guidelines recommend that all patients be placed into one of three risk

categories.[1] The Guidelines also set forth three LDL cholesterol *goal*[2] levels and four LDL cholesterol *cutpoint* levels.[3] LDL cholesterol *goals* are the levels to

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[1] The three risk categories are:

- CHD or CHD Risk Equivalent – The highest risk category, comprised of patients with CHD, established CHD equivalents such as diabetes or "other clinical atherosclerotic diseases" (a 10-year risk for a CHD event of greater than 20%).
- Multiple (2+) Risk Factors – The next risk category, comprised of patients with 2 or more risk factors (a 10-year risk for a CHD event of less than or equal to 20%).
- 0-1 Risk Factors – The lowest risk category, comprised of patients with 0-1 risk factors.

(*See* ECF No. 45-3 at III-1.)

[2] The LDL goals set forth by the Guidelines are as follows:

- CHD and CHD Risk Equivalent – the LDL goal is <100 mg/dL.
- Multiple (2+) Risk Factors – the LDL goal is <130 mg/dL.
- 0-1 Risk Factors category – the LDL goal is <160 mg/dL.

(*See* ECF No. 45-3 at IV-1.)

[3] The Guidelines set forth the following "cutpoints" for the consideration of the initiation of drug therapy:

- CHD and CHD Risk Equivalent – the Guidelines recommend the consideration of drug therapy at LDL levels greater than or equal to 130 mg/dl; drug therapy is "optional" for patients with LDL levels between 100 and 129 mg/dl.
- Multiple (2+) Risk Factors –
  - Patients with a CHD risk level between 10% and 20%: the Guidelines recommend that physicians consider initiating drug therapy at LDL levels greater than or equal to 130 mg/dl.

(cont'd)

which the Guidelines recommend patients aspire in a particular risk category, while LDL cholesterol *cutpoints* are the levels at which the Guidelines recommend that physicians consider adding a drug treatment. *See Polansky I*, 2009 WL 1456582, at *2.

None of these recommendations from the Guidelines have been included within the five labeled, FDA-approved indications for Lipitor for the treatment of elevated cholesterol. More importantly, all references to the Guidelines in the indications section, including the NCEP Guidelines summary chart – on which Polansky has based his entire FCA litigation – were *removed* from the Lipitor label in June 2009 based on an FDA-mandated label change.[4]

The 2009 label change was based on new regulations adopted by the FDA in 2006, governing the content and format of prescription drug labeling. The

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- Patients with a CHD risk under 10%: the Guidelines recommend that physicians consider initiating drug therapy at LDL levels greater than or equal to 160 mg/dl.

- 0-1 Risk Factors – the Guidelines recommend the consideration of drug therapy for those with LDL levels greater than or equal to 190 mg/dl and note that drug therapy is "optional" for those with LDL levels between 160 and 189 mg/dl.

(*See* ECF No. 45-3 at IV-2-4.)

[4] *See* Lipitor Label and Approval History, at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist (last visited June 7, 2013).

amended labeling rules, known as the Physician Labeling Rule (or "PLR"), were designed "to make the labeling easier to use and read" and thereby "to enhance the ability of health care practitioners to access, read, and use prescription drug use labeling." Final Rule, Requirements on Content & Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3922-23 (Jan. 24, 2006) (codified as 21 C.F.R. § 201.57(c)(6) (2010)).

In a preamble to the final PLR, the FDA set forth the following background and objectives of its amended labeling regulations:

> In recent years, there has been an increase in the length, detail, and complexity of prescription drug labeling, making it harder for health care practitioners to find specific information and to discern the most critical information.
>
> The agency's proposed changes were designed to enhance the ability of health care practitioners to access, read, and use prescription drug labeling.

Id. at 3922-23. Among other changes, the revised labeling regulations require manufacturers of prescription medicines to add an introductory "Highlights" section and to reorder and reorganize prescribing information "to make the labeling easier to use and read." *Id.* at 3923.

As amended and approved by the FDA pursuant to the PLR, the June 2009 Lipitor label includes an "Indications and Usage" section both under the introductory "Highlights" and in the "Full Prescribing Information." (*See* ECF No. 91-2.) Neither section refers to or cites the NCEP Guidelines or the purported

LDL "cutpoints" for statin therapy on which Polansky's theory of false claims liability relies. Instead, both sections list the FDA-approved indications for Lipitor as an adjunct to diet for the treatment of high cholesterol and the prevention of cardiovascular disease in various patient populations. (*See id.*) This revision is not Lipitor-specific; the same change has been made to the labels of other statins as part of similar labeling updates pursuant to the PLR.[5]

There is also no reference in the 2009 Lipitor label, under a "Limitations of Use" subsection, to the NCEP Guidelines or to the LDL "cutpoints" that Polansky alleges constrain the medicine's approved uses. The "Indications and Usage" section of the 2009 label *does* continue to include the same LDL thresholds for use in children between the ages of 10 and 17. (ECF No. 91-2.) The FDA-approved indications for Lipitor do *not* include any other LDL thresholds.

The only mention of the NCEP Guidelines in the 2009 label is in a separate section entitled "Dosage and Administration." After noting that doses should be tailored to individual patients, the label references the Guidelines. This section states that "[t]he starting dose and maintenance doses of Lipitor should be

[5] *See, e.g.*, Zocor Prescribing Information, *available at* http://www.merck.com/product/usa/pi_circulars/z/zocor/ zocor_pi.pdf (last visited June 7, 2013); Crestor Prescribing Information, *available at* http://www1.astrazeneca-us.com/pi/crestor.pdf (last visited June 7, 2013).

individualized according to patient characteristics such as goal of therapy and response (see current *NCEP Guidelines*)." (ECF No. 91-2 at Section 2.1.)

B. The Proceedings Below

1. Relator's FCA Claims

Polansky claims that "Pfizer pursued an off-label marketing scheme that caused federal and state health programs to pay false or fraudulent claims for reimbursement for prescriptions of Lipitor other than those indicated on its label." *Polansky I*, 2009 WL 1456582, at *1. (*See, e.g.*, ECF No. 77 at 2-4.) In particular, Polansky alleges that because "Lipitor's FDA-approved labeling specifically incorporates the [NCEP] Guidelines into the prescribing information," (ECF No. 77 at 28-29), the Guidelines "provide the basis for [FDA]-approved indications for the treatment of persons with elevated levels of [LDL cholesterol]," (*id.* at 2-3), and "promoting Lipitor therapy for patients outside" the NCEP Guidelines constitutes "unlawful off-label promotion." (*Id.* at 28-29.) Polansky further alleges that in promoting Lipitor, Pfizer "blur[red] the distinction between goals and cutpoints and encouraged the onset of drug therapy among moderate risk patients at thirty LDL cholesterol points below the level recommended by the Guidelines." *Polansky I*, 2009 WL 1456582, at *2. (*See, e.g.*, ECF No. 77 at 39-41.)

2. Pfizer's First Motion to Dismiss and the May 2009 Order

In April 2008, Pfizer moved to dismiss the false claim counts and most of the employment counts in the Fourth Amended Complaint. On May 22, 2009, the district court (Korman, J.) dismissed Polansky's false claim counts with leave to replead. *Polansky I*, 2009 WL 1456582, at *11.

In dismissing the false claims counts, the court identified numerous defects. For example, the court found that Polansky failed to link his off-label theory to a single false claim that was submitted to the government for payment:

> The complaint does not identify a single false claim or any doctor who received or viewed the Lipitor marketing materials, let alone any doctor who received or viewed these materials and then prescribed Lipitor to a patient for whom the Guidelines did not recommend statin therapy, on the mistaken belief that they did. Nor does the complaint identify any pharmacist who filled a prescription by such a physician, or any person who sought reimbursement for the cost of that prescription.

Id. at *3.

The court further observed that any alleged link between Pfizer's marketing and a putative false claim to the government was undercut by the fact that multiple scientific studies published after the Guidelines were issued had found that statins generally and Liptor in particular could, in fact, provide measurable benefits to patients in the moderate risk categories of patients for whom Polansky claims Lipitor is not approved. *Id.* at *9-10. The court explained:

> These published studies . . . are significant because of the likelihood that physicians would rely on them in choosing to prescribe statins. Significantly, as I have already observed, the FDA does not prohibit physicians, who are free to do so, from prescribing Lipitor for patients with normal cholesterol. Consequently, against the backdrop of the clinical trials and studies discussed above, as well as the tenuous theory underlying his FCA cause of action, the statistical evidence offered by Dr. Polansky [purportedly showing increased sales for Lipitor] does not "strengthen the inference of fraud beyond possibility."

Id. (citation omitted).

3. The Fifth Amended Complaint

On February 10, 2010, Polansky filed his Fifth Amended Complaint. Although the FDA had approved the 2009 Lipitor label eight months earlier, the FAC does not mention the label and continues to assert that Pfizer promoted off-label use of Lipitor by pursuing uses not authorized by the NCEP Guidelines, even though the new label removed almost all reference to the Guidelines.

The Fifth Amended Complaint purports to identify certain *patients* who were allegedly prescribed Lipitor "off-label" under Polansky's definition, (*see, e.g.*, ECF No. 77 at 116), but it does not identify a single "false claim" for Lipitor. There is no allegation of any purported "off-label" patient (or what Polansky erroneously refers to as "Individual Claims," (ECF No. 77 at 116, 119)) who was prescribed Lipitor as a result of his or her doctor's receiving or viewing an "off-label" statement from Pfizer; the date that any "off-label" prescription for Lipitor for the patient was submitted to the government for payment; the person or entity

that submitted any such prescription; or the amount of any claim to or payment by the government for such a prescription.

Nor does Polansky allege any facts that would establish that any patient even fell into Polansky's "off-label" (or "moderate risk") category at the time he or she was first prescribed Lipitor. For example, although Polansky cites information about the cholesterol levels and risk factors of two patients allegedly identified from data collected as part of the National Health and Nutrition Examination Survey ("NHANES"), Polansky alleges only that the patients were "taking Lipitor" and that their LDL levels, as tested at the time their data was collected for NHANES, were below the 160 mg/dL "cutpoint" on which he bases his "off-label" allegation. (ECF No. 77 at 116.) Cholesterol levels, of course, are not static, and Polansky fails to allege, among other critical information, the patients' LDL level at the time they were first prescribed Lipitor or whether the patients had previously been prescribed and taken another statin to treat elevated cholesterol.

4. The Dismissal Order

In June 2010, Pfizer again moved to dismiss the false claims counts pursuant to Rules 9(b) and 12(b)(6). The district court granted the motion, holding that the plain language of the 2005 and 2009 Lipitor labels contradicted Polansky's contention that the label permits Lipitor to be used only when the NCEP Guidelines are satisfied.

The district court reasoned that "the plain meaning of the word 'Guideline' is one of counseling and advice, not mandatory limitation," *Polansky II*, 2012 WL 5595933, at *3-4, and that nothing in the labels suggests that they were using the term guideline in a different fashion. To the contrary, the court found, "[e]verything about the two labels at issue in this case suggests that the NCEP Guidelines, as a matter [of] plain language, fall well within the usual, non-compulsory definition of the word guidelines." *Id.* at *4.

In particular, the court observed that the 2009 label omits the Guidelines chart. *Id*. This omission is particularly significant because the label "does include a guideline range for patients between the ages of ten and seventeen—making the absence of similar guidelines for adults more conspicuous." *Id.* In addition, the only mention of the NCEP Guidelines is in the "Dosage and Administration" section, which addresses "how much [Lipitor] to prescribe and how to give it, not to whom," *id.*, not the "Limitations of Use" section, which is "a perfect place to have inserted any prohibitory language had the FDA desired to do so." *Id.* at *5. Moreover, "there is nothing restrictive" about the sentence in which the Guidelines are referenced; to the contrary, the sentence states that "'the starting dose and maintenance doses of Lipitor should be *individualized according to patient characteristics* such as goal of therapy and response.'" *Id.* at *4 (emphasis added).

The district court likewise found no reason to believe that the 2005 label made the Guidelines mandatory. In the first place, the revisions to the 2009 Lipitor label were intended to make it easier to read, not to broaden its indications. Second, the full text of the Guidelines makes clear that "the report 'should not be viewed as a standard of practice,' but that the Guidelines 'represent general guidance that can assist in shaping clinical decisions' and 'should not override a clinician's considered judgment in the management of individuals.'" *Id*. (quoting ECF No. 45-3 at I-2.) As a consequence, there is no reason to believe that the FDA intended to make these advisory guidelines mandatory simply by including a chart from them. *Id*.

SUMMARY OF THE ARGUMENT

This appeal should be dismissed because there is no final judgment and therefore no appellate jurisdiction. Pfizer did not move to dismiss Polansky's employment claims, and the district court's November 15, 2012 order did not address them. Consequently, those claims were not resolved, and judgment was mistakenly entered. As other circuits have repeatedly recognized, under those circumstances, there was no final judgment, and the policy against piecemeal appeals underlying the final judgment rule requires that the appeal be dismissed.

If the Court finds that it has appellate jurisdiction, it should affirm the dismissal of Polansky's claims under the FCA and related state law claims for

three reasons. *First*, as the district court recognized, Polansky's claims contradict the plain language of the Lipitor label. Polansky's false claims counts are premised on his contention that the recommendations set forth in the NCEP Guidelines, and specifically, the LDL cholesterol levels (or "cutpoints") at which the Guidelines recommend statin therapy, limit the FDA-approved uses or indications for Lipitor. *Polansky I*, 2009 WL 1456582, at *1-2. (*See, e.g.*, ECF No. 77 at 28-33.) In fact, satisfying the NCEP Guidelines has never been a mandatory requirement for the approved use of Lipitor.

By definition, guidelines provide counseling and advice, not mandatory requirements, and the NCEP Guidelines expressly state that they are intended to assist doctors and not to override their considered judgment on how best to treat their patients.

Nothing in the 2009 Lipitor label even remotely suggests that the NCEP Guidelines should be treated as mandatory requirements. To the contrary, although the label has a section on "Limitations of Use," the only reference to the Guidelines is in the "Dosage and Administration" section, in a parenthetical in a sentence concerning the discretion that doctors must exercise in prescribing Lipitor to their patients. Although the 2005 label (and other pre-2009 versions of the label) contained other references to the Guidelines and incorporated a table from them, nothing in these references suggests any intent to make the Guidelines mandatory.

Moreover, as Polansky recognized prior to this appeal, the 2005 label should not be interpreted to impose different requirements than the 2009 label because the label was revised as part of an effort to simplify labels and make them easier to read, not expand approved uses.

Second, Polansky's FCA and related state law claims were properly dismissed because the Fifth Amended Complaint fails to identify any false claim for payment submitted to the Government. The FCA does not create a cause of action against all fraudulent conduct affecting the Government, only conduct that causes a false claim for payment to be submitted. The district court dismissed the Fourth Amended Complaint for failing to satisfy this requirement, and the generalized allegations in the Fifth Amended Complaint concerning purported off-label patients or prescriptions do not cure this defect.

Third, the Fifth Amended Complaint also fails to allege that Pfizer caused any false claim for payment that was predicated upon compliance with the NCEP Guidelines. To state a valid FCA claim, a party must allege not only violation of a contractual or regulatory requirement, but also that compliance with that requirement was a condition or prerequisite of payment. There is no allegation here that compliance with the NCEP Guidelines, even if mandated by the Lipitor label, is a condition or prerequisite for payment of any claims submitted to the Government. For this reason as well, Polansky has failed to state a false claim.

In sum, because Polansky does not allege that Pfizer promoted Lipitor for any purpose other than the approved use of lowering cholesterol in patients with elevated cholesterol levels, much less that Pfizer caused the submission of any non-reimbursable claim for Lipitor, he has not stated a plausible claim under the FCA or related state laws and the district court properly dismissed those claims.

STANDARD OF REVIEW

Should the Court conclude that it has jurisdiction to address the merits of Polansky's appeal, this Court reviews the district court's dismissal under Rule 12(b)(6) de novo. *See ECA v. JP Morgan Chase Co.*, 553 F.3d 187, 196 (2d Cir. 2009). "To survive a motion to dismiss, a complaint must plead 'enough facts to state a claim to relief that is plausible on its face,'" *id.* (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)), which requires "more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

Where, as here, Relator's false claims counts sound in fraud, *see Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1476 (2d Cir. 1995) (per curiam), courts further consider Rule 9(b)'s particularity requirements in assessing whether the complaint states a cognizable claim. *See United States ex rel. Nathan v. Takeda Pharma. N. Am., Inc.*, 707 F.3d 453, 456-58 (4th Cir. 2013); *see also Steiner v.*

Shawmut Nat'l Corp., 766 F. Supp. 1236, 1242 (D. Conn. 1991) (collecting cases dismissing fraud claims under Rule 12(b)(6) based on failure to satisfy Rule 9(b)).

ARGUMENT

I. BECAUSE THE DISTRICT COURT DID NOT RESOLVE POLANSKY'S EMPLOYMENT CLAIMS, THERE IS NO FINAL JUDGMENT AND THIS APPEAL SHOULD BE DISMISSED

After this case was reassigned to him in December 2011, Judge Cogan granted Pfizer's pending motion to dismiss Relator Polansky's claims under the False Claims Act, 31 U.S.C. §§ 3279-3733, and related state law claims, and at the end of his decision he directed the Clerk to enter judgment and dismiss the case. *Polansky II*, 2012 WL 5595933, at *7. As Polansky points out, in so doing, the district court "simply overlooked" his employment claims, (Appellant Br. 61), which were not addressed in Pfizer's motion to dismiss and had lain dormant for several years. Based on this oversight, Polansky asks this Court to reverse the judgment below and reinstate his employment claims. *Id*. However, because the district court overlooked Polansky's employment claims, it did not resolve those claims, which means there was no final judgment below, and there is no appellate jurisdiction. As a consequence, the appropriate course of action is to dismiss the appeal for lack of jurisdiction.

Polansky asserts appellate jurisdiction under 28 U.S.C. § 1291, (Appellant Br. 2-3), which grants courts of appeals jurisdiction over appeals from "final

decisions of the district courts." A decision is final under Section 1291 if it "ends the litigation on the merits and leaves nothing for the court to do but execute the judgment." *Coopers & Lybrand v. Livesay*, 437 U.S. 463, 467 (1978) (quotation and citations omitted). Thus, a decision that does "not dispose of all claims against all parties . . . remains interlocutory and is not appealable." *Kahn v. Chase Manhattan Bank, N.A.*, 91 F.3d 385, 388 (2d Cir. 1996). Moreover, Section 1291 requires an *actual* final judgment; not an interlocutory order mistakenly denominated as a "final judgment." *See Liberty Mutual Insurance Co. v. Wetzel*, 424 U.S. 737, 741-42 (1976). As this Court has recognized, "[a]ppealability turns on what has been ordered, not on how it is described." *Henrietta D. v. Guiliani*, 246 F.3d 176, 181 (2d Cir. 2001); *see also HBE Leasing Corp. v. Frank*, 48 F.3d 623, 631 (2d Cir. 1995) (holding that district court order not properly certified under Rule 54(b) "is not final, whether or not it is labeled a 'judgment'").

Applying these principles, other circuits repeatedly have held that decisions that overlook and do not resolve claims are not final even if they are labeled as final or direct entry of judgment. *See C.H. ex rel. Hardwick v. Heyward*, 404 F. App'x 765, 766–67 (4th Cir. 2010) (holding purportedly final judgment not final because the "district court failed to adjudicate the rights and liabilities of all the parties"); *Blowe v. Bank of Am., NA*, 316 F. App'x 283, 285 (4th Cir. 2009) (holding that judgment entered in the district court was not final because the

district court "made no ruling on Blowe's claims against Bank of America under the [federal disability or age discrimination statutes]"); *AT&T Wireless PCS, Inc. v. City of Atlanta*, 223 F.3d 1324, 1324 (11th Cir. 2000) (holding that district court's judgment was not final because it "never disposed of AT&T Wireless's substantive due process claims"); *Beluga Holding, Ltd. v. Commerce Capital Corp.*, 212 F.3d 1199, 1202–03 (11th Cir. 2000) ("because the district court's summary judgment did not dispose of all of the claims in this case (including the counterclaims and the third party claims), we do not have a final judgment within the meaning of 28 U.S.C. § 1291"); *Witherspoon v. White*, 111 F.3d 399, 403 (5th Cir. 1997) ("Because of the district court's failure to dispose of all parties to the litigation, we find that the 'Final Judgment' order lacks finality thus depriving this court of appellate jurisdiction pursuant to 28 U.S.C. § 1291."); *Stillman v. Travelers Ins. Co.*, 88 F.3d 911, 913 (11th Cir. 1996) ("[A] district court mislabeling a non-final judgment 'final' does not make it so.") (quotation omitted).

For example, in *C.H. ex rel. Hardwick v. Heyward*, the plaintiff filed a First Amendment challenge to rules that prohibited students from wearing clothing that displayed the Confederate Flag as well as a challenge to a prohibition against clothing protesting the dress code. The defendant moved for summary judgment on the prohibition against clothing displaying the Confederate Flag but not on the second prohibition. The district court granted the motion and entered summary

judgment. 404 F. App'x at 766–67. On appeal, the plaintiff argued that the judgment should be vacated in part because the district court did not address her challenge to the ban on clothing protesting the dress code. *Id.* at 767–68. Although the defendant did not question appellate jurisdiction, the Fourth Circuit *sua sponte* found that there was no jurisdiction because the district court had "not yet ruled (or been asked to rule) on [the plaintiff's] First Amendment damages claim." *Id*. at 768. In so doing, the court observed that "'the label used to describe the judicial [decision] is not controlling, meaning we analyze the substance of the district court's decision, not its label or form.'" *Id.* at 767 (quoting *Dodge v. Cotter Corp.*, 328 F.3d 1212, 1221 (10th Cir. 2003)). "'[W]hen the record clearly indicates that the district court failed to adjudicate the rights and liabilities of all the parties, the order is not and cannot be presumed to be final.'" *Id.* (quoting *Witherspoon*, 111 F.3d at 402).

This case is indistinguishable. Here, much as in *C.H.*, Polansky asserted two sets of claims and Pfizer moved to dismiss one set, the district court granted the motion, and it directed the clerk to enter judgment without ever mentioning the second set of claims. Moreover, like the plaintiff in *C.H.*, Polansky argues on appeal that the judgment should be reversed because the district court was not asked to rule and did not rule on his employment claims. Thus, just as in *C.H.*, the record clearly indicates that the district court did not adjudicate all of Polansky's

rights, and therefore the decision below is not final even though the district court labeled it as such.

This conclusion furthers the policies underlying the final judgment rule. One of those policies is to prevent "piecemeal appellate review." *Huminski v. Rutland City Police Dep't*, 221 F.3d 357, 359 (2d Cir. 2000) (quoting *Cuomo v. Barr*, 7 F.3d 17, 19 (2d Cir. 1993)). By dismissing appeals such as this one for lack of jurisdiction, the appellate courts avoid having to entertain two appeals, one from the improperly labeled final judgment and another from the subsequent decision on the claims not resolved in that purported judgment. In addition, permitting appellants such as Polansky to appeal purported judgments entered without resolving all claims would give future litigants a perverse incentive not to bring innocent "mistake[s] arising from an oversight or omission" to the attention of the district courts by moving to correct the mistaken judgment, Fed. R. Civ. P. 60(a), and instead seek improper interlocutory review. The orderly administration of justice is not furthered by allowing litigants to "jump the line" under such circumstances.

II. RELATOR'S FALSE CLAIMS ACT CLAIMS FAIL AS A MATTER OF LAW BECAUSE THE LIPITOR LABEL DOES NOT MAKE THE NCEP GUIDELINES MANDATORY RESTRICTIONS ON USE

If this Court finds that it has appellate jurisdiction and reaches the merits of Relator's appeal, it should affirm the dismissal of the Relator's FCA and related

state law claims because the district court correctly held that Polansky's claims contradict the plain language of the labels on which they purport to be based. The underlying theory of these claims is that the Lipitor label makes guidelines from the National Cholesterol Education Program mandatory. But, as the district court recognized, the term "guideline" usually refers to counseling or advice, not mandatory requirements, and "[e]verything about the two labels at issue in this case suggests that the NCEP Guidelines, as a matter of plain language, fall well within the usual, non-compulsory definition of the word guidelines." *Polansky II*, 2012 WL 5595933, at *4. Indeed, the 2009 label, which was revised to clarify but not make substantive changes to the "indications," or approved uses, of Lipitor, omits almost all mention of the NCEP guidelines. The only remaining mention of them is in connection with decisions concerning dosage that the label clearly leaves to the discretion of individual doctors. Polansky does not even begin to reconcile his FCA claims with this language and the revision of the label.

A. The 2009 Label Does Not Make Satisfaction of the NCEP Guidelines a Mandatory Requirement for Treatment of Elevated Cholesterol in Adult Patients

As the district court recognized in its first order dismissing Polansky's false claim counts, "[t]here is . . . no dispute that Lipitor is a safe and effective drug for lowering cholesterol." *Polansky I*, 2009 WL 1456582, at *6. Moreover, federal law authorizes payment for prescription medications under Medicare and Medicaid

if the prescription is for a "medically accepted indication," 42 U.S.C. § 1396r-8(d)(1)(B)(i), which includes uses approved by the FDA. *See* 42 U.S.C. §§ 1395w-102(e), 1396r-8(k)(6), 1396r-8(g)(1)(B)(i). (ECF No. 77 at 12, 15, 22 (¶¶ 38-39, 54-55, 80).) Thus, claims for Lipitor use that are inconsistent with the NCEP guidelines cannot be false claims if such uses are approved by the FDA. As the 2009 label plainly demonstrates, that is the case.

As the district court recognized, Polansky's suggestion that the FDA permits Lipitor to be used to treat elevated cholesterol only consistent with the NCEP guidelines is implausible. In the first place, "'guidelines' are by definition advisory." *Polansky II*, 2012 WL 5595933, at *3. "Guidelines 'guide," they do not mandate." *Id*.

In addition, nothing about the NCEP Guidelines suggests that they are intended to be mandatory. To the contrary, the full text of the Guidelines makes their advisory nature clear by stating that they "'should not be viewed as a standard of practice,'" but rather "'represent general guidance that can assist in shaping clinical decisions.'" *Id.* at *5. Indeed, the Guidelines state that they do "'***not*** override a clinician's considered judgment in the management of individuals.'" *Id.* (emphasis added). As the district court correctly concluded: "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." *Id.*

Moreover the Guidelines factor in issues of "cost-effectiveness." (ECF No. 45 at II-32 ("ATP III recommendations call for achieving the goals of therapy by the safest and most cost-effective means."); *see also id.* ("Since safety does not appear to be an issue for short term risk reduction in primary prevention with LDL-lowering drugs, the determining factor for the lower risk cutpoint for drug recommendation will be cost-effectiveness."); *id*. at II-55 ("Whereas LDL-lowering therapy is efficacious to further reduce relative risk in lower risk persons, it is not necessarily cost-effective.").) By contrast, the FDA does not consider cost-effectiveness in evaluating medications for approval; its focus is on safety and efficacy. *See* 21 U.S.C. § 355(d).

Nothing in the 2009 Lipitor label suggests that the FDA intended to use the NCEP Guidelines as mandatory restrictions on treatment rather than as the advisory guidance they were formulated to be. To the contrary, there is only one reference to the NCEP Guidelines in the 2009 label. This reference is not in the "Limitations of Use" section. Instead, the reference appears in the section on "Dosage and Administration," and it comes after a recognition of the discretion that doctors exercise in prescribing Lipitor: "The starting dose and maintenance does of LIPITOR should be individualized according to patient characteristics such

as goal of therapy and response (see current *NCEP Guidelines*)." (ECF No. 91-2 at Sectin 2.1.) This recognition that doctors individualize dosing and treatment based on "patient characteristics" does not in any way suggest the NCEP Guidelines or their "cutpoints" are mandatory requirements for the use of Lipitor.

This conclusion is reinforced by other aspects of the 2009 label. As noted above, there is no mention of the NCEP Guidelines in the "Limitation of Use" section even though it is the "perfect place to have inserted any prohibitory language." *Polansky II*, 2012 WL 5595933, at *5. In addition, the Lipitor label explicitly imposes a numerical LDL-cholesterol threshold for use of Lipitor in children ages 10-17: it authorizes use of Lipitor in such children if "after an adequate trial of diet therapy," the LDL level "remains ≥ 190mg/dL" or "≥ 160mg/dL" and certain other risk factors are present. (ECF No. 7-10 at 12.) There is no possible reason why the FDA would specifically list required LDL levels and risk factors for use of Lipitor in children while requiring certain LDL levels and risk factors for adults through a cryptic reference to the NCEP Guidelines in a different section of the label dealing with dosage.

Notably absent from Polansky's brief on appeal is any serious attempt to explain how the 2009 label can be read to make the NCEP Guidelines mandatory requirements. He notes that the 2009 label "directs the reader to the Guidelines"

and asserts that "a reference to the Guidelines is alone enough" (Appellant Br. 48-49), but he offers no explanation why.

Polansky also argues that, under the common-law rule that contracts should be interpreted against their drafter, the 2009 label should be construed against Pfizer because "Pfizer drafted the revised labeling and submitted it to the FDA for review . . . while this lawsuit was pending." (Appellant Br. at 49.) But Polansky fails to explain why that principle should be applied to a drug label that is reviewed and approved by the FDA, especially when dealing with an issue as fundamental as the primary use of a widely employed drug such as Lipitor. It defies reason to suggest that the FDA permitted Pfizer to tuck a key restriction on the use of a medicine into a four-word parenthetical. In any event, the common-law rule that contracts should be construed against their drafter is inapplicable because it applies only to "ambiguous language," *Mastruobono v. Shearson Lehman Hutton, Inc.*, 514 U.S. 52, 62-63 (1995), and Polansky has not shown any ambiguity in the 2009 label concerning the NCEP Guidelines.

B. The 2005 Label Does Not Make Satisfaction of the NCEP Guidelines a Mandatory Requirement

Polansky fares no better with the 2005 label. The fundamental problem that Polansky faces with the 2005 label is that the 2009 label was not intended to change the substance of the approved indications. As Polansky acknowledges, "[a]mendments made pursuant to the PLR [Physician Labeling Rule] are to make

labels more understandable, not to modify or expand FDA-approved indications." (Appellant Br. at 45.) Moreover, the Final PLR Guidelines state that, "[i]nformation under the Indications and Usage heading" of the "Highlights" section of the label "must include a concise statement of each of the drug's indications, *briefly noting any major limitations*." (ECF No. 99-12 at 10 (emphasis added).) Thus, it cannot plausibly be suggested that the FDA previously made the NCEP Guidelines a mandatory limitation but that, in amending the label under the PLR, any reference to the Guidelines was relegated to a parenthetical in the "Dosage and Administration" section. To the contrary, the only plausible conclusion is that the 2009 label does not make the Guidelines mandatory and that the 2005 label (and other pre-2009 versions) did not either.[6]

In any event, even considered apart from the 2009 label, the 2005 label does not make the NCEP Guidelines mandatory requirements. As noted above, by definition, "guidelines" provide counseling and advice, not mandatory requirements, and the NCEP Guidelines were intended to provide guidance and assistance to doctors in making clinical decisions, not to dictate treatment. *See*

[6] The Statement of Interest of the United States that Polansky quotes does not help him. (Appellant Br. at 51.) This is not a case alleging that Pfizer improperly promoted a non-approved use before it was approved and added to the label. It is undisputed that the approval of Lipitor for the treatment of hyperlipidemia in adult patients did not change with the recent PLR label revision. The 2009 label merely confirms this fact; it does not add additional indications that would have previously been considered off-label.

supra at 7-13. Nothing in the table included in the 2005 label or the other references to the NCEP Guidelines suggest that they were intended to be mandatory. As the district court noted, if the FDA had intended to take the unusual position that the Guidelines were mandatory, it easily could have made that clear. *See Polansky II*, 2012 WL 5595933, at *5.

C. Polansky's Objections to the District Court's Interpretation of the Labels Are Unpersuasive

Unable to offer any plausible reading of the Lipitor label suggesting that the NCEP Guidelines are mandatory requirements, Polansky makes a number of scattershot objections to the district court's opinion. None hit the mark.

Polansky contends that the FDA has interpreted labels for two other prescription statin medications, Pravachol and Mevacor, to make compliance with the NCEP Guidelines mandatory. (Appellant Br. 39-41.) Polansky asserts that in a letter concerning advertisements for Pravachol, the FDA concluded that the Guidelines were "mandatory and not mere advice" when it wrote that the advertisements broadened the conditions and patients for which the medicine is indicated. (Appellant Br. 39-40.) In fact, the letter refers to the Guidelines only in the context of stating that the FDA believed the Guidelines were misrepresented in the advertisement. (*See* ECF No. 99-13 at 5-6 (noting that "[a]lthough the ad appears to rely on the" NCEP Guidelines, "they do not provide substantial evidence for" the ad's claims).) There is no suggestion, much less a statement,

anywhere in the letter that the indications for Pravachol or any other statin are restricted by the Guidelines.[7]

Polansky also identifies for the first time in this appeal a letter stating the FDA would not approve a different statin, Mevacor, in a low dose for over-the-counter use. This letter does not "confirm that the use of statins . . . is limited by the NCEP Guidelines." (Appellant Br. at 18.) Rather, the FDA denied approval based on studies that showed that patients taking statins benefited from the individualized therapy and clinical judgment of their treating physicians. Indeed, a principal concern was that women of childbearing age would buy the medicine and use it while pregnant, which is a contraindication for statins. Owen Dyer, *FDA rejects sale of over the counter statins*, Biomedical J., 2005 January 22; 330(7484): 164, *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC545018/ (last visited June 10, 2013).

Similarly, Polansky takes out of context a single reference from the FDA's 1996 review of the New Drug Application ("NDA") for Lipitor, which was not included in the FAC and was cited only in Polansky's opposition brief in the court below. (Appellant Br. at 35-36 (referencing ECF No. 99 at 51-52).) The full

[7] Polansky's reliance on a March 1998 FDA letter to the manufacturer of Pravachol, (ECF No. 99 at 57), is similarly misplaced. The letter characterizes the Guidelines as "guidelines" and a "treatment approach." (ECF No. 99-14 at 36-37.) Nothing in the letter states that they limit any medicine's indications.

paragraph from which the reference is taken directed the removal of certain "broad summary statements" about the "clinical benefits of lipid lowering," and noted that, "[a]t this point in time, there is sufficient general knowledge as to the presumed benefits of cholesterol lowering such that no explicit rationale need be provided in the labeling." (ECF No. 99-11 at 131.) The sentence about the inclusion of the NCEP Guidelines that follows, and on which Polansky relies, does not describe the Guidelines as a restriction on Lipitor's approved uses but rather as what they are: "guidelines" for physicians to use in making prescribing decisions and determining "treatment goals" for each patient. (ECF No. 99-11 at 131.)

Nor do any of the drug compendia on which Polansky relies support his theory that the Guidelines limit Lipitor's approval. (Appellant Br. at 13-14.) The compendia can only (and often do) *expand* the uses for which a product must be reimbursed under the Medicaid Act. *See* 42 U.S.C. § 1396r-8(k)(6).

Polansky also accuses the district court of engaging in impermissible fact finding. (Appellant Br. at 51-57.) That is not so. Whether the Guidelines are "unambiguous" in restricting Lipitor's indications is a purely legal question that the district court was empowered to resolve. *See Scalisi v. Fund Asset Mgtnt., L.P.*, 380 F.3d 133, 137 (2d Cir. 2004) ("[W]e are not required to accept as true the legal conclusions . . . drawn by the non-moving party."). And the fact that Polansky contends that the Lipitor label is subject to competing interpretations does not

make it so. A document "is not made ambiguous simply because the parties urge different interpretations." *Seiden Assocs., Inc. v. ANC Holdings, Inc.*, 959 F.2d 425, 428 (2d Cir. 1992); *see also Hunt Ltd. v. Lifschultz Fast Freight, Inc.*, 889 F.2d 1274, 1277 (2d Cir. 1989).

Although Polansky has sought to rely on documents and other materials *not* referenced in the FAC, (Appellant Br. at 17-18), the *only* factual allegation in the FAC that ostensibly supports Polansky's legal theory is his allegation that, until 2009, the Lipitor label referenced the NCEP Guidelines and contained a chart summarizing them. (ECF No. 77 at 28.) Contrary to Polansky's suggestion, rejecting his legal theories based on the plain language of the Lipitor label and judicially noticeable documents did not require the district court to choose "between two plausible inferences that may be drawn from factual allegations." (Appellant Br. at 52 (quoting *Anderson News, L.L.C. v. Am. Media, Inc.*, 680 F.3d 162, 190 (2d Cir. 2012).)

This is similarly not a case where expert testimony is required to interpret whether a warning in a drug label is sufficient to alert prescribing physicians to a possible adverse event. As the case cited by Polansky acknowledges, expert testimony is not necessary "where the warning is accurate, clear and unambiguous." *DiGidio v. Centocor Ortho Biotech, Inc.*, 2010 WL 4628903, at *4 (N.D. Ohio 2010); *see also Meridia Products Liability Litigation v. Abbott*

Laboratories, 447 F.3d 861, 867 (6th Cir. 2006) (affirming dismissal of failure-to-warn claims because the label of the drug in question was adequate as a matter of law to warn doctors of the injuries alleged). In this case, the district court similarly did not need an expert to conclude that a trained healthcare professional would not read "the NCEP Guidelines in the 2005 label, and the passing reference to them in the 2009 label . . . as a restrictive limitation." *Polansky II*, 2012 WL 5595933, at *7. Rather, "the physicians who wrote prescriptions were not unsophisticated lay persons," and they were familiar with both the Lipitor label and the NCEP Guidelines. *Polansky I*, 2009 WL 1456582, at *8.

In short, the district court correctly found that the 2005 and 2009 labels do not make compliance with the NCEP Guidelines a mandatory requirement. Thus, Polansky's claims that Pfizer improperly promoted Lipitor for off-label use fail as a matter of law.

III. POLANSKY ALSO HAS FAILED TO ALLEGE AN ACTIONABLE FALSE CLAIM BECAUSE HE HAS FAILED TO IDENTIFY ANY CLAIM FOR PAYMENT SUBMITTED TO THE GOVERNMENT OR ANY VIOLATION OF A CONDITION FOR PAYMENT

The dismissal of Polansky's FCA and related state law claims also should be affirmed on two alternate grounds: (i) he failed to identify any claim actually submitted to the government for approval; and (ii) he failed to show that compliance with the NCEP Guidelines was a condition or prerequisite for payment of any claim for Lipitor.

A. Polansky Has Not Identified a Single False Claim Submitted to the Government

The FCA does not create a cause of action against all fraudulent conduct affecting the government. *See Mikes v. Straus*, 274 F.3d 687, 695-96 (2d Cir. 2001). Rather, FCA liability attaches only to a "false or fraudulent claim for payment" or to a "false record or statement [made] to get a false or fraudulent claim paid by the government." 31 U.S.C. § 3729(a)(1)-(2), *amended by* 31 U.S.C. § 3729(a)(1)(A–B). Thus, evidence of a false claim for payment submitted to the Government is the "*sine qua non* of a False Claims Act violation." *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002); *see also United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 504 (6th Cir. 2007) ("[P]leading an actual . . . claim with particularity is an indispensable element of a complaint that alleges a FCA violation in compliance with Rule 9(b)."). Polansky failed to satisfy this essential requirement because he failed to identify any specific claim for payment submitted to the Government.

Medicaid does not flatly prohibit any reimbursement for off-label prescriptions. Instead, as the district court observed, Medicaid leaves the issue to the discretion of the states, which may choose to cover off-label uses and adopt other medicine-specific rules. *Polansky I*, 2009 WL 1456582, at *9 (citing 42

U.S.C. § 1396r-8(d)(1)(B)).[8] Thus, "the mere fact that Pfizer may have been violating FDA regulations" – which Pfizer denies – "does not translate into liability for causing a false claim to be filed." *Id.* at *7; *see also id.* at *5 (the FCA "'attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the "*claim for payment*"'") (quoting *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995) (emphasis added).

For example, in *United States ex rel. Nathan v. Takeda Pharmaceuticals North America, Inc.*, 707 F.3d 453 (4th Cir. 2013), the Fourth Circuit affirmed

[8] Whether a medicine falls into the category of "covered outpatient drug" triggers Medicaid rebates and limits states' ability to exclude or restrict coverage, but it does not delimit the boundaries of Medicaid coverage. *See* 42 U.S.C. § 1396r-8; *see also United States ex rel. Hess v. Sanofi-Synthelabo, Inc.*, No. 4:05CV570, 2006 WL 1064127, at *9 (E.D. Mo. Apr. 21, 2006) (noting that the relevant Medicare administrator chose to apply an exception allowing coverage for off-label uses of the cancer medication at issue). Under the Medicaid statute, "a State . . . may adopt a prior authorization program, maintain a formulary, impose limits on prescription quantities to discourage waste, and address instances of fraud or abuse by individuals." (Gov't Stmt. (ECF No. 98 at 3 n.2) (citing 42 U.S.C. § 1396r-8(d)(4)–(6)).) Plaintiff does not allege any such action taken with respect to Lipitor, much less any that would support his theory that its approved use is restricted by the Guidelines. In fact, government and private health insurance programs regularly adopt such prior authorization and other limitations for specific medications. *See, e.g., United States ex rel. Rost v. Pfizer, Inc.*, 736 F. Supp. 2d 367, 369 (D. Mass. 2010) (describing prior authorizations required for Genotropin, a human growth hormone); *see also* State of New York Dep't of Health, Oct. 29, 2009 Letter to Providers, at http://www.health.state.ny.us/health_care/medicaid/ program/ pharmacy_notices/docs/serostim.pdf (last visited June 7, 2013) (outlining prior authorization procedure for prescription human growth hormone medication Serostim).

dismissal of a *qui tam* complaint alleging improper off-label marketing where the complaint "failed to plausibly allege that any false claims had been presented to the government for payment." *Nathan*, 707 F.3d at 453-54. "Without such plausible allegation of presentment," the court explained, "a relator not only fails to meet the particularity requirements of Rule 9(b), but also does not satisfy the general plausibility standard of *Iqbal*." *Id.* at 457; *see also U.S. ex rel. Bennett v. Boston Scientific Corp.*, CIV.A. H-07-2467, 2011 WL 1231577, at *29 (S.D. Tex. Mar. 31, 2011) (collecting cases).

The same result is warranted here. In dismissing the Fourth Amended Complaint, the district court found that Polansky "has not identified any false claims or physicians who were induced to write a prescription for an off-label use." *Polansky I*, 2009 WL 1456582, at *5. The FAC is similarly deficient. Although Polansky has entitled several paragraphs in the FAC "Individual Claims," (ECF No. 77 at 116 ¶¶ 415-16, 119 ¶ 426), the heading is a complete misnomer. Polansky does not actually identify claims but instead purports to identify individuals who were prescribed Lipitor "off-label," where the "off-label" characterization is based on an alleged measurement of the individual's LDL level on some unspecified date and at some unidentified time relative to the also unidentified date that the patient was first prescribed Lipitor. (*See* ECF No. 77 at 116 ¶¶ 415-16, 119 ¶ 426.)

Moreover, Polansky does not allege how any specific statement or action by Pfizer or any Pfizer employee caused any physician to write an "off-label" prescription of Lipitor for any of these patients. For two of the patients, Polansky alleges that the person "was on Medicaid," (ECF No. 77 at 116 ¶¶ 415-16), and for some of the others, he identifies a government "Payor." (ECF No. 77 at 119 ¶ 426.) But he does not allege that any "off-label" Lipitor prescription for any of the patients was submitted to the government for payment or reimbursement. In the absence of such allegations, Polansky cannot state a valid claim. *See Hopper v. Solvay Pharma, Inc*., 588 F.3d 1318, 1326 (11th Cir. 2009) (holding that an FCA claim may not be stated by simply "pil[ing] inference upon inference" that a "marketing campaign influenced some unknown third parties to file false claims"); *see also Wood ex rel. United States v. Applied Research Assocs., Inc.*, 328 F. App'x 744, 750 (2d Cir. 2009) (affirming dismissal with prejudice of FCA complaint against government contractors where, *inter alia*, the complaint "'[did] not cite to a single identifiable record or billing submission [plaintiff] claim[ed] to be false, or give a single example of when a purportedly false claim was presented for payment by a particular defendant at a specific time'" (citation omitted)).

It is also clear that Polansky's allegations about a "statistical analysis of NHANES data" obtained in connection with this litigation, (ECF No. 77 at 112), cannot serve as a proxy for the missing (and necessary) false claims. Courts have

repeatedly held that allegations of statistical information are insufficient to satisfy Rule 9(b) in a FCA action. S*ee, e.g.*, *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp. 2d 35, 45 (D. Mass. 2000) ("[Rule 9(b)] requires greater specificity than statistical analysis."); *Hopper*, 588 F.3d at 1326 (affirming dismissal where, although the amended complaint "include[d] what the relators describe[d] as 'a highly-compelling statistical analysis [that] render[ed] inescapable the conclusion that a huge number of claims for ineffective off-label uses of Marinol resulted from [Solvay's illegal marketing] campaign,'" it did not allege "a single actual false claim" (citation omitted)). Moreover, Polansky's alleged statistics about the number of "Lipitor prescriptions that were filled by people who," according to Polansky, "did not qualify for statin therapy" because they were "off-guideline," (ECF No. 77 at 112), do not provide any information about reimbursement requests or claims practices, much less any of the requisite details cited by the district court as necessary to meet Rule 9(b). *See Polansky I*, 2009 WL 1456582, at *3.

Likewise, although he claims that he has identified specific "off-label" patients based on their alleged LDL levels, Polansky completely ignores the fact that Lipitor has also been approved for other indications, including the treatment of elevated triglycerides, and, since July 2004, for the prevention of cardiovascular disease, without regard to baseline LDL level (or NCEP Guidelines "cutpoint").

(*See* ECF No. 91-2 at Section 1.1 (listing "Prevention of Cardiovascular Disease" as an approved indication "[i]n adult patients without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as age, smoking, hypertension, low HDL-C, or a family history of early coronary heart disease").) This indication does not include and has never included any reference to a patient's LDL level. (*See* ECF No. 91-2 at Section 14.1 (reporting that the clinical trials supporting the indication for prevention of cardiovascular disease showed a risk reduction "regardless of baseline LDL levels").)[9]

Polansky does not allege, however, for any of the individual "off-label" patients he purports to identify, whether the patient was even prescribed Lipitor to treat elevated LDL cholesterol (an indication that Polansky alleges is limited by the Guidelines' cutpoints) as opposed to prevention of cardiovascular disease (an indication not limited by the cutpoints, even under Polansky's theory). This is yet another critical defect in the FAC that precludes a finding that Polansky has identified a single "off-label" patient or prescription, much less an actual false claim to the government, that is consistent with his own theory of liability.

[9] *See* Lipitor Label and Approval History, *available at* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist (last visited June 7, 2013).

B. Polansky Has Not Alleged that Compliance with the NCEP Guidelines Is a Condition or Prerequisite of Payment

In addition to failing to identify any false claims for payment submitted to the Government, Polansky has failed to show that compliance with the NCEP Guidelines was a condition or prerequisite for payment of any claim for Lipitor. "The FCA is not a general 'enforcement device' for federal statutes, regulations, and contracts." *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 268 (5th Cir. 2010) (citation omitted). Thus, every United States Court of Appeals to consider the issue – including this Circuit – has expressly recognized that "[v]iolations of laws, rules, or regulations alone do not create a cause of action under the FCA." *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996). As this Court has explained, "the False Claims Act was not designed for use as a blunt instrument to enforce compliance with all medical regulations – but rather only those regulations that are a precondition to payment." *Mikes*, 274 F.3d at 699.

FCA liability attaches only where the relator can show *both* a contractual or regulatory violation *and* proof that the requirement was an express "'condition' or 'prerequisite' for payment under a contract." *Steury*, 625 F.3d at 268 (citation omitted); *accord United States ex rel. Hobbs v. MedQuest Assocs., Inc.*, 711 F.3d 707, 714 (6th Cir. 2013). Polansky has not pled that any claims for payment

predicated on compliance with the Lipitor label and NCEP Guidelines were submitted.

Even if the NCEP Guidelines had been incorporated into the Lipitor label as a mandatory requirement, Polansky could not state a valid claim under the FCA by merely alleging that the defendant violated the NCEP Guidelines. In *Mikes*, the relator alleged that the defendants submitted false claims to the government by billing for diagnostic tests that were performed using a device that was not maintained in accordance with guidelines developed by the American Thoracic Society, which were incorporated by reference into several federal statutes and regulation. 274 F.3d at 694. This Court held that the relator failed to state a valid claim because none of the claims for payment submitted by the defendant certified that the regulations concerning the maintenance of the device had been satisfied. *Id.* at 699. Admonishing that "courts are not the best forum to resolve medical issues concerning levels of care," this Court concluded that a medical provider should be found to have implicitly certified compliance with a rule or regulation as a condition of reimbursement "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 in original).

The district court correctly dismissed Polansky's Fourth Amended Complaint because it did not allege that Pfizer made any certifications, implied or

otherwise, concerning compliance with the NCEP Guidelines. *Polansky I*, 2009 WL 1456582, at *7. Polansky's Fifth Amended Complaint does not cure this defect. Polansky continues to allege that every purported "off-label" prescription for Lipitor, no matter why it was written, how much it helped the patient who received it, or how it was submitted for payment, is a "false claim." But "off-label" *prescriptions* for Lipitor, even to the extent Polansky now attempts to identify some by listing alleged "off-label" patients (not individual prescriptions), "[are] not *claims* that were submitted for payment," and are not, therefore, without more, actionable false claims. *Id.* (emphasis added).

Indeed, as the district court recognized, doctors regularly prescribe medications for off-label uses and it is completely appropriate in certain cases. *See id.*; *see also id.* at *10 ("Significantly, as I have already observed, the FDA does not prohibit physicians, who are free to do so, from prescribing Lipitor for patients with normal cholesterol."). There are numerous reasons why a physician may have prescribed Lipitor to a "moderate risk" patient, including published studies reporting benefits in using statins to lower LDL cholesterol levels below the NCEP Guidelines' targets and to treat patients with LDL levels below the Guidelines' "cutpoints." *See id.* at *9-10. Given these facts, "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." *Id.* at *7.

Although the Fifth Amended Complaint lists purported "off-label" Lipitor patients, (ECF No. 77 at 116 ¶¶ 415-16, 119 ¶ 426), it does not allege that any form or statement submitted to the government for reimbursement or payment falsely reported anything about the patient's condition or the prescription of Lipitor for the patient. To the contrary, Polansky concedes that any actual "claims for payment" submitted to the government for Lipitor prescriptions "*do not distinguish between on-label and off-label uses*." (ECF No. 77 at 11 (emphasis added).) Thus, Polansky has failed to allege any false certification and, thus, failed to allege that any off-label promotion in which Pfizer may have engaged resulted in a false claim for payment being submitted. As a result, Polansky has failed to state a valid FCA claim. *See United States ex rel. Hess v. Sanofi-Synthelabo, Inc.*, No. 4:05CV570, 2006 WL 1064127, at *7 (E.D. Mo. Apr. 21, 2006) (holding that off-label promotion of a treatment for early-stage cancer failed to state a valid FCA claim because "the stage of a patient's cancer [was] not material to a doctor's seeking reimbursement").[10]

[10] Polansky's state law claims should be dismissed along with his federal FCA count for all of the reasons set forth above. *See United States ex rel. Rost v. Pfizer Inc.*, 446 F. Supp. 2d 6, 25 (D. Mass. 2006), *aff'd in relevant part*, 507 F.3d 720 (1st Cir. 2007) (dismissing FCA complaint in its entirety because "the *(cont'd)*

CONCLUSION

For the foregoing reasons, this appeal should be dismissed for lack of appellate jurisdiction. Alternatively, Pfizer respectfully requests that the Court affirm the dismissal with prejudice of Counts I and III through XIX of the Fifth Amended Complaint (the False Claims Act claims and related state law claims) and remand the remaining counts (the employment claims) to the district court.

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QUINN EMANUEL URQUHART &
SULLIVAN, LLP

By: /s Mark S. Cheffo

Mark S. Cheffo
212-849-7073
MarkCheffo@quinnemanuel.com
Hayden Coleman
212-849-7598
HaydenColeman@quinnemanuel.com

51 Madison Avenue, 22nd Floor
New York, New York 10010-1601

Attorneys for Defendant-Appellee Pfizer Inc.

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requirements of Rule 9(b) apply equally to Plaintiff's state claims"); *accord Hopper v. Solvay Pharma., Inc.*, 590 F. Supp. 2d 1352, 1363 (M.D. Fla. 2008), *aff'd*, 588 F.3d 1318 (11th Cir. 2009).

CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(7)(C) of the Federal Rules of Appellate Procedure, the foregoing brief is in 14-Point Times New Roman proportional font and contains 11,401 words and thus is in compliance with the type-volume limitation set forth in Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure.

Dated: New York, New York
June 10, 2013

/s/ Mark S. Cheffo
MARK S. CHEFFO