Second Circuit Affirms Dismissal of False Claims Act Suit Based on "Off-Label" Marketing

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The United States Court of Appeals for the Second Circuit recently affirmed an Order of the Eastern District of New York dismissing a *qui tam* False Claims Act (FCA) suit based on "off-label" marketing of prescription drugs. The Second Circuit agreed with the district court's conclusion that the *qui tam* complaint at issue failed to allege any "off-label" promotion or prescriptions and affirmed the district court's dismissal on that basis. It added (though it made clear that it was not deciding the issue and that its holding was not based on this reasoning) that it was "skeptical" that "off-label" promotion could lead to FCA liability, at least where the "off-label" promotion is not "for a purpose obviously not contemplated by the label."

The Allegations of False Claims

Relator, Dr. Jesse Polansky, a former Medical Director for Pfizer, Inc., alleged that Pfizer violated the FCA by improperly marketing Lipitor, "a popular statin, a drug that lowers cholesterol levels by blocking enzymes essential to cholesterol production," "as appropriate for patients whose risk factors and cholesterol levels fall outside the National Cholesterol Education Program Guidelines ('NCEP Guidelines' or 'Guidelines')."[1] Relator alleged that the Guidelines are incorporated into the FDA-approved label for Lipitor and that, by marketing Lipitor's use for patients outside of the Guidelines, Pfizer "induced doctors to prescribe the drug, pharmacists to fill the prescriptions, and federal and state health care programs to pay for 'off-label' prescriptions."[2]

Lipitor is approved to treat elevated cholesterol and to prevent cardiovascular disease. It was approved for five "indications" related to elevated cholesterol during the period of time covered by the *qui tam* complaint.[3] Relator alleged that the approved use of Lipitor was further limited by the NCEP Guidelines, i.e., that use of Lipitor was "off-label," and unapproved, unless the patient's risk factors and cholesterol levels fit within the NCEP Guidelines.[4]

Relevant Law Related to Labeling and Promotion of FDA-Approved Drugs

The Second Circuit summarized provisions regulating the labeling and marketing of pharmaceuticals:

> 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"). [5] The exact wording of the drug's "label" must be approved by the FDA, and thereafter generally cannot be altered without further approval.[6] The label (which can be quite lengthy) must include, *inter alia*, the drug's indications, contra-indications, limitations of

1 *United States ex rel. Polansky v. Pfizer, Inc.*, No. 14-4774 at 2-3, 6-7 (2d Cir. May 17, 2016), available at: http://www.ca2.uscourts.gov/decisions/isysquery/acf9178f-ff08-4710-9cb2-44ce4a048a98/12/doc/14-4774_opn.pdf, last accessed June 12, 2016.
2 *Id.* at 3.
3 *Id.* at 6.
4 *Id.*
5 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).
6 *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.

use, use by specific populations, and dosage instructions.[7][8]

It continued by highlighting the significant role of physicians' clinical judgment in prescribing FDA-approved prescription drugs, both "on-label" and "off-label":

> "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."[9] "Indeed, courts and the FDA have recognized the propriety and potential public value of unapproved or off-label drug use."[10][11]

The Court identified two prohibitions against off-label promotion of FDA-approved prescription drugs: (1) "if the off-label marketing is false or misleading"; or (2) if the off-label marketing "evidences that a drug is intended for such off-label use and is therefore 'misbranded.'[12]"[13]

The Court further noted that, generally, Medicare and Medicaid will pay for prescription drugs only for FDA-approved (on label) use or for use covered in any of three drug compendia.[14]

The Court's Analysis of Relator's FCA Allegations

The Second Circuit began (and ended) its analysis of Relator's "off-label" claims by considering whether Lipitor's label required compliance with the NCEP Guidelines[15] and, therefore, whether promotion outside those Guidelines would, in fact, be considered "off-label." In upholding the district court's determination that the Guidelines were not incorporated into Lipitor's label, and that promotion outside of those Guidelines did not constitute "off-label" marketing, the Second Circuit relied on the following factors:

- The NCEP Guidelines "expressly disclaimed any prescriptive force," indicating that "[t]heir 'general guidance' 'need not hold for individual patients' and 'should not override' a physician's clinical judgment about appropriate treatment of a particular patient";[16]
- The Lipitor label expressly imposes cholesterol-level restrictions solely for pediatric patients, but does not expressly impose such express restrictions for adults;[17]
- The 2009 version of the Lipitor label, which is by law considered substantively identical to the prior version,[18] "omits the Guidelines table, makes no more than fleeting reference to the Guidelines, and fails to mention them

7 21 C.F.R. § 201.57.
8 *Polansky*, at 4.
9 *Caronia*, 703 F.3d at 153; see also 21 U.S.C. § 396 (principle of non-interference with the practice of medicine).
10 *Caronia*, 703 F.3d at 153 (citing cases and FDA draft guidance).
11 *Polansky*, at 4-5.
12 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.").
13 *Polansky*, at 5.
14 *Id.* at 5 *citing* 42 U.S.C. § 1396r-8(k)(2), (3), (6); *id.* § 1395w-102(e)(1), (4); *id.* § 1396r-8(d)(1)(B)(i) (allowing State Medicaid programs to "exclude or otherwise restrict coverage" for off-label uses unless otherwise included in any of the referenced drug compendia).
15 The NCEP Guidelines identified three risk categories—"high risk," "middle risk," and "lowest risk"—and, for each risk category, provided (1) an LDL cholesterol goal; (2) a threshold LDL level that should trigger initiation of lifestyle changes; and (3) a threshold LDL level at which to consider drug therapy. *Id.* at 8.
16 *Id.* at 13-14.
17 *Id.* at 14.
18 *Id.* at 9 (explaining that the 2009 label change was mandated by the FDA's Physician Labeling Rule, that any substantive modifications were required to be disclosed in the new label, that no such modifications were identified in the new Lipitor label, and that the FDA approved the new Lipitor label).

> at all in the 'Indications and Usage' section of the label, which is where a limitation on approved 'usage' would be expected to appear."[19] Adopting the reasoning of the district court, the Second Circuit concluded: "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."[20]

Based on all of these considerations, the Second Circuit affirmed the district court's dismissal of the *qui tam* complaint because the Relator failed to allege that any marketing of Lipitor outside of the NCEP Guidelines was, in fact, "off label.

The Second Circuit's Thoughts on FCA Claims Based on "Off-Label" Promotion

Having determined that Relator's complaint did not, in fact, allege any actual "off-label" promotion, the Second Circuit could have simply affirmed the district court's dismissal of the complaint on that basis and proceeded no further.[21] Instead, the Second Circuit shared its views on the potential success of such claims. It is "skeptical":

> [I]t 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.[22]

The Court further noted the potential for FCA claims based on off-label promotion to intrude on FDA's regulatory authority:

> 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. 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.[23]

It distinguished between "marketing a drug for a purpose obviously not contemplated by the label"[24] and "marketing a drug for its FDA-approved purpose to a patient population that is neither specified nor excluded in the label." It seemingly indicated a high bar for off-label claims: "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."*[25]

Conclusion

Although the Polansky decision, like the *Caronia*,[26] *Amarin*,[27] and *Pacira*[28] matters on which we have written, can

19 *Id.* at 14-15.
20 *Id.* at 15 (citation and quotation marks omitted).
21 *Id.* at 15-16 (indicating it need not "decide whether Polansky has adequately alleged that a request for prescription-drug reimbursement is an implied certification of on-label use").
22 *Id.* at 16; *see also United States ex rel. Polansky v. Pfizer, Inc.*, 04-CV-0704 (ERK), 2009 WL 1456582, at *7 (E.D.N.Y. May 22, 2009) ("[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)).
23 *Polansky*, 14-4774, at 17 (citation and quotation marks omitted).
24 *Id.* at 17-18.
25 *Id.* at 18 (emphasis added).
26 http://www.agg.com/Second-Circuit-Rules-Off-Label-Promotion-Is-Protected-Speech-12-06-2012/.
27 http://www.agg.com/another-one-bites-the-dust-fda-doesnt-like-the-fishy-smell-of-the-latest-court-decision-on-off-label-dissemation-08-19-2015/.
28 http://www.agg.com/its-deja-vu-all-over-again--fda-sued-again-in-off-label-promotion-case-09-21-2015/; http://www.agg.com/FDA-and-Pacira-Settle-First-Amendment-Challenge-to-Off-Label-Dispute-12-17-2015/.

rightfully be viewed as a major victory for pharmaceutical companies, there are several factors that will affect whether the decision will lead to broad ramifications for the pharmaceutical industry.

- The *Polansky* case was decided by the Second Circuit, which means that the ruling only applies to those courts in this federal circuit (New York, Connecticut, and Vermont). Other courts outside the Second Circuit are not bound by the decision, and it remains to be seen whether the Second Circuit's reasoning will influence other courts facing similar off-label cases in the future.

- Different facts may lead to a different decision in a future case, either in the Second Circuit or elsewhere. The broader language of the decision reflecting the Second Circuit's skepticism of FCA off-label claims was not the basis of its decision. This language was contained within the context of what the Second Circuit viewed as "on-label" marketing. Therefore, notwithstanding the broad language used by the Court, it remains to be seen how the Second Circuit would deal with marketing that it views as truly "off-label."

- We continue to advise caution. The case, while a victory for the pharmaceutical industry, is very fact-specific. Moreover, *qui tam* relators are far from the only threat when it comes to "off-label" promotion. Such promotion can result in scrutiny and enforcement actions from FDA, Department of Justice, the Securities and Exchange Commission, State Attorneys General, and others.

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