

Off-Label Use and the False Claims Act: Has the Second Circuit Signaled A Change in the Winds After U.S. v. Pfizer?

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Client Advisory

June 30, 2016 by Michael H. Bauscher

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On May 17, 2016, the United States Court of Appeals for the Second Circuit issued an opinion in *United States ex rel. Polansky v. Pfizer, Inc.* dismissing Dr. Jesse Polansky's *qui tam* False Claims Act ("FCA") suit based on alleged "off-label" marketing of the popular statin Lipitor.^[1] Dr. Polansky asserted that Pfizer violated the FCA by inducing doctors to prescribe Lipitor to patients whose risk factors fell outside the National Cholesterol Education Program Guidelines ("NCEP Guidelines") and to subsequently seek reimbursement from Medicaid and Medicare for those alleged "off-label" uses.^[2] Although the Second Circuit affirmed the District Court's dismissal on the ground that the NCEP Guidelines were only advisory and not a "mandatory limitation,"^[3] the Court went out of its way to express skepticism about imposing FCA liability for non-misleading cases of off-label marketing. While the Court's skepticism is only *dicta*, and thus not binding legal precedent, its reasoning could be a wellspring of changes in potential FCA liability for pharmaceutical and medical device manufacturers.

Background

NCEP Guidelines

To fully understand the allegations in *Pfizer*, it is necessary to grasp a few basic points about the NCEP Guidelines. In 2001, with the support of the National Institutes of Health, NCEP developed and promulgated guidelines to provide "recommendations for cholesterol testing and management."^[4] The NCEP Guidelines were meant to be advisory and expressly disclaimed any intent to replace a doctor's "[c]linical judgment." They provided a three-tiered system of risk categories.^[5] "Each of the three risk categories was accorded (1) an LDL [low-density lipoprotein] 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."^[6]

Prescription Labels and Off-Label Promotion

Under the Food, Drug and Cosmetic Act, pharmaceutical and medical device manufacturers are prohibited from selling a drug or device until it is approved by the FDA for specific indications.^[7] Additionally, pharmaceuticals and medical devices must include labels that are approved by the FDA and that include, among other things, the drug's or device's approved indications, any use limitations, and approved dosages.^[8] A manufacturer may not amend a label without additional FDA approval.^[9] When a drug or medical device is marketed or prescribed for a use not included on the label, it is referred to as an "off-label use."^[10] Although doctors may prescribe drugs and devices for off-label uses if they believe it would be in a patient's best interest,^[11] the FDA has generally prohibited pharmaceutical and medical device manufacturers from marketing off-label uses, with a few limited exceptions.^[12]

Recent court cases have started chipping away at the FDA's rather stringent off-label marketing rules,^[13] and there is a growing consensus that the FDA will eventually permit pharmaceutical and medical device manufacturers to market at least some off-label uses in truthful, non-misleading ways. Indeed, the Second Circuit stated in *Pfizer* that manufacturers "are generally prohibited from promoting off-label uses 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.'"^[14] Despite what some may consider an easing of the prohibition on off-label marketing, "[f]ederal reimbursement for prescription drugs under Medicare and Medicaid is generally limited to drugs prescribed for FDA-approved (on-label) uses."^[15]

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Dr. Polansky was a former Pfizer employee who reported to the government that Pfizer had, among other things, violated the FCA by promoting Lipitor for off-label use and "induc[ing] doctors to prescribe the drug . . . and federal and state health care programs to pay for the 'off-label' prescriptions."^[16] Dr. Polansky's argument was essentially that the Lipitor label implicitly incorporated the NCEP Guidelines and that Pfizer marketed the drug for use by people who fell outside the Guidelines. This practice, argued Polansky, induced doctors to prescribe Lipitor for off-label uses, and caused pharmacies to falsely certify that Lipitor prescriptions were for on-label uses when they submitted reimbursement claims to Medicare or Medicaid for patients who were not covered by the Guidelines.^[17] The Second Circuit rejected that argument and held that the NCEP Guidelines were barely mentioned on the Lipitor label, let alone incorporated by it,^[18] and were intended to be merely advisory and not binding.^[19] The Court therefore held that the challenged uses were not off-label.

The FCA Is Not A "Back-Door Regulatory Regime"

"[T]he 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)."^[20] In addition to the argument that the NCEP Guidelines were mandatory and incorporated into Lipitor's FDA-approved label, Dr. Polansky also argued that there should be FCA liability because "requests for reimbursement of Lipitor prescriptions impliedly certified (falsely) that the prescription was for an on-label use."^[21]

Although not necessary to support its decision, the Second Circuit expressed skepticism that anyone would have "actually submitted a false claim" with respect to Lipitor even if the challenged uses were considered "off-label."^[22] The Court explained that (i) doctors are permitted to prescribe Lipitor for off-label uses, (ii) patients likely do not know if a prescribed use is off-label, and (iii) a physician's prescription script would not inform a pharmacy whether the prescription is for an on- or off-label use.^[23] Accordingly, the Court was "dubious . . . that any of these participants in the relevant transactions would have knowingly, impliedly certified that any prescription for Lipitor was for an on-label use."^[24] The Second Circuit agreed with the district court "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."^[25] That reasoning suggests that the Second Circuit may be unwilling to impose FCA liability for off-label marketing except under extreme circumstances.

That potential unwillingness is exemplified by the Court's apparent concern with intruding on the province of the FDA. The Court adopted the district court's reasoning that "[t]he 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."^[26]

Manufacturers Should Proceed With Caution

Although people may be tempted to characterize the Second Circuit's *Pfizer* decision as yet another victory for pharmaceutical and medical device manufacturers in their quest for more relaxed off-label marketing rules, the Court was careful to explain that it did not decide the case

on off-label marketing grounds. Although the Court did express skepticism, it is unknown how the Second Circuit would view a different FCA case where a manufacturer has actually engaged in off-label marketing. Accordingly, the potential for FCA liability based upon off-label marketing remains unsettled and pharmaceutical and medical device manufacturers should continue to proceed with caution until courts or the FDA provide more controlling guidance.

For more information concerning the matters discussed in this publication, please contact the author **Michael H. Bauscher** (212-238-8785, bauscher@clm.com) or your regular Carter Ledyard attorney. Summer associate **James S. Arrabito** assisted with the preparation of this publication.

Endnotes

[1] *United States ex rel. Dr. Jesse Polansky v. Pfizer, Inc.*, No. 14-4774, slip op. (2d Cir. May 17, 2016).

[2] *See generally id.*

[3] *Id.* at 13.

[4] *Id.* at 7 (citation omitted).

[5] *Id.* at 7-8 (citation omitted).

[6] *Id.* at 8.

[7] *Id.* at 4.

[8] *Id.*

[9] *Id.*

[10] *Id.* at 4-5.

[11] *See id.* (citations omitted).

[12] William F. Sondericker & Michael H. Bauscher, *Promoting Off-Label Uses of Drugs and Medical Devices: Manufacturers Should Exercise Caution Despite Reversal of Conspiracy Conviction in U.S. v. Caronia*, Client Advisory, Carter Ledyard & Milburn LLP, at 2-7 (Dec. 14, 2012) <https://www.clm.com/publication.cfm?ID=411>. *See also* Michael H. Bauscher, *Key Compliance Issues to Keep an Eye On in 2015: Off-Label Marketing and Sunshine Act Reporting*, Pharmaceutical Compliance Monitor, at 1 (June 15, 2015) <http://www.pharmacompliancemonitor.com/key-compliance-issues-to-keep-an-eye-on-in-2015-off-label-marketing-and-sunshine-act-reporting/9216/>.

[13] *See* Sondericker & Bauscher, *supra* note 12, at 1. *See also United States v. Caronia*, 703 F.3d 149, 164 (2d Cir. 2012) (holding that criminalizing off-label marketing is an impermissible content-based restriction on free speech); *Amarin Pharma, Inc. v. U.S. Food & Drug Admin.*, 119 F. Supp. 3d 196, 237 (S.D.N.Y. 2015) (finding that Amarin could engage in truthful, non-misleading off-label marketing during its First Amendment challenge to the FDA's off-label marketing regulations). *Cf. also* Michael H. Bauscher, *Drug Manufacturer Challenges the Constitutionality of FDA Regulations Related to Off-Label Marketing of Drugs and Medical Devices*, Client Advisory, Carter Ledyard & Milburn LLP, at 2-3 (May 18, 2015) <https://www.clm.com/publication.cfm?ID=3528>.

[14] *Pfizer*, slip op. at 5.

[15] *Id.*

[16] *Id.*

[17] *See id.* at 12-13.

[18] *See id.* at 13-15.

[19] *Id.*

[20] *Id.* at 12.

[21] *Id.*

[22] *Id.* at 16.

[23] *Id.*

[24] *Id.* at 16.

[25] *Id.* at 17-18.

[26] *Id.* at 17 (citation omitted).

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related professionals

Michael H. Bauscher / Partner

D 212-238-8785

bauscher@clm.com