

## Whistleblower Lawsuit Against Drug Maker Fails Because “Off-Guideline” Marketing Does Not Constitute “Off-Label” Marketing

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In welcome news for the pharmaceutical industry, the U.S. District Court for the Eastern District of New York, in [United States ex rel. Polansky v. Pfizer, Inc.](#), 2012 U.S. Dist. LEXIS 163557 (E.D.N.Y. Nov. 15, 2012), issued a decision distinguishing between unlawful “off-label” marketing and lawfully marketing a drug for use outside of recommended guidelines. By way of background, the **Food and Drug Administration** approves “labels” (which, in some cases, may be lengthy and more akin to pamphlets or brochures) that must accompany prescription medications. A label states the purposes for which a medication has been determined to be safe and effective, and pharmaceutical companies are prohibited from promoting or marketing the medication for other “off-label” uses.

Since early 2004, Pfizer, Inc. has been defending a *qui tam* action that its former Director of Outcomes Management Strategies, Dr. Jesse Polansky, filed under the **False Claims Act**, [31 U.S.C. § 3729 et. seq.](#) In the lawsuit, which Polansky filed shortly after Pfizer terminated his employment, Polansky alleged that Pfizer encouraged physicians to prescribe the cholesterol drug [Lipitor](#) to patients even when, according to [National Cholesterol Education Program Guidelines](#), the patients’ cardiac heart disease risk factors and cholesterol levels did not call for drug intervention. Polansky alleged that, by marketing the drug for use by patients not within the Guidelines, Pfizer improperly induced doctors to prescribe it. Polansky further alleged that, because Medicare and Medicaid often paid for these drugs, Pfizer’s “off-label marketing” violated the False Claims Act. Pfizer filed a Motion to Dismiss Polansky’s claims.

In analyzing Polansky’s claims, the Court first considered the plain meaning of the term, “guidelines,” and concluded that it pertains to counseling or advice, not a mandate. Moreover, although Lipitor’s labels (different versions were issued in 2005 and 2009) referenced the Guidelines, the Court found the context to be advisory. Indeed, the Court observed that the Guidelines were not referenced in a section of the label entitled, “Limitations of Use.” According to the Court, this section would have been “a perfect place to have inserted any prohibitory language had the FDA desired to do so.”

The Court also observed that Lipitor’s labels defined the drug’s essential purpose as lowering cholesterol. Thus, according to the Court, “as long as Pfizer markets the drug to lower cholesterol, it

is doing what the label permits.”

In its decision, the Court noted “the ease with which the FDA could have limited reimbursable prescriptions of Lipitor to patients within the Guidelines had it wanted to do so.” For instance, the Court explained, the FDA could have required Pfizer to add to the label: “This drug is not approved for, and should not be prescribed to, any patient who falls outside of the NCEP Guidelines.” According to the Court, the FDA “commonly requires such restrictive language in labeling.”

However, the Court cautioned, “[t]his is not to say that every limitation on the use of a particular drug must be expressly set forth in the label, or that only marketing directed to an expressly proscribed use is actionable under the False Claims Act.” The Court acknowledged that “off-label marketing includes marketing for any use that the FDA has not specifically approved.” Nonetheless, the Court indicated that “[t]here is a distinction between off-label marketing to achieve a treatment not contemplated by the label (e.g., hair growth or curing cancer), and marketing to a patient population not specifically mandated by the label.” The Court emphasized that “[o]ff-guideline does not equate to off-label.” Because the Guidelines were “merely informational and advisory rather than restrictive limitations,” Polansky could not maintain his claim based on off-label marketing.

The Court granted Pfizer’s motion and dismissed the lawsuit.

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National Law Review, Volume II, Number 332

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