BOOTS ON THE GROUND: PIL TASK FORCE TARGETING OPIOID PROVIDERS IN THE WAR ON DRUGS

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INTRODUCTION

Attorney General Jeff Sessions announced the creation of the Prescription Interdiction & Litigation ("PIL") Task Force — which Sessions described as a "new front in the war on the opioid crisis" — in a February press release [1]. Notably, Sessions indicated that the PIL Task Force will specifically target distributors and pharmacies to "prevent diversion and improper prescribing." Specifically, the PIL Task Force "will use the False Claims Act and other tools to crack down on pain-management clinics, drug testing facilities, and physicians that make opioid prescriptions." [2]

Of the enforcement tools available to the PIL Task Force, the False Claims Act ("FCA") is among the most powerful. It is also one of the most popular — *qui tam* plaintiffs have found great success using the FCA for civil enforcement [3]. Indeed, even before the PIL Task Force was formed, the FCA was featured in the *United States Attorneys' Bulletin* as a mechanism to fight opioid abuse [4].

Since they are named as PIL Task Force targets, all doctors, pharmacies, and medical providers should be familiar with the FCA and how it has recently been used as a means of enforcement.

THE FCA: AN OVERVIEW

The FCA is violated when one "knowingly presents or knowingly causes to be presented" a false claim to the government or "knowingly makes, uses, or causes to be made or used, a false record or statement material to" a false claim to the government [5].

An FCA suit can be initiated by (1) a private citizen as a *qui tam* plaintiff or (2) by the government. An FCA suit initiated by a private *qui tam* plaintiff has three important features. First, the complaint is filed under seal, meaning that it is not publicly available unless and until it later becomes unsealed. Second, the complaint is not served on the defendant. Third, a copy of the complaint is delivered to the Department of Justice ("DOJ") along with the evidence in the *qui tam* plaintiff's possession. Once delivered, the DOJ has 60 days to decide whether or not it will intervene in the action, although this time period may be extended at the government's request.

During this time, governmental agents from various departments may execute subpoenas or search warrants, perform document reviews, and interview witnesses to investigate the *qui tam* plaintiff's case. Once the

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investigation is finished, the government will decide whether it wants to intervene in the case. If the government does not intervene, the *qui tam* plaintiff has the option to continue the suit on its own.

A POTENTIAL FCA TARGET: OFF-LABEL AND OFF-COMPENDIUM PRESCRIPTIONS

Physicians often prescribe medications, including opioids, to treat conditions and diseases not expressly approved by the Federal Drug Administration ("FDA"). This practice, known as "off-label" prescribing, is legal, and can even be the standard treatment for chronic and progressive medical conditions. However, Medicare Part D and Medicaid prohibit coverage of drugs for off-label use, unless evidence is produced that the off-label use is recognized by a specified drug compendia.

If the prescription is either expressly approved by the FDA (i.e., on-label) or recognized by a specified drug compendia (i.e., on-compendium), the prescription has been made for a "medically accepted indication" and may be eligible for coverage under Medicare Part D or Medicaid. However, where a prescription is both off-label and off-compendium (i.e., not made for a medically accepted indication), Medicare Part D and Medicaid disallow coverage entirely.

THE FCA AT WORK: ANALYZING OFF-LABEL AND OFF-COMPENDIUM PRESCRIPTIONS

Prescribing or dispensing opioids off-label and off-compendium for Medicare Part D and Medicaid beneficiaries can be a major FCA pitfall for providers. This is especially the case in light of the Supreme Court's recent approval of the implied false certification theory for FCA violations [6].

According to the implied false certification theory, when a defendant submits a claim for payment, he or she impliedly certifies compliance with all conditions of payment [7]. Thus, if a claim for payment failed to disclose the defendant's violation of a material statutory, regulatory, or contractual requirement, then the defendant has made a misrepresentation that renders the claim "false or fraudulent" under the FCA [8]. Under this theory, a claim for payment for a drug that has been prescribed off-label and off-compendium may be an implied false certification because the claim fails to indicate that the prescribed drug is not approved for that particular use, a common precondition to payment [9].

Risk to pharmacists. On its face, the implied false certification theory could be used to target any pharmacist that — even unwittingly — fills off-label and off-compendium opioid prescriptions. However, the FCA requires that the claim be submitted knowingly [10]. Generally, a pharmacist is unlikely to know or have reason to know whether an opioid was prescribed off-label and/or off-compendium. For example, under Medicare Part D requirements, dispensing pharmacists "are not required to contact each prescriber to verify [that] a prescription is being used for a medically accepted indication." [11] In other words, a pharmacist may be able to successfully assert a defense of ignorance in response to purported FCA violations [12].

This scenario played out in *United States ex rel. Fox Rx, Inc. v. Omnicare Inc* [13]. In *Omnicare, qui tam* plaintiffs alleged that specialty pharmacies had violated the FCA by seeking "reimbursement for non-covered prescriptions from the Medicare Part D program." [14] The pharmacy-defendants moved for summary judgment, arguing that they had not acted "knowingly" in submitting the claims for payment [15]. The court agreed and granted summary judgment, holding that "[t]he undisputed evidence here does not support that the Defendants or their employees

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knew or had access to information that allowed them to know if doctors had prescribed off-label use of [antipsychotics], and there is no evidence or authority to support that Defendants had a duty to undertake this evaluation." [16] Of course, *Omnicare* only illustrates the application of the FCA's "knowledge" requirement in the Medicare Part D context; it does not absolve, eliminate, or diminish any pre-existing obligation of pharmacists to challenge scripts that appear patently false.

Risk to doctors. In contrast, prescribing doctors may not be able to assert a defense of ignorance because they will likely be deemed to have constructive knowledge of the contents of publicly available compendia. In fact, a doctor who prescribes opioids off-label and off-compendium to a Medicare or Medicaid patient may be liable under the FCA by virtue of writing a prescription, even though the doctor does not ultimately submit the claim for payment [17].

This was the case in *United States ex rel. Watson v. King-Vassel* [18]. In *King-Vassel*, a *qui tam* plaintiff alleged that a psychiatrist prescribed off-label psychotropics to a minor in violation of the FCA [19]. The trial court ruled in favor of the defendants in part because the dispensing pharmacy, and not the physician, was the "cause" of the false claim since the pharmacy submitted the claim for payment [20]. The plaintiff appealed, and the Seventh Circuit reversed the decision, holding in part that notions of proximate causation may form the basis for the psychiatrist's FCA liability [21]. Therefore, intervening events do not necessarily break the causal chain for prescribing physician FCA liability [22].

CONCLUSION

Although off-label prescriptions are legal, the legality of the prescription does not necessarily mean that the government is obligated to pay for a beneficiary's off-label and/or off-compendium prescriptions. And submitting claims for payment to the government for off-label and/or off-compendium prescriptions may violate the FCA. With Attorney General Sessions' indication that the PIL Task Force has set its sights on opioid-related health care fraud as the next target in the war on drugs — specifically mentioning providers — physicians and pharmacists should exercise caution when prescribing or dispensing opioids if it is for an off-label and/or off-compendium use to limit FCA exposure.

Specifically, before writing an off-label prescription, physicians should consider referencing the specified compendia and noting if the prescribed use is recognized or informing the patient that the prescription may not be covered by his or her insurer. Also, before filling prescriptions, pharmacists would be well advised to watch for indicators of abuse, such as frequency of prescriptions and atypical dosages or dosage schedules. While the FCA does not itself establish new standards for opioid providers, it is a powerful tool for enforcing existing standards of which providers should be mindful.

Notes

[1] Office of Public Affairs, *Attorney General Sessions Announces New Prescription Interdiction & Litigation Task Force*, DEP'T OF JUST. (Feb. 27, 2018), https://www.justice.gov/opa/pr/attorney-general-sessions-announces-new-prescription-interdiction-litigation-task-force.

[2] *Id.*

[3] "Qui tam" suits are those initiated by private citizens on behalf of the government. They are explicitly permitted

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by the FCA.
[4] Roger Wenthe, *Fighting Opioid Abuse under Federal Health Programs with the False Claims Act*, 64 U.S. Att'ys Bull. 93 (2016).
[5] 31 U.S.C. § 3729(a)(1)(A), (B).
[6] *Universal Health Servs., Inc. v. United States ex rel*. Escobar, 136 S. Ct. 1989 (2016).
[7] *Id.* at 1996.
[8] *Id.*
[9] *See id.* at 2000.
[10] 31 U.S.C. § 3729(a)(1)(A), (B).
[11] MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL, *Chapter 6 – Part D Drugs and Formulary Requirements*, Section 10.6 (Rev. 18, Jan. 15, 2016).
[12] *E.g., United States ex rel. Fox Rx, Inc. v. Omnicare, Inc*., 2014 WL 2158412 (N.D. Ga. May 23, 2014) (holding that a dispensing pharmacy was not liable under the FCA for dispensing a drug off-label and off-compendium where it had neither actual knowledge nor reason to know of those facts).
[13] *Id.*
[14] *Id.* at *1.
[15] *Id.* at *4.
[16] *Id.* at *6.
[17] *See, e.g., United States ex rel. Watson v. King-Vassel*, 728 F.3d 707 (7th Cir. 2013) (reversing summary judgment for psychiatrist in an FCA claim alleging off-label and off-compendium prescribing of psychotropic medications).
[18] *Id.*
[19] *Id.* at 709.
[20] *Id.* at 714.
[21] *Id.* at 715.
[22] *Id.* at 714–15.

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