UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, *ex rel.* **RICHARD GARDNER,**	)	
Plaintiffs,	)	
v.	)	**Case No. 17-cv-00464 (APM)**
VANDA PHARMACEUTICALS, INC.,	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

I. INTRODUCTION

Relator Richard Gardner alleges that Defendant Vanda Pharmaceuticals, Inc. caused the submission of numerous false claims to the Medicare and Medicaid programs by promoting and marketing two of its drugs, Fanapt and Hetlioz, for off-label uses. Relator asserts claims under the federal False Claims Act ("FCA") and 32 analogous state laws. The United States and the various States declined to intervene in this case, but Relator nevertheless elected to prosecute it. Now before the court is Defendant's motion to dismiss. For the reasons that follow, the court dismisses all of Relator's claims, but gives Relator the opportunity to amend his complaint.

II. BACKGROUND

A. Factual Background

Defendant Vanda Pharmaceuticals, Inc. ("Vanda" or "Defendant") is a pharmaceutical manufacturer based in Washington, D.C. First Am. Compl., ECF No. 20 [hereinafter FAC], ¶ 9. Relator worked for Vanda as a Regional Business Leader from November 2015 until August 2016. Relator's territory included Illinois, Wisconsin, Michigan, Ohio, Western Pennsylvania, West

Virginia, and Indiana. *Id.* ¶ 6. Regional Business Leaders are responsible for managing Defendant's sales force. *Id.* ¶ 56. Relator asserts that his claims are confirmed by another Regional Business Leader at Vanda, Jeff Bourgeois. *Id.* ¶ 51. Bourgeois worked at Vanda from November 2015 through June 2018. *Id.* At different times during his tenure at Vanda, Bourgeois's territory included Louisiana, Arkansas, Texas, and Oklahoma. *Id.*

Defendant owns and markets the two drugs at issue in this case, Fanapt and Hetlioz. *Id.* ¶ 9. Fanapt is an "atypical antipsychotic" used for "the acute treatment of schizophrenia in adults." *Id.* Fanapt was developed in 1995, but before it was released on the market, Defendant discontinued its research on the drug and sold the rights to Titan Pharmaceuticals. *Id.* ¶ 10. Titan later sold Fanapt's development, manufacturing, and marketing rights to another drug company, Novartis. *Id.* The United States Food and Drug Administration ("FDA") approved Fanapt in 2009, and Novartis marketed it until December 2014, when Vanda took over marketing responsibilities. *Id.* ¶ 11. Hetlioz is a circadian regulator, which the FDA approved as a treatment for Non-24-Hour Sleep-Wake Disorder ("Non-24"), *id.* ¶ 12, a circadian rhythm sleep disorder found mostly in blind individuals, *id.* ¶¶ 12–13. Relator alleges that "Defendant has, since at least November 2015, engaged in a scheme to promote . . . Fanapt and Hetlioz for off-label uses, in addition to several other prohibited promotional strategies." *Id.* ¶ 50.

1. Fanapt

The FDA approved Fanapt solely to treat adult schizophrenia patients. *Id.* ¶¶ 9, 62. Other antipsychotics, by contrast, have a wider variety of uses. *Id.* ¶ 62. To increase sales, Relator alleges, Vanda's senior management implemented a plan to promote Fanapt for bi-polar disorder and "other conditions treated by competitors' antipsychotic medications." *Id.* ¶ 63. "Specifically . . . , Vanda trained its sales force to market Fanapt to providers as an effective

substitute for other atypical antipsychotics that have more expansive indications and are commonly prescribed for bipolar disorder rather than schizophrenia." *Id.* ¶ 64; *see also id.* ¶¶ 66–92. According to Relator, Vanda was aware that "a significant portion of the prescriptions secured by its sales force were for off-label uses." *Id.* ¶ 65.

Additionally, Vanda "targeted" competitors' atypical antipsychotic drugs by setting its representatives' sales goals for Fanapt on par with other antipsychotic drugs. *Id.* ¶¶ 93–118. As part of that strategy, Vanda provided "target lists" to its sales representatives, which featured providers who prescribed other atypical antipsychotics. *Id.* ¶ 109. All of the providers on the target lists had at least a few schizophrenia patients, *id.* ¶ 110, but according to Relator, "the target lists were not useful, as they were in place solely to shield Vanda from liability, and as a result nearly all of the sales representatives relied almost exclusively on the target lists they personally created," as Vanda's provided lists would not allow representatives to meet sales expectations, *id.* ¶ 112. Vanda's target lists did not differentiate between providers prescribing atypical antipsychotics for schizophrenia versus other conditions. *Id.* ¶¶ 113–14. Vanda also declined to remove physicians with no schizophrenia patients from its target lists, even when provided the means to do so, and continued to compensate its sales representatives for off-label prescriptions. *Id.* ¶ 114. Vanda incentivized and encouraged its sales force to call on doctors to prescribe Fanapt for off-label purposes. *Id.* ¶¶ 115–18. Finally, internal Fanapt sales projections included off-label prescriptions, Relator says, and Vanda refused to change those projections even when, for example, the Indiana Medicaid program changed its coverage policy so that it no longer reimbursed for off-label uses. *Id.* ¶¶ 119–21.

Vanda also promoted Fanapt for off-label use in pediatric patients. *See id.* ¶¶ 123–35. As evidence of this, Relator points to target lists, which include child psychiatrists. *See id.* "The

fact that Vanda included child psychiatrists in its targets lists demonstrates that [Vanda] intended its sales representatives to promote Fanapt to child psychiatrists," as did its failure to remove child psychiatrists from those lists or to stop sales representatives from calling on child psychiatrists to prescribe Fanapt. *Id.* ¶¶ 130–31.

In addition to off-label promotion and messaging, Relator makes a number of secondary allegations regarding Vanda's improper promotion of Fanapt. First, Relator alleges that Vanda promoted Fanapt as a "first line" treatment when the FDA approved it only as a "second line" treatment. *Id.* ¶¶ 136–40. More specifically, Fanapt's FDA-approved label states that Fanapt prolongs "QT interval," which may be associated with arrhythmia and sudden death, therefore users should "consider using other antipsychotics first," and "[i]n many cases . . . other drugs should be tried first." *Id.* ¶ 136. Despite the FDA's warnings and limitations, "Vanda trained its sales force to promote Fanapt as a first line drug." *Id.* ¶ 137. Second, "Vanda trained its sales representatives to pitch Fanapt to physicians as a once-a-day medication," even though the FDA had approved the drug to be administered twice daily. *Id.* ¶¶ 141–47. Third, "[i]n order to gain FDA approval," Vanda was required to give certain safety warnings about Fanapt to both patients and providers. *Id.* ¶ 148. Yet, Vanda implemented strategies and sales techniques to downplay those risks, thereby misleading users. *Id.* ¶¶ 148–60. Fourth, the FDA-approved Fanapt label states that patients starting the drug should use titration to achieve the target dose. However, according to Relator, "Fanapt sales representatives in some territories were ignoring the FDA-approved titration schedule and giving providers two or three titration packs, rubber banded together, to give to their patients starting Fanapt." *Id.* ¶ 163. Vanda failed to include instructions on how a patient should properly titrate Fanapt using multiple titration packs, *id.* ¶ 171, and this "scheme" therefore "had the effect of increasing the target dose for patients receiving the bundled

titration packs, *id.* ¶ 169. Improper titration could increase a patient's risk for dangerous side effects. *See id.* ¶¶ 173–74. Fifth, Vanda "regularly promoted, falsely, that the clinical studies demonstrate that Fanapt is just as effective as [another antipsychotic]." *Id.* ¶¶ 176–78. Finally, "Relator discovered a fraudulent scheme to misuse Fanapt copay cards which Vanda helped conceal." *Id.* ¶ 179. Relator alleges that in the Detroit, Michigan sales territory there was "a large spike in Fanapt prescriptions among a certain group of physicians." *Id.* Those physicians had historically prescribed two to three Fanapt prescriptions per month, but in October and November of 2015, they wrote more than 70 Fanapt prescriptions. *Id.* Vanda's Head of Sales told Relator that the prescription increase was "the result of a fraudulent scheme between the physicians and local pharmacists to submit hundreds of Fanapt copay cards and prescriptions, receive reimbursement from the insurance provider, and then pocket the money because the prescriptions were never dispensed." *Id.* ¶ 182. Vanda was allegedly an "active participant" in the scheme. *Id.*

2. Hetlioz

In 2010, the FDA granted "orphan drug" status to Hetlioz to treat Non-24 in blind patients without light perception. *Id.* ¶ 187.[1] Approximately 90,000 blind individuals in the United States suffer from Non-24. *Id.* ¶ 188. Non-24 is very rare in sighted people, although the exact number of sighted individuals who suffer from Non-24 is not known. *Id.* ¶ 190. When Vanda sought FDA approval for Hetlioz, it sought approval for use in blind patients. *Id.* ¶ 191. Similarly, Vanda's clinical trials for the drug involved only blind individuals. *Id.* But according to Relator, Vanda

[1] The Orphan Drug Act grants special status to a drug or biological product used to treat a rare disease or condition upon request of a sponsor. This status is referred to as "orphan designation," or "orphan status." A drug will qualify for orphan status only if it meets certain criteria under the Orphan Drug Act and the FDA's implementing regulations. *Designating an Orphan Product: Drugs and Biological Products*, FOOD & DRUG ADMIN., https://www.fda.gov/industry/developing-products-rare-diseases-conditions/designating-orphan-product-drugs-and-biological-products (last visited May 7, 2020).

"quickly turned to sighted patients as their primary target for Hetlioz," a use for which it had not been approved by the FDA. *Id.*

Relator points to a number of marketing strategies implemented by Defendant as evidence. For example, Regional Business Leaders were directed by Vanda's CEO to tell providers that Hetlioz was "effective in treating circadian rhythm disruption," and that psychiatrists "would connect the dots and easily determinate that [ ] Hetlioz . . . would also be able to treat their non-blind patients with other sleep disorders caused by circadian rhythm disruption, such as shift work sleep disorder, jet lag, and insomnia." *Id.* ¶¶ 193–94. One sales representative, who had doctors write over 50 Hetlioz prescriptions in a single quarter, shared that "he simply tells doctors that if they have patients who cannot sleep, they should prescribe them to Hetlioz and get them sleeping right now." *Id.* ¶ 196. Another former sales representative at Vanda said that the company was "forcing sales representatives to promote Hetlioz off-label and convincing doctors to share patient information," and that Vanda wanted its Hetlioz sales force to focus on psychiatrists even though they do not typically treat patients with Non-24. *Id.* ¶¶ 200–01. The former representative convinced several doctors to prescribe Hetlioz, but none of the patients were blind. *Id.* ¶ 202.

In 2017, Vanda started a "Hetlioz to Psychiatrists [I]nitiative." *Id.* ¶ 204. As part of that initiative, Fanapt sales representatives would call psychiatrists to promote Hetlioz. *Id.* During a 2018 earnings call, Vanda's CEO explained an effort to "commercialize" Hetlioz and to create "awareness for non-24 among psychiatrists." *Id.* ¶ 205. According to Vanda's CEO, 2 out of 3 Hetlioz prescriptions "come from psychiatrists and are written for sighted patients." *Id.* ¶ 206. Relator contends that "[b]y instructing sales representatives to focus on Hetlioz's ability to treat circadian rhythm disruption, Vanda intended to secure off-label prescriptions because it knew this sales pitch would cause physicians to ask whether Hetlioz could treat other sleep disorders caused

by circadian rhythm disruption." *Id.* ¶ 207. Vanda thereby "positioned Hetlioz as a treatment option for all sleep disorders caused by circadian rhythm disruption," *id.* ¶ 207, and "intended to convince physicians to use Hetlioz instead of other sleep aides," *id.* ¶ 208. Relator cites The Marcus Aurelius Report, *Vanda: In the Land of the Blind, the One-Eyed Man is King*, MARCUS AURELIUS VALUE (February 11, 2019) [hereinafter Aurelius Report],[2] which apparently "confirms that Vanda promoted Hetlioz as an alternative to other—and much less expensive—sleep aids." FAC ¶ 208. Bourgeois also "corroborates that Vanda's intent was to promote Hetlioz off-label for conditions other than Non-24," and provides additional details about the training of sales representatives and marketing strategies by Vanda. *See id.* ¶¶ 209–17. And according to a "confidential witness," who is a current Vanda sales representative, Vanda is "still pressuring sales representatives to sell Hetlioz at all costs, including off-label sales." *Id.* ¶ 218. The Aurelius Report also details the high annual cost of Hetlioz, which, since its commercial launch in 2014, increased from $84,000 to $188,000 by 2019. *See* Aurelius Report[3]; FAC ¶ 12 ("In 2019, a year supply of Hetlioz costs approximately $188,000.").

According to Bourgeois, "Hetlioz prescriptions for sighted patients quickly became very difficult to get approved by commercial insurance." *Id.* ¶ 219. Only an estimated 20% to 40% of patients prescribed Hetlioz were able to obtain the drug. *Id.* ¶ 220. Quoting the Aurelius Report, the Amended Complaint states that "virtually all prescriptions would automatically be rejected for reimbursement for sighted people by commercial insurers. This is consistent with numerous

[2] Available at: http://www.mavalue.org/research/vanda-in-the-land-of-the-blind-the-one-eyed-man-is-king/.
[3] Because Relator relies on the Aurelius Report throughout his Complaint, FAC ¶¶ 52 & nn. 5–6, 62, 184–86, 197–99, 208, 217, 219–20, the court may properly consider it on a motion to dismiss. *See Hinton v. Corrs. Corp. of Am.*, 624 F. Supp. 2d 45, 46–47 (D.D.C. 2009) ("Matters that are not 'outside' the pleadings a court may consider on a motion to dismiss include 'the facts alleged in the complaint, documents attached as exhibits or incorporated by reference in the complaint,' or documents 'upon which the plaintiff's complaint necessarily relies' even if the document is produced not by the plaintiff in the complaint but by the defendant in a motion to dismiss." (internal citations omitted)).

insurance forms . . . that state that all patients must be completely blind." *Id.* In response, Vanda created "an internal reimbursement hub to assist doctors in getting their Hetlioz prescriptions filled," including assistance with prior authorization and insurance denial appeals. *Id.* ¶ 221. Bourgeois explained that sales representatives were provided very little information regarding Hetlioz prescriptions submitted to the reimbursement hub, both when the hub was in-house and previously when Vanda had used a third-party operator. *Id.* ¶¶ 222–23. Further, Relator notes that because Hetlioz is "a very expensive drug," copayments amounts were also an obstacle to patients receiving the drug. *Id.* ¶ 224. Bourgeois heard that Vanda assisted with patient copayment amounts through "patient assistant programs" and monetary donations to patient assistance foundations to ensure that patient copayments for Hetlioz would be covered. *Id.* Defendant donated to one such foundation for the purpose of "ensur[ing] that patients['] copayments for Hetlioz would be covered" in the summer of 2017 "as the price of Hetlioz was rising." *Id.* Such actions, Relator alleges, violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b.

3. Medicare and Medicaid

The putative victims of Vanda's alleged fraud scheme are the federal Medicare and Medicaid programs.[4] Medicare is a federal health insurance program for individuals over the age of 65 and individuals under 65 with certain disabilities, *id.* ¶ 24, which is administered by the Department of Health and Human Services ("HHS") and its Centers for Medicare and Medicaid Services ("CMS"), *id.* ¶ 7. Medicare Part D pays for prescription drug benefits. *Id.* ¶ 25 (citing

[4] In his Complaint, Relator also discusses TRICARE, a healthcare program established by the Department of Defense. FAC ¶ 36 (citing 10 U.S.C. §§ 1071–1110). The court does not include TRICARE in its discussion, however, because Relator mentions TRICARE only in passing. Aside from introducing TRICARE as a government payor, Relator mentions TRICARE only twice more. Once to say that off-label use "prescriptions were reimbursed by federal health care programs, including Medicare, Medicaid and Tricare," *id.* ¶ 50, and again in Count I to say that "Defendant has submitted and/or caused to be submitted false or fraudulent claims to Medicare, Medicaid, and Tricare," *id.* ¶ 252. Such mentions are conclusory, and Relator makes no actual factual assertions as to any such claims submitted to or paid out by Tricare.

42 U.S.C. § 1395w-101 *et seq.*). Persons enrolled in Medicare Part A or Part B are eligible to enroll in a prescription drug plan under Part D. *Id.* Medicare contracts with private companies, or "sponsors," who are authorized to sell Part D insurance coverage. *Id.* Sponsors submit bids to Medicare with estimates of the actual cost of providing prescriptions to beneficiaries. *Id.* ¶¶ 31–32. The government then makes "interim payments [to the sponsor] . . . based on the Secretary's best estimate of amounts that will be payable after obtaining all of the information." *Id.* ¶ 31 (citing 42 U.S.C. § 1395w-115(d)(1)). Beneficiaries are also responsible for some amount of out-of-pocket prescription costs. *See id.* ¶¶ 28–30. The federal government aims to cover "74.5% of the actual costs of basic prescription drug coverage." *Id.* ¶ 27 (citing 42 U.S.C. § 1395w-115(a)).

Medicaid is a joint federal-state program that provides healthcare benefits for certain low-income and disabled individuals. *Id.* ¶ 33. The percentage of a state's Medicaid payments covered by the federal government—the "Federal Medical Assistance Percentage"—is determined using the state's per capita income. *Id.* (citing 42 U.S.C. § 1396d(b)). States develop Medicaid programs, which are subject to approval by the Secretary of HHS. *Id.* ¶ 34 (citing 42 U.S.C. § 1396a(a)–(b)). The HHS Secretary then pays each state "an amount equal to the Federal medical assistance percentage . . . of the total amount expended during such quarter as medical assistance under the State plan." 42 U.S.C. § 1396b(a)(1); *see also id.* State Medicaid programs reimburse drug providers for prescription drugs, often through private companies who evaluate and process claims on behalf of Medicaid recipients. *Id.* ¶ 35. Every quarter, a state submits to CMS "an estimate of its Medicaid federal funding needs," and CMS then determines the amount of federal funding that the state may draw down as it incurs expenditures during the quarter. *Id.* at 35. States then draw down federal funding based on actual provider claims, including pharmacies seeking payment for prescription drugs, before submitting a final

expenditure report to CMS. *Id.* Adjustments are made to the quarterly federal funding amount as necessary based on actual expenditures. *Id.* (citing 42 U.S.C. § 430.30).

B. Procedural History

On March 10, 2017, Relator filed a Complaint, on behalf of the United States, 28 states, and the District of Columbia, asserting violations of the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and numerous analogous state statutes. *See* Compl., ECF No. 1. After several extensions of time, ECF Nos. 3, 8, 12, 15, the United States and all respective States declined to intervene on January 29, 2019, ECF No. 16. On January 31, 2019, the court ordered the unsealing of the Complaint. *See* ECF No. 17. Relator then filed a 175-page amended complaint on May 8, 2019. *See* FAC.[5] On August 13, 2019, Vanda filed a Motion to Dismiss, which is now before the court. Def.'s Mot. to Dismiss, ECF No. 40, Statement of P. & A. in Supp. of Def.'s Mot. to Dismiss, ECF No. 40-1 [hereinafter Def.'s Mot.].

III. LEGAL STANDARD

A. Rule 12(b)(6) Standard

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible when "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). The factual allegations in the complaint need not be "detailed"; however, the Federal Rules demand more than "an unadorned, the-defendant-unlawfully-harmed-me accusation." *Id.* (citing *Twombly*, 550 U.S. at 555). "Threadbare recitals of the elements of a cause

[5] Relator has since voluntarily dismissed Count XV (Maryland False Claims Act) and Count XXI (New Jersey Medical Assistance and Health Services Act). Relator's Opp'n to Def.'s Mot. to Dismiss, ECF No. 42, at 43–44.

of action, supported by mere conclusory statements, do not suffice." *Id.* (citing *Twombly*, 550 U.S. at 555). If the facts as alleged fail to establish that a plaintiff has stated a claim upon which relief can be granted, a court must grant the defendant's Rule 12(b)(6) motion. *See Am. Chemistry Council, Inc. v. U.S. Dep't of Health & Human Servs.,* 922 F. Supp. 2d 56, 61 (D.D.C. 2013).

In ruling on a motion to dismiss, the court may consider "not only the facts alleged in the complaint, but also . . . any documents appended to a motion to dismiss whose authenticity is not disputed, if they are referred to in the complaint and are integral to a claim." *Douglas v. D.C. Hous. Auth*., 981 F. Supp. 2d 78, 85 (D.D.C. 2013). So long as the "plaintiff's complaint necessarily relies" on the document produced by a defendant in its motion to dismiss, *Hinton v. Corrs. Corp. of Am.*, 624 F. Supp. 2d 45, 46 (D.D.C. 2009) (internal quotation marks and citation omitted), and the plaintiff does not dispute its authenticity, the court may consider the document without converting the defendant's motion into one for summary judgment, *see Feld Entm't Inc. v. Am. Soc'y for the Prevention of Cruelty to Animals*, 873 F. Supp. 2d 288, 323 (D.D.C. 2012).

B. Rule 9(b) Standard

Fraud claims are subject to the heightened pleading requirement of Rule 9(b), which provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b); *see also United States ex rel. Heath v. AT & T, Inc*., 791 F.3d 112, 123 (D.C. Cir. 2015) (applying Rule 9(b) to claims filed pursuant to the False Claims Act); *United States ex rel. Lott v. Not-For-Profit Hosp. Corp.*, 296 F. Supp. 3d 143, 151 (D.D.C. 2017) ("Substantive FCA claims, like common law fraud claims, must satisfy the heightened pleading standard of Rule 9(b)."). "Motions to dismiss for failure to plead fraud with sufficient particularity are evaluated in light of the overall purposes of Rule 9(b)," *United States ex rel. Tran v. Computer Sciences Corp*., 53 F. Supp. 3d 104, 128 (D.D.C. 2014), which include

"ensur[ing] that defendants have notice of the charges against them adequate to prepare a defense," *United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 34 (D.D.C. 2003).

"Rule 9(b) is not an antithesis of Rule 8(a)'s 'short and plain statement' requirement, but rather a supplement to it." *Baker v. Gurfein*, 744 F. Supp. 2d 311, 315 (D.D.C. 2010). Although the rule does not require a complaint "to contain a detailed allegation of all facts supporting each and every instance of submission of a false claim," *Barrett*, 251 F. Supp. 2d at 35, a plaintiff "must . . . provide a defendant with notice of the who, what, when, where, and how with respect to the circumstances of the fraud," *Stevens v. InPhonic, Inc.*, 662 F. Supp. 2d 105, 114 (D.D.C. 2009) (internal quotation marks and citation omitted). Accordingly, the complaint must include "the time, place and content of the false misrepresentations, the fact misrepresented and what was retained or given up as a consequence of the fraud," as well as "identify individuals allegedly involved in the fraud." *United States ex rel. Williams v. Martin-Baker Aircraft Co.*, 389 F.3d 1251, 1256 (D.C. Cir. 2004) (internal quotations and citations omitted); *see also Lott*, 296 F. Supp. 3d at 151. Thus, in order to satisfy Rule 9(b), a plaintiff must "set forth an adequate factual basis for his [FCA] allegations," including a "detailed description of the specific falsehoods that are the basis for his suit." *United States ex rel. Totten v. Bombardier Corp.*, 286 F.3d 542, 552 (D.C. Cir. 2002).

IV. DISCUSSION

A. The Statutory Framework

To understand the parties' merits arguments, it is necessary first to provide some background about the interplay of two key statutes: The Food, Drug, and Cosmetic Act and the False Claims Act.

1. The Food, Drug, and Cosmetic Act

Pharmaceutical manufacturers in the United States, like Vanda, are regulated by the FDA under the Food, Drug, and Cosmetic Act ("FDCA"). The FDCA sets forth a process for the approval of new drugs by the FDA. 21 U.S.C. § 355. "To secure [FDA] approval for a drug or medical device, a manufacturer must demonstrate that its product is safe and effective for each of its intended uses." *Wash. Legal Found. v. Henney*, 202 F.3d 331, 332 (D.C. Cir. 2000) (footnote omitted) (citing 21 U.S.C. § 355(d)). Uses other than those for which a drug has been approved are considered "off-label uses." *Id.*

"[N]either Congress nor the FDA has attempted to regulate the off-label use of drugs by doctors and consumers," and so physicians are free to prescribe drugs for off-label uses as they see fit. *Id.* at 333. And "it is undisputed that the prescription of drugs for unapproved uses is commonplace in modern medical practice and ubiquitous in certain specialties." *Id.*

The FDCA, however, prohibits drug manufacturers "from marketing drugs for . . . 'off-label' uses," *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 723 (1st Cir. 2007) (citing 21 U.S.C. § 321 *et seq.*), *overruled on other grounds by Allison Engine v. United States ex rel. Sanders*, 553 U.S. 662 (2008), and from misbranding drugs, and imposes criminal penalties for doing so, 21 U.S.C. §§ 331(a), 333(a). A drug is considered misbranded if it lacks "adequate directions for use," *id.* § 352(f), in other words, if it lacks "directions under which the layman can use a drug safely and for the purposes for which it is intended," 21 C.F.R. § 201.5. The FDA takes the position that "[a]n approved drug that is marketed for an unapproved use (whether in labeling or not) is misbranded because the labeling of such drug does not include 'adequate directions for use.'" *Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or*

Cleared Medical Devices, Guidance for Industry, U.S. FOOD & DRUG ADMIN. (Jan. 2009) (available at https://perma.cc/XP3Z-SQE7).

2. The False Claims Act

The FDCA does not contain a private right of action. 21 U.S.C. § 337(a); *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance . . . ."). Relator therefore brought his claims under the FCA. The FCA, in relevant part, imposes liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A); who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," *id.* § 3729(a)(1)(B); or who "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government," *id.* § 3729(a)(1)(G). A "claim . . . includes direct requests to the Government for payment as well as reimbursement requests made to the recipients of federal funds under federal benefits programs." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016) (citing 31 U.S.C. § 3729(b)(2)(A)) (internal quotation marks omitted).

To make out an FCA claim, a relator must show not only that the defendant submitted a claim, but also that the claim was false and that the defendant knew the claim was false. *United States v. DynCorp Int'l, LLC*, 253 F. Supp. 3d 89, 98 (D.D.C. 2017) (quoting *United States ex rel. Folliard v. CDW Tech. Servs., Inc.*, 722 F. Supp. 2d 20, 26 (D.D.C. 2010)). And courts have read into the element of falsity a materiality component. *Id.* at 98–99; *see also Escobar*, 136 S. Ct. at 2002–04. Thus, an FCA claim requires the trifecta of falsity, materiality, and scienter.

The FCA is not, however, "an all-purpose antifraud statute, or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Escobar*, 136 S. Ct. at 2003 (internal quotation marks and citation omitted). Accordingly, "FCA liability does not attach to violations of federal law or regulations, such as marketing of drugs in violation of the FDCA, that are independent of any false claim." *Rost*, 507 F.3d at 727.

B. "Reverse False Claims" Cause of Action

Relator brings claims under three subsections of the FCA: Sections 3729(a)(1)(A), 3729(a)(1)(B), and 3729(a)(1)(G). *See* FAC ¶ 253. The court begins with the so-called "reverse false claims" under 31 U.S.C. § 3729(a)(1)(G), and easily disposes of them. Under subsection 3729(a)(1)(G), liability attaches to anyone who "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G). In other words, "a typical reverse false claim action involves a defendant knowingly making a false statement in order to avoid having to pay the government when payment is otherwise due." *United States ex rel. Riedel v. Boston Heart Diagnostics Corp.*, 332 F. Supp. 3d 48, 82 (D.D.C. 2018) (quoting *Pencheng Si v. Laogai Research Found.*, 71 F. Supp. 3d 73, 88 (D.D.C. 2014)).

The court agrees with the Defendant that "Relator has alleged nothing to suggest that Vanda"—or anyone else for that matter—"owed any payments to governmental insurance payors," and therefore "no reverse false claim is pleaded here." Def.'s Mot. at 28. Relator's retort that he states a claim under subsection 3729(a)(1)(G) because Vanda "caused false claims to be submitted to [government healthcare programs] and took action to conceal its fraud," Relator's Opp'n to Def.'s Mot. to Dismiss, ECF No. 42 [hereinafter Relator's Opp'n], at 38, misconstrues the

fundamental nature of such an FCA claim, *see Riedel*, 332 F. Supp. 3d at 83 ("Because the relator does not plead any monetary obligation owed . . . to the government independent of its concealing of its allegedly fraudulent activity, the Court must dismiss the relator's reverse false claims cause of action." (cleaned up)).

C. Off-Label Marketing

In the main, Relator alleges that Vanda violated the FCA by marketing both Fanapt and Hetlioz for off-label uses, thereby causing fraudulent claims to be submitted by prescribers to government payors under the Medicare and Medicaid programs. This is known as an "implied false certification theory." The FCA recognizes such a theory of liability. Where "a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services provided." *Escobar*, 136 S. Ct. at 1999. In this case, Relator's implied false certification theory is once removed, in that Vanda itself is not alleged to have made any "representation[] in submitting a claim"; rather, it is alleged to have caused providers to do so falsely. As Relator characterizes his claims as advancing an implied false certification theory, the court does the same. *See* Relator's Opp'n at 6–7.

Two conditions must be present for such a theory to be viable: (1) "the claim does not merely request payment, but also makes specific representations about the goods or services provided"; and (2) "the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Id.* at 2001. Defendant in this case does not make an argument as to the first of these conditions, only the second. It contends that Relator has not plausibly alleged either the materiality or falsity elements of an FCA claim.

The court first addresses the materiality requirement before turning to falsity.[6] In so doing, the court is mindful of the D.C. Circuit's instruction that "courts should continue to police expansive implied certification theories 'through strict enforcement of the [FCA's] materiality and scienter requirements.'" *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1031 (D.C. Cir. 2017) (quoting *Escobar*, 136 S. Ct. at 2002); *see also United States ex rel. PCA Integrity Assocs., LLP v. NCO Fin. Sys., Inc.*, Civil Action No.: 15-750 (RC), 2020 WL 686009, at *13 (D.D.C. Feb. 11, 2020) ("The Supreme Court has . . . underscored the need for courts to be rigorous in their examination of implied certification theories and engage in 'strict enforcement of the Act's materiality requirements.'" (quoting *Escobar*, 136 S. Ct. at 2002)).

1. Materiality

"[A] misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act." *Escobar*, 136 S. Ct. at 2002. Generally, for something to be considered material, it must have "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* (quoting *Neder v. United States*, 527 U.S. 1, 16 (1999)). The Supreme Court has emphasized that, because the FCA is "not 'an all-purpose antifraud statute,' or a vehicle for punishing garden-variety breaches of contract or regulatory violations," the materiality standard is "demanding." *Id.* at 2003 (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)). It is also a standard that is not "too fact intensive" for courts to resolve on a motion to dismiss. *Id.* at 2004 n.6.

[6] The elements for claims brought under subsections 3729(a)(1)(A) and 3729(a)(1)(B) are "practically identical," so the court does not distinguish between the two in its discussion. *See United States ex rel. Scott v. Pac. Architects and Eng'rs (PAE), Inc.*, 270 F. Supp. 3d 146, 154 (D.D.C. 2017).

In *Escobar*, the Supreme Court made clear that not every failure to disclose an act of noncompliance connected to a government payment meets the materiality standard. The Court rejected the government's "expansive" position that "any statutory, regulatory, or contractual violation is material so long as the defendant knows that the Government would be entitled to refuse payment were it aware of the violation." *Id.* at 2004. Instead, the Court held that "materiality cannot rest on 'a single fact or occurrence as always determinative,'" *id.* at 2001 (quoting *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 39 (2011)), and that courts should be mindful of several considerations when "enforc[ing]" the "demanding" materiality standard, *id.* at 2002–03. First, the Court observed, "the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive." *Id.* at 2003; *see also id.* ("A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment."). Second, "proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Id.* Third, and conversely, "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material." *Id.* Fourth, "if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material." *Id.* at 2003–04.

In this case, Relator rests his materiality allegation primarily on the first of these considerations—noncompliance with statutory requirements as a condition of payment.

According to Relator, "Medicare and Medicaid only pay for drugs that are prescribed for their 'medically accepted indications.'" Relator's Opp'n at 8 (quoting *United States ex rel. Brown v. Pfizer, Inc.*, Civil Action No. 05-6795, 2016 WL 807363, at *11 (E.D. Pa. Mar. 1, 2016)). Starting with the Medicare program, Relator points out that a "covered part D drug" is defined, in part, to mean "any use of a covered Part D drug for a medically accepted indication." 42 U.S.C. § 1395w-102(e)(1), (e)(4)(A)(ii)); *see also* 42 C.F.R. § 423.100 (definition of "Part D drug"); Relator's Opp'n at 8–9. As relevant here, "medically accepted indication" means "any use for a covered outpatient drug which is approved under the [FDCA] or the use of which is supported by one or more citations included or approved for inclusion in any" statutorily recognized drug compendium. 42 U.S.C. § 1396r-8(k)(6); *see also* 42 U.S.C. § 1395w-102(e)(4)(A)(ii) (cross-referencing 42 U.S.C. § 1396r-8(k)(6)). Thus, Relator argues, "if a drug is not approved for a particular use by the FDA, and such use is not supported by a citation in one of the listed compendia, then that use is not a 'medically accepted indication' for the drug and any reimbursement for the drug for that use is not legally covered by Medicare." Relator's Opp'n at 8. Relator makes the same argument with respect to Medicaid program, asserting that only "medically accepted indication[s]" for a drug are covered by the program. *See id.* at 9 (citing 42 U.S.C. § 1396r-8(k)(6)). In summary, according to Relator, a prescription for a "medically accepted indication"—i.e., an "on-label" prescription—is "an express condition of payment" under these programs, and "[t]his necessarily renders such regulatory requirements material." *Id.* at 17.

Relator, however, exaggerates the obligatory nature of an "on-label" use as a condition of payment, at least under the Medicaid program. The Medicaid statute provides that a "State *may* exclude or otherwise restrict coverage of a covered outpatient drug if . . . the prescribed use is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B)(i) (emphasis added). As a

result of this permissive language, multiple courts have declared it "up for debate" whether states are permitted to cover off-label uses under the Medicaid program. *See, e.g.*, *United States ex rel. King v. Solvay Pharm., Inc.*, 871 F.3d 318, 328 n.7 (5th Cir. 2017) (noting that if Medicaid programs have discretion to reimburse for off-label prescriptions, then Relators' claims would fail because they had not presented evidence that any states chose to deny reimbursements for off-label prescriptions, but declining to decide the issue); *United States ex rel. Booker v. Pfizer*, 847 F.3d 52, 58 n.7 (1st Cir. 2017) ("[W]hether state Medicaid programs actually have the discretion to reimburse for off-label uses of a drug under the Medicaid statute 'is up for debate.'"); *United States ex rel. Banigan v. Organon USA Inc.*, 883 F. Supp. 2d 277, 294 (D. Mass. 2012) ("The [Medicaid] statute appears to give states the ability to choose whether they will cover off-label, non-compendium prescriptions." (citing 42 U.S.C. § 1396r-8(d)(1)(B)(i))). Indeed, Relator himself concedes that the Medicaid statute gives states discretion whether to pay for off-label uses. He acknowledges that the Medicaid statute "gives states the option to craft their Medicaid plans to allow, or disallow, coverage of pharmaceuticals for certain uses not allowed under Medicare," and "gives states the ability to decide whether or not to reimburse for certain uses prohibited by Medicare." Relator's Opp'n at 20. This discretion to pay for off-label uses weakens the plausibility of Relator's pleading of materiality with respect to off-label uses of Fanapt and Hetlioz under the Medicaid program.

To be sure, courts have not, for the most part, expressed similar doubts about the exclusion of coverage for off-label uses under the *Medicare* program. *See, e.g.*, *Case v. Azar*, No. 1:17CV741, 2019 WL 1261417, at *3 (M.D.N.C. Jan. 3, 2019) (collecting cases holding that "medically accepted indication" is an element of the statutory definition of "covered Part D drug"); *but see Layzer v. Leavitt*, 770 F. Supp. 2d 579, 587 (S.D.N.Y. 2011) ("The statutory language that

Congress used to define what is meant by 'covered part D drug,' along with the canons of statutory interpretation described above, make clear that the Act does not impose a [requirement that the drug be for a medically accepted indication]."). Thus, insofar as Relator's theory of materiality rests on a statutory condition barring payment for off-label uses under the Medicare program, Relator's FCA claim retains a greater degree of plausibility than with respect to the Medicaid program.

But, of course, on-label usage of a drug as a condition of payment under the Medicare program is not "automatically dispositive" on the question of materiality. *See Escobar*, 136 S. Ct. at 2003; *United States ex rel. Folliard v. Comstor Corp.*, 308 F. Supp. 3d 56, 87 (D.D.C. 2018) (holding that, "[w]ithout more than citations to the regulatory framework, the relator has failed to show that any alleged false claim was material to the government's decision to pay"). The court also should inquire whether the relator has provided any factual allegations establishing that the "defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement," *Escobar*, 136 S. Ct. at 2003; whether "the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated," *id.*; and whether "the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated" and "has signaled no change in position," *id.* at 2003–04. Relator's complaint addresses none of these other considerations and thus falls short of pleading of materiality.

To start, Relator points to over two dozen paragraphs in his Amended Complaint, which he says "allege[ ] that claims for the drugs at issue would not have been paid had [government healthcare programs] known that the drugs were prescribed for Unapproved Uses. This is sufficient to plead materiality," he says. Relator's Opp'n at 18 (citing FAC ¶¶ 247–50, 262, 283,

293, 303, 313, 323, 333, 343, 366, 376, 386, 396, 405, 415, 425, 435, 445, 460, 469, 479, 489, 498, 508, 518, 529, 539, 549, 558, 568). Not so. This string of citations supplies no well-pleaded *factual* support for the assertion that government payors would not have covered the prescriptions had they know about the off-label uses. Rather, these paragraphs contain mere conclusory assertions, which the court is not required to accept as true or give any weight. *See Iqbal*, 556 U.S. at 678.[7] These conclusory allegations are even weaker in the context of off-label prescribing where, for decades, it has been widely recognized that "the prescription of drugs for unapproved uses is commonplace in modern medical practice and ubiquitous in certain specialties." *Henney*, 202 F.3d at 333. The bald assertion that government payors would not have paid for the off-label use of Fanapt and Hetlioz, had they known, clashes with that reality.

Next, Relator cites to a host of actual factual allegations in the Amended Complaint that he asserts demonstrate materiality. *See* Relator's Opp'n at 20–21. Grouped together, these allegations purportedly support following fact propositions: (1) the drug uses Defendant promoted were not medically accepted, *id.* at 20 (citing FAC ¶¶ 4, 9–13, 50, 62, 66, 68, 69, 141, 148, 158, 198, 247–50); (2) Fanapt lacked medical indications of competitor drugs, *id.* (citing FAC ¶¶ 64, 93–101, 198); (3) Defendant created misleading sales pitches to convince prescribers that the drugs were effective for unapproved uses, *id.* (citing FAC ¶¶ 66-92, 136–160, 176–68 [*sic*], 187–218); (4) Defendant deceived providers about the drugs' safety profiles and dangers, *id.* (citing FAC ¶¶ 136–160); (5) sales staff received a book to use in misleading sales pitches, *id.* (citing FAC ¶¶ 67–69); (6) the company's director of marketing resigned over the misleading sales messaging,

[7] *See, e.g.*, FAC ¶ 262 ("Had the State of California known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.")

id. (citing FAC ¶ 91); (7) Defendant used non-FDA approved studies to convince prescribers that Fanapt was effective for treating bipolar disorder, *id.* (citing FAC ¶¶ 67–69, 72–74, 85, 176–78); (8) prescribers had difficulty getting the drugs approved by private insurers for the approved uses, *id.* at 21 (citing FAC ¶¶ 97, 220–224, 246); (9) Defendant created a fake target list of physicians treating schizophrenia "in case they were alleged to have engaged in off-label marketing," *id.* (citing FAC ¶ 110); (10) a prescriber told a sales person that he (the prescriber) had to be careful about prescribing Fanapt because the government monitors such prescriptions to children, *id.* (citing FAC ¶¶ 134–35); (11) Defendant trained its sales staff to advise prescribers that Fanapt would be approved as a first-line drug if approved today, *id.* (citing FAC ¶¶ 137, 156–58); and (12) the company trained its sales force to promote Hetlioz for conditions other than Non-24, *id.* (citing FAC ¶¶ 193–218). As is evident from the descriptions, these contentions largely concern the means employed by Defendant in furtherance of its alleged scheme to promote off-label uses. They do not speak to whether government payors "consistently refuse[ ] to pay claims in the mine run of cases based on" off-label use of prescription drugs, or alternatively, whether government payors were knowingly or unknowingly paying claims based on off-label uses of Fanapt or Hetlioz. *Escobar*, 136 S. Ct. at 2003. The inclusion of *some* allegations addressing these considerations is critical to plausibly pleading materiality, but the Amended Complaint is silent as to them.

In fairness, some of the allegations do suggest efforts to conceal by Defendant, such as the creation of fake target lists "for show" in the event the company "was ever questioned about off-label promotion." FAC ¶ 110. Others suggest awareness by Defendant of government scrutiny of off-label prescribing, such as the allegation that one doctor told a salesperson that "the government monitors more closely prescriptions to children and the elderly." FAC ¶ 134. And yet others suggest some consciousness of guilt by Defendant, such as the allegation that its marketing director

and two other high-level employees resigned over misleading sales messaging. *See id.* ¶ 91. But well-pleaded factual allegations must be enough to raise a right to relief above the speculative level, *see Twombly*, 550 U.S. at 555, and these isolated allegations are insufficient, on their own or in combination with other allegations, to raise Relator's pleading of materiality above the threshold of plausibility, *see id.*

Relator points to two other allegations that, he asserts, supports materiality. Recall, the Supreme Court in *Escobar* observed that, "if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material." 136 S. Ct. at 2003–04. In this case, Relator alleges that two states—Indiana and Texas—took steps to prevent continued Medicaid payments of claims for off-label uses of Fanapt. With respect to Indiana, Relator writes that, "*in response to* off-label claims for pediatric patients that were submitted to Indiana Medicaid, that agency immediately took steps to prevent reimbursing such claims in the future." Relator Opp'n at 21 (citing FAC ¶ 119) (emphasis added). Relator continues, "[s]o, too, did Texas Medicaid when it established a prior authorization system three years after Vanda started promoting Fanapt." *Id.* (citing FAC ¶ 239). But these arguments embellish the causal allegations Relator actually makes about Indiana and Texas. As to Indiana, Relator asserts that in early 2016 the Indiana Medicaid program "changed its coverage policy and it was no longer reimbursing for off-label atypical antipsychotics." FAC ¶ 119. Nowhere does he allege, however, that Indiana changed its policy "in response to off-label claims for pediatric patients," as he argues in his opposition. Similarly, Relator alleges that in early 2018, Texas Medicaid "added a prior authorization requirement to claims for Fanapt." FAC ¶ 239. Nowhere, however, does Relator allege that this change came about to prevent payment of off-label claims for Fanapt, as he now

contends. Relator's allegations thus do not establish that either Indiana or Texas "signaled [a] change in position" specifically to prevent continued payment for prescribed off-label uses of Fanapt. *See Escobar*, 136 S. Ct. at 2004.

In conclusion, Relator's allegations, even when viewed in the light most favorable to him, do not give rise to a plausible inference that the off-label prescription of Fanapt and Hetlioz was material to government payment decisions under either the Medicare or Medicaid programs.

2. Falsity

The court could conclude its analysis here, since Relator has failed to sufficiently plead materiality with respect to his off-label claims. However, because the court will allow Relator to re-plead, the court's views with respect to Defendant's other arguments may prove useful.

Defendant's argument that Relator fails to plead the element of falsity rests on the purported use of prior authorization systems for both Fanapt and Hetlioz by government payors. Def.'s Mot. 13–15. Under such systems, when "a physician chooses to prescribe a drug for an off-label use, that use will be disclosed on any prior authorization document[,] [a]nd based on that information, the payor chooses whether or not it will reimburse for the pharmaceutical in those circumstances." *Id.* at 13. Because of this pre-approval process, says Defendant, "there is no plausible claim that a government payor was defrauded; rather, it was *informed* as to the relevant facts." *Id.; see also id.* at 11 ("Prior authorization thus ensures that the government payor will be fully informed about the indication for which the requested drug will be used, *before* any claim for payment is submitted."). For his part, Relator disputes that a broad prior authorization scheme was in place during the relevant time period, and further argues that Defendant advances arguments that are improper at the motion-to-dismiss stage. *See* Relator's Opp'n at 22–26.

Courts have held that "if a state Medicaid program chooses to reimburse a claim for a drug prescribed for off-label use, then that claim is not 'false or fraudulent,' and liability cannot therefore attach for reimbursement." *Banigan*, 883 F. Supp. 2d at 294; *see also United States ex rel. Durcholz v. FKW Inc.*, 189 F.3d 542, 545 (7th Cir. 1999) ("If the government knows and approves of the particulars of a claim for payment before that claim is presented, the presenter cannot be said to have knowingly presented a fraudulent or false claim . . . . [T]he government's knowledge effectively negates the fraud or falsity required by the FCA."); *United States ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11, 16 (D. Mass. 2008) ("[I]f a state knowingly chose to reimburse for a drug, even for an off-label use, after a prior authorization review, [FCA] liability would not attach because extensive government knowledge would 'negate the intent requirement under the FCA as a matter of law.'") (citation omitted); *cf. United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 490 (3d Cir. 2017) ("Simply put, a misrepresentation is not 'material to the *Government's payment decision*,' when the relator concedes that the Government would have paid the claims with full knowledge of the alleged noncompliance." (citing *Escobar*, 136 S. Ct. at 1996)). Although they frame the issue differently, courts agree: If a government payor knows that it is reimbursing for an off-label use, then an FCA claim cannot lie.

With respect to Hetlioz, the court agrees with Defendant that Relator has not made out a plausible case of falsity due to pervasive pre-authorization requirements for the drug. The annual cost of Hetlioz is staggering. According to an online report cited by Relator in his complaint, since its commercial launch in 2014, the annual cost of Hetlioz increased from $84,000 to $188,000 by 2019. *See* Aurelius Report; FAC ¶ 12 ("In 2019, a year supply of Hetlioz costs approximately $188,000."). Given its breathtaking cost, it should come as no surprise that government payors would insist on prior authorization before agreeing to cover the medication. As Defendant has

shown through judicially noticeable documents,[8] at least a dozen states—including multiple states whose laws Relator alleges Defendant violated—require pre-authorization for Hetlioz prescriptions under their Medicaid programs. *See* Def.'s Mot. at 12 n.6.[9] Medicare payors almost certainly also put in place the same cost controls. *See id.* at 11 (citing Aurelius Report). Notably, the complaint itself confirms the common use of pre-approval systems for Hetlioz. It alleges that Defendant "decided to create an internal reimbursement hub to assist doctors in getting their Hetlioz prescriptions filled. The hub would assist with reimbursement of Hetlioz and Fanapt, performing tasks such as prior authorization and insurance denial appeals." FAC ¶ 221. The widespread use of pre-approval systems significantly diminishes the plausibility that government payors were duped into paying for off-label uses of Hetlioz. *See Banigan*, 883 F. Supp. 2d at 294; *see also Durcholz*, 189 F.3d at 545. Relator does not claim, for instance, that Defendant induced doctors to falsely represent a patient's diagnosis on pre-authorization forms to secure pre-approval. Relator's pleading of falsity with respect to off-label claims for Hetlioz thus falls short.

[8] The court may take judicial notice of documents provided on official government websites. *See, e.g.*, *Democracy Forward Found. v. White House Office of Am. Innovation*, 356 F. Supp. 3d 61, 62 n.2 (D.D.C. 2019) ("[J]udicial notice may be taken of government documents available from reliable sources."); *Kelleher v. Dream Catcher, L.L.C.*, 221 F. Supp. 3d 157, 160 n.2 (D.D.C. 2016) ("Courts in this jurisdiction have frequently taken judicial notice of information posted on official public websites of government agencies." (quoting *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 33 (D.D.C. 2014))).

[9] Def.'s Mot., Ex. D, Alabama Medicaid Agency PDL Reference Tool, at 9 (July 1, 2019), https://perma.cc/S6SC-QGY6; *id.*, Ex. E, Colorado Medical Assistance Program, Prior Authorization Procedures and Criteria and Quantity Limits, at A-17 (July 1, 2017), https://perma.cc/VWL7- FCFR; *id.*, Ex. F, Georgia Medicaid/PeachCare Preferred Drug List, at 21 (Aug. 1, 2019), https://perma.cc/TT7D-7UWM; *id.*, Ex. G, Idaho Medicaid Preferred Drug List, at 52 (July 1, 2019), https://perma.cc/Q9CJ-7BM2; *id.*, Ex. H, Kan. Dep't of Health & Environ., KanCare Preferred Drug List, at 23 (Aug. 1, 2019), https://perma.cc/C8JE-9UM2; *id.*, Ex. I, Louisiana Medicaid Preferred Drug List (PDL)/Non-Preferred Drug List (NPDL), at 48 (July 15, 2019), https://perma.cc/W9JGRSE7; *id.*, Ex. J, Md. Dep't of Health Medicaid Pharmacy Program, Preferred Drug List, at 14 (July 1, 2019), https://perma.cc/P26B-CJMT; *id.*, Ex. K, Mass. Executive Office of Health & Human Servs., Table 72: Agents Not Otherwise Classified (June 2018), https://perma.cc/ZB7H-E2TZ; *id.*, Ex. L, Miss. Division of Medicaid, Universal Preferred Drug List, at 77-78 (July 1, 2019), https://perma.cc/M7HF-A9WC; *id.*, Ex. M, Dep't of Vt. Health Access, Vermont Preferred Drug List and Drugs Requiring Prior Authorization, at 92 (July 12, 2019), https://perma.cc/PQX8- ZYX8; *id.*, Ex. N, Apple Health (Medicaid) Preferred Drug List, at 113 (July 1, 2019) (Ex. N), https://perma.cc/6TEJ-KMW9; *id.*, Ex. O, W. Va. Dep't of Health & Human Res., Office of Pharmacy Serv., Prior Authorization Criteria – Hetlioz (Apr. 1, 2017), https://perma.cc/AL9W-28PW.

The court reaches a different conclusion as to Fanapt. While it is true that the Amended Complaint identifies a pre-approval requirement in two states, Indiana and Texas, FAC ¶¶ 119, 239, and asserts that an internal reimbursement hub was in place for Fanapt prescriptions as well, the factors that caused the court to doubt the plausibility of falsity for Hetlioz are absent for Fanapt. There is no allegation, for example, regarding the high cost of Fanapt. Similarly, Defendant offers no judicially noticeable facts establishing that government payors broadly adopted pre-approval requirements for Fanapt. Defendant wants Relator to bear the burden at the pleading stage to allege that there was *not* a prior authorization requirement, but it cites no case that imposes such a burden. Def.'s Mot. at 15. Presumably, if Defendant could have shown through publicly noticeable documents the widespread use of preapproval systems for Fanapt, it would have done so. But it points to only two of 50 states with a pre-approval requirement for Fanapt, and no federal Medicare payor. As Defendant makes no other argument with respect to the falsity of Fanapt claims, the court finds that element satisfied at the pleading stage.[10]

3. Falsity – Off-Label Promotion of Hetlioz

Defendant makes another argument with respect to the element of falsity. It maintains that, with respect to Hetlioz, Relator's claims fail because he nowhere alleges that Defendant promoted the drug for an actual off-label use. *See* Def.'s Mot. at 26–27. Defendant points out that Hetlioz

[10] Defendant also argues that the mere availability of pre-approval systems negates materiality, whether a payor employed such system or not. Defendant's logic works as follows. If a payor required pre-approval yet approved off-label claims, the purported off-label violation cannot be material. *See* Def.'s Mot. at 17–18. On the other hand, if a payor elects not to implement a pre-approval system, that decision itself negates materiality, because the payor could have, but chose not to, demand treatment information before paying a claim. *See id.* (citing *United States ex rel. King v. Solvay Pharm., Inc.*, 871 F.3d 318, 329 n.9 (5th Cir. 2017) (observing in dicta that if "Medicaid pays for claims without asking whether the drugs were prescribed for off-label uses or asking for what purpose the drugs were prescribed . . . , given that it is not uncommon for physicians to make off-label prescriptions, we think it unlikely that prescribing off-label is material to Medicaid's payment decisions under the FCA")). The court is not prepared to accept Defendant's Catch-22-like logic at the motion-to-dismiss stage. As Relator points out, there are reasons why a payor may not install a pre-approval system, such as cost, that do not necessarily imply that the payor deems off-label uses to be immaterial. *See* Relator's Opp'n at 27–28. Whether payors' non-use of a pre-approval system for Fanapt, for example, demonstrates the off-label use of Fanapt is not material will have to be resolved, if at all, on summary judgment.

is approved for Non-24 in both blind *and* sighted patients, and "[t]hus, in asserting that [Defendant] promoted Hetlioz for sighted patients, Relator's allegations describe *on*-label promotion," which cannot constitute a false claim. *Id.* at 26. As evidence, Defendant points to two approval letters from the FDA. The first approves Hetlioz for "Non-24 hour sleep-wake disorder in blind patients without light perception." *Id.*, Ex. P, ECF No. 40-17.[11] The second provides a correction, stating that Hetlioz is approved for "Non-24 hour sleep-wake disorder." *Id.*, Ex. Q, ECF No. 40-18.[12] The second letter explicitly eliminates the restriction on use in only blind patients, seemingly opening the door to prescriptions for sighted individuals. *Id.* As the court may take judicial notice of the letters, *see, e.g.*, *Democracy Forward Found. v. White House Office of Am. Innovation*, 356 F. Supp. 3d 61, 62 n.2 (D.D.C. 2019) ("[J]udicial notice may be taken of government documents available from reliable sources."), it concludes that Relator has not plausibly pleaded *off*-label prescribing with respect to Hetlioz, at least with respect to the allegations related to sighted Non-24 patients. *See In re Plavix Mktg., Sales Practices & Prods. Liab. Litig.*, 123 F. Supp. 3d 584, 605–06 (D.N.J. 2015) (stating that "a[n] FDA approved drug that has been prescribed for its on-label use is necessarily covered under Medicare Part D" and "[c]onsequently, Plaintiff cannot [ ] state a claim under the FCA in this context"); *United States ex rel. Gohil v. Sanofi-Aventis U.S. Inc.*, 96 F. Supp. 3d 504, 521 (E.D. Pa. 2015) ("By pleading a 'scheme' to promote [the drug] for medically accepted indications," the related counts appear "baseless."); *United States ex rel. Polansky v. Pfizer, Inc.*, 914 F. Supp. 2d 259, 266 (E.D.N.Y. 2012) (finding that the "defendant has not engaged in off-label marketing, and has therefore not violated the FCA").

Relator counters that his pleading "explicitly and sufficiently alleges [Defendant] improperly promoted Hetlioz for all [circadian rhythm sleep disorder] conditions, or any sleep

[11] Available at: https://www.accessdata fda.gov/drugsatfda_docs/nda/2014/205677Orig1s000Approv.pdf.
[12] Available at: https://www.accessdata fda.gov/drugsatfda_docs/appletter/2014/205677Orig1s000ltr.pdf.

disorder." Relator's Opp'n at 29. In other words, Relator argues that, while prescribing Hetlioz to sighted patients suffering from Non-24 may be an on-label use, prescribing it for circadian rhythm sleep disorder conditions more broadly is not. Relator points to alleged directions given to Regional Business Leaders to suggest to prescribers that Hetlioz is effective in treating circadian rhythm sleep disorder more broadly. FAC ¶¶ 193–98, 207. Relator also alleges that Defendant wanted its sales force to promote Hetlioz with psychiatrists, a group that Relator claims does not treat Non-24 patients. *Id.* ¶ 201. He also cites to a former sales representative who "convinced several doctors to prescribe Hetlioz" to sighted patients, though the allegation does not specify whether those patients suffered from a disease other than Non-24. *Id.* ¶¶ 200–02. Relator further details a 2017 initiative in which Fanapt sales representatives "would call on psychiatrists to promote Hetlioz." *Id.* ¶¶ 204–07. The complaint, in short, identifies some attempts on the part of Defendant to promote Hetlioz to treat more than just Non-24. *See id.* ¶¶ 196, 198, 207–10, 217–18. Thus, a theory of falsity premised on off-label use of Hetlioz for illnesses other Non-24 might be plausible, but the court need not reach a firm conclusion at this juncture.

D. Submission of Fraudulent Claims

Next, Defendant argues that Relator has not met the Rule 9(b) pleading standard because he has failed to "offer a non-speculative basis to connect his theory to claims that were actually presented to a government payor." Def.'s Mot. at 19; *see also id.* at 22–23 (asserting that "Relator has failed to plead the requisite 'reliable indicia' of submission of false claims" (citing *United States ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, 707 F.3d 451, 460 (4th Cir. 2013))). Put differently, Defendant asserts that Relator has not pleaded with particularity "the 'presentment' of a false or fraudulent claim to the government for payment or approval." *See Nathan,* 707 F.3d at 455; Def.'s Mot at 19–20.

Rule 9(b) requires a plaintiff to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Such circumstances include the "time, place, and manner" of the fraudulent scheme, or put differently, the "who," "what," "where," and "when" of the alleged scheme. *Heath*, 791 F.3d at 123–124. "[T]he point of Rule 9(b) is to ensure that there is sufficient substance to the allegations to both afford the defendant the opportunity to prepare a response and to warrant further judicial process." *Id.* at 125.

Defendant's argument fails because it demands a more stringent Rule 9(b) pleading than what controlling precedent requires. In *Heath*, the D.C. Circuit held that "the precise details of individual claims are not, as a categorical rule, an indispensable requirement of a viable False Claims Act complaint, especially not when the realtor alleges that the defendant knowingly caused a third party to submit a false claim as part of a federal regulatory program." 791 F.3d at 126 (collecting cases). In such cases, the "central question . . . is whether the complaint alleges 'particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.'" *Id.* (quoting *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)); *see also Lawton ex rel. United States v. Takeda Pharm. Co.*, 842 F.3d 125, 130–31 (1st Cir. 2016) (recognizing a difference "between qui tam actions alleging that the defendant made false claims [directly] to the government and those alleging that the defendant induced third-parties to file false claims with the government," and holding that when a case falls into the latter category, a "more flexible" standard is appropriate, "such that a relator can satisfy Rule 9(b) by providing factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details as to each submitted false claim") (cleaned up).

Relator's Amended Complaint satisfactorily answers this "central question." Relator "provides factual specificity concerning the type of fraud, how it was implemented, and the [ ] materials used" to carry out the alleged fraud scheme. *Heath*, 791 F.3d at 126. He also alleges the number of prescriptions and the dollar amount paid for those prescriptions by the Medicare and Medicaid programs, separately, for each year from 2015 to 2017. FAC ¶¶ 226–237. Further, as to Fanapt, Relator identifies three physicians "who received the off-label Fanapt pitch, and prescribed Fanapt to patients that was reimbursed by Medicare." *Id.* ¶ 238. These allegations, taken together, lead to a "strong inference that claims were actually submitted." *Heath*, 791 F.3d at 126.

Defendant attempts to distinguish *Heath* on the ground that, unlike *Heath*, "[t]he circumstances here . . . rely on several intermediary steps between the alleged conduct of [Defendant] and the submission of any claim." Def.'s Mot. at 22. With respect to Hetlioz, Defendant contends that "Relator pleads *nothing at all* relevant to the actual presentment of false or fraudulent claims," rather "[h]e simply identifies that government payors have reimbursed for some Hetlioz prescriptions." *Id.* at 19–20. As for Fanapt, Defendant insists that Relator's identification of three doctors who prescribed off-label Fanapt "does nothing to cure the deficiencies in the Complaint," because "Relator fails to identify with the requisite particularity the submission of *false* claims to a government payor that, if it knew the truth, would not have paid the claim." *Id.* at 24. These efforts to distinguish *Heath* are unpersuasive. With respect to Hetlioz, Relator does more than allege gross reimbursement numbers. He also alleges that Defendant set up an "internal reimbursement hub to assist doctors in getting their Hetlioz prescriptions filled," including to aid with completing prior authorization requests. FAC ¶ 221. In light of the reimbursement numbers showing government reimbursement for over 1,000 prescriptions in 2015

and over 2,000 prescriptions in 2016 and 2017, *see id.* ¶¶ 226–31, and the allegation that Defendant aided doctors in gaining pre-approvals, *see id.* ¶ 221, Relator has established a plausible inference that off-label claims were actually submitted as to Hetlioz. The same is true for Fanapt. Again, Relator alleges that the internal reimbursement hub assisted doctors in gaining approvals for Fanapt (although, as discussed above, the extent of pre-approvals for Fanapt is unclear). *Id.* ¶ 221. Additionally, Relator points to another sales manager who identified three doctors and a nurse practitioner who "prescribed Fanapt to patients that was reimbursed by Medicare" and the number of prescriptions written for Fanapt by those providers during certain years. *Id.* ¶ 238. To be sure, as Defendant argues, there are some details missing from the complaint, *see* Def.'s Mot. at 23–24, but such specificity is not required to satisfy Rule 9(b) with respect to the submission of claims.

Defendant cites to a host of out-of-Circuit cases to bolster his argument, but none compel a different result. *See id.* at 20–21 (citing *Booker*, 847 F.3d 52; *Nathan*, 707 F.3d 451; *Rost*, 507 F.3d 720; *Lawton*, 842 F.3d 125; *United States ex rel. Ge v. Takeda Pharm. Co.*, 737 F.3d 116 (1st Cir. 2013); *United States ex rel. Kelly v. Novartis Pharms. Corp.*, 827 F.3d 5 (1st Cir. 2016); *King*, 871 F.3d 318). This court's analysis is controlled by *Heath*, which held that "some functional flexibility in reviewing a complaint's allegations" is appropriate where, as here, the relator alleges that the defendant knowingly caused a third party to submit false claims. 791 F.3d at 126. For the reasons discussed, the Amended Complaint satisfies that standard.

E. Additional Theories of Liability

In addition to its primary theory of off-label prescribing, Relator offers a host of other theories about Vanda's improper marketing and promotion of Fanapt. None, however, satisfies Rule 9(b)'s rigorous pleading standard. Specifically, Relator has not pleaded that that there is a plausible connection between the conduct in question and the submission of claims. *See, e.g.*,

Williams, 389 F.3d at 1256; *Totten*, 286 F.3d at 552; *Stevens*, 662 F. Supp. 2d at 114. In this case, that means that Relator must plausibly allege that Vanda's misconduct actually caused a doctor to write a prescription that was then submitted to a government payor, or "reliable indicia" that such a causal chain occurred. Relator has not done so.

For example, Relator alleges that Vanda improperly promoted Fanapt as a "first line treatment" when the FDA had only approved the drug as a second line treatment. *See* FAC ¶¶ 136–40. Relator details the training provided to Vanda's sales force, but fails to allege any facts to suggest that any claims were submitted to Medicare or Medicaid as a result of Vanda's first-line drug promotion. *See id.* Likewise, Relator claims that Vanda provided false messaging about dosing amounts, *id.* ¶¶ 141–47, and improperly gave providers multiple rubber-banded titration packs, *id.* ¶¶ 161–75, but does not allege any facts to support that either scheme led to actual false claims being submitted to government payors. *Cf. Nathan*, 707 F.3d at 460 (holding that a claim was properly dismissed where physicians prescribed a particular dose of a drug based on misleading "sampling practices," but the relator did "not include any details the[ ] physicians wrote for Medicare patients, such as approximate dates or patient information," and did not "contain allegations that the Medicare patients ever 'filled' the[ ] prescriptions or that corresponding claims for reimbursement were ever submitted to the government"). Relator's allegations regarding Defendant's improper downplaying of Fanapt's safety profile, *id.* ¶¶ 148–60, and misleading drug comparisons, *id.* ¶¶ 176–78, similarly fail.

Although a closer call, the court reaches the same conclusion as to Relator's theory concerning Fanapt copay cards. Relator pleads that there was an increase in Fanapt prescriptions written by physicians in the Detroit area in the fall of 2015, as a result of a fraudulent scheme in which doctors and local pharmacists "submit[ted] hundreds of Fanapt copay cards and

prescriptions, receive[d] reimbursement from the insurance provider, and then pocket[ed] the money because the prescriptions were never dispensed." FAC ¶¶ 179–83. Although Relator details aspects of the alleged scheme, he falls short of alleging that increased prescriptions were submitted to a federal or state payor. He contends: "[A]s Fanapt's copay cards *can be used* by Medicare and Medicaid, which itself is a violation, the payments for these fake prescriptions were incurred by the Government." *Id.* ¶ 182. The allegation that the copay cards "can be used" in connection with federal reimbursement is, at best, equivocal. It not only fails to identify any actually submitted claims based on the alleged fake prescriptions, but it also fails to supply the "reliable indicia" that, under *Heath*, would lead to a strong inference that claims were actually submitted. *Heath*, 791 F.3d at 126. Accordingly, any claims as to copay cards likewise fall short.

Lastly, with respect to Hetlioz, Relator contends that Defendant violated the Anti-Kickback Statute by donating money to patient assistance programs ("PAPs") through patient assistance foundations that help pay patient copayment amounts. FAC ¶ 224. This allegation suffers from similar pleading inadequacies. Relator details that, according to Bourgeois, "Vanda executive management would regularly say that [Defendant] has patient assistance programs through foundations that help pay patient copayment amounts," and that he first heard of one such foundation being used for Hetlioz prescriptions in 2017 when the price of Hetlioz was rising. *Id.* According to Relator, "[u]pon information and belief," Defendant donated money to the foundations "to ensure that patients['] copayments for Hetlioz would be covered, in violation of the Anti-Kickback Statute," 42 U.S.C. 1320a-7b. FAC ¶ 224.

In his briefing, Relator cites to an administrative notice, which states that "[i]f a donation is made to a PAP to induce the PAP to recommend or arrange for the purchase of the donor's federally reimbursable items, the [Anti-Kickback] statue could be violated," and further that a

"PAP must not function as a conduit for payments or other benefits from the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries' drug choices." *Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs*, 79 Fed. Reg. 31,120, 31,121 (May 30, 2014).

Relator's barebones allegations, however, do not allow the court to conclude that the PAP was serving as a "conduit for payments" or that the payments to the foundation were for the purpose of "inducing" or "influencing" beneficiaries' decisions to prescribe Hetlioz. All that Relator has pleaded is that Defendant donated to a foundation around the time that "the price of Hetlioz was rising," *see* FAC ¶ 224, along with the conclusory allegation that Defendant donated the money so Hetlioz would be covered. Relator argues that "Vanda must have known that its donations . . . would only be used for copayment assistance for Hetlioz" because Hetlioz is the only drug indicated for the treatment of Non-24, and further, that "Vanda intended to use the [donation] to influence beneficiaries' drug choice, as it ensured that patients could afford the drug." Relator's Opp'n at 39. There is nothing on the face of the complaint, however, that would allow the court to draw such conclusions, aside from entirely conclusory statements regarding Defendant's intent. Furthermore, Relator's allegations again fall short in that they fail to establish that any *actual claims* for Hetlioz were submitted to government payors as a result of Defendant's alleged making of donations to patient assistance foundations. *See* FAC ¶ 224. Relator says that Defendant donated money to "ensure that . . . copayments for Hetlioz would be covered," but fails to allege that any corresponding reimbursement claims were ever actually submitted or covered. Nor do Relator's allegations supply "reliable indicia" that would strongly support an inference that such claims were ever submitted. *See Heath*, 791 F.3d at 126. Accordingly, this allegation too falls short.

V. CONCLUSION AND ORDER

For the foregoing reasons, the court grants Defendant's Motion to Dismiss, ECF No. 40. The court will, however, give Relator the requested opportunity to amend his pleading. *See* Relator's Opp'n at 45 n.22. Relator shall file his Second Amended Complaint on or before June 9, 2020.

Dated: May 19, 2020

Amit P. Mehta
United States District Court Judge