UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA ex rel. JOHN A. WOOD, et al.,	10-CV-5645 (JMF)
Plaintiffs,	OPINION AND ORDER
-v-	
ALLERGAN, INC. and ALLERGAN plc,	
Defendants.	

JESSE M. FURMAN, United States District Judge:

TABLE OF CONTENTS

INTRODUCTION 3
BACKGROUND 4
A. Relevant Statutes 4
B. The Alleged Scheme 7
C. Other Cases and Procedural History 9
LEGAL STANDARDS 11
DISCUSSION 13
A. The Public Disclosure Bar 14
B. The First-to-File Bar 16
1. Related Actions 17
2. Whether the First-to-File Bar Requires Dismissal 20
C. Statute of Limitations 32
D. The Anti-Kickback Statute 41
1. Drug Samples and Patient Care Kits 43
2. Patient Instruction Sheets and Prescription Pads 46
E. The False Claims Act 47
1 The PPACA 52
2. Express Certification 53

3. Implied Certification 58
4. Third-Party Claim Submissions 62
F. Rule 9(b) 64
1. FERA 65
2. Counts I and II: Subsections (a)(1)(A) and (a)(1)(B) 66
3. Count III: Subsection (a)(1)(C) 74
4. Count IV: Subsection (a)(1)(G) 75
5. The Scope of the Scheme and Scienter 76
G. The Retaliation Claim 81
H. State Law Claims 84
1. Wisconsin 84
2. Delaware, New Mexico, and Texas 85
3. Retroactivity and Timeliness 86
CONCLUSION 88

INTRODUCTION

In this *qui tam* proceeding, Plaintiff-Relator John A. Wood brings claims under the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, and state analogues against Defendant Allergan, Inc. ("Allergan"), a pharmaceutical company that develops and manufactures eye care prescription drugs.[1] Wood alleges, among other things, that Allergan violated the FCA and the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), by providing substantial quantities of free drugs and other goods to physicians in exchange for their prescribing to beneficiaries of Medicare, Medicaid, and other government programs the company's brand name drugs. (Docket No. 38 ("Third Am. Compl.") ¶¶ 1-12). Wood also brings parallel claims under state law on behalf of twenty-five states (*id.* ¶¶ 291-473), and alleges that he was unlawfully terminated in retaliation for his whistleblowing actions. (*Id.* ¶¶ 258-274; 288-290). Now pending is Allergan's motion, pursuant to Rules 9(b) and 12(b) of the Federal Rules of Civil Procedure, to dismiss the Third Amended Complaint.

Allergan's motion confirms that, when the Supreme Court observed last year that the FCA's "*qui tam* provisions present many interpretive challenges," it was, if anything, engaging in rhetorical understatement. *Kellogg Brown & Root Servs., Inc. v. ex rel. Carter*, 135 S. Ct. 1970, 1979 (2015). The motion presents several issues that neither the Supreme Court nor the Second Circuit has addressed and upon which other federal courts have divided, including whether the FCA's bar on actions brought while a related action is pending (the so-called "first-to-file" rule) is a jurisdictional or non-jurisdictional rule and, relatedly, whether a violation of the rule compels dismissal or can be cured through the filing of a new pleading; and whether a

[1] Allergan plc, an Irish holding company formed in 2013, was also named as a Defendant in the Third Amended Complaint (*see, e.g.*, Docket No. 38 ("Third Am. Compl.") ¶¶ 24-29), but all claims against the company were dismissed by agreement among the parties on March 17, 2017. (Docket No. 111). Accordingly, the Court need not address any arguments specific to Allergan plc.

relator can rely on a subsection of the statute that permits claims to be brought up to ten years after they accrued where the relevant facts are not known to "the official of the United States charged with responsibility to act." It also calls upon the Court to interpret and apply the Supreme Court's recent decision in *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), which partially altered the FCA landscape.

The issues are too complicated and the Court's holdings are too numerous to usefully summarize here. For now, it suffices to say that, for the lengthy reasons discussed below, Allergan's motion to dismiss is largely denied.

BACKGROUND

Generally, in considering a motion to dismiss, a court is limited to the facts alleged in the complaint and is required to accept those facts as true. *See, e.g.*, *LaFaro v. N.Y. Cardiothoracic Grp., PLLC*, 570 F.3d 471, 475 (2d Cir. 2009). A court, however, may also consider documents attached to the complaint; statements or documents incorporated into the complaint by reference; and, more relevant here, matters of which judicial notice may be taken, such as public records. *See, e.g.*, *McBeth v. Porges*, 171 F. Supp. 3d 216, 221 (S.D.N.Y. 2016). Accordingly, the following facts are taken from the Third Amended Complaint, materials incorporated by reference therein, and documents of which the Court may take judicial notice.[2]

A. Relevant Statutes

The statutes at the heart of this case are discussed in more detail below, but a brief introduction to them is warranted at the outset. As noted, Wood brings claims under the FCA. To the extent relevant here, the FCA imposes significant penalties on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or

[2] In conjunction with its motion to dismiss, Allergan filed a motion asking the Court to take judicial notice of certain documents from two other federal cases relevant to the discussion below. (Docket No. 67). By Order dated March 15, 2017, the Court granted the motion as unopposed. (Docket No. 106).

approval" or any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)-(B); *see also Escobar*, 136 S. Ct. 1989. Under Second Circuit law, a claim can be "factually" false or "legally" false. *See Mikes v. Straus*, 274 F.3d 687, 696 (2d Cir. 2001), *abrogated in part by Escobar*, 136 S. Ct. at 2001. Factually false claims involve "an incorrect description of goods or services provided or a requirement for goods or services never provided," *Mikes*, 274 F.3d at 697, whereas legally false claims are "predicated upon a false representation of compliance with a federal statute or regulation or a prescribed contractual term," *id.* at 696. An "expressly" false claim is one that "certifies compliance with a particular statute, regulation, or contractual term, where compliance is a prerequisite to payment." *Id.* at 698. By contrast, "implied" false claims occur where a defendant makes or causes to be made "representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements," so long as those omissions "render the defendant's representations misleading with respect to the goods or services provided." *Escobar*, 136 S. Ct. at 1999.

As a *qui tam* statute, the FCA permits private persons, known as "relators," to bring actions to recover damages on behalf of the United States. 31 U.S.C. § 3730(b). The statute includes other procedural quirks as well, several of which loom large in this case. First, the statute provides that a relator must file his or her complaint under seal so as to permit the government to decide whether it wants to intervene. *See id.* § 3730(b)(2). At the Government's request, the seal can remain in effect indefinitely; moreover, even if the Government declines to intervene at the outset, it may do so at any point later in the litigation upon a showing of good cause. *See id.* § 3730(b)(3). Second, certain provisions of the statute provide incentives for relators to file quickly, while balancing the Government's interest in notice with concerns about parasitic or opportunistic law suits. The "first-to-file" bar, for instance, states that once an action has been brought, "no person other than the Government may intervene or bring a related action

based on the facts underlying the pending action." *Id.* § 3730(b)(5). Relatedly, the "public disclosure" bar generally requires courts to "dismiss an action" if "substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed" at an earlier date. *Id.* § 3730(e)(4)(A). In isolation, each of these requirements presents interpretive challenges; taken together, they create a veritable thicket of complexity.

The gravamen of Wood's FCA claims, as discussed below, is that Allergan induced physicians to prescribe its drugs to recipients of federal benefits (such as Medicare and Medicaid) by providing unlawful remuneration — including free drug samples — in violation of the AKS, 42 U.S.C. § 1320a-7b(b). To the extent relevant here, the AKS imposes criminal liability on any person who "knowingly and willfully offers or pays any remuneration . . . to induce [any] person" to prescribe a drug "for which payment may be made in whole or in part under a Federal health care program." *Id.* In 2010, Congress amended the AKS to make clear that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim" for purposes of the FCA. Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 111-148, § 6402(f), 124 Stat. 119, 759 (2010). Complicating matters, however, another statute — the Prescription Drug Marketing Act of 1987 ("PDMA"), 21 U.S.C. § 301 *et seq.*— expressly authorizes drug manufacturers to provide samples of their drugs to licensed practitioners who request them, so long as certain recordkeeping requirements are met. 21 U.S.C. § 353(d). That provision — an exemption from the PDMA's prohibition on the sale, purchase, or trade of "any drug sample," defined as "a unit of drug . . . which is not intended to be sold and is intended to promote the sale of the drug," *id.* § 353(c)(1) — is intended to allow a manufacturer to "acquaint the practitioner with the therapeutic value of the medication and thus encourage the written prescription of the drug." S. Rep. No. 100-303, at 2-3 (1988), *reprinted in* 1988 U.S.C.C.A.N. 57, 58-59.

B. The Alleged Scheme

Allergan is a pharmaceutical company that "has been a pioneer in the development of prescription eye care products," which it develops, manufactures, and markets for use in the cataract surgery setting. (Third Am. Compl. ¶ 22). Wood was employed by Allergan as a Senior Territory Manager from October 2008 to July 2010, during which time he discovered that Allergan was engaging in practices that allegedly violated the AKS and the FCA. (*Id.* ¶¶ 18-19). Specifically, Wood alleges that — from at least 2003 through 2011 — Allergan provided substantial numbers of free custom care kits, drug samples, customized patient instruction sheets, and customized, pre-printed prescription pads to induce physicians to prescribe Allergan drugs to their cataract patients, most of whom were Medicare or Medicaid recipients. (*Id.* ¶¶ 42, 100-101, 125). Allergan executives were purportedly aware of, and encouraged, the provision of these free goods in exchange for the prescription of Allergan drugs. (*See* ¶¶ 125-136). For the custom care kits, Allergan sales representatives worked with ophthalmologist offices nationwide to determine which of twelve different versions of the kit each office preferred to receive pursuant to a signed "Custom Care Kit Agreement." (*Id.* ¶¶ 137, 141). Pursuant to these Custom Care Kit Agreements, Allergan provided well over 100 million dollars' worth of free drug samples to physicians. (*See id.* ¶¶ 148-150 (detailing nearly 150 million dollars' worth of samples distributed during a single six-month period)). Notably, however, Allergan provided the free kits only to physicians who agreed to prescribe its drugs and, for physicians already doing so, those who agreed to prescribe large quantities of those drugs. (*Id.* ¶¶ 155-157). Allergan tracked the ratio of free drug samples provided to drugs prescribed by each doctor, and the company would stop providing free kits to physicians who were not prescribing sufficient quantities of its drugs. (*Id.* ¶¶ 155-160). In late 2008, Allergan stopped providing free custom care kits based on growing concerns over the program's legality. (*Id.* ¶¶ 161-163).

After terminating its custom care kit program, Allergan continued to provide free drug samples to physicians, who would submit signed "Sample Shipment Agreements" to the company's sales representatives to order large, six-month supplies of free product samples. (*Id.* ¶¶ 167-173). These Agreements were provided only to physicians who already prescribed or agreed to prescribe Allergan drugs in sufficient quantities; physicians who failed to do so ceased to receive free product samples. (*Id.* ¶¶ 174, 176, 184). In June 2010, Allergan halted its practice of providing these shipments of drug samples, again due to legality concerns. (*Id.* ¶¶ 185-188). Wood alleges, however, that Allergan continued to provide cooperative physicians with office supplies, such as customized prescription pads with pre-printed prescriptions for Allergan drugs and customized patient instruction sheets. (*Id.* ¶ 208). Until December 2008, Allergan representatives worked with physicians to custom design these patient instruction sheets. (*Id.* ¶ 209-210). After 2008, however, the company purchased a subscription to a design website that allowed physicians to create their own instruction sheets, with Allergan covering all the costs of printing and shipping. (*Id.* ¶ 211). Through this website, physicians could also order customized, pre-printed prescription sheets, with all costs again covered by Allergan. (*Id.* ¶ 212, 214). These inducements were also provided only to physicians who prescribed, or agreed to prescribe, Allergan drugs in sufficient quantities. (*Id.* ¶ 215).

Wood alleges that Allergan's provision of these free products — including the drug samples worth hundreds of millions of dollars — induced participating physicians to write hundreds of thousands of prescriptions for Allergan drugs in violation of the AKS. (*Id.* ¶¶ 219-220). Pharmacies then filled these prescriptions, unwittingly submitting "false" claims for reimbursement to federal and state healthcare programs, including Medicare, Medicaid, the Federal Employee Health Benefits Plan ("FEHBP"), and the Department of Defense TRICARE program (formerly known as CHAMPUS), and CHAMPVA. (*Id.* ¶ 101, 230). In doing so, Allergan caused physicians and pharmacies to falsely certify compliance with applicable federal

and state laws. (*Id.* ¶¶ 239-244). For example, pharmacies affix their unique provider identification numbers to every electronic claim submitted for Medicaid reimbursement; these identification numbers "serve as electronic stamps" indicating the pharmacies "are in compliance with all applicable federal and state laws." (*Id.* ¶ 227). Additionally, in the Medicare context, physician-providers must sign agreements certifying their compliance with federal law and their understanding that Medicare reimbursement is conditioned on compliance with, among other statutes, the AKS. (*Id.* ¶ 242 (discussing Centers for Medicare and Medicaid Services ("CMS") Forms 855A and 855I)).[3] Finally, Wood alleges that he was fired by Allergan soon after, and in retaliation for, reporting the illegal sampling and kickback scheme to Allergan's Compliance and Human Resources Departments. (*Id.* ¶¶ 268-274).

C. Other Cases and Procedural History

Significantly, Wood was not the first person to bring FCA claims against Allergan along the lines of those alleged here. On October 29, 2008, a relator filed *United States ex rel.*

[3] For further description of how certification operates under Medicare, Medicaid, and TRICARE (formerly CHAMPUS), see Judge McMahon's thorough opinion in *United States ex rel. Arnstein v. TEVA Pharmaceuticals USA, Inc*., No. 13-CV-3702 (CM), 2016 WL 750720, at *6-8 (S.D.N.Y. Feb. 22, 2016). (*See also* Third Am. Compl. ¶¶ 220-238 (describing Medicaid and Medicare)). The Medicare Part D claims process is particularly relevant here, as cataract surgery is the most common surgical procedure among Medicare beneficiaries, totaling 1.35 million surgeries per year and resulting in the fulfillment of millions of prescriptions for cataract surgery-related drugs. (*Id.* ¶ 113). Medicare beneficiaries receive prescription drug benefits through Part D of the Medicare Program, which "contracts with private companies known as 'Part D sponsors' in order to administer prescription drug plans." *TEVA Pharm.*, 2016 WL 750720, at *6. When a pharmacy dispenses drugs to a Medicare beneficiary, the pharmacy submits an electronic claim to the beneficiary's Part D sponsor. After submitting the claim, the Part D sponsor will reimburse the pharmacy for the portion of the drug not covered by the beneficiary, the pharmacy's dispensing fee, and any sales tax. *See id.* All Part D plan sponsors must certify compliance with "Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of the Federal criminal law, the False Claims Act (31 U.S.C. § 3729 *et seq.*), and the anti-kickback statute (section 1128B(b) of the Act)." 42 C.F.R. § 423.505(h)(1). And "[e]ach and every contract must specify that the related entity, contractor, or subcontractor must comply with all applicable Federal laws, regulations, and CMS instructions." 42 C.F.R. § 423.505(i)(4)(iv).

Lampkin v. Johnson & Johnson, *Inc.*, No. 08-CV-5362 (D.N.J.), alleging that Allergan, along with two other pharmaceutical companies, violated the AKS and thereby the FCA by shipping free surgical kits to physicians nationwide to induce them to prescribe a particular Allergan drug. (*See* Docket No. 68 ("Partridge Decl.") Exs. 2, 3). And on January 11, 2010, another relator filed *United States ex rel. Caryatid, LLC v. Allergan, Inc.*, No. 10-CV-46 (D.D.C.), alleging similar violations resulting from Allergan's provision of free surgical kits to physicians. (*See* Partridge Decl.. Exs. 1, 4). The United States declined to intervene in both actions, resulting in the complaints eventually being unsealed — in *Caryatid*, on July 27, 2011, and in *Lampkin*, on February 16, 2012. (*See id.* Ex. 2 ("*Lampkin* Docket") No. 26; *id.* Ex. 4 ("*Caryatid* Docket") No. 15). On January 23, 2012, the *Caryatid* action was dismissed pursuant to the relator's unopposed motion to dismiss for failure to timely serve Allergan. (*See Caryatid* Docket No. 16). The *Lampkin* action was dismissed with respect to Allergan for failure to serve on December 14, 2012. (*See Lampkin* Docket No. 54). On May 13, 2013, the entire action was dismissed, when the court granted the remaining defendant's motion to dismiss. (*See id.* Docket No. 59).

On July 26, 2010 — during the time that the *Lampkin* and *Caryatid* actions were under seal, but before they were dismissed — Wood filed this action under seal on behalf of the United States, twenty-six states, and the District of Columbia. (Docket No. 1; Docket No. 61 ("Original Compl.")). Nearly six years later, in March 2016, the United States and the states declined to intervene. (Docket Nos. 25, 26).[4] Thereafter, the Court unsealed Wood's original complaint and two amended complaints (which had been filed while the case was entirely under seal). (Docket Nos. 27, 59, 63). On May 23, 2016, Wood filed the operative complaint, the Third Amended Complaint, which expanded his allegations concerning the kickback scheme and dropped claims

[4] Shortly before the case was unsealed, it was reassigned from the Honorable Miriam G. Cedarbaum to the undersigned. (Docket No. 23).

on behalf of Maryland and New Hampshire. (Third Am. Compl.; Docket No. 73 ("Wood Opp'n"), at 1 n.1 (acknowledging that the Third Amended Complaint does not include claims on behalf of New Hampshire even though it is included in the caption)).[5] Allergan moved to dismiss the Third Amended Complaint on August 4, 2016. (Docket No. 64). The United States did not change course and intervene, but it did file two Statements of Interest in connection with the motion to dismiss, primarily to address implications of the Supreme Court's 2016 decision in *Escobar*. (Docket No. 78 ("Gov't SOI"); Docket No. 91 ("Gov't Supp. SOI")). In light of those Statements, and an *amicus* brief filed on behalf of Pharmaceutical Research and Manufacturers of America (Docket Nos. 83, 84), the motion did not become fully briefed until December 23, 2016, when Allergan filed its final reply. (Docket No. 99 ("Allergan Reply")).[6] On March 20, 2017, the Court held oral argument, in which the parties and the United States participated. (*See* Transcript of Oral Argument on March 20, 2017 ("Tr.")).

LEGAL STANDARDS

When reviewing a motion to dismiss pursuant to Rule 12(b)(6), the Court must "accept[ ] all factual allegations in the complaint and draw[ ] all reasonable inferences in the plaintiff's favor." *ATSI Commc'ns, Inc. v. Schaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007). The Court will not dismiss any claims pursuant to Rule 12(b)(6) unless the plaintiff fails to plead sufficient facts to state a claim to relief that is facially plausible, *see Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007), that is, one that contains "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged," *Ashcroft v. Iqbal*,

---

[5] The states on whose behalf Wood brings claims are California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and Wisconsin.

[6] On December 22, 2016, Taxpayers Against Fraud Education Fund moved for leave to file an *amicus* brief. (Docket No. 95). The Court denied the motion as untimely. (Docket No. 98).

556 U.S. 662, 678 (2009). More specifically, a plaintiff must allege facts showing "more than a sheer possibility that a defendant has acted unlawfully." *Id.* A complaint that offers only "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. Further, if a plaintiff has not "nudged [its] claims across the line from conceivable to plausible, [those claims] must be dismissed." *Id.* at 570.

As the FCA is an anti-fraud statute, Wood's claims must also comply with Rule 9(b) of the Federal Rules of Civil Procedure, which requires a plaintiff to plead fraud claims "with particularity." Fed. R. Civ. P. 9(b). To comply with Rule 9(b), a complaint "must: (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Lerner v. Fleet Bank, N.A.*, 459 F.3d 273, 290 (2d Cir. 2006) (internal quotation marks omitted). "In other words, Rule 9(b) requires that a plaintiff set forth the who, what, when, where and how of the alleged fraud." *United States ex rel. Polansky v. Pfizer, Inc.*, No. 04-CV-704 (ERK), 2009 WL 145682, at *4 (E.D.N.Y. May 22, 2009) (internal quotation marks omitted). Whether a complaint complies with the Rule, however, depends "upon the nature of the case, the complexity or simplicity of the transaction or occurrence, the relationship of the parties and the determination of how much circumstantial detail is necessary to give notice to the adverse party and enable him to prepare a responsive pleading." *In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318, 333 (D. Conn. 2004) (internal quotation marks omitted).

In particular, "where the alleged fraudulent scheme involved numerous transactions that occurred over a long period of time, courts have found it impractical to require the plaintiff to plead the specifics with respect to each and every instance of fraudulent conduct." *Id.*; *see United States v. Wells Fargo Bank, N.A.*, 972 F. Supp. 2d 593, 615-16 (S.D.N.Y. 2013). Thus, "where a relator pleads a complex and far-reaching fraudulent scheme with particularity, and provides examples of specific false claims submitted to the government pursuant to that scheme,

a relator may proceed to discovery on the entire fraudulent scheme." *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 510 (6th Cir. 2007). Specific examples, however, "will support more generalized allegations of fraud only to the extent that [they] are representative samples of the broader class of claims." *Id.* (emphasis omitted); *see also Wells Fargo*, 972 F. Supp. 2d at 615-16. By contrast, Rule 9(b) permits scienter to be alleged "generally," Fed. R. Civ. P. 9(b), and requires only that a defendant have acted "knowingly" rather than "proof of [a] specific intent to defraud," 31 U.S.C. § 3729(b)(1).[7]

DISCUSSION

Allergan moves to dismiss the Third Amended Complaint on several grounds. First, Allergan contends that the Court lacks jurisdiction to hear this action under the FCA's "public disclosure" and "first-to-file" bars. Second, Allergan alleges that, even if neither of those bars applies, the majority of Wood's claims fall outside the FCA's statute of limitations, as measured from the Third Amended Complaint. Third, Allergan asserts that Wood fails to plead a predicate violation of the AKS, in part because the PDMA expressly authorizes drug manufacturers to provide free samples to physicians. Fourth, with respect to the FCA claims, Allergan contends both that Wood's theory of falsity (as to pre-PPACA claims) fails as a matter of law and that Wood fails to plead any false claim with the particularity required under Rule 9(b). Fifth, Allergan challenges several of Wood's state law claims on similar grounds. And finally, Allergan asserts that Wood fails to state a retaliation claim as a matter of law. The Court addresses each argument in turn, beginning with the two purportedly jurisdictional issues.

[7] Allergan also moves to dismiss the Third Amended Complaint for lack of subject matter jurisdiction under Rule 12(b)(1) of the Federal Rules of Civil Procedure. (Docket No. 65 ("Allergan Mem.") 1). The Court need not separately discuss the Rule 12(b)(1) standards, however, because — for reasons discussed below — it concludes that Allergan's arguments are either not jurisdictional or without merit whether they are analyzed under Rule 12(b)(1) or (b)(6).

A. The Public Disclosure Bar

Allergan's first argument is that the Court lacks subject-matter jurisdiction because of the FCA's "public disclosure bar," which, as noted above, generally requires courts to dismiss an action or claim "if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed" in a judicial proceeding, a governmental report, hearing, audit, or investigation, or in the news media. 31 U.S.C. § 3730(e)(4)(A). Until 2010, the public disclosure bar was unambiguously jurisdictional: "No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions . . . ." 31 U.S.C. § 3730(e)(4)(A) (2009). In the PPACA, however, Congress amended the provision to remove any reference to jurisdiction. *See* Pub. L. No. 111-148, § 10104(j)(2), 124 Stat. 119, 901-902 (2010). Thus, it now states only that "[t]he court shall dismiss an action or claim" that has been publicly disclosed. 31 U.S.C. § 3730(e)(4)(A) (2010). In the wake of that amendment, courts are divided over whether the public disclosure bar is jurisdictional or non-jurisdictional. *Compare, e.g.*, *United States ex rel. Kester v. Novartis Pharma. Corp. (Novartis V)*, 43 F. Supp. 3d 332, 345-346 (S.D.N.Y. 2014) (jurisdictional), *with Ping Chen ex rel. United States v. EMSL Analytical, Inc.*, 966, F. Supp. 2d 282, 294 (S.D.N.Y. 2013) (non-jurisdictional). Either way, however, it does not apply here.

Whether the public disclosure bar applies turns on whether the allegations in Wood's complaint were "publicly disclosed" prior to his filing of the initial complaint in July 2010. Significantly, nine courts of appeals have held that the bar applies only where there has been a disclosure *outside* of the government. *See, e.g.*, *United States ex rel. Chattanooga-Hamilton Cty. Hosp. Auth.*, 782 F.3d 260, 265-66 (6th Cir. 2015); *United States ex rel. Little v. Shell Exploration Prod. Co.*, 602 F. App'x 959, 974 (5th Cir. 2015); *United States ex rel. Wilson v. Graham Cnty. Soil & Water Conservation Dist.*, 777 F.3d 691, 696-98 (4th Cir. 2015); *United States ex rel. Oliver v. Phillip Morris USA Inc.*, 763 F.3d 36, 42 (D.C. Cir. 2014); *United States*

ex rel. Meter v. Horizon Health Corp., 565 F.3d 1195 (9th Cir. 2009); *United States ex rel. Maxwell v. Kerr-McGee Oil & Gas Corp.*, 540 F.3d 1180, 1184 (10th Cir. 2008); *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 730-31 (1st Cir. 2007); *United States ex rel. Cantekin v. Univ. of Pittsburgh*, 192 F.3d 402, 408 (3d Cir. 1999); *United States ex rel. Williams v. NEC Corp.*, 931 F.2d 1493, 1494 (11th Cir. 1991). These courts have reasoned that "the phrase 'public disclosure' would be superfluous" if "providing information to the government were enough to trigger the bar." *Rost*, 507 F.3d at 729. Equating the terms "government" and "public," they have opined, would also be inconsistent with language elsewhere in the FCA and with the purpose of the public disclosure bar, which "clearly contemplates that the information be in the public domain in some capacity[,] and the Government is not the equivalent of the public domain." *Kennard v. Comstock Res., Inc.*, 363 F.3d 1039, 1043 (10th Cir. 2004).

The Second Circuit has not yet opined on this issue. In light of that vacuum, Allergan invites the Court to follow the Seventh Circuit, the sole court of appeals to conclude that disclosure to a competent public figure, without more, satisfies the "public disclosure" requirement. *See United States ex rel. Mathews v. Bank of Farmington*, 166 F.3d 853, 861 (7th Cir. 1999) (holding that disclosure to a government official "authorized to act for or to represent the community on behalf of government can be understood as public disclosure"); *see also Cause of Action v. Chi. Transit Auth.*, 815 F.3d 267, 275-77 (7th Cir. 2016) (declining to reconsider *Bank of Farmington*). The Court declines that invitation and chooses instead to follow the persuasive reasoning of the nine other Circuits to address the question. That dooms Allergan's public disclosure argument, as there is no suggestion that Wood's allegations were public in any form prior to his filing of the first complaint. Instead, Allergan's argument rests entirely on the proposition that the complaints in *Lampkin* and *Caryatid*, although under seal, had previously been disclosed to officials in the federal government. (Docket No. 65 ("Allergan Mem.") 11; Allergan Reply 6). But a sealed complaint, by definition, does not disclose any

information to the "public." *See, e.g.*, *United States ex rel. LeBlanc v. Raytheon Co.*, 913 F.2d 17, 20 (1st Cir. 1990) ("[T]he district court further assumes that the filing of a *qui tam* action is itself a 'public disclosure.' This cannot be. Such an action is filed under seal without service on anyone other than the United States and remains non-public until the district court enters an order lifting the seal. To hold otherwise would be to render each and every filing a 'public disclosure,' thus barring all *qui tam* actions."). Accordingly, Allergan's reliance on the public disclosure bar is rejected.[8]

B. The First-to-File Bar

Allergan's next argument — that Wood's action must be dismissed pursuant to the FCA's "first-to-file" bar because, when it was filed, the *Lampkin* and *Caryatid* actions were both pending (albeit under seal) — requires a more extended discussion. The bar, codified in Section 3730(b)(5), provides: "When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). The core statutory "command is simple: as long as a first-filed complaint remains pending, no related complaint may be filed." *United States ex rel. Batiste v. SLM Corp.*, 659 F.3d 1204, 1210 (D.C. Cir. 2011). But that simplicity is deceptive. Determining whether the first-to-file bar requires dismissal in the circumstances presented here involves consideration of several complicated issues, at least two of which are the subject of Circuit splits upon which the Second Circuit has not yet opined: whether the first-to-file bar is jurisdictional or non-jurisdictional and (potentially relatedly) whether violation of the first-to-file

[8] In light of this conclusion, the Court need not, and does not, reach Wood's alternative argument that the public disclosure bar is inapplicable because he qualifies as an "original source." (Wood Opp'n 10-11). *See* 31 U.S.C. § 3730(e)(4)(A) (directing the court to dismiss an action that has been publicly disclosed "unless the action is brought by the Attorney General or the person bringing the action is an original source of the information").

bar requires dismissal or can be cured through an amended or supplemental pleading under Rule 15 of the Federal Rules of Civil Procedure.

1. Related Actions

Of course, the Court need not address those two thorny issues if, as Wood argues, the *Lampkin* and *Caryatid* actions were not "related" to this one within the meaning of Section 3730(b)(5), so the Court begins there. Although the Second Circuit has not yet weighed in, every court of appeals that has addressed the issue has held that "[a] second action is 'related,' within the meaning of the first-to-file bar, if the claims incorporate the same material elements of fraud as the earlier action, even if the allegations incorporate additional or somewhat different facts or information." *United States ex rel. Heath v. AT & T, Inc.*, 791 F.3d 112, 121 (D.C. Cir. 2015) (internal quotation marks omitted); *see United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 32 (1st Cir. 2009) (citing cases); *see also, e.g.*, *United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1189 (9th Cir. 2011) ("Limiting § 3730(b)(5) to only bar actions with identical facts would be contrary to the plain language [of the statute] and legislative intent . . . ."). "The first-to-file bar is designed to be quickly and easily determinably, simply requiring a side-by-side comparison" of the original complaints in the two actions. *In re Natural Gas Royalties*, 566 F.3d 956, 964 (10th Cir. 2009); *see also United States ex rel. Jamison v. McKesson Corp.*, 649 F.3d 322, 328 (5th Cir. 2011) (noting that the inquiry turns on the original complaint, not an amended complaint). Relatedness turns on "whether the later complaint alleges a fraudulent scheme the government already would be equipped to investigate based on the first complaint." *Heath*, 791 F.3d at 121 (internal quotation marks and alterations omitted); *see also Heineman-Guta v. Guidant Corp.*, 718 F.3d 28, 37-38 (1st Cir. 2013) ("If the

earlier-filed complaint contains enough material facts to alert the government to potential fraud, a later-filed complaint . . . containing the same essential facts . . . is nonetheless barred").[9]

Applying this "essential facts" standard, the Court concludes that *Lampkin* was indeed "related" to this action.[10] In *Lampkin*, the relator explicitly alleged that Allergan violated the AKS by "pa[ying] kickbacks to doctors nationwide in the form of . . . free surgical kits that ha[d] greater than nominal value"; that Allergan shipped those kits "nationwide on a monthly basis" as inducement for physicians to prescribe Zymar; and that "[c]ompliance with the [AKS] is a condition of payment under federal health care insurance programs," with which providers and

---

[9] During oral argument, the Government urged the Court to follow the Sixth Circuit's decision in *Walburn v. Lockheed Martin Corp.*, 431 F.3d 966 (6th Cir. 2005), which held that an earlier-filed complaint that is "legally insufficient under Rule 9(b)['s]" heightened pleading standards does not bar a later-filed action on the theory that the earlier complaint failed to provide sufficient notice to the Government. *Id.* at 972-73. (Tr. 21-22). Several courts have expressed unease with that approach, pointing out that "[n]othing in the language of Section 3730(b)(5) incorporates the particularity requirement of Rule 9(b), which militates against reading such a requirement into the statute." *Batiste*, 659 F.3d at 1210; *accord United States ex rel. Wickliffe v. EMC Corp.*, 473 F. App'x 849, 850-51 (10th Cir. 2012). Moreover, adopting that approach "would create a strange judicial dynamic, potentially requiring one district court to determine the sufficiency of a complaint filed in another district court, and possibly creating situation in which the two district courts disagree on a complaint's sufficiency." *Batiste*, 659 F.3d at 1210; *see also United States ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371, 378 n.10 (5th Cir. 2009) ("The sufficiency of the [earlier] complaint under Rule 9(b) is a matter for that court to decide in the first instance."); *Wickliffe*, 473 F. App'x at 851 (expressing a similar unease). The Court agrees with those criticisms, and declines to adopt the Sixth Circuit's approach. Accordingly, so long as the first-filed suit "provide[s] . . . sufficient notice for the government to initiate an investigation into the allegedly fraudulent practices," the first-to-file bar applies without regard for Rule 9(b). *Batiste*, 659 F.3d at 1210.

[10] Wood may be on stronger ground in arguing that *Caryatid* was not "related," as the gravamen of the FCA claim in that case was that Allergan unlawfully promoted the use of certain drugs for off-label purposes not approved by the Food and Drug Administration. (*See* Partridge Decl., Ex. 1, ¶¶ 10-13, 15-17, 19). The Court need not decide that question, however, given its conclusion that *Lampkin* was related. Moreover, the *Lampkin* action was filed before the *Caryatid* action (October 29, 2008, versus January 11, 2010), and dismissed later (December 14, 2012, versus January 23, 2012). (*Compare Lampkin* Docket No. 54, *with Caryatid* Docket No. 16). (The *Lampkin* action was not dismissed altogether until May 13, 2014, but all claims against Allergan were dismissed for failure to serve on December 14, 2012. (*See Lampkin* Docket Nos. 54, 59). For present purposes, that distinction is immaterial.)

suppliers certify their compliance on the CMS Provider/Supplier Enrollment Application Form 855. (*See* Partridge Decl., Ex. 3 ("*Lampkin* Compl."), ¶¶ 14-16, 18). Wood's later complaint certainly included more detailed allegations, and some different particulars (for example, the time frame of the alleged fraud), but — by any reasonable measure — the claims alleged were based on the same essential facts and involved the same elements of fraud. *See, e.g., United States ex rel. Wilson v. Bristol-Myers Squibb, Inc.*, 750 F.3d 111, 118 (1st Cir. 2014) ("The overlaps among the two complaints were considerable: the same defendants, the same drugs, the assertion of nationwide schemes, and the allegations of specific mechanisms of promotion common to both and leading to common patterns of submission of false claims under the federal Medicaid program."). Notably, Wood effectively (but perhaps inadvertently) concedes as much, when arguing (in response to Allergan's contention that his claims are time barred, an issue addressed below) that Allergan "received actual notice of the claims in this case no later than the time that . . . [*Lampkin* was] unsealed in 2012." (Wood Opp'n 27).

Wood's strongest argument to the contrary is that the AKS and FCA allegations in *Lampkin* were limited to only one drug (Zymar), while the allegations here relate to additional drugs (Acular and, perhaps, Pred Forte). (*Compare Lampkin* Complaint ¶¶ 4-5, 19, *with* Third Am. Compl. ¶¶ 154, 210-213). In support of that argument, Wood cites cases holding that "the drug itself is an essential element of the fraudulent scheme alleged." *United States ex rel. Banignan v. Organon USA Inc.*, 883 F. Supp. 2d 277, 291 (D. Mass. 2012); *see also In re Pharm. Indus. Average Wholesale Price Litig.*, No. 01-CV-12257 (PBS), 2008 WL 2778808, at *3 (D. Mass. July 15, 2008) (finding that "the failure to specify the drug Erythromycin in the earlier action constitutes a failure to state all the essential facts under the 'same material elements' standard"). (*See* Docket No. 109). But those cases did not announce a categorical rule; they merely applied the general proposition that, for purposes of the first-to-file bar, notice to the Government is key. *See Banignan*, 883 F.3d at 292 ("[T]he policy underlying the

provision counsels that the bar should not apply if the government would uncover such fraud (if at all) only by exhausting its investigative resources."). That proposition might call for allowing an FCA suit against a pharmaceutical company to proceed notwithstanding an earlier-filed FCA suit against the same company, but involving a completely unrelated drug. *See In re Pharma*, 2008 WL 2778808, at *3 ("The complaint in the [earlier case] involved different drugs marketed by a different division of Abbott. Significantly, Erythromycin is primarily a self-administered drug and the other drugs are generally administered by physicians. Notice of fraud in one drug's pricing is not notice of fraud in another drug's pricing . . . because drugs are often marketed, reimbursed, sold, and priced in different ways."). But it does not defeat the first-to-file bar here, as the complaint in *Lampkin* was, like the original complaint here, based on the distribution of drugs through surgical care kits. (*Lampkin* Compl. ¶¶ 14, 16). Whether Allergan unlawfully distributed one drug or more than one drug through those customer care kits is of no moment; either way, the *Lampkin* Complaint contained "enough material facts to alert the government to [the] potential fraud" alleged here. *Heineman-Guta*, 718 F.3d at 37-38. Accordingly, as long as *Lampkin* was a "pending action," 31 U.S.C. § 3730(b)(5), as it was when Wood filed his original complaint (and first two amended complaints), the first-to-file bar applied.

2. Whether the First-to-File Bar Requires Dismissal

The fact that this case is "related" to *Lampkin*, however, does not end the analysis, because *Lampkin* was dismissed on December 14, 2012, and, thus, is no longer a "pending action" for purposes of Section 3730(b)(5). Notably, the Supreme Court recently confronted a remarkably similar scenario in *Kellogg Brown & Root Services., Inc. v. ex rel. Carter*. There, the district court had relied on the first-to-file bar to dismiss an FCA case *with* prejudice; while the case was on appeal, however, the earlier-filed cases were dismissed. *See* 135 S. Ct. at 1974-75. In light of that development, the Fourth Circuit reversed and remanded with instructions to dismiss *without* prejudice, reasoning that the first-to-file bar ceases to apply once the earlier-filed

related action is dismissed. The Supreme Court, after addressing an unrelated statute of limitations question, affirmed that ruling. Relying on the "ordinary meaning" of the word "pending" in Section 3730(b)(5) and the slim chance that Congress would have wanted an abandoned suit "to bar a later potentially successful suit that might result in a large recovery for the Government," the Court held that "an earlier suit bars a later suit while the earlier suit remains undecided but ceases to bar that suit once it is dismissed." 135 S. Ct. at 1978-79. It follows that the first-to-file bar poses no obstacle to Wood pursuing his claims today.

Allergan concedes that point, but argues that dismissal without prejudice is nonetheless required because no amendment can change the fact that Wood initiated this action while at least one related case was "pending." (Allergan Mem. 9). By contrast, Wood — perhaps notably, supported by the Government at oral argument — contends that dismissal is unnecessary because filing the Third Amended Complaint after *Lampkin* was dismissed "cured" the first-to-file defect in his original complaint. (Wood Opp'n 4-8; Tr. at 21-23). Given that any dismissal would be without prejudice to Wood filing a new action, *see Carter*, 135 S. Ct. at 1978, the parties' dispute would be academic, but for one critical fact: During the six years in which the Government investigated Wood's claims and the case remained under seal, the statute of limitations ran on most, if not all, of Wood's FCA claims, *see* 31 U.S.C. § 3731(b), so dismissal — even without prejudice — would, for all intents and purposes, largely immunize Allergan from Wood's claims.[11] Thus, the question of whether a violation of the first-to-file bar can be "cured" by amending or supplementing a complaint — a question left unanswered by the Supreme Court in *Carter*, *see, e.g.*, *United States ex rel. Boise v. Cephalon, Inc.*, 159 F. Supp. 3d 550, 556 (E.D. Pa. 2016) ("The Supreme Court in *Carter* did not mandate a procedural outcome for second-filed

[11] Congress could have addressed that potential problem by including a provision in the FCA tolling the statute of limitations during the pendency of a related lawsuit, but it did not. Nor do the parties suggest that there is any doctrine of equitable tolling that could apply here.

suits whose first-filed counterparts have been dismissed; it only agreed with the Fourth Circuit that the lower court's dismissal with prejudice was in error.") — is critical, if not dispositive.

Complicating matters, the Second Circuit (consistent with the theme that pervades this Opinion) has not addressed that question, and the federal courts that have addressed it have adopted radically different approaches. The majority have held that the first-to-file bar is jurisdictional and (in part as a result) that violation of the bar is not curable by amendment. *See, e.g.*, *United States v. Medco Health Solutions, Inc.*, No. 11-CV-684 (RGA), 2017 WL 63006, at *12; *United States ex rel. Palmieri v. Alpharma, Inc.*, 2016 WL 7324629, at *11-12 (D. Md. Dec. 16, 2016); *United States ex rel. Carter v. Halliburton Co.*, 144 F. Supp. 3d 869, 880 (E.D. Va. 2015); *United States ex rel. Moore v. Pennrose Props., LLC*, No. 11-CV-121, 2015 WL 1358034, at *18 (S.D. Ohio Mar. 24, 2015); *United States ex rel. Branch Consultants, L.L.C. v. Allstate Ins. Co.*, 782 F. Supp. 2d 248, 259 (E.D. La. 2011). At least one district court has held that, while the rule is non-jurisdictional, its violation is still not curable by amendment. *See United States ex rel. Shea v. Verizon Commc'ns,* 160 F. Supp. 3d 16, 28-30 (D.D.C. 2015). And still others (including the only circuit court to weigh in) have held that, whether or not the rule is jurisdictional, its violation *can* be cured by the filing of an amended or supplemental complaint if, as here, the first-filed action is no longer "pending." *See, e.g.*, *United States ex rel. Gadbois v. PharMerica Corp.*, 809 F.3d 1, 3 (1st Cir. 2015), *cert. denied*, 136 S. Ct. 2517 (2016); *United States ex rel. Brown v. Pfizer, Inc.*, No. 05-CV-6795 (RBS), 2016 WL 807363 (E.D. Pa. Mar. 1, 2016); *United States ex rel. Kurnik v. PharMerica Corp.*, No. 11-CV-1464, 2015 WL 1524402, at *6 (D.S.C. Apr. 2, 2015); *Cephalon*, 159 F. Supp. 3d at 558; *United States ex rel. Saldivar v. Fresenius Med. Care Holdings, Inc.*, 157 F. Supp. 3d. 1311 (N.D. Ga. 2015).

Based on a careful review of the FCA's text, structure, and purpose, the Court concludes that Wood and the Government have the better of the argument and that a violation of the first-to-file bar can be cured by amending or supplementing the complaint after the first-filed action

has been dismissed. As an initial matter, the Court agrees with the D.C. Circuit that the first-to-file bar is not jurisdictional. *See Heath*, 791 F.3d at 119-20. Admittedly, the majority of Circuits have ruled otherwise. *See, e.g.*, *Gadbois*, 809 F.3d at 3; *United States ex rel. Carter v. Halliburton Co.*, 710 F.3d 171, 181 (4th Cir. 2013); *Walburn*, 431 F.3d at 970. In recent years, however, the Supreme Court has stressed the need to bring "some discipline to the use of the term jurisdiction[al]," and has repeatedly held that, absent a "clear statement" from Congress, courts "should treat" procedural restrictions "as nonjurisdictional." *Sebelius v. Auburn Reg'l Med. Ctr.*, 133 S. Ct. 817, 824 (2013) (internal quotation marks omitted); *see also Gonzalez v. Thaler*, 132 S. Ct. 641, 648 (2012); *Morrison v. Nat'l Australia Bank Ltd.*, 561 U.S. 247, 254 (2010). As the D.C. Circuit observed in *Heath*, the language of the first-to-file bar "does not speak in jurisdictional terms or refer in any way to the jurisdiction of the district courts." 791 F.3d at 120 (quoting *Arbaugh v. Y & H Corp.*, 546 U.S. 500, 515 (2006)). What is more, other provisions of the FCA do refer explicitly to jurisdiction and thus make plain that Congress knew how to expressly distinguish between jurisdictional and non-jurisdictional rules. *See, e.g.*, 31 U.S.C. § 3730(e)(1) ("No court shall have jurisdiction over an action brought by a former or present member of the armed forces . . . ."); *id.* § 3730(e)(2)(A) ("No court shall have jurisdiction over an action brought . . . against a Member of Congress, a member of the judiciary, or a senior executive branch official . . . ."); *see also, e.g.*, *Nken v. Holder,* 556 U.S. 418, 430 (2009) ("[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.").

Other considerations bolster the conclusion that "the first-to-file rule bears only on whether a *qui tam* plaintiff has properly stated a claim," rather than on the scope of courts' jurisdiction. *Heath*, 791 F.3d at 121. First, the Supreme Court has repeatedly held that "[t]he requirement that jurisdiction be established as a threshold matter . . . is inflexible and without

exception." *Steel Co. v. Citizens for Better Env't*, 523 U.S. 83, 94-95 (1998) (internal quotation marks omitted). Thus, the Supreme Court itself is "require[d]" to "address questions pertaining to its or a lower court's jurisdiction before proceeding to the merits." *Tenet v. Doe*, 544 U.S. 1, 6 n.4 (2005). In *Carter*, however, the Supreme Court examined the import of the first-to-file bar for the relator's claims only *after* the Court had decided a non-jurisdictional statute of limitations question impacting those claims. *See* 135 S. Ct. at 1978-79. Second, as a general proposition, plaintiffs must establish jurisdiction and federal courts must satisfy themselves at the outset of a case that they have jurisdiction. *See, e.g.*, *Steel Co.*, 523 U.S. at 94-95. But, because FCA cases are initially filed under seal and can remain under seal for years, there are likely to be many cases — like this one — in which neither the relator nor the court is in a position to know about an earlier-filed action. (In *Carter*, for example, the parties and the district court learned about the earlier-filed action only "shortly before trial." 135 S. Ct. at 1974.) If the first-to-file rule were jurisdictional — even if it were curable through amendment or supplementation — the result could be problematic, raising questions about whether actions taken by the court while the earlier-action was (unbeknownst to the court) pending are retroactively null and void. *See Henderson ex rel. Henderson v. Shinseki*, 562 U.S. 428, 434-35 (2011) (noting that "[o]bjections to subject-matter jurisdiction . . . may be raised at any time," even by the losing party after trial); *see also, e.g.*, *Ex parte McCardle,* 74 U.S. 506, 514 (1868) ("Jurisdiction is power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause."). The more sensible approach, supported by the language and structure of the FCA, is to treat the first-to-file rule as a non-jurisdictional (albeit mandatory) rule. *See generally* Scott Dodson, *Mandatory Rules*, 61 Stan. L. Rev. 1, 9 (2008) (discussing mandatory non-jurisdictional rules).[12]

[12] It is true, as Allergan notes (Allergan Mem. 9; Allergan Reply 4-5), that the Second Circuit described the first-to-file rule as jurisdictional in *United States ex rel. Pentagon Techs.*

Significantly, most of the courts to hold that a first-to-file rule violation cannot be cured have rested heavily, if not primarily, on their view that the rule is jurisdictional in nature and the "hornbook" principle that "jurisdiction . . . depends upon the state of things at the time of the action brought." *Grupo Dataflux v. Atlas Global Grp., L.P.*, 541 U.S. 567, 570 (2004); *see, e.g.*, *Medco Health*, 2017 WL 63006, at *12 ("[T]he court finds that the reasoning of cases allowing amendment to cure a jurisdictional defect under the first-to-file bar is not persuasive."); *Halliburton*, 144 F. Supp. 3d at 880 ("In this Circuit, the first-to-file bar is jurisdictional. It is consistent with a jurisdictional limitation to apply the first-to-file bar at the time the initial complaint is filed, rather than when the complaint is amended." (citation omitted)); *accord* *Palmieri*, 2016 WL 7324629, at *12; *Pennrose Props.*, 2015 WL 1358034, at *12; *Allstate Ins. Co.*, 782 F. Supp. 2d at 259.[13] That hornbook principle does not apply to non-jurisdictional rules, even those that explicitly call for looking at the circumstances as of the time of filing.

Int'l, Ltd. v. CACI Int'l, Inc., 172 F.3d 39, 39 (2nd Cir. 1999) (summary order). But that decision was an unpublished summary order and, thus, is not binding on the Court. Moreover, the Second Circuit's unpublished decision predated both *Carter* and the Supreme Court's recent efforts to bring more "discipline" to the distinction between jurisdictional and non-jurisdictional rules. *Sebelius*, 133 S. Ct. at 824. Notably, at least one case in that line explicitly found fault with the Second Circuit's approach to the distinction. *See Morrison*, 561 U.S. at 253-54.

[13] It is worth noting also that the "time of filing" rule for jurisdiction may not be as rigid as these courts have assumed. That is, courts do sometimes allow plaintiffs to cure jurisdictional defects in their complaints pursuant to Rule 15. *See, e.g.*, *Mathews v. Diaz*, 426 U.S. 67, 75 (1976) ("We have little difficulty with [the plaintiff's] failure to file an application with the Secretary until after he was jointed in this action. Although . . . filing of an application [is] a nonwaivable condition of jurisdiction, [the plaintiff] satisfied this condition while the case was pending in the District Court. A supplemental complaint . . . [will] eliminate[] this jurisdictional issue. . . . It is not too late, even now, to supplement the complaint to allege this fact."); *Positive Black Talk, Inc. v. Cash Money Records, Inc.*, 394 F.3d 357, 366-67 (5th Cir. 2004) (finding that a post-filing copyright registration cured the jurisdictional failure to register copyright before filing), *abrogated by Reed Elsevier, Inc. v. Muchnick*, 559 U.S. 154 (2010); *Black v. Sec'y of Health & Human Servs.*, 93 F.3d 781, 790 (Fed. Cir. 1996) (holding that the plaintiff's supplemental complaint alleging that he had reached the threshold of $1,000 in reimbursable expenses *after filing* cured a jurisdictionally defective initial complaint under the Vaccine Act); *Green Mountain Realty Corp. v. Leonard*, No. 09-CV-11559 (RWZ), 2010 WL 1461590, at *2 (D. Mass. Apr. 9, 2010) (observing that "case law with respect to supplemental pleadings instructs that subsequent pleadings may in fact cure defects (including unripeness) in an initial

To the contrary, courts routinely allow plaintiffs to cure violations of such rules by filing amended or supplemental complaints pursuant to Rule 15. *See generally* 6 Wright & Miller, Fed. Prac. & Proc. Civ., § 1474 (3d ed.) (noting "the most common use of Rule 15(a) is by a party seeking to amend in order to cure a defective pleading" and listing a wide range of permissible amendments, which courts "liberal[ly]" construe to further "the basic objectives of the federal rules," that is, "the determination cases on their merits"); *id.* § 1505 (listing a wide variety of permissible purposes for supplementation and noting that Rule 15(d) was revised specifically to make clear that courts have "discretion to allow a supplemental pleading even though the original pleading is defective in stating a claim or defense" (internal quotation marks omitted)); *see also, e.g.*, *Klinger v. Corr. Corp. of Am.*, No. 11-CV-2299, 2012 WL 6200393, at *10 (N.D. Ohio Oct. 23, 2012) ("Plaintiff's subsequent appointment as personal representative for his father's estate as alleged in the Fourth Complaint, relates back to the date of the filing of the Complaint under Rule 15(c)(1)(B). This amendment cures the defect regarding Plaintiff's capacity to sue and preserves the estate's wrongful death claims against [the defendants]."); *Woods v. State of Mo. Dep't of Mental Health*, 581 F. Supp. 437, 439 (W.D. Mo. 1984) (granting leave to amend to cure an Eleventh Amendment defect raised in the defendant's motion to dismiss because "allowing the amendment would not result in prejudice to [the] defendant but a

---

complaint"); *see also E.R. Squibb & Sons, Inc. v. Lloyd's & Cos.*, 241 F.3d 154, 163 (2d Cir. 2001) (finding that, "[a]s a general matter, it is widely accepted that amendments to cure subject matter jurisdiction relate back" and holding that "where it is appropriate to relate back an amendment to a pleading under Rule 15, jurisdiction is assessed as if the amendment had taken place at the time the complaint was first filed"). Indeed, as noted above, the First Circuit treats the first-to-file rule as jurisdictional but has nevertheless concluded that a relator can cure a violation of the rule pursuant to Rule 15. *See Gadbois*, 809 F.3d at 6 ("[C]ourts generally have read Rule 15(d) to include defects in subject matter jurisdiction among the deficiencies that may be corrected through a supplemental pleading. . . . The decision in *Mathews* plainly implies that subject matter jurisdiction falls within the cluster of defects that may be cured by a supplemental pleading under Rule 15(d). . . . The weight and consistency of these authorities undermines [the defendant's] attempt to elongate the reach of the familiar rule that jurisdiction is determined by the facts existing at the time of filing an original complaint.").

denial would cause plaintiff significant hardship since his [civil rights claims] would be dismissed"). Thus, stripped of its jurisdictional trappings, the first-to-file rule poses a far less formidable barrier to allowing cure through amendment than many courts have assumed.[14]

Second, and in any event, the structure and purpose of the FCA generally, and the first-to-file rule specifically, call for allowing a relator in Wood's circumstances to avoid dismissal by amending or supplementing his complaint. There can be no dispute that the primary purpose of the FCA is to permit the Government to recover for fraud inflicted upon it. *See Cook County, Ill. v. United States ex rel. Chandler*, 538 U.S. 119, 129-35 (2003). The "most obvious indication" of that purpose is the statute's *qui tam* provisions, which "quicken the self-interest of some private plaintiff who can spot violations and start litigating to compensate the Government, while benefitting himself as well." *Id.* at 131. At the same time, Congress has long sought to eliminate "parasitic lawsuits" and discourage "opportunistic plaintiffs who have no significant information to contribute of their own." *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 649 (D.C. Cir. 1994). Driven primarily by the latter concern, Congress clamped down on *qui tam* suits in 1943. *See, e.g.*, *Pettis ex rel. United States v. Morrison-Knudsen Co.,* 577 F.2d 668, 671 (9th Cir. 1978). But after concluding that those reforms shifted the pendulum too far in the other direction, Congress amended the Act again in 1986, adding both the first-to-file bar and the public disclosure bar. *See Springfield Terminal Ry. Co.*, 14 F.3d at 650-51; *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 234 (3d Cir. 1998). The "primary purpose" of the 1986 amendments "was to shift the advantage back to the government in the fight against fraud." *Id.* at 233-34 (internal quotation marks omitted); *see also United*

[14] *Shea* appears to be the only case in which a court held that the first-to-file rule is non-jurisdictional *and* that a violation of the rule cannot be cured. *See* 160 F. Supp. 3d at 28-30. The Court, however, relied heavily on cases that had treated the first-to-file rule as jurisdictional, *see id.* at 29-30, and did not fully grapple with the import of the distinction between jurisdictional and non-jurisdictional rules when it comes to amendment of a complaint.

States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah, 472 F.3d 702, 725 (10th Cir. 2006) ("The purpose in amending the FCA was 'not only to provide the Government's law enforcers with more effective tools, but to encourage any individual knowing of Government fraud to bring that information forward.'" (quoting S. Rep. No. 99-345, at 2 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5266-67)). More broadly, the amendments also "sought to achieve the golden mean between adequate incentives for whistle-blowing insiders with genuinely valuable information and discouragement of opportunistic plaintiffs who have no significant information to contribute of their own." *LaCorte*, 149 F.3d at 234 (internal quotation marks omitted).

Ignoring Congress's primary intent to aid the Government in fighting fraud, Allergan contends that the first-to-file rule "is intended to 'prevent the filing of more *qui tam* suits once the government already has been made aware of the potential fraud'" and to "discourage . . . parasitic lawsuits that merely feed off previous disclosures of fraud." (Allergan Mem. 8 n.6 (quoting *United States ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 503, 517 (6th Cir. 2009), and *Branch Consultants*, 560 F.3d at 376). That contention does find some support in the case law. But to the extent that an earlier-filed *qui tam* suit remains under seal, the rule does little or nothing to prevent the filing of more suits; after all, later relators and courts (as in this case) will not know of the earlier-filed suit until it is unsealed and, thus, will not be "prevent[ed]" from filing suit. And to the extent that the earlier-filed suit is no longer under seal, the public disclosure bar will generally serve to prevent parasitic lawsuits that merely feed off the earlier-filed suit. As the Tenth Circuit has explained, "[t]he public disclosure bar already [bars] suits brought by relators who simply feed off another relator's complaint and offer no useful information to government officials who should already be on notice of the fraud. Applying that standard to the first-to-file bar will do no more to weed out opportunistic relators than the public disclosure bar already does." *In re Natural Gas Royalties*, 566 F.3d at 963.

In light of the sealing requirement for newly filed *qui tam* suits and the public disclosure bar, therefore, it is hard to see what work the first-to-file rule does in combating parasitic or opportunistic lawsuits. Nor, in light of the fact that it ceases to apply if the earlier-filed action is dismissed, does the rule necessarily shield the Government from being notified of the same fraud more than once. After all,

> [w]hile filing the complaint might put the government on notice, and while the government may remain on notice while the action is pending, the government does not cease to be on notice when a relator withdraws his claim or a court dismisses it. And yet, if that prior claim is no longer pending, the first-to-file bar no longer applies.

Id. at 964. The text and structure of the statute thus suggest that the primary, if not sole, purpose of the first-to-file rule is to help the Government uncover and fight fraud. That is, it "vindicates the goal of encouraging relators to file; it protects the potential award of a relator while his claim remains viable, but, when he drops his action, another relator who qualifies . . . may pursue his own." *Id.*; *see also, e.g.*, *Campbell v. Redding Med. Center,* 421 F.3d 817, 821 (9th Cir. 2005) (stating that the "first-to-file bar . . . encourages prompt disclosure of fraud by creating a race to the courthouse among those with knowledge of fraud"); *Grynberg v. Koch Gateway Pipeline Co.*, 390 F.3d 1276, 1279 (10th Cir. 2004) ("[O]riginal qui tam relators would be less likely to act on the government's behalf if they had to share in their recovery with third parties who do no more than tack on additional factual allegations to the same essential claim.").

Viewing the first-to-file rule in that light, it is plain that barring a relator in Wood's position from curing his violation of the rule would undermine, rather than advance, the purposes of the FCA. For one thing, it would diminish the incentive for any relator with valuable information to file suit, as she would have to discount the probability of laying exclusive claim to any spoils by the risk that, unbeknownst to her, someone else had beaten her to the courthouse door. For another, where, as here, a case remains sealed for an extended period of time, it could result in the relator's claims being precluded by either the public disclosure bar or the statute of

limitations — through no fault of his own. *See, e.g.*, *Medco Health*, 2017 WL 63006, at *12 n.14 (noting that "dismissal and refiling would not be a pointless formality, because it would raise further defenses, including the fact that [the earlier-filed suit] would now be an additional enumerated source under the public disclosure bar" and the statute of limitations). That would not only frustrate Congress's goal of helping the Government fight fraud, but it would also provide a windfall to defendants in Allergan's position — a particularly perverse outcome, as nothing in the text or history of the first-to-file rule suggests that it was intended to benefit FCA defendants as opposed to the conscientious relator and, by extension, the Government.[15] All of which points to a question posed by the Supreme Court in *Carter*: "Why would Congress want the abandonment of an earlier suit to bar a later potentially successful suit that might result in a large recovery for the Government?" 135 S. Ct. at 1979. The answer is that it would not.

In the final analysis, the strongest — perhaps the only — support for Allergan's view that a violation of the first-to-file requires dismissal without prejudice is the plain language of the statute. As the *Shea* Court reasoned: "The first-to-file bar prohibits bringing a 'related *action*,' not a related *complaint*. . . . No matter how many times [a later-filing relator] amends his Complaint, it will still be true that he 'br[ought] a related action based on the facts underlying the [then] pending action.'" 160 F. Supp. 3d at 30 (emphasis omitted). Admittedly, that reasoning is not without force — as the Supreme Court recently reaffirmed, "courts must give effect to the clear meaning of statutes as written." *Star Athletica, L.L.C. v. Varsity Brands, Inc.*, — U.S. —, No. 15-866, 2017 WL 1066261, at *7 (U.S. Mar. 22, 2017). But the plain language here gets one only so far. That is, it may compel the conclusion that Wood violated the first-to-file rule by

---

[15] Of course, the Government itself could always file suit, as the first-to-file rule does not apply to a later Government-filed action. *See* 31 U.S.C. § 3730(b)(5). But that is no answer, as there are many reasons that the Government might decline to bring suit in its own name and the statutory scheme contemplates "a coordinated effort of both the Government and the citizenry." S. Rep. No. 99-345, at 2, *as reprinted in* 1986 U.S.C.C.A.N. at 5267.

filing this action when *Lampkin* was "pending," but it does not necessarily follow that dismissal is *now* the required remedy for that violation given that the rule "ceases to bar" a suit "once [the earlier-filed suit] is dismissed." *Carter*, 135 S. Ct. at 1978. In other words, neither the plain language of Section 3730(b)(5) nor the Supreme Court's decision in *Carter* answers the *procedural* question of what do when, as here, a relator unwittingly violated the first-to-file bar, but the bar no longer applies. *See, e.g.*, *Cephalon*, 159 F. Supp. 3d at 556 ("The Supreme Court in *Carter* did not mandate a procedural outcome for second-filed suits whose first-filed counterparts have been dismissed; it only agreed with the Fourth Circuit that the lower court's dismissal with prejudice was in error."); *see also, e.g.*, *Medco Health*, 2017 WL 63006, at *11 (observing that "*Carter* did not resolve" the "procedural" issue of what to do where "a first-filed action was pending at the time the second action was filed, but is no longer pending").

In sum, the Court concludes (1) that the first-to-file rule is non-jurisdictional and (2) in light of that, as well as the text, purpose, and structure of the FCA, that a violation of the rule is curable through the filing of an amended or supplemental complaint after the earlier-filed action was dismissed. Here, Wood did just that, as he filed the Third Amended Complaint on May 23, 2016, after *Lampkin* (and *Caryatid*) had been dismissed.[16] Under these circumstances, "it would

[16] Admittedly, the Third Amended Complaint does not contain any factual allegations relating to dismissal of the earlier-filed actions. But the Court is not aware of any authority requiring a relator to affirmatively plead the absence of a pending earlier-filed suit to proceed (a point that arguably reinforces the conclusion that the first-to-file rule is non-jurisdictional). *But see Gadbois*, 809 F.3d at 8 (remanding to allow the relator to file a supplemental complaint pursuant to Rule 15(d) to cure a first-to-file jurisdictional defect). In any event, the Court has — at Allergan's request — taken judicial notice of the dockets in *Lampkin* and *Caryatid*. (Docket No. 106). Moreover, had Wood moved to supplement his complaint pursuant to Rule 15(d), the Court would have granted the motion, and would do so now if he were to so move. *See, e.g.*, 6 Wright & Miller, Fed. Prac. & Proc. Civ., § 1504 ("An application for leave to file a supplemental pleading is addressed to the discretion of the court and should be freely granted when doing so will promote the economic and speedy disposition of the entire controversy between the parties, will not cause undue delay or trial inconvenience, and will not prejudice the rights of any of the other parties to the action." (footnotes omitted)); *see also, e.g.*, *Town of New Windsor v. Tesa Tuck, Inc.*, 919 F. Supp. 662, 678 (S.D.N.Y. 1996) ("[A]n increase in defendants' exposure is not grounds for denying leave to amend."). Under the circumstances, it

be a pointless formality" to dismiss the action. *Gadbois*, 809 F.3d at 6. In fact, it would be worse than a pointless informality, as it would — in light of the passage of time — effectively immunize Allergan from liability for what the Court must assume here was fraud. For the reasons stated above, the Court concludes that the law does not require that perverse result.[17]

C. Statute of Limitations

Before turning to the substance of Wood's FCA claims, one last thorny procedural issue remains: whether and to what extent those claims are time barred. The FCA's statute of limitations is set forth in Section 3731(b), which provides as follows:

> (b) A civil action under section 3730 may not be brought —
>
> (1) more than 6 years after the date on which the violation of Section 3729 is committed, or
>
> (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed,
>
> whichever occurs last.

---

would be a pointless exercise to require Wood to file an amended or supplemental complaint to "cure" the first-to-file violation. Instead, the Court treats the Third Amended Complaint (aided by the materials of which the Court has taken judicial notice) as having done so.

[17] As the Court suggested at oral argument on Allergan's motion (Tr. 79-80), there is a strong argument to be made for certifying an interlocutory appeal from the Court's ruling on the "first-to-file" issue. After all, the issue seems to involve "a controlling question of law"; in light of the divide among federal courts, there is plainly a "substantial ground for difference of opinion"; and an immediate appeal from the order would "materially advance the ultimate termination of the litigation" if the Second Circuit were to reverse. 28 U.S.C. § 1292(b); *see, e.g.*, *Atlantic Holdings, Inc. v. Sovereign Wealth Fund Samruk-Kazyna JSC*, 12-CV-8852 (JMF), 2014 WL 1881075, at *1-2 (S.D.N.Y. May 9, 2014) (discussing the relevant standards). On the other hand, an appeal would obviously involve further delay in a case that has already seen its fair share of delay — and could prejudice Wood to the extent the statutes of limitations would continue to run during an appeal. The parties should promptly meet and confer to discuss whether an interlocutory appeal would be appropriate (and, perhaps, whether the statute of limitations should be tolled during the pendency of any appeal).

31 U.S.C. § 3731(b). Ordinarily, the statute of limitations is "an affirmative defense that must be raised in the answer." *Ellul v. Congregation of Christian Bros.*, 774 F.3d 791, 798 n.12 (2d Cir. 2014). It is well established, however, that "a statute of limitations defense may be decided on a Rule 12(b)(6) motion if the defense appears on the face of the complaint." *Id.* (citing *Staehr v. Hartford Fin. Servs. Grp., Inc.*, 547 F.3d 406, 425 (2d Cir. 2008)).

For better or for worse, the parties' dispute once again requires consideration of a complex issue that the Second Circuit has not yet addressed and upon which other courts are divided: namely, whether a relator, such as Wood, can avail himself of the potentially longer statute of limitations set forth in subsection (b)(2) or is limited to the six-year period set forth in subsection 3731(b)(1). Some courts have held that "Congress intended Section 3731(b)(2) to extend the FCA's default six-year period only in cases in which the government is a party." *United States ex rel. Sanders v. N. Am. Bus. Indus., Inc.*, 546 F.3d 288, 293 (4th Cir. 2008); *Regence Bluecross Blueshield of Utah*, 472 F.3d at 725; *United States ex rel. Griffith v. Conn*, 117 F. Supp. 3d 961 (E.D. Ky. 2015). Others have concluded that Congress "intended the tolling provision [in subsection (b)(2)] to apply to *qui tam* plaintiffs as well." *United States ex rel. Hyatt v. Northrop Corp.*, 91 F.3d 1211, 1216 (9th Cir. 1996); *accord United States ex rel. Malloy v. Telephonics Corp.*, 68 F. App'x 270, 272-73 (3d Cir. 2003); *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 474 F. Supp. 2d 75, 85 (D.D.C. 2007). And within the latter camp, there is a further divide: Some courts have held that the potentially longer statute of limitations "runs from the date the [*relator*] knew or reasonably should have known of the facts material to the right of action," *Hyatt*, 91 F.3d at 1213 (emphasis added); *accord United States ex rel. Bidani v. Lewis*, No. 97-CV-6502, 1999 WL 163053, at *9 (N.D. Ill. Mar. 12, 1999), while others look to the knowledge of the applicable "'*official* of the United States charged with responsibility to act in the circumstances,'" *Pogue*, 474 F. Supp. 2d at 85 (emphasis added); *accord United States ex rel. Kreindler & Kreindler v. United Techs. Corp.*, 777 F. Supp. 195

(N.D.N.Y. 1995); *United States ex rel. Colunga v. Hercules Inc.*, No. 89-CV-954B, 1998 WL 310481 (D. Utah. Mar. 6, 1998).[18]

Although there are strong arguments on both sides of this divide, the Court finds the thorough and well-reasoned textual analysis of Judge Lamberth in *Pogue* most convincing. *See* 474 F. Supp. 2d at 84-85. As Judge Lamberth explained, because the major clause of the statute ("A civil action under section 3730 may not be brought . . .") does not differentiate between actions brought by the Government and actions brought by relators, "it applies to both" and "[a]ny exclusionary language therefore must be found in the subordinate clauses." *Id.* at 84. Subsection (b)(2), however, "does not contain any negative words or words of exclusion." *Id.* And while it does refer to "official of the United States," there are "countless ways for Congress to have *explicitly* excluded relators, any of which would have been clearer and more grammatically appealing" than reading the phrase "official of the United States" to *implicitly* exclude relators. *See id.* at 84-85. Moreover, structurally, "subsection (b) opens by including all FCA plaintiffs, and closes with the clause 'whichever occurs last,' indicating that (b)(1) and (b)(2) are to be read together. . . . If subsection (b)(2) applies only to the United States — meaning that only the six-year period can apply to relators in declined cases — then the need to pick 'whichever occurs last' also applies only to (b)(2), and should appear only as part of that

[18] There is yet another question upon which courts have disagreed, albeit one that does not matter here: To the extent that it is the government official's knowledge that controls, does the phrase "official of the United States charged with responsibility to act" refer solely to the Attorney General (or his designee) or to a broader swath of federal officials? *Compare, e.g.*, *Kreindler & Kreindler,* 777 F. Supp. at 204-05 (holding that knowledge of senior army officials in charge of the Black Hawk helicopter project was sufficient to trigger the three-year filing window), *aff'd on other grounds,* 985 F.2d 1148 (2d Cir.), *with United States v. Incorporated Village of Island Park*, 791 F. Supp. 354, 362 (E.D.N.Y. 1992) (interpreting "the official charged with responsibility to act" as "an official within the Department of Justice with the authority to act in the circumstances"). This Court has held that the phrase refers to "the Attorney General (or his designee within DOJ)." *Wells Fargo*, 972 F. Supp. 2d at 608.

clause." *Id.* at 85. It does not. Thus, "the statute says what it says, and it says that (b)(2)'s three-year statute of limitations applies across the board." *Id.*

The plain language of Section 3731 is enough to settle the matter, but Judge Lamberth's interpretation has the added advantage of advancing the FCA's purposes by sometimes giving relators more time to seek recovery on behalf of the Government. *See id.* at 87-88. The cases that conclude otherwise "most frequently cite one concern as the moving force behind their decisions: that would-be relators will 'sleep on their rights,' sit back, and watch false claims build up, perhaps all the way to the ten-year limit." *Id.*; *see, e.g.*, *Griffith*, 117 F. Supp. 3d at 986 (citing that concern). That, in turn, "would render the six-year limitations period superfluous in nearly all FCA cases." *Griffith*, 117 F. Supp. 3d at 986 (internal quotation marks omitted). But these concerns are misplaced. For one thing, the period prescribed by subsection (b)(2) is not fixed and, in some cases, may be shorter than six years; in those cases, subsection (b)(1) would continue to have independent force. Second, as discussed above, the FCA contains several other provisions — most notably, the public disclosure bar and the first-to-file rule — that incentivize relators with valuable claims to bring them quickly. That is, "[a] potential relator has no rights on which to sleep — if he chooses to let claims build up instead of taking early action, he may find that his recovery is reduced by the FCA's [public disclosure] provision, or foreclosed all together by the fact that the government or a more diligent would-be relator brings suit first." *Pogue*, 474 F. Supp. 2d at 88. To put it bluntly, the prospect of the sleeping relator "is too implausible to provide a justification for tweaking the straightforward words of a statute." *Id.*

Admittedly, Judge Lamberth's reading of the text creates an odd result, as a relator's statute of limitations may "turn on the knowledge of a government official — knowledge that the relator would often never be able to discover." *Griffith*, 117 F. Supp. 3d at 985.[19] But that is not

[19] Of course, reading "official of the United States" in subsection (b)(2) to include a relator would avoid this odd result. But that reading is, to put it mildly, hard to square with the plain

a good enough reason to disregard the plain language of the statute, particularly given the unusual — some might say odd — features of the FCA's *qui tam* provisions generally, in which relators stand in the shoes of the Government. (For similar reasons, there is little reason to look for guidance to the mere two other provisions in the United States Code where Congress employed similar language and made clear that the person whose knowledge is relevant is the "the same as, or a part of, the individual or entity bringing suit." *Id.* (citing 15 U.S.C. § 78u-6(h)(1)(B)(iii)(I)(bb) and 28 U.S.C. § 2416(c)). If anything, the existence of those provisions cuts the other way, as they make clear that Congress could have drafted Section 3731(b)(2) to expressly exclude relators if it had wanted to do so.) Moreover, "odd" results flow from *any* reading of Section 3731. For example, if subsection (b)(2) does not apply where a relator proceeds alone, "then the government gets to decide what the statute of limitations will be: six years under § 3731(b)(1) if the government declines to intervene, or as much as ten years under § 3731(b)(2) if the government intervenes and tolling applies." *Pogue*, 474 F. Supp. 2d at 88. What is more, given that the Government retains the right to intervene at any time upon a showing of good cause, *see* 31 U.S.C. § 3730(b)(3), the statute of limitations could expand by as much as four years well into litigation of a case. Such "outcomes are antithetical to the purposes of statutes of limitations and repose, which seek in part to afford some measure of predictability and finality to litigation." *Pogue*, 474 F. Supp. 2d at 88; *see also City of Pontiac Gen. Emps.'*

---

language of the statute. *See Pogue*, 474 F. Supp. 2d at 85; *see also Griffith*, 117 F. Supp. 3d at 985 n.5 (noting that the courts interpreting Section 3731(b)(2) to apply to relators and to run from the relator's own knowledge have "depart[ed] the furthest from the statutory text"). The Court need not rule on the issue here, however, as there is no evidence that the Court may consider suggesting, let alone showing, that the Government learned about the alleged fraud before 2008, when the *Lampkin* relator provided the information contained in her complaint to the United States. (*See Lampkin* Compl. ¶ 9). Similarly, there is no evidence that the Court may consider suggesting, let alone showing, that Wood learned of the alleged fraud before 2008, when he started working at Allergan. (Third Am. Compl. ¶ 18).

Ret. Sys. v. MBIA, Inc., 637 F.3d 169, 175 (2d Cir. 2011) ("[A] statute of limitations is intended to prevent plaintiffs from unfairly surprising defendants by resurrecting stale claims.").

Accordingly, the Court concludes that Wood may avail himself of the potentially longer statute of limitations in Section 3731(b)(2). That does not settle the matter, however, as the parties also dispute whether the relevant complaint for purposes of assessing timeliness is Wood's original complaint (filed on July 26, 2010) or the Third Amended Complaint (filed on May 23, 2016), the first complaint filed after *Lampkin* was dismissed. (*Compare* Allergan Mem. 27, *with* Wood Opp'n 26-27). Wood argues that the Third Amended Complaint "relates back" to the date of the original complaint pursuant to Rule 15(c)(1)(B) because it "asserts a claim or defense that arose out of the conduct, transaction, or occurrence set out — or attempted to be set out — in the original pleading." (Wood Opp'n 27).[20] But there is a potential wrinkle in that argument: The "touchstone" of the Rule 15(c)(1)(B) inquiry is whether the original pleading put the defendant on notice of the relevant claims, *see United States v. The Baylor Univ. Med. Ctr.*, 469 F.3d 263, 270 (2d Cir. 2006); *see also United States ex rel. Kirk v. Schindler Elevator Corp.*, 926 F. Supp. 2d 510, 518-19 (S.D.N.Y. 2013), and the defendant in an FCA action brought by a *qui tam* relator is often not put on notice by the original complaint because it must be filed under seal, *cf. Baylor Univ. Med. Ctr.*, 469 F.3d at 270 (observing that "[t]he secrecy required by [Section] 3730(b) is incompatible with Rule 15(c)(2)," which governs notice to the United States, "because (as is well-settled) the touchstone for relation back pursuant to Rule 15(c)(2) is notice, *i.e.*, whether the original pleading gave a party 'adequate notice' . . . .").

---

[20] Wisely, Wood does not rely on Rule 15(c)(1)(A), which provides that an amended complaint relates back when "the law that provides the applicable statute of limitations allows relation back." The FCA includes an explicit relation-back provision for pleadings by the Government. *See* 31 U.S.C. § 3731(c). In light of that provision, most courts agree that relators cannot rely on Rule 15(c)(1)(A). *See, e.g.*, *United States ex rel. Miller v. Bill Harbert Int'l Const., Inc.*, 608 F.3d 871, 883 (D.C. Cir. 2010); *Hayes v. Dep't of Educ. of City of N.Y.*, 20 F. Supp. 3d 438, 449-50 (S.D.N.Y. 2014).

Substantially for the reasons stated by Judge Failla in *Hayes v. Dep't of Educ. of the City of New York*, 20 F. Supp. 3d 438, 444 (S.D.N.Y. 2014), however, the Court concludes that that makes no difference to the analysis. As Judge Failla explains, "[a] relator may commence a *qui tam* action unilaterally, 31 U.S.C. § 3730(b)(1), but after the action is brought cannot influence when the complaint is ultimately unsealed, *id.* § 3730(b)(3). . . . There is no valid reason to punish an otherwise diligent relator by stripping away claims when the Government, not the relator, is to blame for preventing the defendant from receiving notice of the action against it." *Hayes*, 20 F. Supp. 3d at 444; *see also United States ex rel. Ramadoss v. Caremark Inc.*, 586 F. Supp. 2d 668, 700 (W.D. Tex. 2008) ("Thus, the critical date for statute of limitations purposes for a relator is when the relator files a complaint."), *reversed in part by United States v. Caremark, Inc.*, 634 F.3d 808 (5th Cir. 2011); *United States ex rel. Cericola v. Fed Nat. Mortgage Assoc.*, 529 F. Supp. 2d 1139, 1150-51 (C.D. Cal. 2007) (same).[21] Thus, the Third Amended Complaint relates back to the original complaint — and the relevant date for statute-of-limitations purposes is July 26, 2010 — if it "asserts a claim . . . that arose out of the conduct, transaction, or occurrence set out . . . in the original pleading," without regard for the fact that the original pleading was sealed. Fed. R. Civ. P. 15(c)(1)(B); *see Henderson v. United States*, 517 U.S. 654, 657 n.2 (1996) ("In a suit on a right created by federal law, filing a complaint suffices to satisfy the statute of limitations."). The Third Amended Complaint plainly meets that test, as it asserts the same claims as the original complaint and differs only insofar as it expands and modifies the facts alleged in the earlier pleading. *See, e.g.*, *Slayton v. American Exp. Co.*, 460 F.3d 215, 228 (holding that "[w]here the amended complaint does not allege a new claim but renders prior allegations more definite and precise, relation back occurs" and citing cases); *see*

[21] Indeed, the strength of that reasoning is underscored by the facts of this very case: Wood diligently filed his complaint in July 2010, but the complaint remained sealed — for reasons entirely out of Wood's hands — for nearly six years, until March 2016, when the Government finally completed its investigation and declined to intervene. (Docket Nos. 24, 26).

also 6A Wright & Miller, *Fed. Prac. & Proc. Civ.* § 1497 (noting that "amendments that do no more than restate the original claim with greater particularity or amplify the details of the transaction alleged in the proceeding fall within Rule 15(c)(1)(B)" and citing cases).

Notably, Allergan does not really argue otherwise. Instead, invoking the first-to-file rule, it effectively asks the Court to treat the original complaint (and first two amended complaints) as a legal nullity, to which the Third Amended Complaint — the first pleading that arguably complied with the first-to-file rule — could not relate back. (Allergan Mem. 27-28; Allergan Reply 18-19). In support of that request, Allergan cites *Cephalon* and *Makro Capital of Am., Inc. v. UBS AG*, 543 F.3d 1254 (11th Cir. 2008), but neither decision is persuasive. In the former, the Court did treat the relator's amended complaint as "the operative complaint for measuring the applicable six-year statute of limitations" on the ground that his earlier complaints did not "survive the first-to-file bar." 159 F. Supp. 3d at 561. But the Court did so without analysis; it failed to cite, let alone discuss, Rule 15 or the "relation back" doctrine. Moreover, the Court's action is tainted by the fact that it viewed the first-to-file rule as jurisdictional in nature. *See id.* at 554, 557. After all, as discussed above, courts tend to be more parsimonious in allowing amendment to cure jurisdictional defects traceable to the time of filing. *Makro Capital*, on the other hand, examined whether an amended *qui tam* complaint could relate back an original, non-*qui tam* complaint under Rule 15(c)(1)(C) where the original complaint was jurisdictionally defective under the since-eliminated "government knowledge" bar. 543 F.3d at 1258. Additionally, the *Makro Capital* Court focused on the defendant's lack of notice and knowledge under Rule 15(c)(1)(C), concerns heightened by the fact that the United States had been a co-defendant in the earlier non-*qui tam* action but was the plaintiff in the *qui tam* action. *See id.* at 1259. Finally, the Court observed that "[p]ermitting relation back to a non-*qui tam* claim would thus defeat the purpose" of the FCA's *qui tam* provisions "by allowing multiple

private suits in situations where the government has chosen not to act." *Id.* at 1260. None of those considerations applies here.

By contrast, at least two courts have considered and rejected precisely the argument that Allergan is making here. *See Richards v. City of Bangor, Me.*, 878 F. Supp. 2d 271, 280-281 (D. Me. 2012); *Vaz v. United Airlines Corp.*, No. 11-CV-3816 (JBW), 2011 WL 6019012, at *2 (E.D.N.Y. Nov. 30, 2011). In *Vaz*, for example, the defendant argued that the plaintiff's claims were time barred because even if her "amended complaint is deemed to relate back, her first complaint . . . was barred by the election of remedies doctrine and therefore was a nullity as it was not viable from the state." *Id.* Judge Weinstein characterized that argument as "conceptually intriguing" but "without merit," observing that the defendant could cite "no cases" to "support [the] curious proposition" that Rule 15 was "to be without effect in a case such as this." *Id*. In so holding, he court emphasized that the Federal Rules are "merits-oriented" and "should, if possible, not frustrate a decision on the merits." *Id.* The *Richards* Court reached a similar conclusion, flatly rejecting the argument that relation back for purposes of the statute of limitations cannot occur if the original pleading was defective. *See* 878 F. Supp. 2d at 280-81. Like Judge Weinstein, the Court noted that the defendant had not cited any authority for the proposition that a defect in an original complaint renders the complaint "nonexistent" for purposes of Rule 15. "[T]he original complaint and all of its factual allegations," the Court declared, "clearly 'existed,' whether or not" it was defective at the time of filing. *Id.* at 281; *cf. Green Mountain Realty Corp.*, 2010 WL 1461590, at *2 ("The instant case presents a wrinkle on [Rule 15] in that the original complaint was itself unripe. Defendants contend there can be no relation back to a complaint that was itself not properly filed. However, they cite no authority for that proposition.").

Thus, the Court holds that — even though Wood's original complaint was defective under the first-to-file rule — Rule 15 should be applied in the normal course and that the Third

Amended Complaint relates back to the original complaint for statute-of-limitations purposes. In light of that, and the Court's conclusion above that Wood may avail himself of the potentially (and, here, likely) longer statute of limitations set forth in Section 3731(b)(2), none of Wood's FCA claims may be dismissed at this stage as time barred.

D. The Anti-Kickback Statute

At long last, the Court can turn to the first merits-related issue: Allergan's argument that Wood fails to allege a predicate violation of the AKS. The AKS prohibits offering, paying, soliciting, or receiving "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind . . . in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(1)(A). The statute requires intent to induce a referral or recommendation through the use of "remuneration," which is defined as "transfers of items or services for free or for other than fair market value." *Id.* §§ 1320a-7b(b)(2), 1320a-7a(i)(6). Courts have interpreted "remuneration" expansively to include "anything of value in any form whatsoever." *United States v. The Health All. of Greater Cinn.*, No. 03-CV-0167, 2008 WL 5282139, at *7 (S.D. Ohio Dec. 18, 2008); *see also OIG Anti-Kickback Provisions*, 56 Fed. Reg. 35952, 35958 (July 29, 1991) ("Congress's intent in placing the term 'remuneration' in the statute in 1977 was to cover the transferring of anything of value in any form or manner whatsoever.").

Notably, to prove a violation of the AKS, one need not prove that the primary or sole purpose of the remuneration was to induce the referral of patients or the recommendation of items or services; it is enough if that was "one purpose" of the remuneration. *See, e.g.*, *United States v. McClatchy*, 217 F.3d 823, 835 (10th Cir. 2000) (noting that every circuit to consider this issue has adopted the "one purpose" test); *United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985) ("If the payments were intended to induce the physician to use [the defendant's] services,

the statute was violated, even if the payments were also intended to compensate for professional services."); *see also United States v. Krikheli*, 461 F. App'x 7, 11 (2d Cir. 2012) (summary order) (approving a jury instruction that the defendant could be found guilty under the AKS if the jury found "proof beyond a reasonable doubt that one purpose of the offer or payment" was inducement); *TEVA Pharm.*, 2016 WL 750720, at *17 (following "the Third, Fifth, Seventh, Ninth, and Tenth Circuits" in adopting the "one purpose" test). At the same time, to violate the statute, the remuneration must be directed toward a person or entity "in a position to generate Federal health care program business." *OIG Supplemental Compliance Program Guidance*, 70 Fed. Reg. 4858, 4864 (Jan. 31, 2005); *see United States ex rel. Perales v. St. Margaret's Hosp.*, 243 F. Supp. 2d 843, 852-54 (C.D. Ill. 2003) (finding no AKS violation by a nurse working for a physician who had an illegal referral agreement with a hospital because she had received no remuneration for her referrals).

Here, Wood alleges that Allergan violated the AKS by providing "valuable remuneration to physicians, including a no-cost suite of products and office supplies consisting of large shipments of Allergan drugs, supplies of cataract surgery patient care kits, physician-branded practice-related medical instructions for physicians to provide to patients, and pre-printed physician prescription pads." (Wood Opp'n 12). At first glance, those allegations would seem to clear the plausibility hurdle easily. *See, e.g.*, *OIG Compliance Program Guidance for Pharma. Manu.*, 68 Fed. Reg. 23731-01, 23737 (May 5, 2003) ("Any time a pharmaceutical manufacturer provides anything of value to a physician who might prescribe the manufacturer's product, the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent to induce or reward referrals."). But Allergan argues otherwise on two grounds. First, Allergan contends that the provision of free drug samples and patient care kits containing free drug samples was authorized by the PDMA. More specifically, Allergan contends that, in light of the PDMA, drug samples ultimately passed along to patients have no

monetary value to physicians (unless physicians are unlawfully selling the samples, which is not alleged here), and so by definition cannot constitute remuneration. (Allergan Mem. 12-14). Second, Allergan contends that the supplies such as patient instruction sheets and pre-printed prescription pads were of "nominal" value and benefited patients rather than physicians — removing them from the realm of remuneration. (Allergan Mem. 15-17). The Court considers each argument in turn.

1. Drug Samples and Patient Care Kits

Allergan's first argument — that the free drug samples sent by Allergan do not qualify as remuneration because they were passed on to patients and thus had no "independent value" to the physicians themselves (Allergan Mem. 12-14) — falls short at this stage of the case. Beginning as early as 2003, Allergan provided customizable customer care kits to ophthalmologists who agreed to prescribe or already prescribed Allergan drugs. (Third Am. Compl. ¶¶ 136-161). These kits included "a 'trade-sized, 10 ml sample of Pred Forte, which was quantity sufficient for an entire pre- and post-surgical regime of care; a sample of Acular/Acular LS/Acuvail; a sample of Zymar/Zymadid; a sample of Optive or Refresh artificial tears; protective sunglasses for post-surgical use; a protective eye shield; tape and gauze to construct a protective eye patch; and an over-the-counter analgesic such as Tylenol or Advil." (*Id.* ¶ 137). In this manner, Allergan provided millions of free drug samples to doctors between 2003 and 2008. (*See id.* ¶ 148). And after Allergan stopped distributing the kits in late 2008, the company continued to provide free drug samples through sample shipment agreements with physicians until June 2010 — again providing millions of samples per year to ophthalmologists who agreed to prescribe or already prescribed significant quantities of Allergan drugs. (*See id.* ¶¶ 172-185).

Allergan's argument is not without some force given the language of the PDMA and the Office of Inspector General's Guidelines, *see OIG Compliance Program Guide*, 68 Fed. Reg. at 23739 (noting that drug samples "may not be sold or billed (thus vitiating any monetary value of

the sample)"), but it ultimately goes too far. Cataract surgery is the most frequently performed surgical procedure among Medicare beneficiaries, with almost 1.35 million operations performed annually (resulting in $3.5 billion in costs). (Third Am. Compl. ¶ 113). Medicare, however, reimburses ophthalmologists using a flat rate per surgery (approximately $900 per eye). (*Id.*¶ 116). Moreover, Medicare "does not cover any eye drop drugs that are provided and administered to the patient the day of surgery, including in the pre-operative holding area, intra-operatively, or in the post-operative recovery," as the Medicare reimbursement provisions expressly "exclude eye drops administered before cataract surgery." (*Id.* ¶ 119). The drugs provided by Allergan in the customer care kits and via shipment agreements included drugs like Pred Forte, a topical steroid that is applied pre- and post-operatively. (*See id.* ¶ 45). Taken together, then, Allergan's provision of free drug samples (specifically, eye drop drugs that are administered prior to surgery and thus not reimbursable under Medicare) could plausibly have subsidized surgical costs, increasing ophthalmologists' profit per surgery. (*Id.* ¶ 121). Such profit maximization can constitute remuneration under the AKS. *See, e.g.*, *United States ex rel. Witkin v. Medtronic*, *Inc.*, 189 F. Supp. 3d 259, 270 (D. Mass. 2016) ("[E]ven a physician *legitimately* billing Medicare for properly-supervised iPro clinic services has received remuneration when he otherwise would have had to expend additional money or time to administer the services himself or pay staff to do so."). As the OIG Guidelines themselves note, "if goods or services provided by the manufacturer eliminate an expense that the physician would have otherwise incurred (i.e., have independent value to the physician) . . . the arrangement may be problematic if the arrangement is tied directly or indirectly to the generation of federal health care program business for the manufacturer." 68 Fed. Reg. at 23737.

At a minimum, Wood's allegations raise a question of fact — whether ophthalmologists would otherwise have had to cover the costs of these drugs, thus lowering their profits per surgery — not suitable for resolution at the motion to dismiss stage. *See Ameritox, Ltd. v.*

Millenium Labs, Inc., 20 F. Supp. 3d 1348, 1356 (M.D. Fla. 2014) ("[T]o the extent that the doctors could bill for the POC testing done using a POCT cup and agreed to forego the opportunity to bill for it, the Court concludes that the jury must determine whether [the defendant's] provision of free POCT cups under those circumstances constitutes remuneration under the [AKS]."); *Ameritox, Ltd. v. Millenium Labs, Inc.*, No. 11-CV-776 (TBM), 2015 WL 1169403, at *2 (M.D. Fla. March 13, 2015) ("The jury rejected [the defendant's] argument that the free POCT cups were not an improper inducement for referrals. Instead, the jury credited the evidence that [the plaintiff] presented that many of the doctors with cup agreements could not bill for the POC testing, so those doctors were not giving up anything in exchange for the free POCT cups," constituting "a violation of the AKS." (footnote omitted)). On that score, the OIG Guidelines themselves make clear that free drug sample arrangements can violate the AKS if certain factors — some of which are alleged here — are present. *See OIG Compliance Program Guidance*, 68 Fed. Reg. at 23737 (listing as risk factors that the physician has a large degree of influence on the generation of business for the manufacturer, that the remuneration was given only to doctors who have prescribed or agreed to prescribe the manufacturer's product, that the remuneration was conditioned in whole or in part on prescriptions of Allergan drugs, and that acceptance of the remuneration could diminish or appear to diminish the objectivity of professional judgment). It follows that the Court cannot say as a matter of law, let alone at this stage of the litigation, that Allergan's provision of millions of free drug samples to cooperating physicians did not constitute "remuneration."[22]

---

[22] At oral argument, Wood and the Government pressed an alternative theory of AKS liability based on the PDMA's definition of "drug sample" as "a unit of a drug . . . intended to promote the sale of *the* drug." 21 U.S.C. § 353(c)(1) (emphasis added); *see also* S. Rep. No. 100-303, at 2-3 (1988) (noting that the PDMA was meant to "acquaint the practitioner with the therapeutic value of the medication and thus encourage the written prescription of *the* drug" (emphasis added)). Allergan's conduct, Wood and the Government argued (Tr. 60, 74-75), did not fall within the scope of the PDMA's exemption because it provided samples of certain drugs to induce the prescription of *other* drugs. (*See, e.g.*, Third Am. Compl. ¶ 128 ("Area Manager

2. Patient Instruction Sheets and Prescription Pads

Allergan's argument concerning the patient instruction sheets and pre-printed prescription pads can be more swiftly dispatched. Wood alleges that Allergan provided physicians who prescribed its drugs with customizable patient instruction sheets and customizable, pre-printed prescription pads. (Third Am. Compl. ¶¶ 209-215). Physicians were able to design the sheets and pads, with Allergan covering all printing and shipping costs. (*See id.*). These supplies undoubtedly had monetary value (a standard order of twenty prescription pads, for example, cost $53 (*id.* ¶ 214)). In arguing otherwise, Allergan contends that the supplies lacked any marketing utility as they were provided to patients *after* their surgeries and that the prescription pads could be used only to prescribe Allergan drugs — eliminating any independent value to physicians. (Allergan Reply 9-10 & n.17). But the Third Amended Complaint alleges that these patient instruction sheets were "generally regard[ed]" as a "necessity," raising the plausible inference that physicians would otherwise have had to cover printing and shipping costs themselves. (Third Am. Compl. ¶ 209). And, with respect to the prescription pads, Allergan provided these goods only to ophthalmologists who agreed to prescribe its drugs (rather than its competitor's drugs), again raising the plausible inference that physicians would otherwise have had to purchase their own prescription pads — or certainly that they would have to purchase general prescription pads more often. (*See id.* ¶¶ 212-215). Moreover, the fact that physicians consistently designed and ordered these supplies on Allergan's dime is evidence that they viewed them as having value. (*See id.* ¶¶ 213-217). The provision of these free, customizable supplies over the course of nearly a decade is easily distinguished from goods that have otherwise been found to be of "nominal" value in this context. *See OIG Compliance Program Guidance for Ambulance Supplies*, 68 Fed. Reg. 14245-

---

. . . instructed sales representatives to 'Leverage Pred-Forte!!!!!!!!!!' in order to drive sales of Acular LS.")). The Court need not address the viability of that theory here.

02, 14252 (March 24, 2003) ("[T]oken gifts used on an occasional basis to demonstrate good will or appreciation (e.g., logo key chains, mugs, or pens) will be considered nominal in value"); *see also OIG Advisory Opinion*, No. 04-16, 2004 WL 5701861, at *4 (Nov. 24, 2004) ("[T]he free services and supplies may be viewed, functionally, as a price reduction or discount . . . in exchange for [] referral[s]."). At this stage, then, Wood plausibly alleges violations of the AKS, and Allergan's motion to dismiss on that basis is therefore denied.

E. The False Claims Act

With that, the Court can finally turn to the substantive crux of this case: whether Wood has, as a matter of law, alleged violations of the FCA. The focus of the FCA has always been "on those who present or directly induce the submission of false or fraudulent claims" to the Government. *Escobar*, 136 S. Ct. at 1996. To that end, the Act imposes liability for, among other things, "knowingly" presenting or causing to be presented, a false or fraudulent claim "for payment or approval," 31 U.S.C. § 3729(a)(1)(A), and "knowingly" making, using, or causing to be used "a false record or statement material to [such] a false or fraudulent claim," 31 U.S.C. § 3729(a)(1)(B). In *Mikes*, the Second Circuit laid out the elements required to impose liability under these provisions: A relator must show that the defendant (1) made a claim, (2) to the United States government, (3) that is false or fraudulent, (4) knowing of its falsity, and (5) seeking payment from the federal treasury. *See* 274 F.3d at 695. Additionally, the Act imposes liability where a defendant "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 to the Government." 31 U.S.C. § 3729(a)(1)(G).[23] To prove a claim under that

[23] In 2009, Congress amended several relevant provisions of the FCA, including Section 3729(a)(1)(A) (previously Section 3729(a)(1)), Section 3729(a)(1)(B) (previously Section 3729(a)(2)), and Section (a)(1)(G) (previously Section (a)(3)). *See* Fraud Enforcement and Recovery Act of 2009 ("FERA"), Pub. L. No. 111-21, § 4, 123 Stat. 1617 (2009). These

provision — known as a "reverse false claim" — a relator must show "(1) proof that the defendant made a false record or statement (2) at a time that the defendant had a presently-existing 'obligation' to the government — a duty to pay money or property." *Novartis V*, 43 F. Supp. 3d at 367-68 (internal quotation marks omitted). Finally, to the extent relevant here, the statute provides for liability where the defendant "conspires to commit" a substantive violation. 31 U.S.C. § 3729(a)(1)(C).

Several definitions are in order. The FCA defines a "claim" as "any request or demand . . . for money or property" that "is presented to an officer, employee, or agent of the United States." 31 U.S.C. § 3729(b)(2)(A). The Act also defines "knowing" and "knowingly" to mean that a person has "actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." *Id.* § 3729(b)(1)(A). Finally, the Act defines "material" to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* § 3729(b)(4). By contrast, the Act does not define the terms "false or fraudulent." Instead, the Second Circuit has interpreted those terms to refer to a claim that is "aimed at extracting money the government otherwise would not have paid." *Mikes*, 274 F.3d at 696. False claims, in turn, can fall into two main categories: factually false claims and legally false claims. A claim is factually false where the defendant submitted "an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." *Id.* at 697; *see also Bishop v. Wells Fargo & Co.*, 823 F.3d 35, 43 (2d Cir. 2016) ("[T]he archetypal FCA claim involves a factually false request for payment from the government, as when a contractor delivers a box of sawdust to the military but bills for a shipment of guns."),

---

amendments have no bearing here, so — for simplicity's sake — all citations are to the current version of the FCA. The Court does, however, discuss the import of the FERA amendments when analyzing the parties' Rule 9(b) arguments below.

vacated on other grounds, — U.S. —, 2017 WL 670171 (U.S. Feb. 21, 2017). By contrast, a legally false claim certifies compliance with a particular statute, regulation, or contractual term upon which government payment is conditioned, despite the claimant not having complied with that regulation. *Mikes*, 274 F.3d at 697 ("[A] claim under the Act is legally false only where a party certifies compliance with a statute or regulation as a condition of governmental payment.").

Complicating matters further, legally false claims can be further broken down into two sub-categories: express certification claims and implied certification claims. *See id.* at 697-700. "Express" legal falsity generally arises where "a government program requires participants to submit forms explicitly stating that they have complied with certain statutes. Where the party certifying compliance is, in fact, violating the statute in question, that certification is 'false.'" *TEVA Pharm.*, 2016 WL 750720, at *19-20 (citation omitted); *Mikes*, 274 F.3d at 698. By contrast, the theory of "implied" legal falsity relies on "the notion that the act of submitting a claim for reimbursement itself implies compliance governing federal rules that are a precondition to payment." *Mikes*, 274 F.3d at 699. In *Mikes*, the Second Circuit held that implied certification is "appropriately applied only when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid." *Id.* at 700. In *Escobar*, however, the Supreme Court abrogated that aspect of *Mikes*, concluding that "[s]ection 3729(a)(1)(A) imposes liability on those who present 'false or fraudulent claims' but does not limit such claims to misrepresentations about express conditions of payment." *Escobar*, 136 S. Ct. at 2001.

The Supreme Court's decision in *Escobar* is significant, even if its implications are not yet entirely clear. There, the relators brought an action against a mental health facility after discovering that the facility's practitioners were not licensed to provide mental health treatment under state law. *See id.* at 1997-98. Relying on an implied certification theory, they alleged FCA violations premised on the submission of claims to Medicaid — even though Medicaid

reimbursement was not expressly conditioned on compliance with the violated regulations. *See id.* at 1997-98. The Court affirmed that "the implied false certification theory can, at least in some circumstances, provide a basis for liability." *Id.* at 1999. The Court declined to resolve the broader question of whether "all claims for payment implicitly represent that the billing party is legally entitled to payment," *id.* at 2000, but clarified that "the implied certification theory can be a basis for liability, at least where two conditions are satisfied: first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Id.* at 2001. The Court further explained that the violation need not be of an expressly designated condition for payment; instead, the proper inquiry is whether the misrepresentation was "material to the Government's payment decision." *Id.* at 2002.

The *Escobar* Court emphasized that this materiality standard is "demanding." *Id.* at 2003. The Government's designation that "compliance with a particular statutory, regulatory, or contractual requirement" as a condition for payment does not suffice; nor does the Government's having "the option to decline to pay if it knew of the defendant's noncompliance." *Id.* Moreover, "minor or insubstantial" noncompliance can never be material, as the FCA is not "a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Id.*; *see also id.* at 2001 ("Whether a provision is labeled a condition of payment is relevant to but not dispositive of the materiality inquiry."). Proof of materiality also includes — but is not limited to — "evidence that the defendant knows that the Government consistently refuses to pay claims . . . based on noncompliance with the particular [provision]" or, conversely, evidence that "the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated." *Id.* at 2003-04. After articulating these standards, the Supreme Court vacated the judgment below and remanded for a determination of whether the violated

requirements were "so central to the provision of mental health counseling that the Medicaid program would not have paid the[] claims had it known of the[] violations." *Id.* at 2004.

For present purposes, *Escobar* has several relevant takeaways. First, the Supreme Court did not address the theory of express certification. Thus, there is no reason to believe *Escobar* modified or eliminated existing law (including *Mikes*) pertaining to that theory of falsity. Second, the *Escobar* Court explicitly endorsed the implied certification theory, but addressed only one type of such claims — namely, those involving fraudulent half-truths. *See id.* 2000-01. Accordingly, contrary to the assertions of Allergan and *amicus* PhRMA (Docket No. 84, Ex. 1 ("PhRMA Br."), at 6; Docket No. 99 ("Allergan Final Reply"), at 2-4), *Mikes* also remains good law — and binding on this Court — to the extent it held that falsity may arise from the defendant's submission of a claim for payment that does not include a specific representation about the goods or services provided, coupled with noncompliance with a material payment requirement. *See Mikes*, 274 F.3d at 700.[24] Finally, the *Escobar* Court emphasized that — in lieu of "adopt[ing] a circumscribed view of what it means for a claim to be false or fraudulent"

[24] Allergan and PhMRA suggest that *Mikes* is no longer good law after *Escobar* because the Second Circuit did not "ground" its implied certification analysis "in any principle of common law fraud." (PhRMA Br. at 6; Allergan Final Reply at 2-4). But *Escobar* addressed only the meaning of the term "fraudulent" under the statute, *see* 136 S. Ct. at 1999, and did not categorically hold that all terms in the FCA must be interpreted in accordance with the common law. Absent further guidance from the Supreme Court or the Second Circuit, the Court declines to interpret *Escobar* as silently overruling a wide swath of cases holding that "false" claims can include impliedly certified claims of the sort at issue here. *See, e.g.*, *Mikes*, 274 F.3d at 695-96 (analyzing the definitions of "fraudulent" and "false" separately and holding that "'[f]alse' can mean 'not true,' 'deceitful,' or 'tending to mislead'"). Indeed, absent more definitive guidance, this Court is not free to do so. *See, e.g.*, *Monsanto v. United States*, 348 F.3d 345, 351 (2d Cir. 2003) (noting that district courts and the Second Circuit itself are "required to follow" a Second Circuit decision, even if it is in "tension" with subsequent Supreme Court precedent, "unless and until that case is reconsidered by [the Second Circuit] sitting in banc (or its equivalent) or is rejected by a later Supreme Court decision"); *United States v. Wong*, 40 F.3d 1347, 1373 (2d Cir. 1994) ("[U]ntil the Supreme Court rules otherwise, the district court would be obliged to follow our precedent, even if that precedent might be overturned in the near future.").

— courts should police liability under the FCA through the Act's "rigorous" materiality and scienter requirements. *Escobar*, 136 S. Ct. at 2002.

With these principles in mind, the Court turns to Wood's legal theories of falsity, which the Government has wholeheartedly endorsed in its Statements of Interest. Wood and the Government argue, first, that claims premised on an underlying AKS violation are necessarily "tainted," amounting to *per se* false claims (the "taint theory"). Second, they assert that that the various Medicare and Medicaid provider applications and agreements signed by physicians and pharmacies who were induced by the unlawful kickbacks to subscribe and provide Allergan drugs expressly certify compliance with the AKS (the "express certification theory"). (Wood Opp'n 19-20; Wood Reply 8-9; Gov't SOI 8-15). And third, they contend that the act of submitting a claim for reimbursement itself implies compliance with relevant federal law (the "implied certification theory"). (Wood Opp'n 17-19; Wood Reply 2-12; Gov't SOI 15-16; Gov't Supp. SOI 2-12). Of these, the taint theory is the broadest and most novel. *See TEVA Pharm.*, 2016 WL 750720, at *20 ("declin[ing]" the relator's "invitation" to hold "that any claim tainted by an illegal kickback — or for that matter, any claim submitted in violation of a statute that is a precondition to payment — is *per se* a false claim"). Given that, and given that both Wood and the Government conceded at oral argument that the Court need not address the propriety of that theory if it found that the other theories were viable (Tr. 65-66), the Court begins with the express and implied certification theories of falsity.

1. The PPACA

Before turning to those theories, however, the Court pauses to address one straightforward implication of the PPACA, enacted in 2010. As a result of that statute, the law now provides expressly that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim." 42 U.S.C. § 1320a-7b(g), *as amended by* PPACA, Pub. L. No. 111-148, 124 Stat. 119 (2010); *see Novartis V*, 43 F. Supp. 3d at 364

("[T]he AKS did not 'expressly' state that it was a precondition to payment of claims submitted to federal health care programs prior to March 2010 . . . ."). Putting aside the question of whether that language has a bearing on interpretation of the interplay between the AKS and the FCA before March 23, 2010 — the effective date of the PPACA — it makes plain that Wood's claims are legally sufficient (Rule 9(b) issues aside) to the extent they relate to conduct after that date. Allergan argues that the claims fail nonetheless, because the Third Amended Complaint alleges that the company stopped providing free surgical kits in December 2008 and free drug samples in June 2010. (Allergan Mem. 7 n.4 (citing Third Am. Compl. ¶¶ 136, 185)). Wood alleges violations of the AKS based not only on Allergan's provision of free drug samples, however, but also on its provision of free office supplies — a practice that continued at least until 2011. (*Id.* ¶¶ 208, 217, 251). Accordingly, and because some subset of claims allegedly affected by the free drug samples provided until June 2010 necessarily accrued after March 2010 as well, it is plain that Allergan goes too far. That is, Wood plainly alleges a plausible FCA claim with respect to conduct on or after March 23, 2010.

2. Express Certification

Wood points to several possible bases for express certification here. The first bases relate to Medicare Part D.[25] First, to participate in the Medicare Part D program, all physicians must sign the CMS Provider Agreement forms certifying as follows: "I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to the Federal Anti-Kickback statute and the Stark law)." (Third Am. Compl. ¶ 80 (quoting CMS Form-855I)). This language, moreover, derives from a federal regulation. *See* 42 C.F.R. § 424.510(d)(3); *see also*

[25] Any liability based on the requirements of Medicare Part D would apply only to claims that accrued on or after January 1, 2006, the effective date of the Part D program. *See* Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. 108-173 § 101(a)(2), 117 Stat. 2066, 2071 (2003); *see also* 42 U.S.C. § 1395w-101(a)(2).

United States ex rel. Westmoreland v. *Amgen, Inc.*, 812 F. Supp. 2d 39, 51 (D. Mass. 2011) ("Under 42 C.F.R. § 424.510(d)(3), when a provider signs the Provider Agreement, he or she 'attests that the information submitted is accurate and that [he or she] is aware of, and abides by, all applicable statutes, regulations, and program instructions.'" (alteration in original)).

Wood also alleges that, "when submitting claims data to CMS for payment, Part D plans (and their subcontractors) must certify that the claims data is true and accurate to the best of their knowledge and belief, which includes the absence of any false claims." (Third Am. Compl. ¶ 243 (citing 42 C.F.R. § 423.505(k)(3)). Moreover, those Part D sponsors have agreed to comply with "Federal laws and regulations designed to prevent fraud, waste, and abuse, including but not limited to applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. 3729 *et seq.*), and the anti-kickback statute (section 1128B(b) of the Act)." 42 C.F.R. § 423.505(h)(1). Indeed, CMS regulations require that all subcontracts between Part D plan sponsors and downstream entities, including pharmacies, contain language obligating the pharmacy to comply with all applicable federal laws. *See id.* § 423.505(i)(4)(iv).

These arguments are well founded in case law from this Circuit and beyond. In *TEVA Pharmaceuticals*, for example, Judge McMahon analyzed the CMS Form 855I and concluded that, "while the form itself may be directed at a physician's services (Part B) rather than the provision of medication (Part D), the language of the certification applies to all claims made to Medicare by or at the behest of the physician. The certification under CMS Form 855I is [thus] sufficient to underpin an FCA claim for Medicare Part D reimbursement premised on a violation of the AKS." 2016 WL 750720, at *23; *see also, e.g.*, *McNutt ex rel. United States v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1260 (11th Cir. 2005) ("The government has alleged a valid claim[, as it] has alleged that the [defendants] violated the [AKS]; compliance with the [AKS] is necessary for reimbursement under the Medicare program; and the [defendants] submitted claims for reimbursement knowing that they were ineligible for payments demanded in those claims.");

United States ex rel. Kester v. Novartis Pharma. Corp. (Novartis IV), 41 F. Supp. 3d 323, 337-38 (S.D.N.Y. 2014) ("The AKS is unquestionably one of the 'applicable Federal laws' governing Medicare Part D that is cited in the subcontract certification. . . . Accordingly, subcontracting pharmacies who certify compliance 'with all applicable Federal laws, regulations, and CMS instructions' certify compliance with the AKS. 42 C.F.R. § 423.505(i)(4)(iv). . . . [Thus t]he Government has adequately alleged that all the [relevant drug] claims the pharmacies submitted to Medicare Part D during the course of the kickback scheme were rendered 'false' by the express certifications of AKS compliance that they made in their subcontracts with Part D plain sponsors."); *In re Pharma. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 12, 18 (D. Mass. 2007) ("[T]he Medicare program requires providers to affirmatively certify that they have complied with the Anti-Kickback statute; failure to comply with the kickback laws, therefore, is, in and of itself, a false statement to the government."); *United States ex rel. Smith v. Yale Univ.*, 415 F. Supp. 2d 58, 91 (D. Conn. 2006) ("Medicare Regulations and the CMS [Provider Agreement] expressly provide that certification is a precondition to governmental reimburse. In order to obtain reimbursement and as a condition to governmental payment, providers must certify that they are in compliance with the terms of the [Provider Agreement].").

Allergan's (and PhMRA's) arguments to the contrary are unpersuasive. The company contends that the Medicare Provider Agreement contains "forward-looking statements regarding a provider's agreement to comply, *in the future*, with applicable laws" that are not actionable absent a "then-existing intent not to abide by the pledge." (Allergan Mem. 18). But Allergan's sole support for that argument, *United States ex rel. O'Donnell v. Countrywide Home Loans, Inc.*, 822 F.3d 650, 662 (2d Cir. 2016), involved an allegedly false representation in the underlying contract itself, not in any subsequently submitted claims. *See id.* at 663 ("[T]he Government identified provisions in the [contracts] — and only those provisions — as representations underlying its fraud claim, despite acknowledging that the contracts' execution

pre-dated the alleged scheme to defraud."). Moreover, although *O'Donnell* was initiated as a *qui tam* FCA action, it was ultimately tried by the Government solely for claims under the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 ("FIRREA"), 12 U.S.C. § 1833a. Thus, the Second Circuit's analysis in that case did not relate to the FCA. *See id.* at 652-53; *id.* at 666 ("Because we construe the federal mail and wire fraud statutes to require such proof, consistent with the common law, the Government has not proven the prerequisite violation necessary to sustain an award of penalties under FIRREA."). Here, by contrast, Wood alleges the submission of false claims, premised on underlying AKS violations, even *after* the Medicare Provider Agreements were signed. Precedent in this Circuit supports bringing express certification claims under the FCA in such circumstances. *See TEVA Pharm.*, 2016 WL 750720, at *27 ("I [previously] held that the phrase 'I *agree* to abide by' applicable laws and regulations 'does not predict future behavior; it obligates the provider to behave in a certain manner.'"); *United States ex rel. Kester v. Novartis Pharma. Corp. (Novartis VII)*, No. 11-CV-8196 (CM), 2015 WL 109934, at *20 (S.D.N.Y. Jan. 6, 2015) (noting that "the legion of cases endorsing the use of enrollment agreements" in FCA cases is far more persuasive than a few cases cited "for the proposition that forward-looking promises can never qualify as false certification").

Outside of the Medicare Part D context, however, Wood's claims are on less solid ground. To be eligible for reimbursement under Medicaid, Wood alleges that healthcare providers must "sign and submit to CMS various Provider Applications, Provider Agreements, and Claims Forms that include various certifications of compliance with applicable laws — including the AKS." (Third Am. Compl. ¶ 78). Although these "Medicaid Provider Application[s] var[y] from state to state, the provider typically affirms and undertakes compliance with all applicable state and Federal laws." (*Id.* ¶ 79). Additionally, the standardized Claim Form, Form CMS 1500, used for Medicaid and TRICARE/CHAMPUS (as well as Medicare), requires providers to certify as follows: "I understand that payment and

satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws." (Third Am. Compl. ¶ 82). The problem for Wood, however, is that the Third Amended Complaint fails to identify any express certifications for these claims (a defect that could be construed as a failing on the merits or a failure to meet the heightened pleading standards of Rule 9(b), which are discussed below). *See TEVA Pharm.*, 2016 WL 750720, at *27 (observing "that conclusory allegations that 'many states' require AKS compliance certifications [is] insufficient to state a claim premised on express certification," as a relator "must *identify* the express certification"); *see also Novartis IV*, 41 F. Supp. 3d at 339 ("The Government pleads no facts supporting this general assertion [that many states require express AKS compliance certifications]. Without more, these allegations are insufficient to plead an express false certification."). Similarly, Form CMS 1500, as quoted in the Third Amended Complaint, makes no explicit mention of the AKS. *See TEVA Pharm.*, 2016 WL 750720, at *27 (noting that the CMS 1500 claim form "appears to contain no certification as to compliance with the AKS" and so cannot support an express theory of liability); *see also id.* at *26 (holding that the relators had failed to sufficiently allege express certification of claims relating to TRICARE). Thus, for Wood's non-Medicare Part D claims to survive, he must rely on the implied certification theory. *See, e,g.*, *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 313 (3d Cir. 2011) (considering Medicaid certifications and concluding "we need not decide whether the amended complaint states a claim under an express false certification theory because appellants' allegations in the amended complaint clearly state a claim for relief under an implied false certification theory"); *United States ex rel. Pogue v. Diabetes Treatment Centers of Am.*, 565 F. Supp. 2d 153, 158 (D.D.C. 2008) (finding that the "theory of implied certification is most relevant to this action" involving Medicare and Medicaid claims).

3. Implied Certification

After *Escobar*, liability under the implied certification theory does not require "violation of a contractual, statutory, or regulatory provision that the Government expressly designated a condition of payment." 136 S. Ct. at 2001. Nor does it require a showing that the submitted claims amount to "misleading half-truths," *id.*, as the *Escobar* Court expressly refrained from defining the outer limit of implied certification claims, *see id.* at 2000 (declining to resolve whether "all claims for payment implicitly represent that the billing party is legally entitled to payment"). Read together, then, *Escobar* and *Mikes* stand for the proposition that liability can be predicated on a "false representation of compliance with a federal statute or regulation or a prescribed contractual term," *Mikes*, 274 F.3d at 696, so long as compliance with that regulation is "material" to the Government's payment decision, *see Escobar*, 136 S. Ct. at 2002. Applying that rule in the healthcare context, courts have held that a claimant who requests payment from the Government implies that it has held up its end of the bargain — that is, that it complied with the AKS and other statutes and regulations. As the Third Circuit explained, "to avoid FCA liability under an implied certification theory, participants making claims to the Government under the federal health care programs have to ensure that they are not violating the federal health care laws which they agreed to follow when they entered into contracts with CMS." *Wilkins*, 659 F.3d at 314. Although that "does not require perfect adherence to regulations which are not prerequisites to payments from the Government," it "does require a participant in a federal health care program to refrain from offering or entering into payment agreements which violate the AKS, while making claims for payment to the Government under that program." *Id.* After all, the Government "does not get what it bargained for when a defendant is paid by CMS for services tainted by a kickback." *Id.*

Notwithstanding Allergan and PhRMA's arguments to the contrary, these conclusions align with the text of the statute, *cf. Allison Engine Co. v. U.S. ex rel. Sanders*, 553 U.S. 662, 671

(2008) ("The inclusion of an express presentment requirement in subsection (a)(1), combined with the absence of anything similar in subsection (a)(2), suggests that Congress did not intend to include a presentment requirement in subsection (a)(2)."), and Congress's intent "to reach all types of fraud, without qualification, that might result in financial loss to the Government," *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968); *see also* S. Rep. No. 99-345, at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274 ("The [FCA] is intended to reach all fraudulent attempts to cause the Government to pay ou[t] sums of money or to deliver property or services."). Indeed, the implied certification theory helps to ensure that the Government can still recover for fraud (limited, of course, by *Escobar*'s materiality and scienter requirements) in circumstances where the relevant forms do not require explicit verification that the goods or services are free from illegal influence. *Cf. United States v. Rogan*, 517 F.3d 449 (7th Cir. 2008) ("The district judge gave careful attention to the codes on the records and concluded that the physicians used codes to identify referred patients. [The defendant] could hardly expect the admitting form to read 'patient acquired by kickback' as opposed to some seemingly innocuous notation that those in the know . . . would take as the cue to pay the agreed price to the referring physician."). That will not, as PhRMA hyperbolically claims, result in "federal contractors who file claims for payment without disclosing every instance of regulatory noncompliance" being found to have "automatically commit[ted] fraud against the government." (PhRMA Br. 1). *Escobar*'s "rigorous" materiality and scienter requirements are sufficient to address such "concerns about fair notice and open-ended liability" for would-be defendants. *See* 136 S. Ct. at 2002 ("The Government might respond [to a more stringent standard] by designating every legal requirement an express condition of payment. But billing parties are often subject to thousands

of complex statutory and regulatory provisions. Facing [FCA] liability for violating any of them would hardly help would-be defendants anticipate and prioritize compliance obligations.").[26]

In this case, Wood points to several relevant healthcare certifications: the Standard Medicaid Provider Application, the Standard Medicare Provider Agreement, and the Claim Form 1500 used for submission of Medicare, Medicaid, and TRICARE/CHAMPUS claims. (Third Am. Compl. ¶¶ 79-80, 82). All require compliance with "applicable Federal or State laws," *see, e.g.*, *Smith*, 415 F. Supp. 2d at 63-64 (discussing CMS Form 1500), a universe that plainly encompasses the AKS. The fact that they do not explicitly reference the AKS is of no moment. Indeed, "the conclusion that [AKS] compliance is a precondition of payment is rendered inescapable when the purpose of the [AKS] is considered within the context of" these healthcare statutes. *Westmoreland*, 812 F. Supp. 2d at 53. After all, "[k]ickbacks are designed to influence providers' independent medical judgment in a way that is fundamentally at odds with the functioning of the system as a whole. . . . If providers could demand payment for claims resulting from kickback violations, then the [AKS] would be meaningless." *Id.* at 53-54; *accord United States ex rel. Thomas v. Bailey*, No. 06-CV-0465 (JLH), 2008 WL 4853630, at *8 (E.D. Ark. Nov. 6, 2008) (noting that "case law supports the proposition that compliance with [the AKS] is a condition of payment under" federal health care programs); *The Health All. of Greater Cinn.*, 2008 WL 5282139, at *11 (similar).[27]

---

[26] For similar reasons, there is no merit to PhRMA's contention that, "when someone submits a bare claim for payment unaccompanied by affirmative representations, the only implied representations that the submitter makes are about facts that 'go to the basis, or essence, of the transaction.'" (PhMRA Br. 4 (quoting Restatement (Second) of Torts § 151 cmt. j)). Under *Escobar*, distinguishing between conditions of payment that are covered and conditions of payment that are not is a task for the materiality standard.

[27] PhMRA appears to concede that some violations of the AKS could give rise to liability under the FCA, but only where they involve "kickbacks that cause the Government to pay for medically unwarranted treatment" because "only those kickbacks could affect the underlying value of the transaction to the Government." (PhRMA Br. 9). Nothing in the relevant statutes, regulations, or precedents, however, suggests that courts should engage in this sort of "slicing-

The sole remaining question, then, is whether compliance with the AKS is "material" to a payment decision by the Government. *See Escobar*, 136 S. Ct. at 2002. The *Escobar* Court did not adopt a precise definition of materiality; instead, the Court instructed that, "[u]nder any understanding of the concept, materiality looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Id.* (internal quotation marks omitted).[28] Applying that "holistic" approach here, *see United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 109 (1st Cir. 2016), the Court has no trouble concluding that compliance with the AKS is a "material" condition of payment. First, violation of the AKS is a far cry from an "insubstantial" regulatory violation like, say, requiring "that [government] contractors buy American-made staplers" rather than foreign staplers. *See Escobar*, 136 S. Ct. at 2004. Indeed, Congress has made it a felony offense punishable by up to five years in prison, *see* 42 U.S.C. § 1320a-7b, and, as noted, the law now provides explicitly that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim," *id.* § 1320a-7b(g). Second, Medicare Part D Provider Agreements and the majority of state Medicaid Provider Applications expressly designate AKS compliance as a condition of payment. (Third Am. Compl. ¶¶ 80, 82). And third, neither Allergan nor PhRMA points to evidence that the Government pays Medicaid or Medicare claims "in full despite its

---

and-dicing" of kickback claim types. Moreover, kickback schemes of the sort alleged here *do* result in higher costs to the Government — and thus "affect the underlying value of the transaction to the Government" — insofar as they result in the prescription of brand name drugs rather than lower-cost generic drugs.

[28] The Supreme Court declined to decide whether the materiality requirement in Section 3729(a)(1)(A) is derived from Section 3729(b)(4) or from the common law, *see* 136 S. Ct. at 2002, but it is safe to assume that the same standard applies to both "fraudulent" claims and "false" claims. *See United States v. Wells*, 519 U.S. 483, 489 (1997) (considering "materiality of falsehood" as an element and concluding that the term "material" in that context means "having a natural tendency to influence, or being capable of influencing, the decision of the decisionmaking body to which it was addressed" (alterations omitted)).

actual knowledge" of AKS violations. *Escobar*, 136 S. Ct. at 2003. In fact, the Government has actively pursued FCA actions and criminal proceedings to deter and punish AKS violations and recoup funds. *See, e.g.*, *United States ex rel. Bilotta v. Novartis Pharm. Corp.*, 50 F. Supp. 3d 497, 506 (S.D.N.Y. 2014); *McClatchey*, 217 F.3d at 829-34. These considerations, by themselves, are enough to establish that compliance with the AKS is plausibly a material condition of payment under the federal health care programs at issue in this case.[29]

4. Third-Party Claim Submissions

One last argument relating to liability under the FCA warrants discussion (although it bleeds into the issue of scienter, which is discussed in the next section): Allergan's argument that the FCA does not extend to claims that, like those here, are rendered false by one party (Allergan) but submitted to the Government by another (the pharmacists). (*See, e.g.*, Allergan Mem. 19 ("Absent some allegation — and the TCA includes none — that the unnamed pharmacies somehow violated applicable federal and state law themselves, the pharmacies' statements are literally true . . . . (emphasis omitted)); *see also* PhMRA Br. 7 ("[T]he Government fails to point to any misrepresentations that *Allergan* made. The Government points only to false statements made by pharmacists and physicians.")). That argument "borders on frivolous." *United States ex rel. Feldman v. City of New York*, 808 F. Supp. 2d 641, 650

[29] To the extent that Wood is required to allege facts that would support a finding of materiality in the Third Amended Complaint, *see Escobar*, 136 S. Ct. at 2004 n.6 (noting that FCA plaintiffs must plead their claims "with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b) by, for instance, pleading facts to support allegations of materiality"), he has done so. Wood provides evidence of agreements expressly designating compliance with the AKS as a condition of payment (Third Am. Compl. ¶¶ 62; 80-82); details alerts and guidance documents issued by the Government during the relevant time period warning against AKS violations (*id.* ¶¶ 68-73); notes the severity of civil and criminal punishment for such violations (*id.* ¶ 75); describes the legislative history indicating "Congress' commitment to the fundamental principle that Federal healthcare programs will not tolerate the payment of kickbacks" (*id.* ¶ 76); and pleads a kickback scheme that, taken as true, defrauded the government into paying "hundreds of millions of dollars in prescription drug claims that were not eligible for reimbursement." (*Id.* ¶ 12).

(S.D.N.Y. 2011). For one thing, the FCA imposes liability not only on a person who presents a false or fraudulent claim, but also on a person who "*causes*" the false or fraudulent claim "to be presented." 31 U.S.C. § 3729(a)(1)(A) (emphasis added). Additionally, case law makes clear that the FCA reaches claims rendered false by one party, even if they are submitted to the Government by another downstream entity. *See, e.g.*, *Feldman*, 808 F. Supp. 2d at 650; *see also United States v. Bornstein*, 423 U.S. 303, 313 (1976) (holding a subcontractor liable under the FCA for causing a contractor to submit claims seeking payment for materials that, seemingly unbeknownst to the contract, were incorrectly labeled). Not surprisingly, therefore, courts in this Circuit have consistently rejected the "third-party" argument pressed by Allergan in circumstances similar to those here. *See, e.g.*, *TEVA Pharm.*, 2016 WL 750720, at *24 (upholding liability against a pharmaceutical company where "the kickbacks were allegedly paid to doctors, who prescribed the drugs that were ultimately dispensed by the pharmacies"); *Novartis IV*, 41 F. Supp. 3d at 337 (upholding liability against a supplier where the FCA claims were predicated on kickbacks allegedly paid to pharmacies that certified compliance with the AKS). A contrary holding would immunize upstream entities from FCA liability — a result Congress "could hardly have intended." *TEVA Pharm.*, 2016 WL 756720, at *24 (further observing that "[t]he fact that there is an extra link in the casual chain does not render the claims submitted for reimbursement any less false").

Moreover, to the extent Allergan argues that the pharmacies' "unwitting" submission of claims defeats either theory of falsity — presumably due a lack of requisite scienter (*see* Allergan Mem. 19-20 ("[T]hat the 'unwitting[]' pharmacies did not know of Allergan's alleged violations of the AKS . . . eliminates the pharmacies' certifications as a basis for falsity.")) — that argument is of no moment here. Where the defendant is a non-submitting entity, courts merely ask "whether that entity knowingly caused the submission of either a false or fraudulent claim or false records or statements to get such a claim paid. The statute makes no distinction

between how non-submitting and submitting entities may render the underlying claim or statements false or fraudulent." *United States ex rel. Hutchenson v. Blackstone Med., Inc.*, 647 F.3d 377, 389 (1st Cir. 2011); *see also United States ex rel. Nevyas v. Allergan, Inc. (Nevyas II)*, 09-CV-0432, 2015 WL 4064629, at *3 (E.D. Pa. July 2, 2015) (finding that the relators "adequately alleged Allergan induced physicians to write kickback-tainted prescriptions for its products filled by pharmacists and, as natural consequence of the scheme, Allergan 'caused to be presented' 'false or fraudulent' claims to the United States."). It does not matter that "the pharmacies may not have known about [Allergan's] conduct." *TEVA Pharm.*, 2016 WL 756720, at *23.[30]

F. Rule 9(b)

Having concluded that Wood's theories of express and implied certification are generally viable, the Court turns to the more specific question of whether Wood's claims, as pleaded, satisfy the heightened pleading standards of Rule 9(b). Rule 9(b)'s particularity requirement serves several purposes, including "to provide a defendant with fair notice of a plaintiff's claim, to safeguard a defendant's reputation from improvident charges of wrongdoing, and to protect a defendant against the institution of a strike suit." *Rombach v. Chang*, 355 F.3d 164, 171 (2d Cir. 2004) (internal quotation marks omitted). The requirement also "discourage[s] the filing of complaints as a pretext for discovery of unknown wrongs." *Madonna v. United States*, 878 F.2d 62, 66 (2d Cir. 1989) (internal quotation marks omitted). The Second Circuit "has held that FCA claims fall within the scope of Rule 9(b)," meaning the pleadings must "(1) specify the

[30] In light of the foregoing conclusions, the Court need not reach two other theories of implied certification pressed by Wood: first, that the claims at issue can be treated as factually false claims, specifically "fraudulent inducements" (Wood Reply 6-8); and, second, that claims submitted by the pharmacies contained "misleading half-truths" because each claim included the "pharmacies' unique provider identification number" and "the unique National Drug Code" for the relevant Allergan drugs. (*See* Wood Opp'n 18-19). Nor, as discussed above, does the Court need to address whether the taint theory is a valid basis for a claim under the FCA.

statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Bishop*, 823 F.3d at 43. At bottom, a party alleging fraud is required to "state with particularity the circumstances constituting fraud or mistake," Fed R. Civ. P. 9(b), although scienter "may be alleged generally," *id.* Significantly, however, in the FCA context "these 'circumstances' depend upon the elements of the subsection at issue." *United States ex rel. Kester v. Novartis Pharma. Corp. (Novartis II)*, No. 11-CV-8196 (CM), 2014 WL 2619014, at *4 (S.D.N.Y. June 10, 2014). The Court analyzes Wood's claims under each subsection and concludes the majority of his claims are sufficient to satisfy the Rule 9(b) standards.

1. FERA

Before doing so, however, it is necessary to note that the relevant provisions of the FCA were amended in 2009 by FERA, which expanded liability under the Act. Prior to FERA, the three subsections relevant here established liability, where: a defendant "knowingly present[ed], or cause[d] to be presented to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1); "knowingly [made], use[d], or cause[d] to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government," *id.* § 3729(a)(2); or "conspire[d] to defraud the Government by getting a false or fraudulent claim allowed or paid," *id.* § 3729(a)(3). FERA amended these provisions to "clarif[y] that liability under section 3729(a) attaches whenever a person knowingly makes a false claim . . . without regard to whether the wrongdoer deals directly with the Federal Government . . . or with a third party contractor, grantee, or other recipient of such money or property." S. Rep. No. 111-10, 2009 WL 787872, at *11 (2009). As amended, civil liability now attaches under the Act where: a defendant "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A); "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 "conspires to commit a violation of [another subsection of the FCA]," *id.* § 3729(a)(1)(C). Wood also alleges violations of subsection (a)(1)(G) — formerly subsection (a)(7) — which provides for liability where a defendant "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."

Making the task more difficult, FERA specified that subsection (a)(1)(B) applies retroactively; the other amendments apply only prospectively. *See* Pub. L. No. 111-21, § 386, 123 Stat. 1617 (2009) (noting that subsection (a)(1)(B) "shall take effect as if enacted on June 7, 2008"). The Second Circuit has recognized the application of subsection (a)(1)(B) to all legal claims pending before courts on or after June 7, 2008. *See United States ex rel. Kirk v. Schindler Elevator Corp.*, 601 F.3d 94, 113 (2d Cir. 2010), *rev'd sub nom on other grounds by* 536 U.S. 401 (2011). Wood's subsection (a)(1)(B) claim is thus governed entirely by the post-amendment language. With respect to his other claims, however, the pre-amendment subsections apply to acts committed prior to FERA's effective date of May 20, 2009, and the post-amendment language applies to acts committed after that date. Fortunately, these distinctions do not substantively bear on the sufficiency of Wood's pleadings at this stage. The Court will therefore refer to the amended subsections when necessary.

2. Counts I and II: Subsections (a)(1)(A) and (a)(1)(B)

Wood's core claims turn on violations of subsections (a)(1)(A) and (a)(1)(B). To prove a violation of the former, a relator must show that "(1) there was a false or fraudulent claim, (2) the defendant knew it was false or fraudulent; (3) the defendant presented the claim, or caused it to be presented, to the United States, and (4) it did so to seek payment from the federal treasury." *United States ex rel. Kester v. Novartis Pharma. Corp. (Novartis I)*, 23 F. Supp. 3d 242, 252

(S.D.N.Y. 2014) (citing *Mikes*, 274 F.3d at 695). For the latter, a relator must show that "(1) the defendant made (or caused to be made) a false statement, (2) the defendant knew it to be false, and (3) the statement was material to a false claim." *Id.* This provision includes a "double falsity" requirement because a relator must allege both a false record *and* a false claim. *See Feldman*, 808 F. Supp. 2d at 656. Strictly speaking, only subsection (a)(1)(A) expressly requires that a claim be "paid or approved by the Government"; courts in this Circuit, however, generally agree that "plaintiffs asserting subsection (a)(1)(B) claims must likewise plead the 'claim' submission element with particularity." *Novartis I*, 23 F. Supp. 2d at 252. As a general matter, therefore, a relator "cannot circumscribe the Rule 9(b) pleading requirements by alleging a fraudulent scheme in detail and concluding, that as a result of the fraudulent scheme, false claims must have been submitted." *United States ex rel. Polansky v. Pfizer*, 04-CV-0704 (ERK), 2009 WL 1456582, at *5 (E.D.N.Y. May 22, 2009) (collecting cases).

The Second Circuit has not clearly articulated what constitutes "particularity" in this context, but district courts in this Circuit consistently require relators to "provide a detailed factual basis" to support allegations that a defendant "submitted a false claim *in this specific instance*, not just that the defendant had a custom of submitting claims." *Novartis I*, 23 F. Supp. 3d at 255; *see also id.* at 257 (collecting district court cases). Still, "where the alleged fraudulent scheme involved numerous transactions that occurred over a long period of time, courts have found it impractical to require the plaintiff to plead the specifics with respect to each and every instance of fraudulent conduct." *Wells Fargo*, 972 F. Supp. 2d at 616. Instead, it suffices for a relator to provide identifying information about a representative sample of false claims, such as "dates of claims, contents of claims, identification numbers, reimbursement amounts, goods or services provided, and individuals involved in the billing." *Novartis I*, 23 F. Supp. 3d at 258 (discussing *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220 (1st Cir. 2004)). Notably, however, there is no "checklist of mandatory requirements" for every

complaint. *Karvelas*, 360 F.3d at 233; *see In re Cardiac Devices*, 221 F.R.D. at 337-38 ("Rule 9(b) does not impose a 'one size fits all' list of facts that must be included in every FCA complaint"). Whether a complaint satisfies Rule (b) ultimately "depends upon the nature of the case, the complexity or simplicity of the transaction or occurrence, the relationship of the parties, and the determination of how much circumstantial detail is necessary to give notice to the adverse party and enable him to prepare a responsive pleading." *Wells Fargo*, 972 F. Supp. 2d at 616 (internal quotation marks omitted). At bottom, "the complaint must include sufficient details about the false claims such that the defendant can reasonably identify the particular false claims for payments that are at issue." *Novartis I*, 23 F. Supp. 3d at 256 (internal quotation marks and alteration omitted).

In this case, Allergan argues that the Third Amended Complaint fails to identify the "*sine qua non*" of an FCA action: the false claims. More specifically, Allergan asserts that Wood fails to identify any particular false or fraudulent claims submitted to the Government or any specific pharmacy (the actor alleged to have submitted the claim) involved in the scheme. (Allergan Mem. 20-21; Allergan Reply 16-17). There is some truth to that assertion, but that does not doom Wood's pleading. Instead, the circumstances here are analogous to those in *TEVA Pharmaceuticals*, in which the relators alleged that "all claims in a similarly defined pool [were] false." 2016 WL 750720, at *15. In that case, Judge McMahon upheld the complaint because the relators had sufficiently circumscribed the pool of allegedly false claims. *See id.* (noting that the pool was "comprised of all claims for reimbursement (1) relating to prescriptions of Copaxone and Azilect, (2) prescribed by doctors who participated in the allegedly 'sham' speaker programs, (3) that were submitted for reimbursement to certain specified government programs, (4) from 2003 to the present" (footnote omitted)); *see also Novartis I*, 23 F. Supp. 3d at 250 (finding the complaint sufficient despite "[n]o particular claim that a pharmacy submitted for reimbursement" being attached or identified because "the Government's theory [was] that all

claims for [two specific drugs] submitted by [the defendant's] co-conspirators during the life of the kickback scheme were 'false'").

Similarly, the 161-page Third Amended Complaint here identifies a defined pool of false claims relating to prescriptions for certain Allergan drugs. (*See, e.g.*, Third Am. Compl. ¶ 125). Like the *TEVA Pharmaceuticals* relator who identified "121 speaker program participants whose prescriptions of the [d]rugs resulted in claims," 2016 WL 750720, at *15, Wood identifies a multitude of specific physicians and healthcare centers who received alleged kickbacks from Allergan, including the type and amount of remuneration, and — for many physicians — the corresponding number of Allergan drug prescriptions written. (*See* Third Am. Compl. ¶¶ 130-131; 148-150). To provide just one example: Wood alleges that "Dr. Neil Griffin" of Southern Pines, N.C., received "133 samples per month" from October 2, 2008 to January 22, 2009, during which time he was the fourth highest Medicare prescriber of Zymar in the country, with 727 claims submitted for a gross drug cost of $53,898.89. (*Id.* ¶ 131; *see also id.* ¶ 130). Moreover, Wood provides lists of customer care kit and sample shipment agreements entered into with the specific physicians. (Third Am. Compl. ¶¶ 146, 171, 173). Each of these lists identifies the name and address of the physician, the contract number and expiration date, the effective dates of the agreements, and which specific drugs were provided. (*See id.*). Wood also specifies the federal programs at issue: Medicare, Medicaid, TRICARE/CHAMPUS, CHAMPVA, and FEHBP. (*Id.* ¶ 62). Taken together, this information suffices to define the pool of claims against which Allergan must defend: (1) all claims for reimbursement relating to the prescriptions of Zymar, Zymaxid, Acular LC, and Acuvail; (2) prescribed by doctors who received free customer care kits, drugs samples, or goods; (3) that were submitted for reimbursement to the specified federal healthcare programs; (4) from 2003 to 2011. *See TEVA Pharm.*, 2016 WL 750720, at *15-16; *Novartis I*, 23 F. Supp. 3d at 249; *see also, e.g.*, *Duxbury*, 579 F.3d at 30 (finding a complaint sufficient where the relator had "identified, as to each of the

eight medical providers (the who), the illegal kickbacks (the what), the rough time periods and locations (the where and when), and the filing of the false claims themselves").

Allergan's arguments to the contrary fall short. First, Allergan challenges the lack of specific allegations relating to the third-party pharmacies that submitted the claims to the Government. (Allergan Mem. 21-22). But the double-layered scheme alleged here differs from the usual FCA case in which the defendant either directly submits false claims to the Government or causes the next-level entity to do so. *See Wells Fargo*, 972 F. Supp. 2d at 616 (cautioning that particularity must take into account the "complexity" of the interaction and "relationship of the parties"). In *Novartis I*, for example, the Government alleged a scheme in which the defendant provided kickbacks in exchange for certain pharmacies' promoting its drugs. *See* 23 F. Supp. 3d at 263-64. The *Novartis* Court concluded that identifying the specific pharmacies and the precise time period during which they submitted claims, among other factors, was sufficient to sustain the complaint. *See id.* at 265. Insofar as Allergan did not deal directly with the pharmacies, the analog in this case is identifying those physicians whose prescriptions were tainted by kickbacks — which Wood does. By providing the names, locations, and relevant time periods for these physicians, Allergan can "connect the dots" to determine the pharmacies (and subsequent claims) that were produced by the underlying kickback scheme.

Notably, courts have consistently recognized "a distinction between a qui tam action alleging that the defendant made false claims to the government, and a qui tam action in which the defendant induced *third parties* to file false claims with the government." *Duxbury*, 579 F.3d at 29. "Particularly where, as here, the defendant is alleged to have induced third parties to submit false claims, the relator cannot reasonably be expected to allege details about the individual claims that were submitted." *United States. ex rel. Brown v. Celgene Corp.*, No. 10-CV-3165 (GHK), 2014 WL 3605896, at *9 (C.D. Cal. July 10, 2014). Nor is this a case where Wood could have accessed the relevant information but failed to do so. *See, e.g.*, *Ping Chen*,

966 F. Supp. 2d at 302 (acknowledging that a court may "relax[]" Rule 9(b) "in a case where the plaintiff is not in a position to know specific facts until after discovery" but declining to do so where the plaintiff could not "reference a single specific false claim submitted by [the defendant directly] despite having worked there from 2006 to 2010"); *Mooney v. Americare, Inc.*, No. 06-CV-1806 (FB), 2013 WL 1346022, at *5 (E.D.N.Y. Apr. 3, 2013) (observing that a "relaxed standard may be appropriate where the plaintiff contends that the pertinent facts are solely in defendants' possession" but that this relaxation typically occurs where the plaintiff "never had access to billing information" and so was inapplicable because the plaintiff worked in the defendant's billing department). Requiring Wood to plead information to which he had no access, when his allegations are otherwise sufficient, would be to "effectively immunize from FCA liability pharmaceutical companies who rely on unknowing pharmacists to seek reimbursement." *United States ex rel. Nevyas v. Allergan, Inc. (Nevyas I)*, No. 09-CV-0432, 2015 WL 3429381, at *1 n.1 (E.D. Pa. May 26, 2016).

Next, Allergan claims that the Third Amended Complaint makes "only a feeble effort" to connect the named physicians to the actual submission of false claims. (Allergan Mem. 22). To the extent Allergan is arguing that Wood generally fails to allege the submission of false claims to the Government, the argument lacks merit. The Third Amended Complaint expressly and repeatedly states that claims tainted by kickbacks were submitted to the Government. (*See, e.g.*, Third Am. Compl. ¶¶ 10, 130-132, 223-224). Additionally, that Medicare and Medicaid reimburse the majority of cataract surgery-related drugs is evident from that fact that cataract surgery is the "No. 1 line-item cost of Medicare reimbursement," amounting to $3.5 billion in costs annually. (*Id.* ¶ 113). Taking Wood's allegations together, "it is easy to infer" that claims affected by purported kickbacks were submitted to the federal Government during the alleged time period. *Brown*, 2014 WL 3605896, at *9-10 (finding the same where Medicare and Medicaid paid for the majority of certain drug prescriptions and the relator had alleged that

"almost all" those drug sales were for off-label use). To this, Allergan contends that Wood must allege that physicians who received kickbacks prescribed more Allergan drugs than before. (Allergan Mem. 22). But Allergan fails to cite any support for that proposition, and, in any event, Wood more than sufficiently alleges such a relationship. (*See, e.g.*, Third Am. Compl. ¶ 5 (noting that the company tracked the ratio of free goods to prescriptions written); ¶ 21 (detailing Allergan's internal databases for such tracking)). In particular, Allergan maintained spreadsheets for the explicit purpose of tracking the "ratio" of free samples provided to the number of prescriptions written for each physician, noting in red any ratio that fell below seventy percent. (*Id.* ¶ 158). In response to a low ratio, Allergan would then lower or cease its provision of free samples. (*Id.* ¶ 159 (detailing specific instances)). The Third Amended Complaint thus establishes a relationship between the kickbacks and the prescription of Allergan drugs. *See, e.g.*, *United States ex rel. Boise v. Cephalon, Inc.*, No. 08-CV-287, 2015 WL 1724572, at *14 (E.D. Pa. Apr. 15, 2015) (concluding that "the properly pled kickback allegations of speakers fees and allegations of [the defendant's] detailed tracking mechanisms to monitor the effectiveness of its schemes" meant that the relators had "properly alleged" that "false claims were actually submitted due to [the defendant's] reimbursement services").

Finally, Allergan argues that even if Wood's Medicare claims survive under Rule 9(b), his other claims fail because the Third Amended Complaint contains no representative examples under those programs. (Allergan Mem. 22-23). But "[p]roviding sample claim information for one program with respect to the drugs at issue is a sufficient basis for the Court to infer that similar claims were submitted to the other named government programs." *TEVA Pharm.*, 2016 WL 750720, at *15. At least with respect to Medicaid and TRICARE/CHAMPUS, Wood — as discussed above — alleges a viable theory of implied certification through the Medicaid application agreements and general CMS Form 1500 claims forms. Thus, he "need not submit sample claims for each government program." *Id.* By contrast, Wood mentions two other

programs — CHAMPVA and the FEHBP — in only one paragraph of the Third Amended Complaint. (Third Am. Compl. ¶ 101). Because Wood neither pleads the mechanisms of reimbursement for these programs, nor any certifications associated with them, the Court dismisses Wood's CHAMPVA and FEHBP claims with leave to amend. *See Luce v. Edelstein,* 802 F.2d 49, 56 (2d Cir. 1986) ("Complaints dismissed under Rule 9(b) are almost always dismissed with leave to amend." (internal quotation marks omitted)).

In short, then, the Court concludes that Wood's allegations are sufficient to support the bulk of his subsection (a)(1)(A) and (a)(1)(B) claims. The purpose of Rule 9(b)'s heightened standard is to ensure that defendants have sufficient notice — not to immunize them from suit at the outset. *See Wells Fargo*, 972 F. Supp. 2d at 617 ("A court should hesitate to dismiss a complaint under Rule 9(b) if the court is satisfied . . . that the defendant has been made aware of the particular circumstances for which [it] will have to prepare a defense at trial . . . ." (quoting *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 (4th Cir. 1999)); *see also Novak v. Kasaks*, 216 F.3d 300, 314 (2d Cir. 2000) ("The primary purpose of Rule 9(b) is to afford defendant fair notice of the plaintiff's claim and the factual ground upon which it is based."). *See generally United States ex rel. Prather v. Brookdale Senior Living Communities*, Inc., 838 F.3d 750, 771–73 (6th Cir. 2016) (explaining that Rule 9(b) does not support dismissal of FCA claims where the relator "can otherwise allege facts — based on personal knowledge of billing practices — supporting a strong inference that particular identified claims were submitted to the government for payment" because "[r]equiring a relator to plead with particularity the details of specific claims submitted to the government for payment in these circumstances would provide no further notice to a defendant of the charged wrongdoing, and the concern for warding off frivolous claims is already served by requiring detailed personal knowledge of billing practices and specific identified claims"). The Third Amended Complaint serves that purpose here, and to conclude otherwise might "allow the more sophisticated entity to escape liability"

merely because of "the complexity of their scheme." *United States ex rel. Taylor v. Gabelli*, 345 F. Supp. 2d 313, 326 (S.D.N.Y. 2004).

3. Count III: Subsection (a)(1)(C)

Wood, relatedly, alleges a violation of subsection (a)(1)(C), the FCA's conspiracy provision. To state a claim under this subsection, a relator must show that: "(1) the defendant conspired with one or more persons to get a false or fraudulent claim allowed or paid by the United States" and "(2) one or more conspirators performed any act to effect the object of the conspiracy." *Taylor*, 345 F. Supp. 2d at 331. The Second Circuit has not decided whether (and, if so, how) Rule 9(b) applies to subsection (a)(1)(C), and district courts in this Circuit seem to have diverged on the question. *Compare Novartis II*, 2014 WL 2619014, at *10 ("Since no false claim need have been submitted for subsection (a)(1)(C) liability to attach, no claim need be identified with particularity), *with United States ex rel. Capella v. Norden Sys., Inc.*, No. 94-CV-2063 (EBB), 2000 WL 1336487, at *11 (D. Conn. Aug. 24, 2000) (requiring a relator to "specify the particulars of how and when [the] alleged conspiracy arose, who entered into it, or what act was committed in furtherance of the conspiracy" under Rule 9(b)'s pleading standard). Most circuit courts have held that Rule 9(b)'s requirements apply to conspiracy claims. *See United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 45 (1st Cir. 2009) (listing circuit court cases). The Court agrees that Rule 9(b) applies to the extent it requires a relator to "specify the who, what, where, and when of the allegedly false or fraudulent representation" — as is required for a substantive claim to survive under subsections (a)(1)(A) and (a)(1)(B); whether the heightened pleading standard applies beyond that (for example, to the who, what, where, and when of the unlawful agreement itself) is a more difficult question.

Regardless, taking all the allegations in the Complaint as true, Wood's claim survives. For example, Wood provides the names and addresses of several physicians, how many free samples were provided to those physicians over what time period, and the corresponding number

of Allergan drug prescriptions written by those physicians. (Third Am. Compl. ¶¶ 130-131). Moreover, the Complaint alleges that Allergan sales representatives "made it clear to health care professionals" that "Allergan would only provide free products, including drugs and CCKs, to physicians who agreed to prescribe and continue prescribing its products in return." (*Id.* ¶ 132). The Third Amended Complaint also includes charts describing specific physicians, the number of samples provided to those physician, and specific customer care kit and drug sample shipment agreements entered into with specific physicians. (*See id.* ¶¶ 146, 148-150, 171, 173). To receive these goods, Wood alleges, the ophthalmologists had to "coordinate[] with an Allergan sales representative," and these agreements all required the "signatures of the healthcare professional, sales representative, and Area Manager." (*Id.* ¶ 140, 156, 167). Finally, Wood alleges special inducements provided to certain physicians who prescribed high quantities of Allergan drugs — detailing specific providers, Allergan representatives, meetings, and telephone calls relating to the provision of those inducements. (*See id.* ¶¶ 192-207). Wood's conspiracy allegations are thus far from conclusory and sufficient to survive at this stage (and, notably, Allergan does not specifically argue otherwise). *See, e.g.*, *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 193-94 (5th Cir. 2009) (reversing dismissal of a conspiracy claim where "a reasonable jury could infer [that the defendants] were in agreement between themselves and some members of the nursing staff to improperly record unprovided services for the purpose of getting fraudulent claims paid by the Government.").

4. Count IV: Subsection (a)(1)(G)

Wood's final claim — under subsection (a)(1)(G), the "reverse false claims" provision — calls for a different result. Liability here must be premised on a "false statement[] designed to conceal, reduce, or avoid an obligation to pay money or property to the Government." *Wood ex rel. United States v. Applied Res. Assocs., Inc.*, 328 F. App'x 744, 748 (2d Cir. 2009). To prove such a claim, a relator must show: "(1) proof that the defendant made a false record or statement

(2) at a time that the defendant had a presently-existing 'obligation' to the government," *i.e.*, a "duty to pay money or property." *Novartis V*, 43 F. Supp. 3d at 367 (internal quotation marks omitted). A complaint that "makes no mention of any financial obligation that the [defendant] owed to the government" and "does not specifically reference any false records or statements used to decrease such an obligation" must be dismissed. *Wood*, 328 F. App'x at 748. Here, Wood does not "identify any existing financial obligation that [Allergan] owed to the Government," let alone "any specific false record or statement that [Allergan] made to avoid the purported obligation." *Haas v. Guiterrez*, No. 07-CV-3623 (GDB), 2008 WL 2566634, at *5 (S.D.N.Y. June 26, 2008). (*See* Third Am. Compl. ¶ 286 (stating entirely conclusory claim)). Accordingly, Wood's subsection (a)(1)(G) claim must be and is dismissed under Rule 9(b), with leave to amend. *See Luce*, 802 F.2d at 56.

5. The Scope of the Scheme and Scienter

The Court thus concludes that most of Wood's subsection (a)(1)(A), (a)(1)(B), and (a)(1)(C) claims are pleaded with sufficient particularity to satisfy Rule 9(b), but Wood's subsection (a)(1)(G) claim fails. Before moving on, though, the Court must briefly consider two other arguments raised by Allergan and PhRMA that go to the sufficiency of the Third Amended Complaint, even though they were not necessarily styled as Rule 9(b) challenges.

First, Allergan contends that the Third Amended Complaint "does not plead a multi-state, multi-year scheme with particularity" and, thus, asks the Court to limit the temporal and geographic scope of the case. (Allergan Mem. 23). Allergan's argument appears to hinge on Wood's sampling data, which derives from a particular time period (2008 to 2009) and region (the Midwest). But Wood's representative samples are just that — samples. Allergan offers no support for the proposition that a relator who, consistent with Rule 9(b), provides a slew of representative examples is then limited to the scope of those examples. Instead, Allergan's cases stand for the proposition that a pleading entirely lacking in detail that puts forth a single

occurrence of fraud is insufficient. *See Hericks v. Lincare Inc.*, No. 07-CV-387, 2014 WL 1225660, at *9 (E.D. Pa. Mar. 25, 2014) (declining to "assume that some claims at some point from some center must have resulted in illegal practices" when those kickback claims were themselves "rooted in conjecture, speculation, or supposition"); *United States ex rel. West v. Ctr. for Diagnostic Imaging, Inc.*, 787 F. Supp. 2d 1213, 1222 (W.D. Wash. 2011) (declining to "extrapolate a broader scheme from [a] lone statement"); *United States ex rel. Wall v. Vista Hospice Care, Inc.*, 778 F. Supp. 2d 709, 723 (N.D. Tex. 2011) ("The specific facts [the relator] has alleged relate solely to her work in Denton, Texas, and cannot support by inference her general pleading.").

Moreover, the Third Amended Complaint includes evidence that the alleged scheme was implemented nationwide by Allergan's sales team and corporate officials (*see* Third Am. Compl. ¶¶ 35-41, 47, 129), and lists sample shipment agreements with physicians in well over thirty states. (*Id.* ¶¶ 171, 173). This is more than sufficient to sustain the geographic scope of Wood's claims at this stage. *See, e.g.*, *Novartis II*, 2014 WL 2619014, at *4 (disposing "easily" of the argument that the relator had not sufficiently pleaded the specifics of a wide-ranging kickback scheme given the "detailed allegations about the mechanics" of that scheme in the complaint); *Brown*, 2014 WL 3605896, at *10 (finding "no reason to conclude that [the defendant's] alleged misconduct was limited" to a single state where the complaint "makes allegations about [the defendant's] nationwide, systemic practices"); *see also United States ex rel. Spay v. CVS Caremark Corp.*, 913 F. Supp. 2d 125, 177 (E.D. Pa. 2012) ("Certainly, [plaintiffs] cannot be expected to plead with particularity each and every false claim nationwide without the benefit of at least some discovery . . . .").

Second, Allergan and PhRMA make several arguments with respect to the FCA's scienter requirement.[31] As noted above, "knowing" and "knowingly" are defined under the statute as having "actual knowledge" of information or acting in "deliberate ignorance" or "reckless disregard" of the "truth or falsity of the information." 31 U.S.C. § 3729(b)(1). The Act does not require proof of "a specific intent to defraud," *id.* § 3729(b)(1)(B), and scienter may be alleged generally, *see* Fed. R. Civ. P. 9(b). As the *Escobar* Court cautioned, however, the requirement is still "rigorous." 136 S. Ct. at 2002. More specifically, "[w]hat matters is . . . whether the defendant *knowingly* violated a requirement that the defendant *knows* is material to the Government's payment decision. 136 S. Ct. at 1996 (emphases added).[32] The purpose of the scienter requirement is to avoid punishing "honest mistakes or incorrect claims submitted through mere negligence." *United States v. Sci. Applications Int'l Corp*., 626 F.3d 1257, 1274 (D.C. Cir. 2010).

To the extent *Escobar* requires knowledge that a violation of the AKS is material to the Government's payment decisions, the allegations in the Third Amended Complaint plainly suffice. Allergan certainly knew that violation of the statute carried substantial penalties, and Allergan's own internal documents required employees to comply with the statute. (Third Am.

---

[31] For reasons discussed above, the Court need not address further Allergan's and PhRMA's arguments relating to the scienter of the physicians and pharmacists that served as intermediaries between Allergan and the Government. (*See, e.g.*, Allergan Mem. 19-20; Allergan Final Reply 12). Put simply, their scienter is irrelevant to Allergan's liability under the FCA, which provides for liability where the *entity being sued* "knowingly caused to be presented" a false or fraudulent claim, 31 U.S.C. § 3729(a)(1) or "knowingly caused to made or used" a false record or statement to get a false or fraudulent claim paid, 31 U.S.C. § 3729(a)(2); *see, e.g.*, *Nevyas I*, 2015 WL 3429381, at *1 n.1 (finding liability where "Allergan allegedly caused false claims to be submitted to the United States" despite the pharmacists' "unknowing[ly] having submitted the claims).

[32] Although PhRMA appears to urge the Court to apply the common law definition of "knowing" to the statute (PhRMA Br. 13), the *Escobar* Court explicitly noted that the FCA "abrogates the common law in certain respects. For instance, the Act's scienter requirement 'require[s] no proof of specific intent to defraud.'" 136 S. Ct. at 1999 n.2 (quoting 31 U.S.C. § 3729(b)(1)(B)).

Compl. ¶ 126 (quoting from an Allergan document stating that "Allergan employees may never provide samples to induce a health care professional to purchase, prescribe, or recommend Allergan products, or to reward a health care professional for doing so")). The closer question is whether Allergan knew or recklessly disregarded the possibility that its actual conduct violated the AKS in light of, among other things, the provisions of the PDMA authorizing free samples. (*See* Allergan Mem. 14 n.13). That is because some courts have held that a defendant's "reasonable interpretation of any ambiguity inherent in the regulations belies the scienter necessary to establish a claim of fraud under the FCA." *United States ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825, 832 (8th Cir. 2013); *accord United States ex rel. Johnson v. Golden Gate Nat'l Senior Care, L.L.C.*, No. 08-CV-1194 (DWF), 2016 WL 7197373, at *4 (D. Minn. Dec. 9, 2016) ("In short, if a regulation is ambiguous, a defendant may escape liability if its interpretation of the regulation was reasonable in light of available official guidance — even if the interpretation was 'opportunistic.'"). At the same time, courts have observed that, even where a statute may be ambiguous and a defendant's interpretation reasonable, "there remains the question whether [the defendant] had been warned away from that interpretation." *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 288 (D.C. Cir. 2015).

At this stage, taking all of Wood's allegations as true, the Court concludes that the Third Amended Complaint plausibly alleges that Allergan acted at least with reckless disregard to the possibility that its specific actions were in violation of the AKS. For one thing, its own internal documents "strictly prohibited" providing "samples based on a health care professional's past or future prescribing habits." (Third Am. Compl. ¶ 126). *See, e.g. United States v. Dynamic Visions, Inc.*, No. 11-CV-0695 (CKK), 2016 WL 6208349, at *11 (D.D.C. Oct. 24, 2016) (finding the defendant "demonstrated its knowledge of the materiality of these requirements through its own conduct" where it had "prepared a 'policy and procedure manual' for its employees" that detailed how to comply with the ultimately violated regulations). Allergan was

also aware (or should have been aware) of relevant guidance issued by the Department of Health and Human Services during the period of the alleged scheme, which cautioned manufacturers, at a minimum, to closely examine whether they were providing a "valuable tangible benefit" in violation of the AKS any time they provided items to physicians. (Third Am. Compl. ¶ 69; *see also id.* ¶¶ 65-80 (describing relevant guidance documents)). Notwithstanding that guidance, Allergan still encouraged its sale representatives to track the ratio of free samples to prescriptions written, to stop providing samples to physicians who failed to subscribe Allergan drugs, and to strategically leverage samples of certain drugs to ensure prescriptions of others. (*See, e.g.*, *id.* ¶¶ 157-159, 176). Finally, Allergan was itself aware and concerned about its potential liability under the AKS, prompting the company to stop providing free care kits in late 2008 and free drug samples in June 2010. (*See, e.g. id.* ¶ 161 (describing a presentation slide stating "[p]hysician's acceptance of free kits can be interpreted as being in violation of the Federal Anti-Kickback statutes"); *id.* ¶ 185 (noting that an Allergan Vice President informed the entire sales force that the company needed to "change the way we do business so Allergan is not giving the appearance of engaging in any quid pro quo)).

In light of these detailed allegations, Allergan's position may not have been objectively reasonable at the time of the alleged violations. *United States ex rel. Brown v. Celgene Corp.*, No. 10-CV-3165 (GHK), 2016 WL 7626222, at *14 (C.D. Cal. Dec. 28, 2016) ("We do not think Celegene's position was objectively reasonable at the time of the alleged violations. Then, as now, there was a CMS regulation stating that Medicare would only reimburse medically accepted uses. There was no judicial authority to the contrary. At the time of the alleged violations, it was simply not the case that the statutory text and relevant court and agency guidance allowed for more than one reasonable interpretation." (internal quotation marks, footnote, citation, alteration, and emphasis omitted)). At a minimum, they raise questions of fact that cannot be resolved at this stage of the proceedings. *See, e.g.*, *In re Cardiac Devices*, 221

F.R.D. at 340 ("Whether the facts will bear out these claims or whether the facts will show only an innocent mistake or mere negligence on the part of the defendant-hospitals are issues that cannot be resolved on a motion to dismiss. At this juncture, we are required to accept as true all factual allegations of the complaint and draw all reasonable inferences in favor of the plaintiff."); *Nevyas II*, 2015 WL 4064629, at *6 ("We find Allergan's interpretation of the law focuses on its state of mind and is properly addressed after full development of the factual record. Allergan's reasonable interpretation of the law and applicable regulatory framework may well be a defense to liability, but it is not appropriate at the motion to dismiss stage when there are reasonable interpretations to the contrary"); *cf. United States v. Fulton Cty., Georgia*, 14-CV-5071 (WSD), 2016 WL 4158392, at *11 n.16 (N.D. Ga. Aug. 5, 2016) (dismissing on scienter grounds where, "[e]xcept for two conclusory assertions that simply parrot language from the FCA, the Complaint does not allege, even in general terms, that Defendants knew their claims were false").

G. The Retaliation Claim

Wood's final federal claim is that Allergan unlawfully retaliated against him by terminating his employment after he engaged in protected activity under the FCA, namely investigating and reporting the alleged fraud. (Third Am. Compl. ¶¶ 258-274; 288-290). Section 3730(h) of the FCA, which was amended in 2009, provides that an employee "shall be entitled" to relief "if that employee . . . is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against . . . because of lawful acts done by the employee . . . in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter." 31 U.S.C. § 3730(h)(1).[33] The provision is meant "to protect persons who assist the

[33] The amended version of Section 3730(h)(1) plainly applies here, as Wood alleges that he engaged in protected conduct beginning in April 2010 and was terminated in retaliation for that conduct in July 2010. *Cf. United States ex rel. Sasaki v. New York Univ. Med. Ctr.*, No. 05-CV-6163 (LMM), 2012 WL 220219, at *11-12 (S.D.N.Y. Jan. 25, 2012) (applying the earlier version of Section 3730(h)(1) because all alleged protected conduct occurred prior to 2009).

discovery and prosecution of fraud and thus to improve the federal government's prospects of deterring and redressing crime." *Neal v. Honeywell, Inc.*, 33 F.3d 860, 861 (7th Cir. 1994). To state a claim under it, a plaintiff must plausibly allege (1) that he engaged in conduct protected under the statute, which includes internal reporting about potential FCA violations; (2) that the defendant was aware of his conduct; and (3) that he was terminated in retaliation for his conduct. *See United States ex rel. Sarafoglou v. Weill Med. Coll. of Cornell Univ.*, 451 F. Supp. 2d 613, 624 (S.D.N.Y. 2006); *see also, e.g.*, *Smith*, 415 F. Supp. 2d at 105 (noting that "[i]nternal reporting has been held to constitute protected activity"); 155 Cong. Rec. E1295-03, E1300 (June 3, 2009) (observing that Section 3730(h)(1), as amended, protects steps "taken to remedy . . . misconduct through methods such as internal reporting to a supervisor or company compliance department"). Notably, "Rule 9(b)'s heightened pleading standard does not apply to [a] plaintiff's FCA retaliation claim since no showing of fraud is required." *Mooney*, 2013 WL 1346022, at *8; *see also Garcia v. Aspira of N.Y.*, No. 07-CV-5600 (PKC), 2011 WL 1458155, at *3 n.1 (S.D.N.Y. Apr. 13, 2011).

Wood alleges that, in April 2010, he prepared a written proposal for winning back the business of an ophthalmology group from Allergan's rival, Alcon, through means in line with Allergan's long-standing business practices. (Third Am. Compl. ¶¶ 259-261, 264). After an Alcon salesperson "lodged a complaint" that the proposal was unlawful, Wood told Allergan's legal team that he "was only following company policy, including directions he had been given by his manager." (*Id.* ¶ 263). Wood subsequently "reported his concerns about the illegal sampling and kickback scheme" to the company's compliance and human resource departments. (*Id.* ¶ 268). In doing so, he alleges that he provided "Allergan personnel with specific information regarding sampling directives and activities that he believed, in good faith, were in violation of Allergan's policies and Federal law," including (1) the provision of inducements to health care professionals with the intent to influence them to recommend or purchase products

that may be reimbursed by a federal health care program, (2) the provision of goods to health care professionals in exchange for "any implicit or explicit agreement or understanding" to use and prescribe Allergan products, (3) improperly using prescription drug samples other than in response to a licensed practitioner's request. (*Id.* ¶ 269). Wood was fired on July 6, 2010 — "just after he internally reported" these purported violations. (*Id.* ¶ 270).

These allegations are plainly sufficient to satisfy the second and third elements of a retaliation claim, and Allergan (wisely) does not suggest otherwise. Whether they are sufficient to satisfy the first element is a closer question — if only because Wood does not allege that he explicitly reported "false claims or fraudulent activity in connection with Government payment." (Allergan Mem. 19). But the Third Amended Complaint alleges that Wood internally reported "the provision of free goods" meant to influence providers to use or prescribe "products that may be reimbursed by a federal health care program." (Third Am. Compl. ¶¶ 10, 269). That, combined with Wood's knowledge that Medicare and Medicaid provided reimbursements for a significant portion of Allergan drugs used or prescribed by ophthalmologists (*see id.* ¶ 147), is enough to show that his "investigation reasonably could have led to a FCA action." *Boone v. MountainMade Found.*, 64 F. Supp. 3d 216, 231 (D.D.C. 2014); *see Smith*, 415 F. Supp. 2d at 103-04 (finding conduct protected "when a potential plaintiff engages in an investigation in which it would be reasonable to conclude there is a 'distinct possibility' that he or she would find evidence of an FCA violation"); *Mikes*, 889 F. Supp. at 746-52 (concluding that the plaintiff's conduct was protected where she observed the misuse of certain tests, investigated the medical histories of patients treated with these tests, and confronted defendants with her observations, despite no explicit allegation of fraud, as "[t]aking these allegations as true, evidence that the defendants fraudulently billed these tests would form a reasonable basis for bringing a *qui tam*

action under the FCA").[34] Accordingly, Allergan's motion to dismiss Wood's retaliation claim must be and is denied.

H. State Law Claims

Finally, the Court turns to Wood's claims under state law analogs to the FCA. Allergan argues that Wood's claims, under the law of twenty-four states, either fail or must be curtailed under the applicable statutes of limitation, but the company devotes less two pages of briefing to the issues in total. (Allergan Mem. 28-29; Allergan Reply 19). Accordingly, the Court will address the claims only in passing as well.

1. Wisconsin

First, Allergan contends that Wood's Wisconsin claim must be dismissed because the state's legislature repeated its false claims act in July 2015. (Allergan Mem. 28). It is true that the legislature repealed the law in its entirety, *see* 2015 Wisconsin Act 55 § 945n (July 12, 2015), but — as Wood notes without rebuttal from Allergan (Wood Opp'n 28) — Wisconsin law provides that "[t]he repeal of a statute hereafter shall not remit, defeat or impair any civil or criminal liability for offenses committed, penalties, or forfeitures incurred or rights of action accrued under such statute before the repeal thereof," Wis. Stat. § 990.04. As Wood's claims all accrued prior to July 2015, his claims therefore survive under Wisconsin law. *See, e,g.*, *United States ex rel. Presser v. Acacia Mental Health Clinic, LLC*, 836 F.3d 770, 773-75 (7th Cir. 2016) (evaluating a relator's claims under WFCA, despite its repeal, since the action was filed in 2013).

---

[34] That conclusion is reinforced by the 2009 amendment of Section 3730(h)(1), which was intended to "widen the scope of protected activity" by ensuring, among other things, that "steps taken to remedy the misconduct" are protected "whether or not such steps are clearly in furtherance of a potential or actual qui tam action." 155 Cong. Rec. at E1300; *see, e.g.*, *Layman v. MET Labs., Inc.*, No. 12-CV-2860 (RDB), 2013 WL 2237689, at *7 (D. Md. May 20, 2013) ("While post-[amendment] courts continue to apply the distinct possibility standard, sufficiently pleading the protected activity prong of an FCA retaliation claim is subject to a broader standard."); *see also Stone v. INS*, 514 U.S. 386, 397 (1995) ("When Congress acts to amend a statute, [courts should] presume it intends its amendment to have real and substantial effect.").

2. Delaware, New Mexico, and Texas

Second, Allergan contends that Wood's Delaware, New Mexico, and Texas claims must be wholly or partially dismissed because, under those state laws, a relator cannot proceed in the absence of either state intervention or (in the case of Delaware and New Mexico) a written determination by the state that substantial evidence of a violation exists. (Allergan Mem. 28-29). New Mexico law requires the state to "make a determination of whether there is substantial evidence that a violation has occurred" and directs that a complaint "shall be dismissed" if the state "determines that there is not substantial evidence that a violation has occurred." N.M. Stat. Ann. § 27-14-7(E)(2). Delaware law included a similar requirement until 2009. *See* Del. Code Ann. tit. 6, § 1203(b)(2) (2005), *amended by* Claims Reports Delaware False Claims & Reporting Act, 2009, 2009 Del. Legis. Serv. 166 (West). But while those provisions may well doom Wood's New Mexico and Delaware claims in the long run, they are not a valid basis for dismissal under Rule 12(b)(6), as they require consideration of matters outside of the record. *See, e.g.*, *United States ex rel. King v. Solvay S.A.*, 823 F. Supp. 2d 472, 520 (S.D. Tex. 2011), *vacated on reconsideration on other grounds*, 2012 WL 1067228 (S.D. Tex. Mar. 28, 2012).[35]

As for Texas, the parties appear to agree that Wood's claims should be dismissed to the extent they pertain to fraudulent conduct occurring before May 4, 2007. (Allergan Mem. 28-29; Wood Opp'n 29). On that date, the state amended its false claims act to remove a provision that required dismissal of an action if the state declined to intervene. *Compare* Tex. Hum. Res. Code Ann. § 36.104 (2001), *with* Tex. Hum. Res. Code Ann. § 36.104 (2010). Although some courts

---

[35] Arguably, the Delaware provision would not even apply to Wood's claims as it was eliminated in 2009, before he filed his original complaint. *See, e.g.*, *Dale v. Abeshaus*, No. 06-CV-04747 (JKG), 2013 WL 5379384, at *15 n.75 (E.D. Pa. Sept. 26, 2013) ("Delaware has since amended its false claims act. However, the 2006 version is applicable in this case [because the relator's original complaint was filed in October 2006]."). Counterintuitively, however, some courts continue to apply the provision's requirements to claims that accrued before the 2009 amendments. *See, e.g.*, *Cephalon*, 2015 WL 1724572, at *14. In any event, the Court need not (and in light of the parties' inadequate briefing on it, would not) reach the issue here.

have held that the amended statute applies where, as here, the lawsuit was filed or the state's decision not to intervene occurred on or after May 4, 2007, *see King*, 823 F. Supp. 2d at 522; *United States ex rel. Lisitza v. Johnson & Johnson,* 765 F. Supp. 2d 112, 130-31 (D. Mass. 2011), most courts have allowed Texas claims "to proceed without intervention if filed after the date of the amendment, but *only* as they pertain to fraudulent conduct occurring after the date of amendment," *United States v. Planned Parenthood Gulf Coast, Inc.*, 21 F. Supp. 3d 825, 838 (S.D. Tex. 2014) (internal quotation marks omitted) (emphasis added) (citing cases). As the parties have not engaged this division of authority, the Court will not analyze the issue. Instead, it will grant Allergan's motion as unopposed to the extent that Wood's claims pertain to fraudulent conduct that occurred before May 4, 2007.

3. Retroactivity and Timeliness

Allergan next argues that claims under Connecticut, Georgia, Indiana, Minnesota, Montana, New Jersey, New Mexico, Oklahoma, Rhode Island, and Virginia law fail because the false claims acts in those states were enacted between 2003 and 2011 — the time period of the fraudulent conduct alleged here — and not made retroactive. (*See* Allergan Mem. 29).[36] Wood appears to admit as much, stating that the Third Amended Complaint "does not seek to apply any state statute to conduct that occurred prior to its effective date." (Wood Opp'n 29). The Court therefore grants Allergan's motion on this score as unopposed and dismisses Wood's claims to the extent they relate to conduct that predated each state statute's effective date. *See, e.g.*, *United States ex rel. Streck v. Allergan*, *Inc.*, 894 F. Supp. 2d 584, 605 (E.D. Pa. 2012) (declining to retroactively apply the false claims acts of Indiana, Montana, New Jersey, Oklahoma, Rhode Island, Virginia); *King*, 823 F. Supp. 2d at 520-21 (same as to the false claims acts of

[36] The effective dates for each state statute are as follows: Connecticut, October 5, 2009; Georgia, May 24, 2007; Indiana, July 1, 2005; Minnesota, July 1, 2010; Montana, May 1, 2005; New Jersey, March 13, 2008; New Mexico, May 19, 2004; Oklahoma, November 1, 2007; Rhode Island, July 1, 2007; Virginia, January 1, 2003. (Allergan Mem. 29 n.30 & App'x 1).

Connecticut, Georgia, Indiana, Minnesota, Montana, New Jersey, Oklahoma, Rhode Island, and Virginia). With respect to Virginia, however, Wood's claims survive in their entirety, as the Virginia Fraud Against Taxpayers Act went into effect on January 1, 2003, and Wood does not appear to allege any fraudulent conduct prior to 2003. Va. Code Ann. § 8.01-216.1 *et seq*.

Finally, Allergan challenges Wood's claims under the laws of twenty-one states on timeliness grounds. (Allergan Mem. 27-28). As Allergan concedes, however, these states' laws have statute-of-limitations provisions that are substantially similar, if not identical, to the federal FCA's statute-of-limitations provision discussed above. *See* Cal. Gov't Code § 12654(a); Colo. Rev. Stat. § 25.5-4-307(1)(a); Conn. Gen. Stat. § 17b-3011; Del. Code. Ann. tit. 6, § 1209(a)(1); D.C. Code § 2-381.05(a)(1); Fla. Stat. § 68.089(1)(a); Ga. Code Ann. § 23-3-123(a); 740 Ill. Comp. Stat. 175/5(b)(1); Ind. Code § 5-11-5.5-9(b)(1); La. Rev. Stat. Ann. § 46:439.1(B); Mass. Gen. Laws ch. 12, § 5K(1); Mich. Comp. Laws § 400.614(1)(a); Minn. Stat. Ann. § 15C.11(a); Mont. Code § 17-8-404; Nev. Rev. Stat. § 357.170(1); N.C. Gen. Stat. § 1-615(a); N.J. Stat. Ann. § 2A:32C-11; Okla. Stat. tit. 63, § 5053.6(B)(1); R.I. Gen. Laws § 9-1.1-5(b)(1); Tenn. Code Ann. § 71-5-184(b)(1); Va. Code Ann. § 8.01- 216.9. (Allergan Mem. 8 n.5). Additionally, Allergan devotes no separate briefing to these state laws, instead incorporating by reference its arguments as to the federal FCA. Following Allergan's lead, the Court applies its holding as to the federal FCA here, and declines to delve into the law of each state. Accordingly, Wood's California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, North Carolina, Oklahoma, Rhode Island, Tennessee, and Virginia claims may proceed in their entirety (subject to the Court's rulings above). New Mexico, however, has a four-year statute of limitations, *see* N.M. Stat. Ann. §§ 27-14-13, 37-1-4, so Wood's New Mexico claims survive only with respect to conduct occurring on or after July 26, 2006.

CONCLUSION

In *Carter*, the Supreme Court candidly acknowledged that its holding could produce "practical problems" with respect to the FCA's *qui tam* provisions. 135 S. Ct. at 1979. No doubt, the same could be true of this Court's holdings above. But, to borrow the *Carter* Court's words again, the FCA's "*qui tam* provisions present many interpretive challenges, and it is beyond [the Court's] ability in this case to make them operate together smoothly like a finely tuned machine." *Id.* So too here. Instead, the Court thus holds as follows:

- With respect to Wood's federal FCA claims (Counts I-V):
  - *First*, Wood's claims are not precluded by the FCA's public disclosure bar, 31 U.S.C. § 3730(e)(4)(A), as the allegations were disclosed only to government officials at the time Wood filed his original complaint;
  - *Second*, the instant action is "related" to the earlier-filed *Lampkin* and *Carytid* actions for purposes of the FCA's first-to-file bar, 31 U.S.C. § 3730(b)(5), but that bar is non-jurisdictional, and — in light of that fact as well as the text, purpose, and structure of the FCA — the first-to-file defect in the original complaint was cured by the filing of the Third Amended Complaint after the earlier-filed actions had been dismissed;
  - *Third*, the FCA's statute-of-limitations provision permitting claims to be brought for up to ten years depending on when the relevant facts are known or should be known to "the official of the United States charged with responsibility to act," 31 U.S.C. § 3731(b)(2), applies to actions brought by private relators;
  - *Fourth*, Rule 15(c)(1)(B) of the Federal Rules of Civil Procedure applies to the question of whether the Third Amended Complaint "relates back" to the original complaint, even though the original complaint was filed under seal and in violation of the "first-to-file" rule;
  - *Fifth*, under Rule 15(c)(1)(B), the Third Amended Complaint relates back to the original complaint for purposes of the statute of limitations because it merely expands on the claims alleged in the initial pleading;
  - *Sixth*, Wood alleges plausible violations of the AKS relating to Allergan's provision of free surgical kits, drug samples, and office supplies;
  - *Seventh*, Wood alleges at least two viable theories of liability under the FCA: express certification of compliance with the AKS for Medicare Part D claims and implied certification of compliance with the AKS for non-Part D Medicare, Medicaid, and TRICARE/CHAMPUS claims;
  - *Eighth*, Wood's core claims under 31 U.S.C. § 3729(a)(1)(1) and (a)(1)(B) satisfy the heightened pleading requirements of Rule 9(b) with respect to Medicare, Medicaid, and TRICARE/CHAMPUS and may proceed, but his CHAMPVA and FEHBP claims are dismissed with leave to amend;

- *Ninth*, Wood's conspiracy claim under 31 U.S.C. § 3729(a)(1)(C) satisfies the heightened pleading requirements of Rule 9(b) and may proceed;
- *Tenth*, Wood's "reverse false claims" claim under 31 U.S.C. § 3729(a)(1)(G) does not meet the heightened pleading requirements of Rule 9(b) and is dismissed with leave to amend; and
- *Eleventh*, Wood alleges a plausible claim of unlawful retaliation, 31 U.S.C. § 3730(h), as he was terminated just after internally reporting purported violations of federal law;

- With respect to Wood's state law claims (Counts VI-XXXI):
  - *First*, Wood's claims under California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Michigan, Nevada, New York, North Carolina, Tennessee, Virginia, and Wisconsin law survive in their entirety; and
  - *Second*, Wood's claims under the remaining state laws at issue are limited to conduct on or after certain dates as follows: Georgia, May 24, 2007; Indiana, July 1, 2005; Minnesota, July 1, 2010; Montana, May 1, 2005; New Jersey, March 13, 2008; New Mexico, July 26, 2006; Oklahoma, November 1, 2007; Rhode Island, July 1, 2007; and Texas, May 4, 2007.

Accordingly, Allergan's motion to dismiss the Third Amended Complaint is DENIED in part and GRANTED in part. To the extent that Wood has been granted leave to file a Fourth Amended Complaint, he shall do so **within thirty days**. Allergan shall answer **within thirty days of that deadline or the filing of the Fourth Amended Complaint, whichever is later**.

The Clerk of Court is directed to terminate Docket No. 64.

SO ORDERED.

Dated: March 31, 2017
New York, New York

JESSE M. FURMAN
United States District Judge