UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, Plaintiff, -against- NOVARTIS PHARMACEUTICALS CORPORATION and BIOSCRIP, INC., Defendants.	**11 CIV. 8196 (CM)**

NOVARTIS PHARMACEUTICALS CORPORATION'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS THE AMENDED COMPLAINT IN INTERVENTION OF THE UNITED STATES OF AMERICA

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Defendant Novartis Pharmaceuticals Corporation ("NPC") respectfully submits, pursuant to Rule 9(b) of the Federal Rules of Civil Procedure, this Memorandum of Law in support of its motion to dismiss the Government's Amended Complaint in Intervention ("Amended Complaint").

PRELIMINARY STATEMENT

The purpose of NPC's motion is to require the Government to particularize and narrow the now-sweeping allegations in the Amended Complaint, which attempts to plead that NPC violated the False Claims Act ("FCA") in connection with "tens of millions of dollars" of prescriptions via two separate and unrelated "kickback" schemes with specialty pharmacies. Although NPC disputes that it engaged in any kickback scheme with specialty pharmacies, it understands that the Court must accept as true the assertions in the Amended Complaint and therefore does not seek, at this initial stage, dismissal of the Amended Complaint with prejudice. What NPC does seek, however, is for the Government to plead with particularity — as courts have widely held it must — specific false claims that resulted from the "kickback schemes." Without that information, NPC cannot fairly defend itself.

The purported "schemes" alleged by the Government involve two different NPC drugs: one alleged scheme relates to Exjade®, the other to Myfortic®. With respect to Exjade, the Amended Complaint contends that NPC provided BioScrip, Inc. ("BioScrip"), a specialty pharmacy, with discounts, rebates and additional patient prescriptions in exchange for BioScrip's increased efforts to promote medication adherence by pressuring patients to order Exjade refills that were somehow not "needed or clinically appropriate." With respect to Myfortic, the Amended Complaint contends that NPC paid "kickbacks" to "twenty or more" specialty pharmacies in the form of discounts and market share rebates pursuant to unwritten side

agreements whereby the pharmacies allegedly committed to undertake efforts to persuade doctors to switch their patients to (or continue prescribing) Myfortic. Notably, however, the Amended Complaint fails to identify any specific claims submitted to the Government that resulted from either of these purported "schemes." This omission is flatly inconsistent with decisions in this Circuit, which require a plaintiff to plead specific false claims with particularity in order to satisfy Rule 9(b).

It is no answer for the Government to plead in conclusory and generalized fashion that every reimbursement claim for Exjade or Myfortic submitted over a multi-year period by the specialty pharmacies is false; the law is clear that only claims resulting from a kickback can be considered false under the FCA. Yet the Government makes no attempt to specify which Exjade refills (if any) resulted from BioScrip calls to patients, let alone those that were actually "unnecessary or clinically inappropriate," a critical omission given that the Government does not challenge the validity of any physician's pre-existing Exjade prescription or identify any instance in which BioScrip contravened a physician's treatment decision. Indeed, the Government's sweeping contention that all Exjade reimbursement claims BioScrip submitted to Medicare or Medicaid were somehow false because of BioScrip's refill calls would include claims for the initial dispensing of Exjade pursuant to a doctor's prescription — claims that, again, could not legitimately be at issue in this litigation. Similarly, the Government makes no attempt to identify which Myfortic prescriptions written by transplant doctors (if any) resulted from any purported influence by specialty pharmacies. The Government simply lumps together all Myfortic reimbursement claims as "false."

There is no justification for the Government's failure to identify actual false claims. During its years-long investigation, the Government received millions of pages of

documents from NPC, the subject pharmacies and hospitals, deposed numerous employees of NPC and the pharmacies and collected and analyzed government claims data for Myfortic and Exjade (to which it had unfettered access). In short, the Government had all the necessary information to properly plead its case and to specify which claims it believes were falsely presented. The Government's failure to do so warrants dismissal of the Amended Complaint in its present form.

FACTUAL BACKGROUND[1]

Exjade

NPC researches, develops, manufactures and markets innovative prescription medicines. One of those medicines is Exjade (deferasirox), a once-daily oral medication approved by the Food and Drug Administration in 2005, that is indicated for the treatment of chronic iron overload resulting from blood transfusions. (Am. Compl. ¶ 151). Chronic iron overload is a dangerous condition that, if left untreated, can damage organs such as the liver and pancreas and can ultimately be fatal. (*See id.*).

Myfortic

Myfortic, a medicine also developed and sold by NPC, is prescribed to kidney transplant patients to help prevent the body's rejection of the transplanted kidney. (*Id.* ¶ 39). Approved by the Food and Drug Administration in 2004, Myfortic (mycophenolic acid) works by suppressing the body's immune response. (*Id.*). The other immunosuppressant in Myfortic's class of medications is CellCept, which is sold in branded form by F.Hoffman-LaRoche Ltd.

[1] For purposes of this motion, NPC must accept as true the allegations in the Amended Complaint. Nothing in this brief, however, is intended or should be construed as an admission by NPC of any of the alleged conduct.

Cellcept became available in generic forms (mycophenolate mofetil or "MMF") in 2009. (*Id.* ¶ 42).

Specialty Pharmacy Distribution of Exjade and Myfortic

The pharmacies involved in this case are primarily "specialty pharmacies." Myfortic is distributed by various specialty pharmacies across the United States. The distribution and dispensing of Exjade is largely coordinated through a single point of contact called Exjade Patient Assistance & Support Services ("EPASS") that receives prescriptions for new Exjade patients and conducts an initial benefits investigation to evaluate patients' insurance coverage for the product. Thereafter, EPASS sends the Exjade prescription to one of three specialty pharmacies (including BioScrip) in the EPASS distribution network. (*Id.* ¶ 161). The specialty pharmacies dispense Exjade to patients, contact them about refills and provide patient education and counseling. (*Id.* ¶¶ 161, 163-164).

The Government's Lawsuit

In November 2011, relator David Kester, then a Sales Manager for NPC's cystic fibrosis medicine TOBI®, initiated this case by filing a *qui tam* suit under seal. Following the filing of the *qui tam* suit, the Government conducted an extensive investigation of NPC's relationships with specialty pharmacies regarding the dispensing of Exjade and Myfortic. In the course of its lengthy investigation, the Government issued over fifty civil investigative demands, obtained more than 15 million pages of documents from NPC, pharmacies and hospitals, and deposed and interviewed numerous NPC and pharmacy employees. In addition, the Government had access to its own data on claims reimbursed by government healthcare programs including Medicare and Medicaid.

The Government intervened as to the relator's allegations concerning Myfortic and filed its original Complaint in Intervention on April 23, 2013. NPC answered the original

Complaint on June 28, 2013. On October 30, 2013, the Government filed a notice of intervention as to the relator's allegations concerning Exjade. On January 8, 2014, the Government filed its Amended Complaint in Intervention, adding BioScrip as a defendant and allegations related to Exjade.

1. The Exjade Allegations

The Government alleges that from February 2007 to May 2012 NPC paid kickbacks to BioScrip in exchange for which BioScrip engaged in "intensive" adherence-related efforts — namely, encouraging patients to refill their Exjade prescriptions and/or resume Exjade therapy that they had discontinued. (Am. Compl. ¶¶ 144-45). These alleged kickbacks took the form of contractual discounts and rebates, as well as the allocation of additional patients to BioScrip through NPC's oversight of the EPASS process, when BioScrip showed improvement in patient adherence. (*Id*. ¶ 145).

NPC first contracted with BioScrip to dispense Exjade in 2005, at which time it provided discounts to BioScrip under an agreement that also provided that BioScrip would contact patients about refills, provide patient education and ship Exjade to patients, among other activities. (*Id.* ¶¶ 163-164). The Government does not allege that the discounts paid beginning in 2005 violated the Anti-Kickback Statute ("AKS") or the FCA.

Rather, the Government contends that a "threat" by NPC in February 2007 to reconsider whether BioScrip should be part of EPASS because its refill levels were below those of the other two EPASS pharmacies transformed BioScrip's patient outreach calls and refill reminders into improper activity and NPC's discounts into purported "kickbacks." The Government contends that after 2007 BioScrip used insufficiently trained and unqualified personnel to call patients (*id.* ¶ 196) and prompted patients to order refills of Exjade that were not "needed or clinically appropriate" (*id.* ¶ 194). This conduct, according to the Government,

resulted in the submission of "tens of thousands of false claims to Medicare and Medicaid." (*Id.* ¶ 231). The Government, however, does not identify or allege with any specificity any such claims or any particular instances in which BioScrip's medication adherence activities usurped the treatment decisions of an Exjade patient's doctor. (There is no suggestion anywhere in the Amended Complaint of any misconduct by NPC in the form of promotion outside the indications of Exjade or Myfortic, or improper payments to doctors with respect to either drug).

2. The Myfortic Allegations

The Government also alleges that discounts and market share rebates in NPC's contracts from 2005 to the present with "twenty-some" pharmacies concerning their purchases of Myfortic constitute kickbacks in violation of the AKS. (*Id.* ¶¶ 61, 127). The discounts and rebates set forth in NPC's written contracts with these pharmacies are the only form of remuneration that the Government asserts NPC provided to the pharmacies in violation of the AKS. These purported kickbacks allegedly resulted in "tens of thousands" of false claims for payment being presented to Government healthcare programs for Myfortic prescriptions. (*Id.* ¶ 141).

The Government contends that agreements outside the four corners of the written contracts, through which the pharmacies supposedly "committed" to NPC that they would encourage doctors to "switch" patients to Myfortic from CellCept and "prevent" those doctors from using generic CellCept, transformed these contractual discounts and rebates into illegal kickbacks. (*Id.* ¶¶ 5, 64-66). The Amended Complaint includes snippets of emails and other documents about these supposed side agreements for only a handful of the pharmacies that the Government claims were paid kickbacks. With respect to the vast majority of the "twenty or more" pharmacies that supposedly received kickbacks from NPC, the Government's Amended Complaint is silent — not even identifying those pharmacies by name. As with Exjade, the

Government alleges that these agreements collectively resulted in "tens of thousands" of false claims without identifying a single claim that allegedly resulted from a pharmacy exerting improper influence over a prescribing doctor to either switch a patient to Myfortic or to maintain a patient on Myfortic.

ARGUMENT

I. THE GOVERNMENT MUST PLEAD ITS FCA CLAIMS WITH PARTICULARITY.

Claims asserting fraud — such as claims brought under the FCA — are governed by the heightened pleading standard set forth in Rule 9(b), which requires the plaintiff to "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b); *Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1477 (2d Cir. 1995) (holding that Rule 9(b) applies to FCA claims).

A. The FCA Prohibits "False Claims," Not Generalized Schemes, and Such Claims Must Be Pled with Particularity.

The FCA prohibits the submission of false claims to the Government for payment and making false statements material to such a claim. *See* 31 U.S.C. § 3729(a)(1)(A)-(B). The Government alleges that NPC violated three subsections of the FCA. These subsections create potential civil liability where a defendant: (i) "knowingly present[ed], or caus[ed] to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A); (ii) "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim," 31 U.S.C. § 3729(a)(1)(B); or (iii) conspired to violate the FCA, 31 U.S.C. § 3729(a)(1)(C).

Importantly, it is not the fraudulent scheme that the FCA seeks to punish; it is the actual submission of a claim or use of a false statement on which the Government ultimately makes payment that creates liability under the FCA. *See U.S. ex rel. Dunn v. N. Mem'l Health Care*, 739 F.3d 417, 419 (8th Cir. 2014) ("The FCA is not concerned with regulatory

noncompliance. Rather, it serves a more specific function, protecting the federal fisc by imposing severe penalties on those whose false or fraudulent claims cause the government to pay money. Accordingly, the FCA generally attaches liability, not to the underlying fraudulent activity, but to the claim for payment.") (internal citations omitted); *U.S. ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 456 (4th Cir. 2013) ("[T]he critical question is whether the defendant caused a false claim to be presented to the government, because liability under the Act attaches only to a claim actually presented to the government for payment, not to the underlying fraudulent scheme.") (citing *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995)).

Because evidence of an actual false claim is "the *sine qua non* of a False Claims Act litigation," Rule 9(b) requires an FCA complaint to allege "with particularity" the "actual false claims submitted to the government." *See U.S. ex rel. Moore v. GlaxoSmithKline, LLC*, No. 06-6047, 2013 WL 6085125, at *5 (E.D.N.Y. Oct. 18, 2013) (quoting *U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir. 2004)); *U.S. ex rel. Polansky v. Pfizer, Inc.*, No. 04-0704, 2009 WL 1456582, at *5 (E.D.N.Y. May 22, 2009) ("[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.").

As Judge Cogan recently observed, "the weight of authority from district courts within this Circuit is that where an alleged FCA violation involves the submission of a false claim to the Government for reimbursement, the details of that false claim must be pled with particularity." *Moore*, 2013 WL 6085125, at *3; *see U.S. ex rel. Siegel v. Roche Diagnostics Corp.*, No. 11-5378, 2013 WL 6847689, at *4 (E.D.N.Y. Dec. 30, 2013); *U.S. ex rel. Chen v. EMSL Analytical, Inc.*, No. 10-7504, 2013 WL 4441509, at *16 (S.D.N.Y. Aug. 16, 2013)

("Courts in the Second Circuit have held that 'allegations of violations of federal regulations are insufficient to establish a claim under the FCA if plaintiff cannot identify, with any particularity, the actual false claims submitted by the defendant.'" (citation omitted)).

B. Where FCA Claims are Premised on AKS Violations, Rule 9(b) Requires Identification of Claims Resulting from the Alleged Kickbacks.

The FCA claims in this case are premised on alleged underlying violations of the AKS, which, in relevant part, makes it illegal to offer or pay "any remuneration (including any kickback, bribe, or rebate)" to any person to induce that person to "purchase, order, or recommend purchasing or ordering any good or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). By its own terms, the AKS creates FCA liability only for claims "resulting from" a violation of the AKS: "[A] claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g).

This express causation requirement for FCA liability necessitates that the Government plead with particularity the link between the alleged kickback scheme and specific false claims. *See, e.g.*, *Chen*, 2013 WL 4441509, at *18 ("[G]iven that . . . the Complaint does not provide any details as to the who, when or why of the false claims themselves, the precise manner in which Defendants' 'fake' samples and 'false' testing reports *are linked* to the 'false reports and invoices' allegedly submitted to the government remains unclear (not to mention what false statements those reports and invoices actually contained).") (emphasis added); *U.S. ex rel. Mooney v. Americare, Inc.*, No. 06-1806, 2013 WL 1346022, at *3-4 (E.D.N.Y. Apr. 3, 2013) (dismissing allegations on Rule 9(b) grounds because details about the fraudulent kickback scheme were "unconnected to specific claims"); *U.S. ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 35 (D.D.C. 2003) (dismissing FCA claims because the

complaint alleged a kickback scheme but did not "link [the] scheme to claims for payment made to the United States").

C. The Government's Complaint Must Meet a Higher Degree of Particularity Because of the Government's Extensive Pre-Filing Investigation.

Where, as here, the plaintiff has already taken substantial pre-filing discovery, courts have required a higher degree of particularity in pleadings. *See*, *e.g.*, *Devaney v. Chester*, 813 F.2d 566, 569 (2d Cir. 1987) ("[W]e recognize that the degree of particularity required should be determined in light of such circumstances as whether the plaintiff has had an opportunity to take discovery of those who may possess knowledge of the pertinent facts."); *Billard v. Rockwell Int'l Corp.*, 683 F.2d 51, 57 (2d Cir. 1982) ("[P]laintiffs here have had access to full discovery. . . . The policies underlying Rule 9(b) call upon us to require greater precision than is found in this complaint when full discovery has been had in a prior case."); *U.S. ex rel. Monda v. Sikorsky Aircraft Corp.*, No. 99-1026, 2005 WL 1925903, at *5-6 (D. Conn. Aug. 11, 2005) (applying strict interpretation of Rule 9(b) to relator who had three months to examine defendant's records and interview its personnel), *aff'd*, 207 F. App'x 28 (2d Cir. 2006). This principle applies with equal force when the Government is the plaintiff. *See SEC v. Tambone*, 417 F. Supp. 2d 127, 131 (D. Mass. 2006) (granting defendants' motion to dismiss, and noting that the government's prior witness and document discovery mandated "rigorous" application of Rule 9(b)'s particularity requirement).

As detailed below, despite the Government's lengthy investigation, during which it deposed and interviewed numerous NPC employees and pharmacy personnel, collected documents from specialty pharmacies, transplant centers, reimbursement claims data related to federal healthcare programs and more than 15 million pages of documents from NPC, the Government has failed to allege the requisite particulars needed to satisfy Rule 9(b).

II. THE GOVERNMENT'S AMENDED COMPLAINT FAILS TO MEET RULE 9(B) PLEADING STANDARDS.

Despite the clear weight of authority in this Circuit, the Government fails to "identify, with any particularity, the actual false claims submitted" as to Exjade or Myfortic. *See Chen*, 2013 WL 4441509, at *16. Instead, the Government simply aggregates the Medicare claims submitted for reimbursement over a multi-year period by BioScrip for Exjade (Am. Compl. ¶ 229) and by a handful of pharmacies for Myfortic (*id*. ¶¶ 82, 91, 100, 109, 121), without identifying which (if any) resulted from the alleged kickback schemes.[2]

As the First Circuit recently held, such "aggregate expenditure data" — without "times, amounts and circumstances" — is insufficient to plead that any false claim was actually submitted. *U.S. ex rel. Ge v. Takeda Pharm. Co.*, 737 F.3d 116, 124 (1st Cir. 2013); *accord Nathan*, 707 F.3d at 460 (affirming dismissal on Rule 9(b) grounds because aggregate data — that 9,000 false claims were submitted to government healthcare programs — without requisite details about specific claims does "not constitute plausible allegations that [defendant] caused presentment of a false claim to the government"). In finding insufficient a pleading alleging that all claims for the medication at issue submitted by healthcare providers were false, the *Ge* court stated:

> Dr. Ge . . . made no attempt in her complaints to allege facts that would show that some *subset* of claims for government payment for the four subject drugs was rendered false as a result of Takeda's alleged misconduct. And any theory that all claims submitted during this period were false has even less basis to

[2] With respect to Medicaid, the allegations are even more wanting. The Amended Complaint is completely silent as to the aggregate number of Medicaid claims each of the named pharmacies submitted for Myfortic. As for Exjade, the Government vaguely asserts that BioScrip submitted "tens of thousands of Exjade claims" to state Medicaid agencies for reimbursements totaling "tens of millions of dollars," but provides the aggregate number of claims submitted for only one state. (Am. Compl. ¶ 230).

> survive. Dr. Ge attempts to satisfy the Rule 9(b) requirements with a per se rule that if sufficient allegations of misconduct are made, it necessarily follows that false claims and/or material false information were filed. We reject that approach, which violates the specificity requirements of Rule 9(b).

Ge, 737 F.3d at 124 (emphasis in original).

The Government's similar attempt here to use aggregate data to contend that all Exjade and Myfortic claims submitted by the referenced pharmacies over a multi-year period were false likewise fails to meet Rule 9(b). The Government's theory — that all claims submitted by these pharmacies are false — ignores critical distinctions between the roles of pharmacies and prescribing physicians. For Exjade, it is the physician — not BioScrip — who makes the initial prescribing decision, including how long the patient should remain on an Exjade treatment regimen and thus how many refills the patient should order. For Myfortic, it is the transplant doctor — not the pharmacy — who makes both the initial prescribing decision and any subsequent decisions regarding which immunosuppressant drug his or her patients should take. The specialty pharmacies at issue unquestionably would have submitted claims for Exjade and Myfortic even if they had no influence — for example, when a patient filled the *initial* prescription for Exjade or Myfortic. To require NPC to defend against "tens of thousands" of allegedly false claim submissions, when the Government has failed to identify a single one that actually resulted from the alleged "kickback schemes," is unfair, burdensome and inconsistent with Rule 9(b) and applicable case law in this Circuit.

A. The Amended Complaint Fails to Identify False Claims That Resulted from BioScrip's Adherence Communications with Exjade Patients.

Nowhere in the Amended Complaint does the Government identify with particularity any false reimbursement claims for Exjade submitted to a government healthcare program, let alone one that resulted from any pressure BioScrip purportedly exerted on a patient

to order an unnecessary or clinically inappropriate refill. This failure is particularly conspicuous and significant because refills of medications are the natural and intended consequence of a doctor's initial prescribing decision, and are particularly necessary and clinically appropriate for a medicine like Exjade that must be taken over an extended period of time to be effective. Indeed, the Government itself has recognized that patients' adherence to their prescribed medication therapy, including ordering refills, is beneficial and should be encouraged. For example, the Government, in administering Medicare, incentivizes refill calls by requiring Part D plan sponsors to establish Medication Therapy Management Programs that include "medication refill reminders" and "compliance programs." 42 U.S.C. § 1395w-104(c)(2)(B)(ii). And, despite the Government's allegations here that BioScrip personnel were insufficiently qualified and untrained, nowhere does the Government specify in its Amended Complaint which advanced degrees or professional training those employed by specialty pharmacies must possess when calling patients about their refills in order for those pharmacies and the manufacturer of the medicine to avoid violating the AKS or FCA.

Although it recognizes elsewhere that refills are often appropriate, the Government in this case makes no effort to describe which Exjade claims were actually false under its theory — that is, which claims resulted from interactions between BioScrip and Exjade patients that led to unnecessary or inappropriate refills — as required by the heightened pleading standard of Rule 9(b). *See Chen*, 2013 WL 4441509, at *16-18; *Mooney*, 2013 WL 1346022, at *3-4. The Amended Complaint does not allege any instance where a doctor's prescribing order was overturned — or even influenced — by BioScrip. Nor does the Government identify any instance in which a BioScrip employee is alleged to have told a patient to act contrary to his or her doctor's orders. In fact, the Amended Complaint does not even identify any specific instance

in which statements by BioScrip affected a patient's decision one way or the other about an Exjade refill, let alone a refill that was not necessary for the health of the patient or that was not intended by his or her physician.

Instead, the Government's Amended Complaint includes blanket assertions that all claims submitted by BioScrip from February 2007 forward were false, ignoring that some patients undoubtedly requested refills without even being contacted by BioScrip, or would have done so even if they had not been contacted. The Government also fails to account for patients' *initial* Exjade prescriptions filled by BioScrip and how these prescriptions could be rendered "false" by BioScrip's efforts regarding refills. There can be no serious contention that a claim for the initial prescription for Exjade is false or fraudulent due to BioScrip's subsequent adherence activities, even assuming the legitimacy of the Government's novel kickback theory. Yet the Government seeks to recover for all Exjade prescriptions filled by BioScrip after February 2007. In summary, the Government's failure to identify with sufficient particularity any specific false claims that allegedly resulted from BioScrip's adherence activities warrants dismissal of the Amended Complaint as to the Exjade allegations.

B. The Amended Complaint Fails to Identify Specific False Claims that Resulted from Any Specialty Pharmacy's Alleged Conversion Efforts with Doctors Regarding Myfortic.

Like its Exjade claims, the Government's Myfortic claims fail to allege a link between the Myfortic-related "kickback scheme" alleged by the Government and the submission of actual false claims to Medicare or Medicaid. The Government provides no basis to determine which Myfortic claims it contends were actually false — that is, which claims resulted from efforts by a pharmacy to persuade a doctor to convert a patient to, or maintain a patient on, Myfortic for inappropriate reasons.

For example, the Government alleges that the owner of Bryant's Pharmacy was "very influential" in the area's transplant community, that he "used his influence to promote Myfortic for Novartis," and that as a result he was able to change patients' prescriptions from CellCept to Myfortic. (Am. Compl. ¶¶ 72, 74). But with respect to how this "scheme" actually resulted in any false claims, the Amended Complaint alleges only that Bryant's Pharmacy's owner "used his influence" (*id.* ¶ 74) and "argued against" switching patients to generic CellCept (*id.* ¶¶ 77-78). The Government does not identify the specifics of any communication between Bryant's Pharmacy and a prescribing physician or a single prescribing decision that was purportedly influenced by Bryant's Pharmacy. The closest the Government comes to providing the requisite specificity is alleging that unidentified patients were converted from CellCept to Myfortic (*id.* ¶ 74) or that an unidentified doctor, at some point after Bryant's Pharmacy's owner "argued against" switching Myfortic patients to generic CellCept, decided to continue prescribing Myfortic to patients already taking it (for unspecified reasons, which could well have been clinical reasons). (*Id.* ¶¶ 76-77).

From these vague and conclusory allegations, the Government makes the unsupported leap that all claims submitted by Bryant's for Myfortic during the alleged time period were false. (*Id.* ¶ 82 (alleging that aggregate data from Medicare shows that "since 2005, Bryant has submitted more than 8,300 Myfortic claims to Medicare Part B alone and has obtained more than $3.2 million in reimbursement on such false claims")). The Amended Complaint's allegations regarding other named pharmacies follow this same pattern.[3]

[3] With respect to Baylor, the Government fails to allege that the Baylor outpatient pharmacy influenced a single doctor to change his or her prescribing decision. Similar failures infect the Government's allegations as to the other named pharmacies, including Transcript, Kilgore's and Twenty-Ten — where the Government alleges no link between a prescription

It is not sufficient for the Government to allege that ***all*** claims from a specialty pharmacy are false; such a sweeping theory is simply not plausible. For example, where specialty pharmacies dispensed Myfortic to patients whose transplant surgeons had prescribed Myfortic immediately after surgery in the hospital, the ensuing "maintenance" prescriptions resulted from the physician's initial prescribing decision — not a pharmacy's "influence." Similarly, Myfortic prescriptions that resulted from a doctor's independent judgment that Myfortic was more clinically appropriate for the patient than Cellcept could not be said to have been influenced by the pharmacies. Indeed, transplant doctors may decide to prescribe or switch a patient to Myfortic for any number of reasons, including to alleviate side effects that patients may be experiencing on Cellcept or MMF, without any input from a pharmacist whatsoever. Yet the Government alleges that all Myfortic prescriptions dispensed by each of the pharmacies in its complaint are fraudulent, making no attempt to identify those prescriptions (if any) that resulted from the conduct it alleges.

C. The Government's Allegations Regarding Numerous Unnamed Myfortic Pharmacies Do Not Satisfy Rule 9(b)'s Heightened Pleading Standard.

Beyond failing to identify actual false claims, the allegations in the Government's Amended Complaint relating to Myfortic also fail to identify the vast majority of the numerous specialty pharmacies with which NPC purportedly entered into "side agreements" outside the written market share rebate contracts. If the Government contends that there are "twenty-some" specialty pharmacies at issue, it should have identified those remaining pharmacies and pleaded particulars about any so-called side agreements in which such pharmacies were paid kickbacks in exchange for undertaking conversion activities. Indeed, one would expect that, if the

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and the alleged kickback scheme, relying instead on aggregate sales data and trends that fail to meet Rule 9(b).

Government had any basis for alleging such a scheme with respect to these other pharmacies, it would have done so; after all, the Government conducted an extensive investigation, which included depositions, interviews and the collection of millions of pages of materials from NPC, the specialty pharmacies and transplant centers.

Moreover, even if the specific examples pled by the Government with respect to a handful of pharmacies were sufficient (which they are not), those examples cannot be extrapolated to cover the other "twenty-some" specialty pharmacies referenced in the Amended Complaint. The "ability to plead examples . . . is not a 'license to base claims of fraud on speculation and conclusory allegations.'" *U.S. ex rel. Fox Rx Inc. v. Omnicare, Inc.*, No. 11-962, 2013 WL 2303768, at *7 (N.D. Ga. May 17, 2013) (quoting *U.S. ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1314 n.25 (11th Cir. 2002)). That holds particularly true where, as here, the Government's distinctions between lawful and unlawful activity regarding Myfortic (at least as alleged in the complaint) appear to turn entirely on the inclusion of factual allegations (the purported side agreements) in the Amended Complaint. This is because the AKS contains an exception for "discount[s] or other reduction[s] in price" that are "properly disclosed." 42 U.S.C. § 1320a-7b(b)(3)(a).

Moreover, the Government's failure to plead with particularity any facts concerning the other specialty pharmacies poses exactly the problems Rule 9(b) is intended to prevent. Like the failure to identify claims resulting from the alleged "kickback schemes," the lack of particularity as to these other pharmacies deprives NPC of the notice a complaint is supposed to provide so that a defendant may guide its discovery efforts and prepare its defense. *See*, *e.g.*, *Buckley v. Deloitte & Touche USA LLP*, No. 06-3291, 2007 WL 1491403, at *11 (S.D.N.Y. May 22, 2007) (pleading should be particular enough to "place the defendants on

notice of the precise misconduct with which they are charged") (internal citations and quotations omitted). Without some understanding of what the Government contends the other side agreements at issue are, and thus why they are unlawful, NPC cannot prepare its defense.

In such circumstances, courts have recognized that they have the power and authority to require more of plaintiffs, including the Government. *See U.S. ex rel. Dhawan v. N.Y.C. Health & Hosp. Corp.*, No. 95-7649, 2000 WL 1610802, at *3 (S.D.N.Y. Oct. 27, 2000) (dismissing *qui tam* in part because details provided about an allegedly fraudulent arrangement between the defendants and several hospitals did not permit relator to "then make[] an unjustified quantum leap" that because other hospitals had similar contracts with the defendants, the same fraudulent conduct must have occurred); *Fox Rx Inc.*, 2013 WL 2303768, at *7 (finding that, under Rule 9(b), a broader scheme — involving claims in other years or that were submitted through other PDP sponsors — could not be "inferred from the conduct for which Relator alleges actual information"); *United States v. Bank of N.Y. Mellon*, 941 F. Supp. 2d 438, 482 (S.D.N.Y. 2013) (dismissing on 9(b) grounds the Government's allegations regarding misrepresentations made to ERISA clients because "an example of a non-ERISA client is not 'representative' of ERISA clients when that distinction is essential to a finding of fraud"); *U.S. ex rel. Thomas v. Bailey*, No. 06-0465, 2008 WL 4853630, at *6 (E.D. Ark. Nov. 6, 2008) (dismissing allegation of a national corporate policy of kickbacks because the complaint only offered five anecdotal examples).

III. THE GOVERNMENT'S UNJUST ENRICHMENT CLAIM SHOULD BE DISMISSED.

The Government's unjust enrichment claim (Am. Compl. ¶¶ 247-250, 266-269) should be dismissed because it fails to articulate how NPC was unlawfully enriched. To properly plead such a claim, the Government must show that: "(1) . . . the defendant benefitted; (2) at the plaintiff's expense; and (3) . . . equity and good conscience require restitution." *Fed. Treasury Enter. Sojuzplodoimport v. Spirits Int'l N.V.*, 400 F. App'x 611, 613 (2d Cir. 2010) (unpub.). Because the unjust enrichment claim is premised entirely on the alleged submission of reimbursement claims rendered false by AKS violations (Am. Compl. ¶¶ 141-142), the unjust enrichment claim should be dismissed for the same reasons as the FCA claim. *See, e.g.*, *LaCroix v. U.S. Bank, N.A.*, No. 11-3236, 2012 WL 2357602, at *7 (D. Minn. June 20, 2012) (dismissing unjust enrichment claim that was premised on an alleged kickback scheme after determining kickback scheme was not adequately pleaded); *Bonner v. Redwood Mortg. Corp.*, No. 10-0479, 2010 WL 1267069, at *6-7 (N.D. Cal. March 29, 2010) (same); *see also In re Pfizer Inc. S'holder Derivative Litig.*, 722 F. Supp. 2d 453, 465-66 (S.D.N.Y. 2010) (dismissing unjust enrichment claim where underlying allegation of illegal marketing by pharmaceutical company failed to state a claim for relief).

CONCLUSION

For the foregoing reasons, the Court should grant NPC's motion and dismiss the Amended Complaint in Intervention of the United States.

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Respectfully submitted,

/s/ Michael A. Rogoff
Michael A. Rogoff
Manvin Mayell
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
Tel. No.: 212-836-8000
michael.rogoff@kayescholer.com

Evan R. Chesler
Rachel G. Skaistis
CRAVATH, SWAINE & MOORE LLP
Worldwide Plaza
825 Eighth Avenue
New York, New York 10019
Tel. No.: 212-474-1000

Faith E. Gay
Manisha M. Sheth
QUINN EMANUEL URQUHART & SULLIVAN LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
Tel. No.: 212-849-7000

Counsel for Defendant
Novartis Pharmaceuticals Corporation