UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES, et al. ex rel.
OSWALD BILOTTA,

Plaintiffs and Relator,

-against-

NOVARTIS PHARMACEUTICALS
CORPORATION,

Defendant.

MEMORANDUM OPINION & ORDER

11 Civ. 0071 (PGG)

PAUL G. GARDEPHE, U.S.D.J.:

In this qui tam action, Relator Oswald Bilotta alleges that Defendant Novartis Pharmaceuticals Corporation ("Novartis") violated the False Claims Act ("FCA"), 31 U.S.C. §§ 3729(a)(1)(A)-(B) and related state laws by (1) causing false claims for reimbursement for patient prescriptions – that were written in exchange for kickbacks in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b and related state laws – to be submitted to federal and state health care programs ("the kickback claims"); and (2) promoting the drug Valturna for off-label use, thereby causing the submission of false claims to federal and state health care programs ("the off-label promotion claims").[1] The United States (the "Government") and the State of New York (collectively, the "Government Entities" or "Plaintiffs") have intervened as to the kickback claims.

Novartis has moved to dismiss the Government's Amended Complaint-in-Intervention, New York's Complaint-in-Intervention, and the Relator's Third Amended

[1] Bilotta is a former Novartis sales representative. (See Relator's Third Am. Cmplt. ("TAC") (Dkt. No. 50) ¶ 9; Relator Br. (Dkt. No. 105) at 1)

Complaint. For the reasons stated below, Novartis's motions will be denied in part and granted in part.

BACKGROUND

I. FACTS[2]

A. The Alleged Kickback Scheme

Plaintiffs allege that from January 2002 through at least November 2011, Novartis systematically bribed doctors to induce them to prescribe drugs from Novartis's cardiovascular division for their patients. (See U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 1, 66; N.Y. Cmplt. (Dkt. No. 61) ¶¶ 2, 3, 57) These drugs include Lotrel, Diovan, Diovan HCT, Tekturna, Tekturna HCT, Exforge, Exforge HCT, Valturna, Tekamlo, and Starlix.[3] (See U.S. Am. Cmplt. (Dkt. No. 62) ¶ 66; N.Y. Cmplt. (Dkt. No. 61) ¶ 57) Novartis sold these drugs through a network of sales representatives who met with health care professionals throughout the United States. (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 67; N.Y. Cmplt. (Dkt. No. 61) ¶ 58)

Novartis induced doctors to prescribe these drugs primarily through the use of "sham" speaker events. (U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 1-3; N.Y. Cmplt. (Dkt. No. 61) ¶¶ 2-4) According to Novartis's internal policies, speaker events were intended to be educational programs; Novartis would pay doctors to educate other doctors and health care professionals about Novartis drugs by presenting slides prepared by Novartis. (U.S. Am. Cmplt. (Dkt. No. 62)

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[2] The Court's factual statement is drawn from the Relator's Third Amended Complaint (Dkt. No. 50), the Government's Amended Complaint-in-Intervention (Dkt. No. 62), and New York's Complaint-in-Intervention (Dkt. No. 61). The facts alleged in these pleadings are presumed true for purposes of resolving Defendant's motion to dismiss. See Kassner v. 2nd Ave. Delicatessen, Inc., 496 F.3d 229, 237 (2d Cir. 2007).

[3] A 2010 settlement between Novartis, the Department of Justice, and several states released claims relating to Diovan, Tekturna, and Exforge through December 31, 2009. (U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 63, 172; N.Y. Cmplt. (Dkt. No. 61) ¶¶ 54, 133) Accordingly, the only claims related to those drugs here are those that arise from conduct that occurred after December 31, 2009. (See U.S. Am. Cmplt. (Dkt. No. 62) ¶ 173; N.Y. Cmplt. (Dkt. No. 61) ¶ 134)

¶ 2; N.Y. Cmplt. (Dkt. No. 61) ¶ 4) These events were organized and conducted by Novartis sales representatives. (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 72; N.Y. Cmplt. (Dkt. No. 61) ¶ 69) They chose the speaker, topic, and venue for the events, as well as the attendees. (See U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 72-73, 81; N.Y. Cmplt. (Dkt. No. 61) ¶¶ 6, 69)

Novartis held thousands of speaker events at which few or no slides were shown, however, and at which the attendees spent little or no time discussing the drugs that were allegedly the focus of the programs. (U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 2, 95; N.Y. Cmplt. (Dkt. No. 61) ¶¶ 4, 82) These events thus served as little more than upscale social outings designed to induce doctors to write prescriptions for Novartis drugs. (U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 1, 77, 121, 135-36; N.Y. Cmplt. (Dkt. No. 61) ¶¶ 2, 4, 82, 86-87)

According to Plaintiffs, the sham nature of these events was apparent from the attendees, speakers, subject matter, and venues. (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 95; N.Y. Cmplt. (Dkt. No. 61) ¶ 82) Frequently, groups of the same doctors would repeatedly attend speaker events on the same topic within a short period of time, with the doctors taking turns in the roles of attendees and "speakers." (U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 95-120, 126; N.Y. Cmplt. (Dkt. No. 61) ¶¶ 82-85) For example, one doctor attended the same presentation ten times between July 2010 and October 2011, and the same three doctors were consistently present at nine of those events. (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 97; N.Y. Cmplt. (Dkt. No. 61) ¶ 84) Moreover, Novartis hosted many of its speaker events at high-end restaurants or sports bars without private rooms, making it difficult or impossible to hear the speaker or show slides; it was common for no slides to be shown at such events. (U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 121, 125-28, 130, 133-34; N.Y. Cmplt. (Dkt. No. 61) ¶¶ 86-90) Other venues were similarly inappropriate

for the types of "educational" events that Novartis purported to be hosting, such as "round table" programs at Hooters restaurants and fishing trips. (U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 122-24)

Sales representatives frequently asked speakers who they should invite as attendees to these events, and doctors used this as an opportunity to invite their friends. (Id. ¶ 136; N.Y. Cmplt. (Dkt. No. 61) ¶ 91) Often the drug that was supposed to be the subject of the speaker program was never discussed. (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 137; N.Y. Cmplt. (Dkt. No. 61) ¶ 92)

The doctors who Novartis designated as "speakers" for these events were paid "honoraria" by Novartis, even though they spent little or no time discussing the drugs that were supposedly the subject of the programs. (U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 3, 78; N.Y. Cmplt. (Dkt. No. 61) ¶¶ 4, 92) "Speakers" were paid between $750 and $1500 for each event, with some speakers being paid as much as $3000. (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 79; N.Y. Cmplt. (Dkt. No. 61) ¶ 67) In some instances, speaker events reflected in Novartis records never took place, or doctors recorded as attending were not, in fact, present; nevertheless, the designated "speakers" were compensated for these non-existent events. (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 138-44; N.Y. Cmplt. (Dkt. No. 61) ¶ 93)

Novartis's internal analysis showed that its speaker programs had a high "return on investment," as doctors who attended the events – as either speakers or attendees – wrote an increased number of prescriptions for Novartis drugs. (U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 3, 145-48; N.Y. Cmplt. (Dkt. No. 61) ¶¶ 94-96) Novartis found that the more incentives doctors received in the form of meals, entertainment, and honoraria from these events, the more Novartis prescriptions the doctors would write. (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 147; N.Y. Cmplt. (Dkt. No. 61) ¶ 95) The highest return on investment came from doctors who were paid to "speak" at

the events. (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 3) Novartis considered its speaker programs to be a "key component of [Novartis's] promotional activities aimed at increasing its sales of drugs" from 2002 to at least 2011. (Id. ¶ 71; N.Y. Cmplt. (Dkt. No. 61) ¶ 61) Novartis spent more than $65 million for more than 38,000 speaker programs ostensibly about Lotrel, Starlix, and Valturna between January 1, 2002 and November 2011. (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 71; N.Y. Cmplt. (Dkt. No. 61) ¶ 61)

Novartis intended its speaker programs to increase prescription-writing, and doctors knew this. (U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 147-50; N.Y. Cmplt. (Dkt. No. 61) ¶¶ 97-99) Doctors were chosen to be speakers if they wrote a high number of prescriptions for Novartis cardiovascular division drugs, and they had to maintain or increase that level of prescription-writing in order to be invited to appear as a "speaker" again. (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 149; N.Y. Cmplt. (Dkt. No. 61) ¶ 98) Accordingly, once they began receiving honoraria, many doctors significantly increased the number of prescriptions that they wrote for Novartis drugs, or started prescribing Novartis drugs if they had not done so before. (U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 150-58; N.Y. Cmplt. (Dkt. No. 61) ¶¶ 99-124) Doctors often continued to increase their prescription-writing as the amount of honoraria they received increased. (U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 150-58; N.Y. Cmplt. (Dkt. No. 61) ¶¶ 99-124) Novartis placed no limit on the number of programs a doctor could attend or how often a doctor could attend the same program. (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 84; N.Y. Cmplt. (Dkt. No. 61) ¶ 71)

Novartis also encouraged sham events by creating incentives for its sales representatives to host them. Sales representatives in the cardiovascular division were compensated based upon the number of prescriptions that doctors wrote for Novartis drugs. (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 75; N.Y. Cmplt. (Dkt. No. 61) ¶¶ 6, 64) They were given

budgets to use on speaker events, and they were pressured to exhaust their budgets for such events. (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 76) Although Novartis policies provided for caps on the price per meal for attendees at these events, sales representatives could avoid these caps by attributing costs that exceeded the caps to "unmet minimums," i.e., the difference between a restaurant's minimum spending requirement for an event and the amount that sales representatives were permitted to spend per attendee under the caps. (Id. ¶¶ 87-88; N.Y. Cmplt. (Dkt. No. 61) ¶¶ 74-75) By inviting few attendees and attributing the excess to a restaurant's "unmet minimum" cost, speakers could spend lavishly on food and alcohol well beyond the caps. (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 88; N.Y. Cmplt. (Dkt. No. 61) ¶ 75) Accordingly, spending for dinners frequently exceeded the caps, with hundreds of dollars being spent on each individual attendee's meal. (U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 88, 130-32; see N.Y. Cmplt. (Dkt. No. 61) ¶ 75)

Novartis also turned a blind eye as to whether its speaker programs were being used for illegitimate purposes. (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 5; N.Y. Cmplt. (Dkt. No. 61) ¶ 6) Novartis did not require signatures on attendance sheets at speaker events, and it was the sales representatives themselves who were responsible for reviewing the accuracy of receipts from speaker event venues. (U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 91-92; N.Y. Cmplt. (Dkt. No. 61) ¶¶ 78-79) There was no system in place to prevent sales representatives from repeatedly selecting the same doctors as attendees at speaker programs on the same topics, or to prevent them from arranging for the same doctors to take turns speaking and attending each other's programs repeatedly. (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 84; N.Y. Cmplt. (Dkt. No. 61) ¶ 71) When sales representatives were reported for misconduct, Novartis's only punishment was a "slap on the wrist," such as placing a "conduct memo" in the employee's file. (U.S. Am. Cmplt.

(Dkt. No. 62) ¶¶ 5, 169-71; N.Y. Cmplt. (Dkt. No. 61) ¶ 6) In some circumstances, sales representatives who were reported for non-compliance were even later promoted. (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 5; N.Y. Cmplt. (Dkt. No. 61) ¶ 6)

When doctors wrote increased prescriptions for Novartis drugs as a result of kickbacks – which pharmacies then filled, submitting claims for reimbursement to federal and state healthcare programs – they violated federal and state anti-kickback laws. According to Plaintiffs, compliance with these laws is a precondition for reimbursement. (U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 17-18, 175-82; N.Y. Cmplt. (Dkt. No. 61) ¶¶ 135-44) Accordingly, as a result of the kickbacks it offered to physicians, Novartis caused thousands of false claims to be submitted for payment to federal healthcare programs – including Medicare, Medicaid, TRICARE, and the Veterans Administration healthcare program, (U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 6, 20-56, 175) – and state healthcare programs, including New York Medicaid. (N.Y. Cmplt. (Dkt. No. 61) ¶¶ 7, 135-46)

B. Alleged Off-Label Promotion

Novartis allegedly promoted one of its cardiovascular – Valturna – for off-label use. (Relator Third Am. Cmplt. ("TAC") ¶¶ 104-25)

Prior to June 2010, Novartis had been selling Diovan, a "blockbuster" hypertension drug. (See id. ¶¶ 104, 108) Diovan generated more than $4 billion for Novartis in 2009. (Id. ¶ 104) Novartis's patent for Diovan was set to expire in 2012. (Id.)

To make up for anticipated losses resulting from the expiration of the Diovan patent, Novartis sought to build the market share of Valturna. (Id. ¶ 105) Novartis's strategy was to market Valturna to diabetic patients who might experience high blood pressure, as opposed to hypertensive patients who were already adequately controlled on existing therapies.

(Id. ¶ 106) Novartis did so by training sales representatives in off-label sale and marketing practices, and using promotional materials and speaker events to suggest that hypertensive diabetics would benefit from Valturna, even though the drug was not indicated for that particular patient population. (Id. ¶¶ 109-11, 113) Novartis's promotional materials also included data from trials on rodents; sales representatives were instructed to present the data in such a way that doctors would assume that the data reflected results in humans. (Id. ¶ 112)

When healthcare providers prescribed Valturna and subsequently submitted claims for payment, they were required to certify – as a pre-condition to payment – that the services for which they were billing were "medically indicated and necessary for the health of the patient." (Id. ¶ 114) Relator alleges that Novartis's off-label promotion of Valturna caused healthcare providers to submit claims for reimbursement that were false, because the drug was neither medically indicated nor necessary for the treatment of diabetic patients. (Id.)

C. Novartis's 2010 Settlement

In September 2010, Novartis entered into an agreement with the United States Department of Justice and several states, including New York, to settle a number of FCA claims that had been brought against it. (See U.S. Am. Cmplt. (Dkt. No. 62) ¶ 4; N.Y. Cmplt. (Dkt. No. 61) ¶ 5) In the settlement agreement, Novartis acknowledged that it had "provided illegal remuneration, through mechanisms such as speaker programs, advisory boards, and gifts (including entertainment, travel and meals), to health care professionals to induce them to promote and prescribe the [Novartis] drugs Diovan, Zelnorm, Sandostatin, Exforge, and Tekturna, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. 1320a-7b(b)." (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 63; N.Y. Cmplt. (Dkt. No. 61) ¶ 54) By offering kickbacks to health care professionals, Novartis had caused false claims – in the form of claims for reimbursement for

prescriptions for those drugs – to be submitted to federal and state healthcare programs. (See U.S. Am. Cmplt. (Dkt. No. 62) ¶ 4; N.Y. Cmplt. (Dkt. No. 61) ¶ 5)

In connection with the 2010 settlement, Novartis signed a Corporate Integrity Agreement ("CIA") with the U.S. Department of Health and Human Services Inspector General's Office in which Novartis agreed to implement a rigorous compliance program to comply with the Anti-Kickback Statute and the FCA. (See U.S. Am. Cmplt. (Dkt. No. 62) ¶ 4; N.Y. Cmplt. (Dkt. No. 61) ¶ 5) The CIA required Novartis to "ensure that [its] Policies and Procedures address . . . appropriate ways to conduct Promotional Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the federal anti-kickback statute . . . and the False Claims Act," and to enact polices and procedures that "address . . . programs to educate sales representatives, including but not limited to presentations by [health care professionals]" in order "to ensure that the programs are used for legitimate and lawful purposes. . . ." (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 64; N.Y. Cmplt. (Dkt. No. 61) ¶ 55) The CIA further required Novartis to enact compliance policies that "address . . . compensation (including . . . salaries, bonuses, and contests) for . . . sales representatives" "to ensure that financial incentives d[id] not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of Novartis'[s] Government Reimbursed Products." (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 65; N.Y. Cmplt. (Dkt. No. 61) ¶ 56)

II. PROCEDURAL HISTORY

Relator Oswald Bilotta – a former Novartis sales representative – filed the qui tam Complaint in this action on January 5, 2011. (Relator Cmplt. (Dkt. No. 1)) According to Bilotta, in paying kickbacks to doctors, Novartis caused the submission of false claims in relation to drugs other than those named in the 2010 settlement, and Novartis did not disclose this fact

during the settlement negotiations. Bilotta further claims that Novartis continued its unlawful practices even after the 2010 settlement, with respect to drugs that were named in the settlement, as well as additional drugs. Bilotta also alleges that Novartis caused false claims to be submitted by promoting Valturna for off-label use.

Bilotta – as Relator – asserted claims on behalf of the United States, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, Wisconsin, the District of Columbia, the City of Chicago, and the City of New York.

On April 26, 2013, the United States elected to intervene as a plaintiff in this case – but only as to the kickback claims – and filed a Complaint-in-Intervention. (Dkt. Nos. 13, 16) On July 10, 2013, Relator filed a Third Amended Complaint ("TAC") asserting both the kickback and off-label promotion claims. (Dkt. No. 50) On August 26, 2013, New York State filed a Complaint-in-Intervention, electing to intervene as to the kickback claims only. (N.Y. Cmplt. (Dkt. No. 61)) All other states and municipalities declined to intervene.

In July 2013, Novartis submitted a pre-motion letter indicating that it intended to move to dismiss the Government's Complaint-in-Intervention. A pre-motion conference was held on July 18, 2013. Although it had not yet intervened, New York attended this conference. The Court questioned whether the Government's Complaint-in-Intervention satisfied the pleading requirements of Fed. R. Civ. P. 9(b), because the pleading did not "contain any allegations about who submitted the [false or fraudulent] claims, how they were submitted and paid, or when they were submitted, and in particular when they were paid within the 11-year

time frame cited in the complaint." (July 18, 2013 Tr. (Dkt. No. 53) at 11). This Court granted the Government leave to amend its pleading. (Dkt. No. 51)

After this conference, the Government filed an Amended Complaint-in-Intervention. (U.S. Am. Cmplt. (Dkt. No. 62)) The Amended Complaint includes 316 pages of spreadsheets that list allegedly false or fraudulent claims for reimbursement – relating to prescriptions that were written for Novartis drugs – that were submitted by pharmacies to specific federal programs. (See U.S. Am. Complt. (Dkt. No. 62), Exs. A-O) The Government asserts claims for violations of Sections 3729(a)(1)(A) and (a)(1)(B) of the FCA, as well as a common law claim for unjust enrichment. (Id. ¶¶ 183-92)

On August 26, 2013, New York filed its Intervenor Complaint (the "New York Complaint"). (N.Y. Cmplt. (Dkt. No. 61)) New York asserts claims for (1) violation of the New York False Claims Act ("N.Y. FCA"), N.Y. State Fin. Law § 189(1)(a), relating to the filing of false claims for Medicaid reimbursement; (2) violation of the N.Y. FCA, N.Y. State Fin. Law § 189(1)(b), involving use of false records; (3) violation of New York Social Services Law §145-b), (4) violation of New York Executive Law § 63(12) by engaging in repeated and persistent fraud; (5) violation of New York Executive Law § 63-c; and (6) unjust enrichment. (Id. ¶¶ 148-67) The New York Complaint includes 249 pages of spreadsheets that list allegedly false or fraudulent claims, "certification statements" executed by doctors who had written the prescriptions that resulted in the submission of those false claims, and signed certification statements for the pharmacies that submitted those claims. (See id., Exs. A-C)

On October 24, 2013, Novartis moved to dismiss the Government's Amended Complaint and the New York Complaint. (Dkt. Nos. 79, 81) On December 20, 2013, Novartis moved to dismiss the Relator's TAC. (Dkt. No. 98)

DISCUSSION

I. LEGAL STANDARD

A. Pleading Standards on Motion to Dismiss

1. Fed. R. Civ. P. 12(b)(6) Standard

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "In considering a motion to dismiss . . . the court is to accept as true all facts alleged in the complaint," Kassner v. 2nd Ave. Delicatessen Inc., 496 F.3d 229, 237 (2d Cir. 2007) (citing Dougherty v. Town of N. Hempstead Bd. of Zoning Appeals, 282 F.3d 83, 87 (2d Cir. 2002)), and must "draw all reasonable inferences in favor of the plaintiff." Id. (citing Fernandez v. Chertoff, 471 F.3d 45, 51 (2d Cir. 2006)).

A complaint is inadequately pled "if it tenders 'naked assertion[s]' devoid of 'further factual enhancement,'" Iqbal, 556 U.S. at 678 (quoting Twombly, 550 U.S. at 557), and does not provide factual allegations sufficient "to give the defendant fair notice of what the claim is and the grounds upon which it rests." Port Dock & Stone Corp. v. Oldcastle Ne., Inc., 507 F.3d 117, 121 (2d Cir. 2007) (citing Twombly, 550 U.S. at 555). "In considering a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6), a district court may consider the facts alleged in the complaint, documents attached to the complaint as exhibits, and documents incorporated by reference in the complaint." DiFolco v. MSNBC Cable L.L.C., 622 F.3d 104, 111 (2d Cir. 2010) (citing Chambers v. Time Warner, Inc., 282 F.3d 147, 153 (2d Cir. 2002); Hayden v. Cnty. of Nassau, 180 F.3d 42, 54 (2d Cir. 1999)).

2. Fed. R. Civ. P. 9(b) Standard

"Because the False Claims Act is an anti-fraud statute, 'claims brought under the FCA fall within the express scope of Rule 9(b).'" United States v. New York Soc. for the Relief of the Ruptured & Crippled, Maintaining the Hosp. for Special Surgery, No. 07 Civ. 292 (PKC), 2014 WL 3905742, at *7 (S.D.N.Y. Aug. 7, 2014) (quoting Gold v. Morrison-Knudsen Co., 68 F.3d 1475, 1477 (2d Cir. 1995)). Rule 9(b) provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). "The purpose of Rule 9(b) is threefold – it is designed to provide a defendant with fair notice of a plaintiff's claims, to safeguard a defendant's reputation from 'improvident charges of wrongdoing,' and to protect a defendant against the institution of a strike suit." O'Brien v. Nat'l Analysts Partners, 936 F.2d 674, 676 (2d Cir. 1991) (quoting Ross v. Bolton, 904 F.2d 819, 823 (2d Cir. 1990)).

"Rule 9(b) does not impose a 'one size fits all' list of facts that must be included in every FCA complaint." U.S. ex rel. Kester v. Novartis Pharm. Corp., -- F. Supp. 2d --, 88 Fed. R. Serv. 3d 1261, at *15 (S.D.N.Y. May 29, 2014) (quoting In re Cardiac Devices Qui Tam Litig., 221 F.R.D. 318, 337-38 (D. Conn. 2004)). "Ultimately, whether a complaint satisfies Rule 9(b) '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.'" Id. (quoting United States v. Wells Fargo Bank, N.A., 972 F. Supp. 2d 593, 616 (S.D.N.Y. 2013)). This "is a fact-specific inquiry." Id.

B. False Claims Act

1. Federal False Claims Act

"The FCA facilitates restitution to the federal government when money is fraudulently taken from it." New York Soc., 2014 WL 3905742, at *8. "The FCA permits a relator to bring a qui tam action 'for a violation of section 3729 for the person and for the United States Government. The action [is] brought in the name of the Government.'" Id. (quoting 31 U.S.C. § 3730(b)(1)). "[W]hile the False Claims Act permits relators to control the False Claims Act litigation, the claim itself belongs to the United States." United States ex rel. Mergent Services v. Flaherty, 540 F.3d 89, 93 (2d Cir. 2008). "At the same time, 'the United States is a "party" to a privately filed FCA action only if it intervenes in accordance with the procedures established by federal law.'" New York Soc., 2014 WL 3905742, at *8 (quoting United States ex rel. Eisenstein v. City of New York, 556 U.S. 928, 933 (2009)).

"If the United States declines to intervene, and the relator successfully pursues the action, the relator may receive between 25 and 30 percent of any recovery." Id. (citing 31 U.S.C. § 3730(d)(2)). "If the Government proceeds with an action . . . [the relator] shall . . . receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action." 31 U.S.C. § 3730(d)(1).

"The relator may bring an action [under the FCA] against any person who 'knowingly presents, or causes to be presented, to an officer or employee of the United States . . . a false or fraudulent claim for payment or approval. . . .'" New York Soc., 2014 WL 3905742, at *9 (quoting 31 U.S.C. § 3729(a)(1)(A)). "A relator also may bring claims against any person who 'knowingly makes, uses or causes to be made or used, a false record or

statement to get a false or fraudulent claim paid or approved by the Government." Id. (quoting 31 U.S.C. § 3729(a)(1)(B)). "Claim" means "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that . . . is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government – [1] provides or has provided any portion of the money or property requested or demanded; or [2] will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded." 31 U.S.C. § 3729(b)(2).

2. New York False Claims Act

"The N.Y. FCA, enacted on April 1, 2007, is closely modeled on the federal FCA." U.S. ex rel. Pervez v. Beth Israel Med. Ctr., 736 F. Supp. 2d 804, 816 (S.D.N.Y. 2010). It "provides for liability with respect to any person who, inter alia, (1) knowingly presents a false or fraudulent claim to the State or a local government for payment, [or] (2) knowingly makes a false statement to get a false claim paid. . . ." Id. "New York courts rely on federal FCA precedents when interpreting the NYFCA." New York Soc., 2014 WL 3905742, at *11.

II. STANDARD FOR PLEADING FALSE CLAIMS

The parties dispute the degree of particularity that is required to plead the false or fraudulent claims that form the basis of an FCA cause of action. The United States, New York, and Relator argue that the Fifth Circuit's relaxed pleading standard – set forth in U.S. ex rel. Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009) – should apply here. The Grubbs court held that "to plead with particularity the circumstances constituting fraud for a False Claims Act § 3729(a)(1) claim, a relator's complaint, if it cannot allege the details of an actually submitted

false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." Id.

Courts in this District have rejected Grubbs, concluding that it violates Second Circuit precedent requiring that fraud claims be pled with particularity. See New York Soc., 2014 WL 3905742, at *15 ("Grubbs would likely not be accepted as the law of this Circuit."); Kester, 88 Fed. R. Serv. 3d 1261, at *11 ("[T]he Grubbs standard borders on requiring no particularity for the 'claim' element at all. It allows the plaintiff to make fairly conclusory allegations that claims were submitted for medical services pursuant to a standard billing practice. . . . A complaint's description of a fraudulent scheme paired with information about a defendant's standard billing practice is not enough 'particular' information to fulfill the purposes of Rule 9(b); the plaintiff must provide a detailed factual basis to support his allegation that the defendant submitted a false claim in this specific instance, not just that the defendant had a custom of submitting claims.") (emphasis in original).

Courts in this Circuit have held that "to satisfy Rule 9(b), an FCA claim must allege the particulars of the false claims themselves, and that allegations as to the existence of an overall fraudulent scheme do not plead fraud with particularity." New York Soc., 2014 WL 3905742, at *11 (emphasis added); see also Kester, 88 Fed. R. Serv. 3d 1261, at *12 ("[A] plaintiff must plead both the particular details of a fraudulent scheme and 'details that identify particular false claims for payment that were submitted to the government.'" (quoting U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 232 (1st Cir. 2004) (emphasis in Kester). Accordingly, "both the fraudulent scheme and the submission of false claims must be pled with a high degree of particularity." Kester, 88 Fed. R. Serv. 3d 1261, at *12.

In reaching this conclusion, courts have looked to the pleading requirements of Rule 9(b) and the intent of the FCA. "Generally speaking, Rule 9(b) requires a plaintiff alleging fraud to: '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.'" U.S. ex rel. Polansky v. Pfizer, Inc., No. 04-CV-0704 (ERK), 2009 WL 1456582, at *4 (E.D.N.Y. May 22, 2009) (quoting Rombach v. Chang, 355 F.3d 164, 170 (2d Cir. 2004)). Under the FCA, liability attaches "'not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment.'" Id. at *5 (United States v. Rivera, 55 F.3d 703, 709 (1st Cir. 1995)). Accordingly, FCA pleadings are "inadequate unless they are linked to allegations, stated with particularity, of actual false claims submitted to the government that constitute the essential element of an FCA qui tam action." Karvelas, 360 F.3d at 232; see also Polansky, 2009 WL 1456582, at *5 (collecting cases). As the Eleventh Circuit explained in United States ex rel. Clausen v. Laboratory Corporation of America, Inc.,

> [t]he submission of a claim is . . . the sine qua non of a False Claims Act violation.
>
> As such, Rule 9(b)'s directive that "the circumstances constituting fraud or mistake shall be stated with particularity" does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government. . . . [I]f Rule 9(b) is to be adhered to, some indicia of reliability must be given in the complaint to support the allegation of an actual false claim for payment being made to the Government.

290 F.3d 1301, 1311 (11th Cir. 2002) (emphasis in original) (quoting Fed. R. Civ. P. 9(b)).

Accordingly, in this Circuit, courts have held that the complaint must

> provide details that identify particular false claims for payment that were submitted to the government. . . . [D]etails concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the

> government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices are the types of information that may help a [plaintiff] to state his or her claims with particularity. These details do not constitute a checklist of mandatory requirements that must be satisfied by each allegation included in a complaint. However, . . . some of this information for at least some of the claims must be pleaded in order to satisfy Rule 9(b).

Polansky, 2009 WL 1456582, at *5; (quoting Karvelas, 360 F.3d at 232-33); see also Kester, 88 Fed. R. Serv. 3d 1261, at *12-13 ("In line with the weight of authority in this Circuit, I adopt the Karvelas standard – plaintiffs asserting subsection (a)(1)(A) and (a)(1)(B) claims must plead the submission of a false claim with a high enough degree of particularity that defendants can reasonably 'identify particular false claims for payment that were submitted to the government.'") (quoting Karvelas, 360 F.3d at 232).

This Court joins the other courts in this Circuit that have rejected Grubbs, and holds that in order to sufficiently plead violations of the FCA, Plaintiffs must allege the false claims themselves with sufficient particularity to satisfy Fed. R. Civ. P. 9(b); merely alleging a fraudulent underlying scheme with particularity is not enough.

III. KICKBACK CLAIMS

A. Effect of Government's Intervention on Relator's Federal Kickback Claims

Given the Government's intervention in this action, the status of Relator's federal FCA claims related to the kickback scheme must be addressed.[4] Novartis has moved to dismiss

[4] Novartis argues that the Government's intervention in this action warrants dismissal of all of Relators' kickback claims, both federal and state. (See Def. MTD-Relator Br. (Dkt. No. 99) at 6-7; Def. MTD-Relator Reply Br. (Dkt. No. 102) at 2-3 ("NPC's present motion . . . relates to whether the Relator has standing to maintain, separate from the Government, any kickback claims alleged in his Complaint.")) Relator concedes that – with the filing of the Government's Complaint-in-Intervention – the Government's "federal kickback claims [became] . . . the only operative [federal kickback] claims." (Relator Br. (Dkt. No. 105) at 7) This Court concludes – for the reasons discussed below – that Relator's kickback claims under the federal FCA have been superseded by the Government's Amended Complaint. The parties have not briefed the

these claims, arguing that "[w]here the government partially intervenes in a qui tam action, a relator may proceed only with those claims in which the government declined to intervene." (Def. MTD-Relator Br. (Dkt. No. 99) at 6)

Relator claims that "it is more accurate to deem the federal kickback claims asserted in the TAC to be superseded by the Government's intervention (as opposed to dismissed) as a technical matter." (Relator Br. (Dkt. No. 105) at 7) "Relator acknowledges that the Government's Complaint supersedes the Relator's Complaint for all intervened claims[,] [and] [t]hus, . .the Government has primary responsibility for prosecuting the claims upon which it has intervened, while the Relator's role and position becomes essentially derivative to the claims upon which the Government has intervened." (Id. at 7 n.5) While Relator acknowledges that he may not "engage in any disruptive, repetitious or otherwise counterproductive actions," he objects to any limitation on his participation in this action with respect to the federal kickback claims. (Id.)

Novartis responds that its "present motion does not pertain in any way to Relator's ability to continue to participate in the Government action. Rather, it relates to whether the Relator has standing to maintain, separate from the Government, any kickback claims alleged in his Complaint." (Def. MTD-Relator Reply Br. (Dkt. No. 102) at 2)

The Government takes the position that its claims have superseded Relator's federal kickback claims, but acknowledges that Relator remains a party as to these claims. (See Jan. 17, 2014 U.S. Ltr. (Dkt. No. 96)) Neither the United States nor New York seeks to limit

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issue of whether the Government's Complaint-in-Intervention has any effect on Relator's state law kickback claims. Accordingly, Novartis's motion to dismiss Relator's state law kickback claims will be denied without prejudice.

Relator's participation in this action. (Jan. 17, 2014 U.S. Ltr. (Dkt. No. 96); Jan. 17, 2014 N.Y. Ltr. (Dkt. No. 97))

The False Claims Act provides that "[i]f the Government proceeds with the action, it shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action. Such person shall have the right to continue as a party to the action, subject to [certain] limitations set forth in [the Act]." 31 U.S.C. § 3730(c)(1). Accordingly, courts have held that "by automatic operation of the statute, the Government's complaint in intervention becomes the operative complaint as to all claims in which the government has intervened." United States ex rel. Sansbury v. LB & B Associates, Inc., No. CV 07-251 (EGS), -- F. Supp. 2d -- , 2014 WL 3509789, at *6 (D.D.C. July 16, 2014); see also U.S. ex rel. Feldman v. City of New York, 808 F. Supp. 2d 641, 648 (S.D.N.Y. 2011) ("[W]hen the Government decides to intervene in a qui tam action, the Government's claims become the operative claims insofar as they are duplicative of those of the relator."). "However, a relator's . . . complaint continues to be the operative complaint for all non-intervened claims[,] and relators remain a party to the Government's intervened claims and continue to have rights to participate in those claims under 31 U.S.C. § 3730(c)(1) and to receive any relator's recovery permitted by 31 U.S.C. § 3730(d), subject to the limitations of the FCA and the facts and circumstances of a particular case." Sansbury, 2014 WL 3509789, at *6; see also Feldman, 808 F. Supp. 2d at 648 ("[I]f the Government only partially intervenes in an action, a relator may retain standing to prosecute those aspects of his or her complaint as to which the Government has not intervened.").

In FCA qui tam cases in which the Government has intervened, a number of courts have dismissed the relator's claims on which the Government intervened. See, e.g., U.S.

ex rel. Badr v. Triple Canopy, Inc., 950 F. Supp. 2d 888, 895 n.1 (E.D. Va. 2013) ("Count I of Relator's Complaint is superseded by the Government's Complaint and therefore dismissed. . . ."); U.S. ex rel. Robinson-Hill v. Nurses' Registry & Home Health Corp., No. Civ. A. 5:08-145-KKC, 2012 WL 4598699, at *9 (E.D. Ky. Oct. 2, 2012), reconsideration denied, No. Civ. A. 5:08-145-KKC, 2013 WL 1184370 (E.D. Ky. Mar. 20, 2013) ("[T]he qui tam Complaint's FCA claims must be dismissed to the extent that the Government's Complaint supersedes those claims. . . . Dismissal of the qui tam Complaint's FCA claims does not, however, diminish the Relators' statutory rights under § 3730. . . ."); Feldman, 808 F. Supp. 2d at 649 ("[T]he Court can identify no material aspect of the Relator's Amended Complaint not covered by the Government's Amended Complaint. The Court concludes that Feldman's Amended Complaint is superseded in its entirety by the Government's Amended Complaint and therefore dismisses Feldman's Amended Complaint for want of standing. The Court notes, however, that this dismissal in no way diminishes Feldman's continuing statutory rights delineated in § 3730 of the FCA. . . ."). These decisions provide little insight as to why the procedural mechanism of dismissal was chosen, however.

The District Court for the District of Columbia recently considered the question and concluded that dismissal is unnecessary, because the Government's claims automatically supersede identical claims asserted by the relator. See Sansbury, 2014 WL 3509789, at *6-7. The court observed that "dismissal is by no means required especially where, as here, Defendants have made no showing that the Relators' participation during the course of the litigation will cause them undue burden or expense that would justify limiting their participation." Id. at *7. Rather than dismiss the relator's claims, the court concluded that "because the Government's complaint in intervention supersedes Relators' complaint with respect to the intervened claims,

and because Relators have the right to continue as parties to this action, the Court will deny Defendants' motion to dismiss Relators' claims, to the extent that they are duplicative of the Government's claims, as moot." Id.

Although the procedural mechanism adopted here will make no practical difference, the D.C. District Court's approach is logical. All of the parties agree that the Government's federal kickback claims have superseded Relator's federal kickback claims, and no party seeks to limit the Relator's participation as to those claims. By definition, "superseded" means "[t]o annul, make void, or repeal by taking the place of." Black's Law Dictionary (9th ed. 2009). Because Relator's kickback claims under the federal FCA have already been superseded by the Government's kickback claims under the federal FCA, there is – as to the Relator's federal kickback claims – nothing to dismiss. Accordingly, Defendant's motion to dismiss Relator's kickback claims under the federal False Claims Act will be denied as moot.[5]

B. Whether the Government Entities' FCA Kickback Claims Have Been Pled with Sufficient Particularity Under Rule 9(b)

Novartis moves to dismiss the kickback claims under the FCA and New York FCA in the Government's Amended Complaint and in the New York Complaint, respectively,

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[5] This determination is consistent with the "well established [principle] that an amended complaint ordinarily supersedes the original and renders it of no legal effect." Int'l Controls Corp. v. Vesco, 556 F.2d 665, 668 (2d Cir. 1977); see, e.g., West v. Arbogast, No. 09 CV 3792 (RRM) (RML), 2010 WL 5057262, at *2 (E.D.N.Y. Nov. 5, 2010), report and recommendation adopted sub nom., West v. Arbogast, No. 09-CV-3792 (RRM) (RML), 2010 WL 5067974 (E.D.N.Y. Dec. 6, 2010) ("By filing the Amended Complaint, plaintiff mooted the original Complaint."); Meserole v. Sony Corp. of Am., No. 08 CV. 8987 (RPP), 2009 WL 2001451, at *1 (S.D.N.Y. July 9, 2009) ("By filing a Second Amended Complaint, Plaintiffs have supplanted the Complaint."); Kucher v. Alternative Treatment Ctr. of Paterson, LLC, No. 05-CV-3733 (SJ) (JMA), 2009 WL 1044626, at *3 (E.D.N.Y. Mar. 27, 2009), report and recommendation adopted, No. 05CV3733 (SJ) (JMA), 2009 WL 1045989 (E.D.N.Y. Apr. 20, 2009) ("By filing the Amended Complaint, plaintiffs mooted the Original Complaint."). As to the federal FCA kickback claims, the effect of the Government's Complaint-in-Intervention on Relator's complaint is akin to the effect of an amended complaint on an initial complaint.

for failure to plead with sufficient particularity under Fed. R. Civ. P. 9(b). (Def. MTD-U.S. Br. (Dkt. No. 80) at 6-22; Def. MTD-N.Y. (Dkt. No. 82) at 5-18) Because Novartis makes essentially the same arguments as to each pleading, the two complaints will be considered together.

1. Pleading of the Underlying Anti-Kickback Statute Violations

Novartis contends that the Government Entities have failed to plead the anti-kickback violations underlying their FCA and New York FCA claims with sufficient particularity. (Def. MTD-U.S. Br. (Dkt. No. 80) at 6-13; Def. MTD-N.Y. (Dkt. No. 82) at 5-11) In particular, Novartis claims that the pleadings are deficient in that they (1) rely on only a handful of sham speaker events as examples of the alleged nationwide kickback scheme, (2) improperly premise the alleged anti-kickback violations on violations of Novartis's internal policies and the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals (the "PhRMA Code"), and (3) do not plead facts adequate to demonstrate the requisite scienter.

a. Federal and New York Anti-Kickback Statutes

Where an FCA claim is premised on violations of the anti-kickback statute, plaintiff must "plead with particularity the 'who, what, when, where and how' of the fraudulent . . . scheme." U.S. ex rel. Mooney v. Americare, Inc., No. 06-CV-1806 (FB) (VVP), 2013 WL 1346022, at *4 (E.D.N.Y. Apr. 3, 2013).

"The [federal Anti-Kickback Statute] makes it illegal to 'knowingly and willfully offer[ ] or pay[ ] any remuneration (including any kickback, bribe, or rebate) . . . to any person to induce such person' to 'purchase or . . . recommend purchasing' a drug that is covered by a federal health care program." Kester, 88 Fed. R. Serv. 3d 1261, at *19 (quoting 42 U.S.C. §

1320a–7b(b)(2)). "The [Statute] defines 'remuneration' as including 'transfers of items or services for free or for other than fair market value.'" U.S. ex rel. Fair Lab. Practices Assocs. v. Quest Diagnostics Inc., No. 05 Civ. 5393 (RPP), 2011 WL 1330542, at *2 (S.D.N.Y. Apr. 5, 2011), aff'd sub nom., United States v. Quest Diagnostics Inc., 734 F.3d 154 (2d Cir. 2013) (quoting 42 U.S.C. § 1320a–7a(i)(6)). "[T]he [Statute] [also] outlaws 'knowingly and willfully solicit[ing] or receiv[ing] any remuneration (including any kickback, bribe, or rebate)' 'in return for purchasing . . . or recommending purchasing' a drug covered by a federal health care program."[6] Kester, 88 Fed. R. Serv. 3d 1261, at *19 (quoting 42 U.S.C. § 1320a–7b(b)(l)).

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[6] While the federal Anti-Kickback Statute states that violations must be committed "knowingly and willfully," see 42 U.S.C. § 1320a–7b(b), courts have observed that "[i]nterpreting the mens rea requirement of the Anti-Kickback Statute has yielded different results." U.S. ex rel. Bartlett v. Ashcroft, No. Civ. A. 3:04-57, 2014 WL 4179862, at *20 n.18 (W.D. Pa. Aug. 21, 2014). "The terms 'knowing and willfully' are not defined by statute, and the courts of appeals are divided on the issue" of whether knowledge of and intent to violate the statute itself is required. Id.; see United States v. Mittal, 36 F. App'x 20, 21 (2d Cir. 2002) (describing circuit split). Compare Hanlester Network v. Shalala, 51 F.3d 1390, 1400 (9th Cir. 1995) ("We construe 'knowingly and willfully' in . . . the anti-kickback statute as requiring appellants to (1) know that [the statute] prohibits offering or paying remuneration to induce referrals, and (2) engage in prohibited conduct with the specific intent to disobey the law."), with United States v. Starks, 157 F.3d 833, 838 (11th Cir. 1998) (holding that knowledge of the specific criminal statutes is not required and that "knowledge that conduct is unlawful is all that is required"; "the giving or taking of kickbacks for medical referrals is hardly the sort of activity a person might expect to be legal; . . . such kickbacks are more clearly malum in se, rather than malum prohibitum"), and United States v. Jain, 93 F.3d 436, 440-41 (8th Cir. 1996) ("Both the plain language of th[e] [anti-kickback] statute, and respect for the traditional principle that ignorance of the law is no defense, suggest that a heightened mens rea standard should only require proof that Dr. Jain knew that his conduct was wrongful, rather than proof that he knew it violated 'a known legal duty.'"). The Second Circuit has not yet decided this issue. See Mittal, 36 F. App'x at 21 ("We have not yet decided whether, in a prosecution for a violation of the Medicare anti-kickback statute, the Government is required to prove that the defendant knew of and intended to violate that specific statute. We recognize the lack of unanimity among the other Circuits that have addressed this particular question. . . . However, we decline to reach the issue. . . ."). It is not necessary to decide this issue here, however. As discussed below, both the United States and New York have alleged that Novartis and the doctors involved in the alleged kickback scheme were aware of the anti-kickback laws and nevertheless engaged in conduct violating

"Thus, the [Statute] forbids offering, paying, soliciting, or receiving kickbacks in exchange for recommending drugs covered by [federal health care programs]." Id.

"A 2010 amendment to the Anti-Kickback Statute, which became effective on January 1, 2011, states that a claim for services that violates the Anti-Kickback Statute also violates the FCA." New York Soc., 2014 WL 3905742, at *10 (quoting 42 U.S.C. § 1320a-7b(g)).

New York's anti-kickback statute similarly provides that

> [n]o medical assistance provider shall:
>
> (a) solicit, receive, accept or agree to receive or accept any payment or other consideration in any form from another person to the extent such payment or other consideration is given: (i) for the referral of services for which payment is made under title eleven of article five of this chapter; or (ii) to purchase, lease or order any good, facility, service or item for which payment is made under title eleven of article five of this chapter; or
>
> (b) offer, agree to give or give any payment or other consideration in any form to another person to the extent such payment or other consideration is given: (i) for the referral of services for which payment is made under title eleven of article five of this chapter; or (ii) to purchase, lease or order any good, facility, service or item for which payment is made under title eleven of article five of this chapter[.]

N.Y. Soc. Serv. Law § 366-d(2). A medical assistance provider is "any person, firm, partnership, group, association, fiduciary, employer or representative thereof or other entity who is furnishing care, services or supplies under" the New York Medicaid program. Id. § 366-d(1).

b. The Government Entities Have Sufficiently Pled the Underlying Anti-Kickback Violations

Here, the Government Entities allege that Novartis used sham speaker events as a vehicle to provide remuneration to doctors in order to induce them to write prescriptions for Novartis cardiovascular division drugs. As discussed above, both the United States and New

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those laws. Accordingly, the Amended Complaint and the New York Complaint allege that Defendant engaged in activity that would satisfy even the stricter scienter standard.

York have described in their pleadings – in detail – how this scheme worked. (See, e.g., U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 1-2, 77; N.Y. Cmplt. (Dkt. No. 61) ¶¶ 3, 65) They allege that Novartis hosted lavish events that – while ostensibly intended to "educate" attendees about Novartis cardiovascular division drugs – actually provided little to no information about the drugs. Instead, the events constituted upscale, all-expense paid social outings for the doctors, as evidenced by the fact that (1) Novartis sales representatives repeatedly invited the same participants and "speakers" to attend events concerning the same drug or topic in a short span of time; (2) Novartis spent exorbitant amounts of money on these events, both at the macro level and at the individual event level; (3) doctors were paid thousands of dollars to "speak" at these events, even when Novartis drugs were not discussed or the events did not take place; and (4) the events were held in venues that were not appropriate for their purported "educational" purpose, such as at crowded sports bars and restaurants, at Hooters restaurants, and on fishing trips.

The Government Entities further claim that Novartis intended to use the sham speaker events to induce doctors to write more prescriptions for its cardiovascular division drugs. According to Plaintiffs, Novartis's return-on-investment analyses revealed that this strategy was successful in inducing prescription-writing. Accordingly, Novartis used the sham speaker events as a key mechanism to promote its drugs. In doing so, Novartis allegedly violated its own internal policies governing speaker programs. Novartis also created incentives for its sales representative to hold more sham events, by basing representatives' compensation on the number of prescriptions that doctors wrote and by turning a blind eye to the sham nature of the events.

The Government Entities further allege that Novartis invited doctors to be speakers – and therefore receive additional compensation – based on the number of prescriptions they wrote for Novartis drugs, and that the doctors were aware of this practice. According to the

Government Entities, the Novartis drugs that these doctors then prescribed in exchange for remuneration from Novartis were covered by federal and state healthcare programs, and claims for reimbursement for the prescriptions the doctors wrote were submitted to these programs.

Both the Government's Amended Complaint and the New York Complaint describe specific examples of alleged sham speaker events, as well as specific doctors who were repeat speakers or attendees.[7] In particular, the United States lists twelve doctors who were paid as speakers by Novartis to give the same presentation to the same group of doctors over short periods of time.[8] (U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 97-120) The Amended Complaint identifies the time period during which each doctor attended these speaker events, the name of the presentations, the number of repeat attendees, the doctor's geographic location, and – for several of the speakers – the amount of compensation they received from Novartis. (See id.)

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[7] The Government Entities identify these doctors by their initials in the pleadings. However, both the United States and New York have provided a list to the Court and to Novartis that identifies the doctors by first and last name. (Aug. 26, 2013 U.S. Ltr.; Aug. 26, 2013 N.Y. Ltr.) Plaintiffs request that the names of the doctors remain under seal pursuant to Lugosch v. Pyramid Co. of Onondaga, 435 F.3d 110, 120 (2d Cir. 2006). That request is granted.

[8] The Government's Amended Complaint identifies fifteen doctors who allegedly wrote Novartis prescriptions in exchange for kickbacks. As to two of these doctors (S.D.2 and L.M.), however, the Government has not pled what sham speaker events they attended as "speakers." (See U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 151-52, 155-56, 176) Accordingly, this Court has not considered these two doctors in determining the sufficiency of the Government's Amended Complaint.

Novartis argues that claims relating to prescriptions written by Doctor T.M. should not be considered in evaluating the sufficiency of the Amended Complaint, because claims against Novartis relating to T.M.'s prescription-writing were released in the 2010 settlement agreement. (Def. MTD-U.S. Br. (Dkt. No. 80) at 18 n.12) The Government responds that "[t]he fact that Dr. T.M. was also identified as a recipient of kickbacks in a case that Novartis previously settled . . . is of no consequence here, as the Government's current claims are based on kickbacks to Dr. T.M. that resulted in tainted claims for drugs that were not at issue in the prior settlement, or for time periods that were not covered by that settlement." (U.S. Br. (Dkt. No. 90) at 13 n.4) This Court need not resolve this issue. As described below, even if claims pertaining to Dr. T.M. are disregarded, the Amended Complaint pleads sufficient representative examples with requisite particularity to survive a motion to dismiss.

The Amended Complaint also describes several additional "clusters" of doctors who repeatedly attended Novartis events on the same topic within a short period of time, and who exchanged roles as attendees and speakers at these events. The Government has also identified the geographic location of these events. (Id. ¶¶ 107, 111, 114) The United States has also provided the dates and locations of two fishing trips that were allegedly speaker events; the dates and locations of seven Hooters "round table" events; the dates and locations of seventeen events at high-end restaurants that resulted in exorbitant bills (including the amount of the bills and, in some instances, the doctors who attended identified by initials); and the dates and locations of at least 22 events that were inaccurately reported by Novartis sales representatives, either because they were not held at all or because not all the doctors who reportedly attended actually attended. (Id. ¶¶ 121-44) The Amended Complaint also identifies at least ten doctors who began prescribing Novartis drugs, or increased their prescriptions for Novartis drugs, after attending speaker events and/or receiving honoraria for speaking at Novartis events, the time periods during which the doctors attended the events, and the change in their prescribing of Novartis cardiovascular division drugs during these time periods. (Id. ¶¶ 153-54, 157)

The New York Complaint describes four New York doctors who were paid as speakers by Novartis to give the same presentation to the same doctors over a short period of time.[9] (N.Y. Cmplt. (Dkt. No. 61) ¶¶ 84-85, 103-05, 110-11) The Complaint identifies the speakers, the names of the repeated presentations, the time frame during which the presentations were given, and the repeat attendees. (See id.) The New York Complaint also describes two

[9] New York identifies one additional doctor – E.C. – who increased the number of prescriptions he wrote for Novartis drugs during the period he was receiving honoraria from Novartis. (See N.Y. Cmplt. (Dkt. No. 61) ¶¶ 117-21) The Amended Complaint does not plead, however, that the events E.C. spoke at were sham events. (See id.) Accordingly, this Court has not relied on E.C. in evaluating the sufficiency of the New York Complaint.

lavish dinners Novartis hosted at upscale restaurants in New York City, listing the dates of the events, the number of attendees, and the restaurants. (See id. ¶¶ 89-90) The New York Complaint also describes two scheduled events that did not take place, but for which Novartis compensated the "speaker." (Id. ¶ 93) Once again, New York has listed the date the event was supposed to occur, the speaker by name, and the compensation Novartis paid to the "speaker." (See id.) New York's Complaint also describes the increase in the prescription-writing of the four doctors who were attendees and/or speakers for Novartis speaker events during the time that these events were taking place, identifying the doctors by name, the dates of these events, the purported topics of these events, and the change in the number of prescriptions for Novartis drugs these doctors wrote compared to their earlier prescription-writing. (See id. ¶¶ 84-85, 100-01, 103-16)

Given these particularized examples and the specificity with which the pleadings describe the manner in which sham speaker events were conducted, the Government Entities have described the underlying kickback scheme with sufficient particularity to satisfy the requirements of Rule 9(b).

c. The Representative Examples Set Forth in the Government Entities' Complaints are Adequate to Plead the Underlying Anti-Kickback Violations

Novartis argues that the facts the Government Entities have alleged are not sufficient to plead the underlying anti-kickback violations with sufficient particularity. Courts in this Circuit have repeatedly held, however, that "[i]n cases where the alleged fraudulent scheme is extensive and involves 'numerous transactions that occurred over a long period of time, . . . it [is] impractical to require the plaintiff to plead the specifics with respect to each and every instance of fraudulent conduct [to comply with Rule 9(b)].' Pleading the specifics of thousands

of claims would be 'cumbersome, unwieldy, and would accomplish no purpose.'" Kester, 88 Fed. R. Serv. 3d 1261, at *15 (quoting In re Cardiac Devices, 221 F.R.D. at 333, 338); see Mooney, 2013 WL 1346022, at *3 ("Courts in this Circuit have . . . relaxed the pleading requirement 'in cases involving complex fraudulent schemes or those occurring over a lengthy period of time. . . .'" (quoting U.S. ex rel. Tiesinga v. Dianon Sys., Inc., 231 F.R.D. 122, 123 (D. Conn. 2005))). Rather, "in setting forth a 'complex and far-reaching scheme' the government need allege only 'representative samples' of fraudulent conduct to satisfy Rule 9(b)." United States v. Bank of New York Mellon, 941 F. Supp. 2d 438, 481-82 (S.D.N.Y. 2013).

Here, the alleged kickback scheme took place over nine years and involved thousands of sham speaker events that took place nationwide. To require Plaintiffs to plead the details of every one of those events or every one of the doctors who was a speaker or attendee at those events would be "'cumbersome, unwieldy, and would accomplish no purpose.'" Kester, 88 Fed. R. Serv. 3d 1261, at *15 (citation omitted). The doctors identified in the Amended Complaint and in the New York Complaint were either attendees or speakers at lavish Novartis speaker events for Novartis's cardiovascular division drugs. At these events, no substantive presentation or discussion about Novartis drugs took place, but the doctors who were "speakers" were nonetheless compensated, while the same attendees repeatedly appeared at the same sham programs. During the time period that these doctors were being paid as "speakers" and/or enjoying lavish dinners, they wrote more prescriptions for Novartis's cardiovascular division drugs. The drugs referenced in these prescriptions later became the subject of claims for reimbursement that were submitted to federal and New York healthcare programs. This Court concludes that the examples provided in the Government Entities' complaints of the doctors who were "speakers" for or attended sham speaker events are sufficiently representative of the

widespread kickback scheme to satisfy the requirements of Rule 9(b). See U.S. ex rel. Pogue v. Diabetes Treatment Centers of Am., Inc., 238 F. Supp. 2d 258, 267-68 (D.D.C. 2002) ("The Fourth Amended complaint describes a twelve year fraudulent scheme in which [defendant] ran diabetes centers in various hospitals, and appointed doctors to serve as medical directors. . . . The hospitals in which the centers were housed paid DTCA a per-patient fee, which Relator alleges was a kickback of the type prohibited by the Anti-Kickback laws. Then the hospitals submitted reimbursement claims to Medicare for the care provided to the patients. . . . Here, Relator has set out a sufficiently 'detailed description' of the specific scheme and its 'falsehoods.' The time and place are alleged with less specificity, the time given is a twelve year range, and while the scheme is alleged to be nationwide the only specific place mentioned is West Paces Medical Center. The Court finds that this is sufficient. . . .").

d. The Government Entities Rely on More than Internal Policies and Industry Standards to Demonstrate the Underlying Anti-Kickback Violations

Novartis argues that the Government Entities have not sufficiently alleged the underlying kickback scheme because their pleadings cite Novartis's internal policies and the PhRMA Code as evidence of what a proper speaker program should entail, and violations of internal policies are not sufficient to demonstrate an anti-kickback violation. (Def. MTD-U.S. Br. (Dkt. No. 80) at 11-12; Def. MTD-N.Y. Br. (Dkt. No. 82) at 9-10) This argument is meritless. While the policies may bolster Plaintiffs' argument that Novartis knew that the speaker events were improper and illegal, the Amended Complaint and the New York Complaint present facts that independently show the "sham" nature of the speaker events. These facts include the repeat attendance of the same doctors at the same speaker events over short periods of time; the fact that doctors were compensated for events that did not occur; the inappropriate

venues where the events were held; the fact that speaker invitations were extended based on the number of prescriptions that a doctor had written for Novartis drugs; and the fact that the speaker events were nothing more than lavish social outings for doctors that involved no substantive discussion of Novartis drugs. Plaintiffs have alleged more than mere violations of internal policies; they have pleaded facts demonstrating that doctors violated the anti-kickback laws when they wrote prescriptions for Novartis cardiovascular division drugs – knowing that claims for reimbursement would be submitted in connection with those prescriptions – in exchange for "speaker" fees and the opportunity to attend lavish dinners and other social events.

e. The Government Entities Have Sufficiently Pled Scienter for the Underlying Anti-Kickback Violations

Novartis also argues that the Government Entities have not pled facts sufficient to adequately allege the requisite scienter for an anti-kickback violation. Under Fed. R. Civ. P. 9(b), "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Here, the Government Entities have alleged that Novartis sales representatives provided compensation and lavish dinners to doctors in exchange for the doctors writing more prescriptions for Novartis drugs. The allegations in the pleadings also link the sales representatives' conduct to Novartis's senior management: the complaints allege that Novartis encouraged its sales representatives to host sham events by basing representatives' compensation on doctors' prescription-writing; by failing to monitor events; and by imposing no discipline when sales representatives were reported for non-compliance with Novartis policies and the anti-kickback laws.

The pleadings further allege that Novartis's Ethics and Compliance Policies – which were issued in 2003 and re-issued in January 2006 – describe the Federal Anti-Kickback Statute's prohibition of bribes and kickbacks, and state that "[i]nteractions with Healthcare

Professionals should be focused on providing information about [Novartis] products, providing scientific and educational information[,] and supporting medical research and education in venues that are conducive to such discussions." (U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 57-58; N.Y. Cmplt. (Dkt. No. 61) ¶¶ 46-48) In instructing that speaker programs must be held at venues "conducive to an exchange of medical information," Novartis's policies provide that food and beverages should be "ancillary to meaningful discussion" and modest in quantity and cost. (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 60; N.Y. Cmplt. (Dkt. No. 61) ¶ 50) The policies also require speakers to make a presentation using slides provided by Novartis, and require at least three health care professionals and one sales representative to be present at every speaker program. (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 62; N.Y. Cmplt. (Dkt. No. 61) ¶ 53) Novartis's conduct – as alleged in the pleadings – violates each of these policies, raising a strong inference that Novartis acted knowingly and willfully in using the speaker events to induce prescription-writing in violation of the anti-kickback laws.

Plaintiffs have also alleged that the Pharmaceutical Research and Manufacturers of America – a trade organization of which Novartis is a member – issued the PhRMA Code in 2004, and that Novartis is a signatory to and certified that it is in compliance with this Code. (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 59; N.Y. Cmplt. (Dkt. No. 61) ¶ 49) The PhRMA Code provides that interactions between pharmaceutical company employees and health care professionals "should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical education." (U.S. Am. Cmplt. (Dkt. No. 62) ¶ 59; N.Y. Cmplt. (Dkt. No. 61) ¶ 49) As to speaker events, the PhRMA Code states that "it is appropriate for occasional meals to be offered as a business courtesy . . . so long as the presentations provide scientific or educational value and the meals (a) are modest as

judged by local standards; (b) are not part of an entertainment or recreational event; and (c) are provided in a manner conducive to informational communication." (U.S. Am. Cmplt. (Dkt. No. 82) ¶ 61; N.Y. Cmplt. (Dkt. No. 61) ¶ 51) The PhRMA Code further provides that "companies should continue to ensure that speaking arrangements are neither inducements nor rewards for prescribing a particular medicine or course of treatment." (U.S. Am. Cmplt. (Dkt. No. 82) ¶ 61; N.Y. Cmplt. (Dkt. No. 61) ¶ 52) The conduct alleged in the pleadings likewise violates these pharmaceutical industry standards, supporting an inference that Novartis acted with the requisite scienter here.

The Government Entities have also sufficiently alleged that the doctors who wrote prescriptions for Novartis drugs in exchange for compensation or other benefits from Novartis possessed the requisite scienter for an anti-kickback violation. The pleadings support a strong inference that the doctors recognized that the Novartis speaker events were shams. The doctors allegedly attended and/or were paid to speak at lavish events where there was no substantive presentation about or discussion of Novartis drugs. Moreover, the same doctors repeatedly attended the same sham events. The doctors arranged for their friends to attend these events, which took place at high-end restaurants, at sports bars, at Hooters restaurants, and at fishing venues. The Government Entities have further alleged that the doctors (1) were aware that they would receive increased compensation and other benefits from Novartis based on the number of prescriptions that they wrote for Novartis drugs; and (2) wrote more prescriptions for Novartis drugs in order to receive more "speaker" fees and to attend more lavish dinners and social outings. The allegations in the pleadings are sufficient to support a strong inference that the doctors knowingly and willfully violated the anti-kickback laws when they wrote prescriptions for Novartis drugs in exchange for this remuneration, knowing that the prescriptions they wrote

would be paid for by Medicare or Medicaid. Moreover, in order to participate in the government programs that provided reimbursement for those prescriptions, the doctors were required to certify that they were not in violation of state and federal laws, including anti-kickback laws. (See, e.g., U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 37, 41-44, 53, 56; N.Y. Cmplt. (Dkt. No. 61) ¶¶ 29-37)

Novartis argues, however, that the doctors – many of whom prescribed Novartis drugs before attending Novartis speaker events – may have prescribed Novartis cardiovascular division drugs for proper purposes, rather than in exchange for kickbacks, and that the court must take this into account as a "plausible opposing inference" in determining whether scienter has been sufficiently pled. (Def. MTD-U.S. Br. (Dkt. No. 80) at 21-22; Def. MTD-N.Y. Br. (Dkt. No. 82) at 17-18) While it is true that the doctors identified in the pleadings allegedly prescribed Novartis cardiovascular division drugs before they attended sham speaker events, the Government Entities allege that the doctors' prescriptions for Novartis drugs significantly increased after they began attending and/or receiving honoraria for these events. This assertion is supported by the pleadings, which provide examples of the prescribing habits of the identified doctors, including the number of prescriptions they wrote before and after they attended the events and/or received honoraria for "speaking" at the events. (See U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 153-54, 157; N.Y. Cmplt. (Dkt. No. 61) ¶¶ 100, 101, 106-07, 112-14) These allegations, considered with the other evidence supporting scienter described above, are sufficient to allege that the doctors were prescribing Novartis drugs in exchange for kickbacks, and outweigh – at the pleading stage – the "opposing inference" that Novartis posits.

* * * *

Given the examples of doctors and sham speaker events set forth in the pleadings, and the detailed description of how the scheme functioned, the Government Entities have pled the underlying anti-kickback violations with sufficient particularity to satisfy the requirements of Rule 9(b).

2. Pleading of False Claims Act Violations

Novartis argues that the FCA and New York FCA claims must be dismissed because the pleadings have not "sufficiently link[ed] [Novartis's] alleged wrongdoing to the submission of false claims." (Def. MTD-U.S. Br. (Dkt. No. 80) at 13; Def. MTD-N.Y. Br. (Dkt. No. 82) at 11) In particular, Novartis argues that the Government Entities have not (1) linked anti-kickback violations to particular false claims; (2) sufficiently alleged a nationwide scheme, given that Plaintiffs have cited only a comparatively small number of doctors who submitted false claims; (3) alleged that the doctors who attended speaker events for certain Novartis drugs increased their prescription-writing for the particular drug or drugs that were the subject matter of those events, or alleged that all of the Novartis drugs at issue were the subject of sham speaker events; and (4) alleged sufficient facts to demonstrate that Novartis possessed the requisite scienter for an FCA or New York FCA claim.

a. The Government Entities Have Adequately Linked Particular False Claims to Anti-Kickback Violations

Novartis claims that the Government Entities have not pled sufficient facts to link actual false claims to underlying anti-kickback violations. As noted above, however, the Government Entities have attached as exhibits to their complaints hundreds of pages of spreadsheets listing particular alleged false claims. The records submitted by the United States include (1) the name of the prescribing doctor, (2) the name of the Novartis drug prescribed, (3) the National Drug Code for the drug prescribed, (4) the government program the claim was

submitted to, (5) the date the prescription was filled, (6) the name of the pharmacy that dispensed the drug, (7) the identification number for the pharmacy that dispensed the drug, (9) the cost of the prescription, and (9) the date that the claim was processed and paid.[10] (See U.S. Am. Cmplt. (Dkt. No. 62), Exs. B-C, E-J, L-O) The United States alleges that each of the prescriptions listed was written by a doctor who was induced to write prescriptions in exchange for honoraria and/or other remuneration, and that each prescription was written during the time period that the doctor was receiving remuneration from Novartis. (See id. ¶ 176) According to the United States,

> Novartis is liable to the federal government for damages based on the payment of the[se] . . . claims and all other claims submitted to federal health care programs for prescriptions written by these physicians for the relevant Novartis drugs beginning from the time they began receiving honoraria payments or other remuneration and running through at least 2011, because the claims were the result of prescriptions induced by honoraria or other remuneration.
>
> [ ] Compliance with the Anti-Kickback Statute is a precondition of payment by virtue of federal and statute statutes, regulations, provider agreements, and contracts.
>
> [ ] The certifications and attestations signed by physicians, pharmacies, PBMs, and Part D sponsors certified compliance with the [Anti-Kickback Statute]. Kickbacks that were paid to physicians as alleged herein rendered those certifications and attestations false . . .
>
> [ ] Claims for Novartis[] prescription[ ] drugs arising from the kickbacks expressly and impliedly misrepresent[ed] compliance with a material condition of payment, to wit, compliance with the [Anti-Kickback Statute].

(Id. ¶¶ 178-81) The United States also describes in detail the processes by which the prescriptions these doctors wrote were submitted to pharmacies, which filled them and submitted

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[10] Novartis argues that the false claims identified in the Government's Amended Complaint are "no more informative than the chart of prescribing data included in the Initial Complaint." (Def. MTD-U.S. Br. (Dkt. No. 80) at 17-18) To the contrary, in its initial complaint, the United States did not identify particular false claims or offer any details about individual claims. Instead, the Government merely summarized the number of alleged false claims and the total amount of reimbursement obtained through federal healthcare programs from these claims for each prescribing doctor. (See U.S. Cmplt. (Dkt. No. 16) ¶ 152)

claims for reimbursement to each of the government programs listed in the Amended Complaint. (Id. ¶¶ 20-56) For each of these government programs, the United States further identifies the relevant "statutes, regulations, provider agreements, and contracts" that it alleges made doctors' compliance with the Anti-Kickback Statute a condition of payment. (See id.)

The records of false claims attached to the New York Complaint list (1) the pharmacy provider identification number for each claim, (2) the pharmacy name, (3) the name of the prescribing physician, (4) the date of service, (5) the amount that New York Medicaid paid toward the drug, (6) the payment date, (7) the formulary (drug) code, (7) the name of the Novartis drug prescribed, and (8) the weight of the prescribed tablets or capsules. (N.Y. Cmplt. (Dkt. No. 61), Ex. A) New York alleges that these claims "were reimbursed by Medicaid for those Novartis drugs referenced in th[e] Complaint which were prescribed by . . . physicians [who] wrote prescriptions for Novartis drugs which were induced by honoraria and exorbitant meals and entertainment provided by Novartis. The claims listed . . . are limited to claims submitted after these physicians began attending Novartis events." (Id. ¶ 136) New York further alleges that

> in order to submit claims to Medicaid, physicians are required to sign a Certification Statement attesting that the care, services, or supplies for which claims to Medicaid are submitted were furnished "in accordance with applicable federal and state laws and regulations," including but not limited to the Federal and New York Anti-Kickback Statutes.
>
> [ ] In addition, in order to dispense and submit claims to Medicaid for prescription medications, pharmacies are required to sign the same Certification Statement . . .
>
> . . .
>
> [ ] The Certification Statements are representations of compliance with a material condition of payment, namely that the Novartis drugs for which claims for payment were made to Medicaid were provided in accordance with all applicable Federal and State laws regarding the provision of health care services, including

> the Federal and New York Anti-Kickback Statutes. Kickbacks that Novartis paid to physicians as alleged herein render those certifications false.
>
> . . .
>
> [ ] Claims for payment for Novartis drugs prescribed by physicians who received kickbacks from Novartis as alleged herein expressly and impliedly misrepresent compliance with multiple material conditions of payment of the New York State Medicaid Program.

(Id. ¶¶ 137-38, 141, 143) New York also describes in detail the regulations that govern the submission of claims to the New York Medicaid Program, and the process by which claims for reimbursement are submitted to the Medicaid program by pharmacies filling prescriptions. (Id. ¶¶ 28-37) In addition to the list of alleged false claims, New York also attaches to its Complaint signed certification statements for the doctors and pharmacies associated with the submission of the alleged false claims. (Id., Exs. B-C)

Novartis argues that "[t]he raw data of all . . . [federally- or state-]reimbursed prescriptions written by [a few] doctors . . . does not make clear which of these claims were allegedly fraudulent," particularly because some of these doctors were prescribing Novartis drugs prior to attending sham speaker events. (Def. MTD-U.S. Br. (Dkt. No. 80) at 17-18 (internal quotations omitted); Def. MTD-N.Y. Br. (Dkt. No. 82) at 14 (internal quotations omitted)) Viewing the pleadings in the light most favorable to Plaintiffs and drawing all inferences in their favor, however – as the Court must do on a motion to dismiss – the United States and New York have sufficiently alleged that all of the claims attached to their pleadings are false claims, because they were submitted by doctors at a time when the doctors were writing prescriptions for Novartis cardiovascular division drugs in exchange for kickbacks, while certifying that they were in compliance with state and federal laws, including anti-kickback statutes. At the pleading stage, it is not necessary for the Government Entities to demonstrate

with precision that every prescription written by every doctor was written in exchange for a kickback. To the extent that there is evidence that a prescription was written appropriately, that issue may be raised at summary judgment and/or at trial. See U.S. ex rel. Lisitza v. Johnson & Johnson, 765 F. Supp. 2d 112, 128-29 (D. Mass. 2011) ("J & J strenuously objects to relators' assertion that the alleged 'kickbacks' to Omnicare caused the submission of false claims to Medicaid. [J & J argues that] ['e]ven if we accept, for purposes of argument, the "kickback" allegations, the complaint lacks any factual or legal basis to support an inference that each and every claim for reimbursement of a J & J drug resulted from a "kickback." Nor could there be: to so allege, Plaintiffs would have to take the nonsensical position that no J & J product ever would have been provided to a nursing home patient by Omnicare but for the purported "kickbacks." That claim is belied by the United States' complaint itself, which acknowledges that, even before the period at issue, Omnicare purchased more than $100 million in J & J product[s].['] The argument – if borne out by discovery – strikes the court as one more appropriate for summary judgment. For present purposes, the Complaint of the United States is sufficiently pled."); see also Kester, 88 Fed. R. Serv. 3d 1261, at *22 ("[T]he Government provides enough details for Novartis to be able to reasonably identify which of the Medicare claims submitted were 'false.' The Complaint does not contain vague allegations. . . . Rather, it contains detailed identifying information. . . . The Complaint defines several small pools of claims – for six specific pharmacies, the 'false' claims are all the claims for either Exjade or Myfortic submitted by these pharmacies during the time that it was receiving kickbacks to promote that drug, and yet certifying that it was in compliance with the [Anti-Kickback Statute]. For each pharmacy, the Complaint states the exact time frame, drug, and government program at issue, and it approximates the number of claims submitted and the total reimbursement amount.

With this level of detail, it should not be difficult for Novartis to identify which Medicare and Medicaid claims are alleged to be false – it is every single claim in each narrowly defined pool.") (emphasis in original).

The Court rejects Novartis's contention that "it [is] impossible for [Novartis] to determine [from the pleadings] . . . which doctors (other than [those] . . . identified) were allegedly induced, when within the nearly ten-year time frame doctors were allegedly induced, and the value of any resulting prescriptions." (Def. MTD-U.S. Br. (Dkt. No. 80) at 18; Def. MTD-N.Y. Br. (Dkt. No. 82) 14-15) The examples of false claims that the Government Entities have pleaded, combined with the detailed allegations concerning the sham speaker programs, are sufficient to put Novartis on notice of which claims the Government Entities assert are false. The claims that are at issue here relate to prescriptions for Lotrel, Diovan, Diovan HCT, Tekturna, Tekturna HCT, Exforge, Exforge HCT, Valturna, Tekamlo, and Starlix that (1) were written by doctors between January 2002 and 2011; (2) were written after these doctors had attended or received honoraria for "speaking" at Novartis sham speaker events, and (3) resulted in claims for reimbursement to Medicare, Medicaid, TRICARE, and the Veterans Administration health care program (as to the Government's Amended Complaint) or New York Medicaid (as to the New York Complaint).

The cases Novartis cites in support of its argument that the Government Entities have not sufficiently pled false claims are unpersuasive. In most of these cases, no particular false claims were alleged. See Mooney, 2013 WL 1346022, at *6 ("[P]laintiff has not specified a single claim that was submitted to Medicaid."); United States ex rel. Piacentile v. Novartis AG, No. 04 Civ. 4265 (NGG) (RLM) (E.D.N.Y. Feb. 7, 2010) (Order (Dkt. No. 84) at 15) ("Plaintiffs . . . do not specify a single physician who submitted false claims to any of the listed

government programs, let alone a single false claim submitted by anyone to any government program, or even a specific type of claim submitted by Novartis-linked physicians to anyone.") (emphasis in original); Polansky, 2009 WL 1456582, at *5 ("[Plaintiff] has not identified any false claims or physicians who were induced to write a prescription for an off-label use."); U.S. ex rel. Smith v. New York Presbyterian Hosp., No. 06 Civ. 4056 (NRB), 2007 WL 2142312, at *6-7 (S.D.N.Y. July 18, 2007) ("Although Smith manages to sketch out the nature of that claim by generally stating the 'who, what, where, when and how' of his theory of fraud, he fails to provide sufficient detail about . . . any specific fraudulent claim. Notably, he does not list a single NYPH employee or hospital technician who is alleged to have been involved in submitting any of the thousands of purportedly fraudulent claims that went to the government[,] and he gives no specific amounts, dates or other details for any fraudulent claims either made or paid. . . . [D]espite the filing of this case in Connecticut in 2002, Smith still has not provided defendants with sufficient details regarding any particular fraudulent claim. . . . [N]one of the exhibits provides evidence of a specific, fraudulent bill sent to and paid for by the government."); U.S. ex rel. Smith v. Yale Univ., 415 F. Supp. 2d 58, 88 (D. Conn. 2006) ("In light of the[ ] multiple purposes [of Rule 9(b)], in conjunction with the fact that the complaint at issue does not identify any particular false or fraudulent claim allegedly submitted nor does it provide the source of information or factual basis for Relator's conclusory allegations that Defendant submitted false or fraudulent bills, this Court finds that Relator has failed to satisfy the Rule 9(b) particularity requirements.").[11] Similarly, in Mason v. Medline Indus., Inc., Civ. A. No. 07 C 5615, 2009 WL 1438096, at *4 (N.D. Ill. May 22, 2009), the court concluded that

[11] Novartis's reliance on U.S. ex rel. Sasaki v. New York Univ. Med. Ctr., No. 05 Civ. 6163 (LMM) (HBP), 2012 WL 220219, at *6 (S.D.N.Y. Jan. 25, 2012), is misplaced. In Sasaki, the court addressed a motion for summary judgment. Id. at *1. Here, only the sufficiency of the pleading – not the merits of the underlying claims – is at issue.

the alleged kickbacks were not tied to any false claims where the relator had "offer[ed] no facts at all supporting his characterization of the donations as kickbacks or bribes[,] . . . d[id] not identify who . . . authorized these donations[,] . . . d[id] not provide any detail suggesting . . . an understanding as to an illicit purpose of the donations[, and] . . . d[id] not tie a donation to any false CMS cost report."

Here, the pleadings explain in detail why the speaker events were shams and how they served as a vehicle for kickbacks. The pleadings also tie particular claims to particular doctors during the time period that the doctors were attending sham speaker events. Novartis has cited no case demonstrating that the Government Entities' pleading of particular false claims is deficient.

b. Examples of False Claims Are Pled With Sufficient Particularity to Allege the Larger Fraud Scheme

Novartis also argues that the examples of false claims pled in the Government's Amended Complaint and in the New York Complaint are "insufficient . . . to extrapolate a [nationwide or statewide] scheme." (Def. MTD-U.S. Br. (Dkt. No. 80) at 19-20; Def. MTD-N.Y. (Dkt. No. 82) at 15-16)

"In cases where the alleged fraudulent scheme is extensive and involves '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.' . . . Instead, the complaint must provide the defendant with enough details to be able to reasonably discern which of the claims it submitted are at issue. In cases with extensive schemes, plaintiffs can satisfy this requirement [by] . . . providing example false claims." See Kester, 88 Fed. R. Serv. 3d 1261, at *15 (quoting Cardiac Devices, 221 F.R.D. at 333); Mooney, 2013 WL 1346022, at *7 ("Plaintiff has pled particular facts for twelve specific claims of

fraudulent alteration. Although plaintiff has not identified every false claim allegedly filed pursuant to the fraudulent alteration scheme, the Court finds that she has pled twelve specific claims with sufficient particularity to justify permitting the whole fraudulent alteration scheme pertaining to Medicare claims to survive the motion to dismiss."); U.S. ex rel. Joshi v. St. Luke's Hosp., Inc., 441 F.3d 552, 557 (8th Cir. 2006) ("Dr. Joshi alleges a systematic practice of St. Luke's and Dr. Bashiti submitting and conspiring to submit fraudulent claims over a sixteen-year period. Clearly, neither this court nor Rule 9(b) requires Dr. Joshi to allege specific details of every alleged fraudulent claim forming the basis of Dr. Joshi's complaint. . . . [T]o satisfy Rule 9(b)'s particularity requirement and to enable St. Luke's and Dr. Bashiti to respond specifically to Dr. Joshi's allegations, Dr. Joshi must provide some representative examples of their alleged fraudulent conduct, specifying the time, place, and content of their acts and the identity of the actors.") (emphasis in original). "[P]laintiffs can plead the submission of thousands of claims with particularity by providing example claims which are representative of those arising from the fraudulent scheme." Kester, 88 Fed. R. Serv. 3d 1261, at *16.

As discussed above, the Government Entities have identified specific false reimbursement claims for prescriptions for Novartis cardiovascular division drugs that were submitted to federal healthcare programs and the New York Medicaid program during the period that the doctors who wrote the prescriptions were receiving remuneration from Novartis through sham speaker events. The doctors are identified by name and geographic location, and the pleadings particularize the nature of the speaker events that they attended, the time frame in which they attended or were chosen as speakers for the events, their increased prescription-writing for particular Novartis cardiovascular division drugs during that time frame, and the

specific claims that were submitted for the prescriptions they wrote. These claims are sufficiently representative of the larger scheme to satisfy the pleading standard of Rule 9(b).[12]

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[12] Novartis cites U.S. ex rel. Thomas v. Bailey, No. 4:06CV00465 (JLH), 2008 WL 4853630, at *6 (E.D. Ark. Nov. 6, 2008); United States ex rel. Dhawan v. N.Y.C. Health & Hosp. Corp., No. 95 Civ. 7649 (LMM), 2000 WL 1610802, at *3 (S.D.N.Y. Oct. 27, 2000), aff'd sub nom., United States v. New York Med. Coll., 252 F.3d 118 (2d Cir. 2001); and U.S. ex rel. Fox Rx, Inc. v. Omnicare, Inc., No. 1:11-CV-962-WSD, 2013 WL 2303768, at *7 (N.D. Ga. May 17, 2013) in support of its argument that the examples provided in the complaints are insufficient to plead a nationwide or statewide scheme.

Contrary to Novartis's characterization, the court in Thomas did not merely "dismiss[ ] the allegation of a national corporate policy of kickbacks because the complaint only offered five anecdotal examples." (Def. MTD-U.S. Br. (Dkt. No. 80) at 19) Instead, the Thomas court found that the complaint was not pled with sufficient particularity because it did not

> allege the "who, what, where, when, and how" of th[e] alleged nationwide corporate policy. The second amended complaint d[id] not identify who at [the defendant company] initiated, discussed, or adopted this alleged corporate policy; what the corporate policy was; where the corporate policy was adopted or in what documents it was reflected; when the corporate policy came into being or under what circumstances; or how the corporate policy was adopted or proposed to be communicated to salesmen and implemented throughout the country. Instead, the second amended complaint allege[d] five episodes, anecdotal in nature, based on hearsay – in some instances from other salesmen who competed against Blackstone – reporting that Blackstone or Bailey offered kickbacks or hired a family member or friend of a physician. One of these anecdotes involved a physician in Jackson, Mississippi; one involved physicians in Springfield, Missouri; and three involved physicians in different cities in Arkansas. The second amended complaint specifie[d] allegedly false claims with respect to only one physician other than [a physician as to whom the court determined the alleged false claims were sufficiently plead].

Thomas, 2008 WL 4853630, at *6.

Here, as previously discussed, the Government Entities have described in significant detail how Novartis encouraged sham speaker programs, how it overlooked misconduct by sales representatives, how doctors were induced by the sham speaker programs to write prescriptions for Novartis drugs, and how the false claims specifically identified in the pleadings are connected to doctors who received remuneration in connection with the sham speaker events. In short, the pleadings in the instant cases contain substantially more particularity than the complaint in Thomas.

Likewise, in Dhawan, 2000 WL 1610802, at *3, the court held that the pleading was insufficient as to three of the named defendants because – in contrast to the FCA allegations related to two

c. The Government Entities Need Not Show a Connection Between a False Claim and an Announced Topic of a Sham Speaker Event

Novartis argues that the Government Entities' complaints must be dismissed because (1) not all of the doctors identified in the pleadings are alleged to have increased their prescriptions for the specific drugs that were the announced topic of speaker events they attended or were speakers for; and (2) not all of the drugs for which false claims were allegedly submitted were the topic of alleged speaker events. (Def. MTD-U.S. Br. (Dkt. No. 80) at 15-17; Def. MTD-N.Y. Br. (Dkt. No. 82) at 13-14) These arguments misapprehend the Government Entities' theory of liability here.

The Government Entities claim that the speaker events were "shams" hosted by Novartis's cardiovascular division to induce doctors to prescribe the division's drugs more frequently. From the perspective of the Government Entities, the announced topics for the sham speaker events are largely irrelevant, because no substantive presentation or discussion about

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other defendants, HHC and NYMC – no details regarding the underlying fraud or fraudulent claims had been alleged. "Rather, the complaint alleg[ed] detailed facts as to HHC and NYMC, then ma[de] an unjustified quantum leap contending that since NYU, Montefiore and Columbia ha[d] similar affiliation contracts with HHC hospitals and Medicare/Medicaid, there must be the same fraudulent conduct." Id. Such "conclusory allegations [were] insufficient to overcome defendants['] motion to dismiss." Id. Here, in contrast, the Government Entities allege facts that tie Novartis to an underlying scheme that involved inducing doctors to write prescriptions for Novartis drugs in exchange for payments and other benefits offered through a sham speaker program.

In Fox Rx, 2013 WL 2303768, at *7, the court found that the relator had not sufficiently pled false claims – other than those that he had personal knowledge of – where "Relator concede[d] that it lack[ed] direct knowledge of any false claims submitted by Defendants through other . . . sponsors, but argue[d] that the 'Court has no reason to conclude that Defendants have different policies. . . in different states.'" The court rejected "Relator's contention[ ] that Defendants' 'nationwide' conduct should be inferred from the conduct for which Relator alleges actual information" because that is "exactly what is proscribed by Rule 9(b)." Id. Here, the Government Entities have identified specific doctors and specific false claims that were connected to Novartis's larger kickback scheme, and they have provided sufficient detail about that larger scheme to demonstrate that it had a nationwide scope.

Novartis's drugs took place at these sham events. What the Government is alleging is bribery without a fig leaf.

Given that no substantive discussion concerning any Novartis drug took place at the sham speaker events, it is not surprising – from the perspective of the Government Entities – that the announced topic for Novartis speaker events has little or no direct connection to the particular Novartis cardiovascular division drug or drugs that the attendees or speakers at these events later prescribed. In hosting these lavish events, Novartis's alleged purpose was to induce doctors to look favorably on the cardiovascular division's drugs generally. There was no attempt – at these sham speaker events – to "sell" doctors on the merits of a particular Novartis drug. That would have required a substantive presentation, of course, and the Government Entities' theory here is that there was no substance to the sham speaker events. (See U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 1-2, 95, 121, 135-37; N.Y. Cmplt. (Dkt. No. 61) ¶¶ 2-4, 82, 86-88, 91-92) Despite the absence of substantive presentations, the doctors who attended these events did – according to the Government Entities – increase the number of prescriptions they wrote for Novartis cardiovascular division drugs. Given Plaintiffs' theory, their complaints sufficiently link the underlying anti-kickback violations to the alleged false claims.

Novartis also points out that not all of the cardiovascular division drugs named in the pleadings are alleged to have been the subject of increased prescribing by the doctors identified in the Government Entities' complaints. As discussed above, given the magnitude of the scheme alleged here, Plaintiffs are permitted to plead through representative examples. Moreover, given that Plaintiffs' theory is that speaker events hosted by Novartis's cardiovascular division induced doctors to write more prescriptions for the division's drugs as a whole, the specific examples of increased prescription-writing – even though they do not include examples

of all the drugs listed in the complaints – are sufficiently representative to satisfy the pleading requirements of Rule 9(b).

d. The Government Entities Have Adequately Pled Scienter for the FCA Claims

"[T]he text of the FCA expressly states that it does not require 'proof of specific intent to defraud.'" New York Soc., 2014 WL 3905742, at *8 (quoting 31 U.S.C. § 3729(b)(1)(B)). Rather, a defendant violates the FCA if it "knowingly . . . causes to be presented[ ] a false or fraudulent claim for payment or approval," or "knowingly . . . 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). A defendant acts knowingly within the meaning of the FCA if it – "(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." Id. § 3729(b)(1)(A) (emphasis added). "'[T]his does not conflict with Rule 9(b),' since '[m]alice, intent, knowledge, and other condition of mind of a person may be averred generally.'" New York Soc., 2014 WL 3905742, at *8 (quoting Gold, 68 F.3d at 1477).

For the same reasons discussed above in connection with the underlying anti-kickback violations, the pleadings sufficiently allege Novartis's scienter as to the FCA claims. Considered together, the allegations raise a strong inference that Novartis caused the submission of false claims to federal and New York healthcare programs and that it acted with actual knowledge in doing so or, at the very least, in deliberate ignorance or reckless disregard of that fact. This strong inference arises from the abundant evidence – as pled in the complaints – that the purpose of the speaker program was not to disseminate medical or scientific information to doctors, but rather to reward those who prescribed large quantities of Novartis drugs, and to encourage other doctors to prescribe larger quantities of Novartis drugs. This inference also

arises from evidence demonstrating that Novartis intentionally encouraged these sham speaker events, and failed to properly supervise the sales representatives who hosted them. See 31 U.S.C. § 3729(b)(1).

* * * *

For the reasons stated above, Novartis's motion to dismiss the Government Entities' kickback claims for failure to comply with Rule 9(b) will be denied.

C. Falsity of Medicaid Claims Submitted Prior to the Affordable Care Act

Novartis has moved to dismiss the FCA and New York FCA claims related to alleged false or fraudulent claims that were submitted to Medicaid programs prior to the 2010 amendments to the Anti-Kickback Statute. Novartis argues that those Medicaid claims are not "false" or "fraudulent" within the meaning of the FCA. (See Def. MTD-U.S. Br. (Dkt. No. 80) at 22-24; Def. MTD-N.Y. Br. (Dkt. No. 82) at 18-20)

"[T]he Anti-Kickback Statute was . . . amended [in 2010] to explicitly state that a violation of its terms is actionable under the FCA."[13] New York Soc., 2014 WL 3905742, at *19. As codified in the Patient Protection and Affordable Care Act of 2010 (the "Affordable Care Act"), Pub. L. No. 111-148, § 6402(f), 124 Stat. 119, codified at 42 U.S.C. § 1320a-7b(g), the statute now provides that "a claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the federal False Claims Act]." "Prior to this amendment, [however,] the [Anti-Kickback Statute] did not

[13] Courts in this District have noted that the amendment does not provide for retroactive application. See New York Soc., 2014 WL 3905742, at *10 ("[The] 2010 amendment to the Anti-Kickback Statute, which . . . states that a claim for services that violates the Anti-Kickback Statute also violates the FCA[,] . . . contains no retroactivity provision."); id. at *19 ("The revised statute does not provide for retroactive application."); Kester, 88 Fed. R. Serv. 3d 1261, at *24 n.8 ("The March 2010 amendment to the Anti–Kickback Statute is not retroactive and, thus, does not apply to any claims for payment submitted before its enactment.").

explicitly state that compliance with the statute was a precondition for . . . Medicaid reimbursement, and that claims submitted in violation of the [Anti-Kickback Statute] were 'false' under the FCA." Kester, 88 Fed. R. Serv. 3d 1261, at *24.

Novartis argues that "prior to the 2010 enactment of [the Affordable Care Act], a violation of the [Anti-Kickback Statute] was not a per se violation of the FCA" (Def. MTD-U.S. Br. (Dkt. No. 80) at 23 n.13; Def. MTD-N.Y. Br. (Dkt. No. 82) at 19 n.11), and that accordingly – in order to allege the falsity of pre-amendment claims – Plaintiffs must plead that those who submitted claims to Medicaid did so with "an express or implied certification of compliance with anti-kickback statutes" as a pre-condition to payment, as described by the Second Circuit in Mikes v. Straus, 274 F.3d 687 (2d Cir. 2001). (See Def. MTD-U.S. Br. (Dkt. No. 80) at 22-24; Def. MTD-N.Y. Br. (Dkt. No. 82) at 18-20) Plaintiffs respond that the Affordable Care Act merely codified existing law and that – even under the Mikes standard – the falsity of the Medicaid claims at issue here has been sufficiently alleged. (See U.S. Br. (Dkt. No. 90) at 18-24; N.Y. Br. (Dkt. No. 89) at 14-18)

1. The Government Entities' Pleading of Falsity as to the Medicaid Claims

The Government's Amended Complaint contains the following allegations regarding the falsity of the claims that were allegedly submitted to Medicaid:

> 41. Claims arising from illegal kickbacks are not authorized to be paid under state regulatory regimes. For example, the New York regulatory regime provides that an "overpayment includes any amount not authorized to be paid under the medical assistance program, whether paid as the result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse or mistake." N.Y. Comp. Codes R. & Regs. Title 18 § 518.1(c). "Unacceptable practice" is defined to include "[b]ribes and kickbacks," id. § 515.2(b)(5), and lists within this category both "soliciting or receiving," id. § 515.2(b)(5)(ii), and "offering or paying," id. § 515.2(b)(5)(iv), "either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending

any medical care, services or supplies for which payment is claimed under the program," id. § 515.2(b)(5)(ii), (iv). New York's anti-kickback statute forbids kickbacks in similar terms. See N.Y. Soc. Serv. Law §§ 366-d-f.

42. Providers who participate in the Medicaid program must sign enrollment agreements with their states that certify compliance with the state and federal Medicaid requirements, including the [Anti-Kickback Statute]. Although there are variations among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies furnished.

43. Furthermore, in many states, Medicaid providers, including both physicians and pharmacies, must affirmatively certify, as a condition of payment of the claims submitted for reimbursement by Medicaid, compliance with applicable federal and state laws and regulations.

44. In New York, for example, physicians and pharmacies must periodically sign a "Certification Statement for Provider Billing Medicaid," in which the provider certifies that claims submitted "to the State's Medicaid fiscal agent, for services or supplies furnished," "will be subject to the following certification. . . . I (or the entity) have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations."

(U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 41-44)

As to the falsity of the Medicaid claims alleged in its Complaint, New York states:

29. Pursuant to 18 NYCRR § 504.1, "Any person who furnishes medical care, services or supplies for which payments under the [Medicaid] program are to be claimed; or who arranges the furnishing of such care, services or supplies; or who submits claims for or on behalf of any person furnishing or arranging for the furnishing of such care, services or supplies must enroll as a provider of services prior to being eligible to receive such payments, to arrange for such care, services or supplies or to submit claims for such care or supplies." 18 NYCRR § 504.1(b)(1).

30. Before submitting claims for payment to the New York State Medicaid program, whether in paper or electronic form, providers, including physicians and pharmacies, are required to first sign a Certification Statement for Provider Billing Medicaid (hereinafter, "Certification Statement"). See EMedNY New York State Medicaid General Billing Guidelines-Professional, Version 2013-01, at p. 5; New York State EMedNY Billing Guidelines-Pharmacy, Version 2013-01 at p. 5. In

the Certification Statement, the provider certifies that, for all claims submitted to Medicaid, "I (or the entity) have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations."

31. Accordingly, providers must affirmatively certify, as a condition of payment of the claims submitted for reimbursement by Medicaid, compliance with applicable federal and state laws and regulations.

32. A provider must renew her Certification Statement periodically by signing a new Certification Statement. The Certification Statement last signed by the provider remains in effect for all claims until a new Certification Statement is signed by the provider.

33. Since in or about 2007, the Certification Statement has applied to all claims submitted to Medicaid, whether submitted electronically or on paper. Prior to 2007, for paper claims the provider's certification statement was included on the paper claim form submitted to Medicaid, and the provider certified that the care, services or supplies listed on the claim form were "furnished in accordance with applicable Federal and State laws and regulations" when submitting the claim form for payment.

34. 18 N.Y.C.R.R. § 515.2(b) specifically prohibits as an "unacceptable practice":

> (5) Bribes and Kickbacks . . .
>
> (ii) soliciting or receiving either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care, services or supplies for which payment is claimed under the [Medicaid] program;
>
> * * *
>
> (iv) offering or paying either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care, services or supplies for which payment is claimed under the [Medicaid] program
>
> * * *

35. 18 N.Y.C.R.R. § 515.2(a) also specifically prohibits as an "unacceptable practice" conduct that is contrary to:

> (3) the official rules and regulations of the Departments of Health, Education and Mental Hygiene, including the latter department's

> offices and division, relating to standards for medical care and services under the [Medicaid] program; or
>
> (4) the regulations of the Federal Department of Health and Human Services promulgated under title XIX of the Federal Social Security Act.
>
> 36. Pursuant to 18 N.Y.C.R.R. § 518.1(c) "overpayment includes any amount not authorized to be paid under the medical assistance program, whether paid as the result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse or mistake."
>
> 37. Title 18 provides further that "[n]o payments will be made to or on behalf of any person for the medical care, services or supplies furnished . . . in violation of any condition of participation in the program," nor will payments be made [ ] "for any medical care, services or supplies ordered or prescribed in violation of any condition of participation in the program." 18 N.Y.C.R.R. § 515.5(a), (b). Accordingly, all claims for payment to Medicaid resulting from kickbacks are in violation of a material condition of payment of the New York State Medicaid Program.

(N.Y. Cmplt. (Dkt. No. 61) ¶¶ 29-37)

2. Certification Theories Under Mikes v. Straus

The Second Circuit addressed the issue of whether a claim is "false or fraudulent" within the meaning of the FCA in the seminal case of Mikes v. Straus, 274 F.3d 687 (2d Cir. 2001). In that case, the court acknowledged that "the term 'false or fraudulent' is not defined in the Act." Id. at 696. However, it found that "[t]he language of the[ ] [Act's] provisions [pertaining to 'false or fraudulent claims'] plainly links the wrongful activity to the government's decision to pay." Id.

The plaintiff in Mikes premised the falsity of the alleged claims on "the 'certification theory' of liability, which is predicated upon a false representation of compliance with a federal statute or regulation or a prescribed contractual term . . . [and] has also been called 'legally false' certification." Id. This theory "differs from 'factually false' certification, which involves an incorrect description of goods or services provided or a request for reimbursement

for goods or services never provided." Id. at 697. The Second Circuit found that legally false certification could present a basis for falsity under the FCA, observing that "[a]lthough the False Claims Act is 'not designed to reach every kind of fraud practiced on the Government,' it was intended to embrace at least some claims that suffer from legal falsehood." Id. (quoting United States v. McNinch, 356 U.S. 595, 599 (1958)). "Thus, 'a false claim may take many forms, the most common being a claim for goods or services not provided, or provided in violation of contract terms, specification, statute, or regulation.'" Id. (quoting S. REP. NO. 99-345, at 9 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5274) (emphasis in Mikes).

The Second Circuit noted, however, that "a claim for reimbursement made to the government is not legally false simply because the particular service furnished failed to comply with the mandates of a statute, regulation or contractual term that is only tangential to the service for which reimbursement is sought." Id. "[W]hile the Act is 'intended to reach all types of fraud, without qualification, that might result in financial loss to the Government,' it does not encompass those instances of regulatory noncompliance that are irrelevant to the government's disbursement decisions." Id. (quoting United States v. Neifert-White Co., 390 U.S. 228, 232 (1968)). Accordingly, the Second Circuit held that "a claim under the Act is legally false only where a party certifies compliance with a statute or regulation as a condition to governmental payment." Id.

The court found that legal falsity could be premised on two certification theories: (1) expressly false certification or (2) impliedly false certification. See id. at 697-700.

"An expressly false claim is, as the term suggests, a claim that falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment." Id. at 698. To demonstrate that a claim is false on an express

certification theory, a plaintiff must show that "defendants certified they would comply with the terms [of the statute, regulation, or contract]," "that such compliance was a precondition of governmental payment," and that the conduct alleged "implicated the standard" that defendants certified they would comply with. See id. at 698. In Mikes, for example, plaintiff claimed that defendants had submitted "false" claims to Medicare when they sought reimbursement for procedures performed with a machine that was "unreliable," because defendants had not calibrated it in accordance with industry guidelines. See id. at 693-95.

In support of her express certification theory, plaintiff argued that defendants

> submit[ted] claims for Medicare reimbursement on HCFA-1500 forms . . . [which] expressly say: "I certify that the services shown on this form were medically indicated and necessary for the health of the patient and were personally furnished by me or were furnished incident to my professional service by my employee under my immediate personal supervision." Both the form, which further provides [that] "[n]o Part B Medicare benefits may be paid unless this form is received as required by existing law and regulations," and the Medicare Regulations, see 42 C.F.R. § 424.32, state that certification is a precondition to Medicare reimbursement.

Id. at 698.

Although the Second Circuit "agree[d] that defendants certified they would comply with the terms on the form and that such compliance was a precondition of governmental payment," the court concluded that plaintiff had not sufficiently demonstrated the falsity of the alleged claims under an express certification theory because "[t]he term 'medical necessity' [as used in the certifications] d[id] not impart a qualitative element mandating a particular standard of medical care" for the procedures that were performed, and therefore did not support plaintiff's contention that the claims defendants submitted were "false" – that is, submitted for services that "were not medically necessary." Id. at 698-99. The fact that the machine was not calibrated in

accordance with industry guidelines did not demonstrate that the services defendants provided were not medically necessary. See id.

The court then considered whether plaintiff had demonstrated falsity under the implied certification theory. "An implied false certification claim is based on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment." Id. at 699. Although the Second Circuit found "[f]oundational support" for this theory as to "at least some kinds of legally false claims," the court cautioned that this theory should not be read "expansively and out of context." Id. "[A] medical provider should be found to have implicitly certified compliance with a particular rule as a condition of reimbursement . . . 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 (emphasis in original). If this requirement is satisfied, then "[l]iability under the Act may properly be found . . . when a defendant submits a claim for reimbursement while knowing – as that term is defined by the Act – that payment expressly is precluded because of some noncompliance by the defendant." Id. (citation omitted). The Mikes court found that the plaintiff's claims failed under this theory as well, because the statutory provision plaintiff relied upon for her implied certification theory expressly conditioned "participation" in the Medicare program – rather than reimbursement, i.e., "payment," from that program – on compliance with the statute's terms. Id. at 701-02.

3. The Government Entities' Argument that Pleading Falsity Under a Certification Theory is Not Required

As an initial matter, the Government claims that it need not rely on the certification theories described in Mikes to allege the falsity of the Medicaid claims here, because the mere submission of claims for reimbursement for prescriptions that were written in

violation of the Anti-Kickback Statute makes those claims per se false. (See U.S. Br. (Dkt. No. 90) at 20) Specifically, the United States argues that "although one way in which a claim may be 'false' is where it rests upon an express or implied certification of compliance with a federal statute or regulation, that is not the only way. A claim may also be 'false' under the FCA where it contains no certifications at all, so long as the claim is ineligible for payment, such as a claim resulting from illegal kickbacks." (Id.) Similarly, New York contends that "the deliberate kickback schemes alleged here are by their nature fraudulent and violate Medicaid program regulations that expressly state that the State may withhold and recover funds if the provider fails to comply [with those regulations]. Accordingly, the Second Circuit's holding in Mikes does not control this case." (N.Y. Br. (Dkt. No. 89) at 17-18 (citation omitted))

The force of these arguments is questionable. When considering whether a claim is false or fraudulent under the FCA, courts in this Circuit focus their analysis on the falsity theories described in Mikes. See U.S. ex rel. Qazi v. Bushwick United Hous. Dev. Fund Corp., 977 F. Supp. 2d 235, 239 (E.D.N.Y. 2013) ("[T]here are two types of false claims under the FCA: factually false claims and legally false claims. . . . The false certification of compliance [for a legally false claim] may either be express or implied."); United States v. Dialysis Clinic, Inc., No. 5:09-CV-00710, 2011 WL 167246, at *13 (N.D.N.Y. Jan. 19, 2011) ("Generally, there are two types of FCA violations, legally false claims (a claim provided in violation of a contract, specification, regulation or statute) and factually false claims (a claim for goods or services not provided)."); see also Michael Holt & Gregory Klass, Implied Certification Under the False Claims Act, 41 PUB. CONT. L.J. 1, 7 (2011) ("a claim can be false or fraudulent for the purposes of FCA liability in three different ways" – factual falsity, express legal falsity, or implied legal falsity). Moreover, "[m]ost Circuit courts have adopted the 'false certification' theory of legal

'falsity' described in Mikes." Kester, 88 Fed. R. Serv. 3d 1261, at *18 (citing U.S. ex rel. Wilkins v. United Health Group, Inc., 659 F.3d 295, 306 (3d Cir. 2011); Chesbrough v. VPA, P.C., 655 F.3d 461, 467 (6th Cir. 2011); U.S. ex rel. Lemmon v. Envirocare of Utah, Inc., 614 F.3d 1163, 1167-71 (10th Cir. 2010); U.S. ex rel. Gross v. AIDS Research Alliance-Chicago, 415 F.3d 601, 604 (7th Cir. 2005); U.S. ex rel. Siewick v. Jamieson Sci. & Eng'g, Inc., 214 F.3d 1372, 1376 (D.C. Cir. 2000); Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 786-87 (4th Cir. 1999); U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 902 (5th Cir. 1997); U.S. ex rel. Hopper v. Anton, 91 F.3d 1261, 1266-67 (9th Cir. 1996)). Although "[t]he First Circuit has implemented a less rigid version of legal 'falsity' that does not rely as heavily on the distinctions between 'express' and 'implied' certifications[,] [s]ee New York v. Amgen Inc., 652 F.3d 103, 110 (1st Cir. 2011)[,] [d]istrict courts in this Circuit routinely recognize the 'express' and 'implied' false certification theories of claim falsity." Kester, 88 Fed. R. Serv. 3d 1261, at *18.

Courts in this district have also applied the Mikes analysis to FCA claims premised on violations of anti-kickback statutes, such as the claims at issue here. See New York Soc., 2014 WL 3905742, at *17-18 (dismissing FCA claims premised on violations of the Anti-Kickback Statute for failing to sufficiently allege a theory of express or implied certification); Kester, 88 Fed. R. Serv. 3d 1261, at *17-21. If claims submitted to government programs in violation of the anti-kickback laws were per se false, this type of analysis would not be necessary.

The Government Entities argue, however, that "[a] claim [is] 'false' under the FCA . . . so long as the claim [for reimbursement] is ineligible for payment, such as a claim resulting from illegal kickbacks." (See U.S. Br. (Dkt. No. 90) at 20) Submitting an ineligible

claim for reimbursement under the circumstances here, however, is the other side of the coin of "submitting a claim for reimbursement . . . impl[ying] compliance with [the anti-kickback statutes] . . . that [is] a precondition to payment." Mikes, 274 F.3d at 699. And the latter theory is the essence of implied false legal certification. See id.; see also Kester, 88 Fed. R. Serv. 3d 1261, at *19 ("[T]he Government's theory is more accurately characterized as 'legal' falsity[;] it contends that the pharmacies' claims for reimbursement of Myfortic and Exjade claims were false because they were tainted by violations of the Anti-Kickback Statute. The Government asserts that Novartis and the pharmacies certified compliance with the [Anti-Kickback Statute] when, in fact, Novartis was paying kickbacks to the pharmacies in exchange for their promises to promote Myfortic or Exjade.").

It is not necessary to resolve this issue here because – as set forth below – the Court concludes that the Government Entities have adequately pled the falsity of the Medicaid claims based on the implied certification theory set forth in Mikes.

4. Plaintiffs' Certification Theories

The Government Entities argue that falsity has been properly pleaded under both the express and implied legal falsity theories.

a. Express Certification

The Government Entities have alleged that doctors who submitted claims to Medicaid were required to submit certification statements in order for those claims to be eligible for reimbursement from Medicaid. According to Plaintiffs, in signing those statements, the doctors certified that they were acting in compliance with applicable federal and state laws. In support of their contention that the doctors were certifying compliance with the anti-kickback laws in signing their certification statements, the Government Entities cite regulations that

prohibit reimbursement for claims submitted in violation of the anti-kickback laws. This combination of express language in the certification statements and provisions in the underlying regulations indicating that doctors who sign such statements are certifying that they are complying with the anti-kickback laws – such compliance being a pre-condition of government payment – provides a basis for an express certification argument here. See Mikes, 274 F.3d at 698 (concluding that defendants had expressly certified that they would comply with Medicare's requirement that the services performed were medically indicated and necessary as a precondition payment, where defendants signed forms stating "I certify that the services shown on this form were medically indicated and necessary" and "No Part B Medicare benefits may be paid unless this form is received as required by existing law and regulations," and where "the Medicare Regulations . . . state[d] that certification [was] a precondition to Medicare reimbursement").

It is not clear from either of the Government Entities' complaints when the certifications were submitted or whether they were submitted in connection with individual claims, however. It appears that some of the alleged certifications were made in enrollment forms, while other certification statements were submitted at later points in time. This lack of clarity creates an issue as to whether the certifications were false at the time they were made:

> "[T]he problem here is not necessarily the 'forward-looking' language of the certification[s] or that the certification[s] [are] contained in . . . enrollment form[s] instead of a claim form, but rather that the Plaintiffs have not alleged that providers expressly made such statements knowing their falsity. The Plaintiffs do not allege that when the providers signed the enrollment forms, they knew that they would be accepting kickbacks from the Defendants in violation of the anti-kickback statute. Without such pleading, there can be no 'false claim' . . . under the express certification theory."

See Dialysis Clinic, Inc., 2011 WL 167246, at *14 (quoting U.S. ex rel. Westmoreland v. Amgen, Inc., 707 F. Supp. 2d 123, 136 (D. Mass. 2010), aff'd in part, rev'd in part sub nom.,

New York v. Amgen Inc., 652 F.3d 103 (1st Cir. 2011)). Accordingly, this Court must consider whether the falsity of the statements is adequately pled under an implied certification theory.

b. Implied Certification

The Government Entities allege that the statutes, rules, and regulations governing Medicaid "expressly state[ ] [that] the provider must comply [with the anti-kickback laws] in order to be paid." Mikes, 274 F.3d at 700 (emphasis in original). For example, the Government's Amended Complaint asserts that "[c]laims arising from illegal kickbacks are not authorized to be paid under state regulatory regimes." (See U.S. Am. Cmplt. (Dkt. No. 62) ¶ 41) New York likewise alleges that "all claims for payment to Medicaid resulting from kickbacks are in violation of a material condition of payment of the New York State Medicaid Program" under New York Medicaid regulations. (See N.Y. Cmplt. (Dkt. No. 61) ¶ 37; see also ¶¶ 34-36)

New York Medicaid regulations – which are cited by the United States and New York in their pleadings – require compliance with federal and state anti-kickback statutes as a precondition to the payment of claims submitted to Medicaid. Under these regulations, "[b]y enrolling [in Medicaid] the provider agrees[ ] . . . to submit claims for payment only for services actually furnished and which were medically necessary or otherwise authorized under the Social Services Law when furnished and which were provided to eligible persons." N.Y. Comp. Codes R. & Regs. tit. 18, § 504.3(e). The Social Services Law – which contains New York's Anti-Kickback Statute – states that "[n]o medical assistance provider shall . . . solicit, receive, accept or agree to receive or accept any payment or other consideration in any form from another person to the extent such payment or other consideration is given . . .to purchase, lease or order any good, facility, service or item for which payment is made under title eleven of article five of this chapter." N.Y. Soc. Serv. Law § 366-d(2)(a).

New York Medicaid regulations further provide that

> [n]o payments will be made to or on behalf of any person for the medical care, services or supplies furnished by or under the supervision of the person . . . in violation of any condition of participation in the program. . . . [and]
>
> [n]o payment will be made . . . for any medical care, services or supplies ordered or prescribed in violation of any condition of participation in the program.

N.Y. Comp. Codes R. & Regs. tit. 18, § 515.5(a)-(b) (emphasis added). These provisions together indicate that compliance with anti-kickback statutes is a condition for payment of claims that medical providers submit to Medicaid. Under these provisions, medical providers in New York not only agree to comply with the anti-kickback statute as a condition of participation in the Medicaid program; payments from that program are also expressly premised on compliance with this condition.

New York regulations governing Medicaid's recovery of overpayments support this conclusion. Those regulations provide that "[w]hen the department has determined that any person has submitted or caused to be submitted claims for medical care, services or supplies for which payment should not have been made, it may require repayment of the amount determined to have been overpaid. . . . An overpayment includes any amount not authorized to be paid under the medical assistance program, whether paid as the result of . . . improper claiming, unacceptable practices, fraud, [or] abuse . . ." Id. § 518.1(b)-(c) (emphasis added). "Unacceptable practices" are defined as

> conduct by a person which is contrary to:
>
> . . .
>
> (3) the official rules and regulations of the Departments of Health, Education and Mental Hygiene, including the latter department's offices and divisions, relating to standards for medical care and services under the program; or

> (4) the regulations of the Federal Department of Health and Human Services promulgated under title XIX of the Federal Social Security Act.
>
> . . .
>
> [and] conduct which constitutes fraud or abuse [including:]
>
> . . .
>
> (ii) soliciting or receiving either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care, services or supplies for which payment is claimed under the program;
>
> . . .
>
> (iv) offering or paying either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care, services or supplies for which payment is claimed under the program.

Id. § 515.2(a)(3)-(4), (b)(5)(ii), (iv).

Viewed together, the statutes and regulations cited by the Government Entities expressly state that healthcare providers must comply with the anti-kickback laws in order for claims that they cause to be submitted to Medicaid to be reimbursed. Because Plaintiffs have alleged that the claims submitted to the Medicaid program here violate the anti-kickback statutes in that these claims stemmed from prescriptions written by doctors in exchange for bribes – knowing that claims for reimbursement would be submitted to the Medicaid program as a result – Plaintiffs have sufficiently pled that those claims were false under an implied certification theory. See Mikes, 274 F.3d at 700.

In addition to falsely certifying compliance with the anti-kickback laws, the Government Entities have also alleged that the doctors falsely certified that they were in compliance with contractual provisions that were conditions for payment – specifically, earlier

certification statements that the doctors signed in order to enroll in Medicaid and bill for claims. The United States alleges that

> [p]roviders who participate in the Medicaid program must sign enrollment agreements with their states that certify compliance with the state and federal Medicaid requirements, including the [Anti-Kickback Statute]. Although there are variations among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies furnished.
>
> [ ] Furthermore, in many states, Medicaid providers, including both physicians and pharmacies, must affirmatively certify, as a condition of payment of the claims submitted for reimbursement by Medicaid, compliance with applicable federal and state laws and regulations.

(U.S. Am. Cmplt. (Dkt. No. 62) ¶¶ 42-43 (emphasis added))

New York similarly alleges that "[b]efore submitting claims for payment to the New York State Medicaid program . . . physicians . . . are required to first sign a Certification Statement for Provider Billing Medicaid . . . [in which they] must affirmatively certify, as a condition of payment of the claims submitted for reimbursement by Medicaid, compliance with applicable federal and state laws and regulations," and that a physician "must renew her Certification Statement periodically by signing a new Certification Statement . . . [which] remains in effect for all claims until a new Certification Statement is signed by the provider." (N.Y. Cmplt. (Dkt. No. 61) ¶¶ 30-32 (emphasis added))

These certifications, therefore, are part of doctors' agreements with Medicaid that permit them to submit claims for payment. See also N.Y. Comp. Codes R. & Regs. tit. 18, § 504.1(b)(1) ("Any person who furnishes medical care, services or supplies for which payments under the medical assistance program are to be claimed; or who arranges the furnishing of such care, services or supplies; or who submits claims for or on behalf of any person furnishing or arranging for the furnishing of such care, services or supplies must enroll as a provider of

services prior to being eligible to receive such payments, to arrange for such care, services or supplies or to submit claims for such care or supplies.").

Furthermore, the New York Certification Statement – which is cited by both Government Entities, and which is attached to the New York Complaint[14] – states:

> I . . . have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations. . . . In submitting claims under this agreement I understand and agree that I . . . shall be subject to and bound by all rules, regulations, policies, standards, fee codes, and procedures of the New York State Department of Social Services as set forth in title 18 of the Official Complication of Codes, Rules and Regulations of New York State [which includes New York's Medicaid regulations].

Doctors participating in New York's Medicaid program also certify:

> I UNDERSTAND THAT MY SIGNATURE HEREON GUARANTEES THE ABOVE CERTIFICATION WILL APPLY TO ALL ELECTRONIC CLAIMS SUBMITTED, USING MY . . . MEDICAID PROVIDER IDENTIFICATION NUMBER. THIS CERTIFICATION REMAINS IN EFFECT AND APPLIES TO ALL CLAIMS UNTIL SUPERSEDED BY ANOTHER PROPERLY EXECUTED CERTIFICATION STATEMENT.

(N.Y. Cmplt. (Dkt. No. 61), Ex. B)

Accordingly, by causing claims to be submitted in violation of applicable federal and state laws and regulations, doctors violate their express agreement with Medicaid that they will only bill for, or cause Medicaid to be billed for, "care, services and supplies" provided lawfully. The breach of this certification to Medicaid when claims are later submitted in

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[14] Although the United States has not attached the New York "Certification Statement for Provider Utilizing Electronic Building" to its Amended Complaint, the form is incorporated by reference. (See U.S. Am. Cmplt. (Dkt. No. 62) ¶ 44 ("In New York, for example, physicians and pharmacies must periodically sign a "Certification Statement for Provider Billing Medicaid. . . .'")) The Court will therefore take judicial notice of the certification statement in deciding the motion to dismiss the Government's Amended Complaint. See Bldg. Indus. Elec. Contractors Ass'n v. City of New York, 678 F.3d 184, 187 (2d Cir. 2012) ("In assessing the legal sufficiency of [a plaintiff's] claim[s] [on a motion to dismiss], [the court may] . . . consider . . . the complaint and any documents attached thereto or incorporated by reference and 'documents upon which the complaint "relies heavily."'" (quoting In re Citigroup ERISA Litig., 662 F.3d 128, 135 (2d Cir. 2011) (quoting DiFolco, 622 F.3d at 111))).

violation of anti-kickback laws therefore provides another ground for concluding that such claims are false under an implied certification theory.

* * * *

The Government Entities have sufficiently pled that the claims allegedly submitted to Medicaid are "false" within the meaning of the FCA and the New York FCA. Defendants' motion to dismiss the causes of action related to Medicaid claims submitted prior to the 2010 amendments to the Anti-Kickback Statute will be denied.

c. The Government's Common Law Unjust Enrichment Claim

Novartis's argument for dismissal of the Government's common law unjust enrichment claim is premised on this Court's dismissal of the Government's anti-kickback claims. (Def. MTD-U.S. Br. (Dkt. No. 80) at 24-25) Because this Court has rejected Novartis's arguments concerning the Government's anti-kickback claims, Novartis's motion to dismiss the Government's unjust enrichment claim will be denied

d. New York's State Law Claims Related to Kickbacks

1. Claims for Violations of Social Services Law § 145-b and Executive Law §§ 63(12) and 63-c, and for Unjust Enrichment

Novartis argues that "[c]ounts three through six of the [New York] Complaint should be dismissed because they do not sufficiently allege that [Novartis] engaged in and benefitted from a fraudulent action." (Def. MTD-N.Y. Br. (Dkt. No. 82) at 20-21) Those counts allege violations of New York's Social Services Law § 145-b and Executive Law §§ 63(12) and 63-c and include a claim for unjust enrichment. (N.Y. Cmplt. (Dkt. No. 61) ¶¶ 154-67) Novartis's argument for dismissal of these claims is premised on this Court's dismissal of the Government's anti-kickback claims. (Def. MTD-N.Y. Br. (Dkt. No. 82) at 20) Having found

Novartis's arguments regarding the sufficiency of the pleading of the underlying kickback scheme to be without merit, its motion to dismiss these claims on this grounds will be denied.

2. **Claims Relating to Conduct Prior to April 1, 2007**

Novartis argues that to the extent New York's claims under the New York FCA are based on claims submitted prior to the April 9, 2007 enactment of the New York FCA, they must be dismissed because recovery for such claims would violate the Ex Post Facto clause of the United States Constitution. (Def. MTD-N.Y. Br. (Dkt. No. 82) at 21-23)

Under the Ex Post Facto Clause, the government may not "enact a law that punishes an act that was innocent prior to the enactment. . . ." Hobbs v. County of Westchester, 397 F.3d 133, 157 (2d Cir. 2005). "The Ex Post Facto Clause applies only to criminal punishments and in civil cases 'where the civil disabilities disguise criminal penalties.'" U.S. ex rel. Drake v. NSI, Inc., 736 F. Supp. 2d 489, 498 (D. Conn. 2010) (quoting Louis Vuitton S.A. v. Spencer Handbags Corp., 765 F.2d 966, 972 (2d Cir. 1985)) (emphasis added).

"To determine whether the Clause applies, the court must determine whether (1) the law is retrospective and applies to conduct that occurred before its enactment; and (2) the law disadvantages affected parties." Id. (citing United States v. Kilkenny, 493 F.3d 122, 127 (2d Cir. 2007)). In the context of civil matters, the court must further

> ascertain whether the legislature meant the statute to establish "civil" proceedings. If the intention of the legislature was to impose punishment, that ends the inquiry. If, however, the intention was to enact a regulatory scheme that is civil and nonpunitive, [the court] must further examine whether the statutory scheme is so punitive either in purpose or effect as to negate the State's intention to deem it "civil." Because we ordinarily defer to the legislature's stated intent, only the clearest proof will suffice to override legislative intent and transform what has been denominated a civil remedy into a criminal penalty.

Id. (quoting Smith v. Doe, 538 U.S. 84, 92 (2003)).

The inquiry therefore begins with an analysis of whether the New York FCA applies retroactively. In enacting the New York FCA, the New York legislature provided that "section thirty-nine of this act [which amended the New York Finance Law to add the New York FCA] shall apply to claims filed or presented prior to, on or after April 1, 2007." New York Public Health Care Reform Act, 2007 Sess. Law News of N.Y. Ch. 58, §§ 39, 93(5) (S. 2108-C) (McKinney's) (emphasis added). Such language expressly provides for retroactive application of the Act. See Kuhali v. Reno, 266 F.3d 93, 110-11 (2d Cir. 2001) ("Congress ha[d] made explicit that the new provisions should apply retroactively" by stating in the statutory text and notes to that text that the statute would apply "before, on, or after" the date of enactment). Other courts in this district, as well as New York state courts, agree that the New York FCA has retroactive application. See United States v. Huron Consulting Grp., Inc., No. 09 Civ. 1800 (JSR), 2010 WL 3467054, at *3 (S.D.N.Y. Aug. 25, 2010) ("[T]he Court . . . concludes that the state False Claims Act, which was enacted on April 1, 2007, applies retroactively to the claims at issue, which were filed before that enactment."); United States v. NYSARC, No. 03-CV-7250 (SHS) (S.D.N.Y. Mar. 20, 2009) (Tr. 16-17) ("NYSARC tries to argue that the New York False Claims Act is not retroactive. The statute is explicitly retroactive. New York False Claims Act 2007 New York Session Law, Chapter 58 S2108-C of April 9, 2007 states that Section 39 of the New York . . . False Claims Act 'shall apply to claims filed or presented prior to, o[n] or after April 1, 2007.' It doesn't matter that the provision concerning retroactivity is not officially codified in the New York State Finance Law. And the Court has to give the statute specifically stated retroactive [e]ffect. The state statute is retroactive and relator['s] claims pursuant to it are appropriate."); New York ex rel. Colucci v. Beth Israel Med. Ctr., Index No. 112059/07 (N.Y. Sup. Ct. N.Y. Cty. July 23, 2009) (Tr. 44-45) ("[T]here is a specific very clear statement of

intention that . . . the act shall apply to claims filed prior to April 1, 2007. . . . [I]t is not ambiguous, it is very specific."); cf. People v. Sprint Nextel Corp., 114 A.D.3d 622, 622 (1st Dep't 2014) ("The court also properly rejected defendants' argument that the New York False Claims Act with respect to statements made under the Tax Law should not be given its stated retroactive effect.").[15]

Having concluded that the New York FCA has retroactive application, the next step of the analysis is easily disposed of: Novartis would be disadvantaged by retroactive application of the statute here because it will be exposed to liability for conduct that occurred prior to April 1, 2007. This Court therefore turns to an analysis of whether application of the New York FCA to pre-April 1, 2007 claims would violate the Ex Post Facto Clause.

In conducting an Ex Post Facto Clause analysis, this Court must determine whether the legislature intended the New York FCA "to establish 'civil' proceedings" and – if so – whether the Act is "so punitive either in purpose or effect as to negate the State's intention to deem it 'civil.'" Smith, 538 U.S. at 92.

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[15] Novartis's reliance on U.S. ex rel. Romano v. New York-Presbyterian Hosp., No. 00 Civ. 8792 (LLS), 2008 WL 612691, at *2 (S.D.N.Y. Mar. 5, 2008), is misplaced. There, the court stated that "[t]he New York False Claims Act itself has no express statutory grant of retroactivity. An uncodified provision of Assembly Bill A04308 states that 'section thirty-nine of this act shall apply to claims filed or presented prior to, on or after April 1, 2007.'" While the text of the New York State Finance Law §§ 187-94 – the New York FCA – does not itself contain the "prior to, on or after" language, this language is clearly part of the New York Sessions Laws that enacted and governs the New York FCA. See Nysarc, No. 03-CV-7250 (SHS) (Tr. 16-17) ("It doesn't matter that the provision concerning retroactivity is not officially codified in the New York State Finance Law."). Moreover, although the court in Romano may have expressed skepticism as to whether the New York FCA applies retroactively, the court's statement on this point is dicta. The court ultimately concluded that this issue was irrelevant to the disposition of the claims in that case, because "neither the New York False Claims Act itself, nor the uncodified Session Law's reference to claims presented 'prior to' the Act's effective date, contains any language implying that the Act would revive claims barred by its own statute of limitations." Romano, 2008 WL 612691, at *1-2.

In People ex rel. Schneiderman v. Sprint Nextel Corp., 41 Misc. 3d 511 (N.Y. Sup. Ct. N.Y. Cnty. 2013), aff'd sub nom., Sprint Nextel Corp., 114 A.D.3d 622, the New York Supreme Court concluded that "[t]he [New York] legislature expressed the objective of the law [as civil] in the statutory text itself," and ruled that the Act "is not sufficiently punitive in nature and effect as to warrant preclusive application of the Ex Post Facto Clause to [defendant's] alleged conduct prior to [the date of a 2010 amendment to the New York FCA]." Schneiderman, 41 Misc. 3d at 521, 524; see also Sprint Nextel Corp., 114 A.D.3d at 622 ("The court also properly rejected defendants' argument that the New York False Claims Act with respect to statements made under the Tax Law should not be given its stated retroactive effect. Defendants fail to show that the Act's sanction of civil penalties, including treble damages, is so punitive in nature and effect as to have its retroactive effect barred by the Ex Post Facto Clause (U.S. Const., art. I, § 10).").

While this Court has considered the state court opinions, it must, of course, undertake its own analysis of this constitutional question. See Warburton v. Underwood, 2 F. Supp. 2d 306, 318 (W.D.N.Y. 1998) ("[N]either the decision of another federal district [c]ourt or that of the New York State Court of Appeals regarding the interpretation of federal constitutional law are binding precedent.").

This Court agrees that the New York legislature intended the New York FCA to be civil in nature. The Act states that "any person who[ ] [violates its provisions] . . . shall be liable to the state or a local government, as applicable, for a civil penalty. . . ." N.Y. State Fin. Law § 189(1) (emphasis added). The Act further states that "[a] person who violates this section shall also be liable for the costs, including attorneys' fees, of a civil action brought to recover any such penalty or damages." Id. § 189(3) (emphasis added). Accordingly, "[t]he express

language used indicates the legislature's preference for a civil label." Schneiderman, 41 Misc. 3d at 521.

Novartis argues, however, that the statutory scheme is "so punitive either in purpose or effect as to negate the State's intention to deem it 'civil.'" Smith, 538 U.S. at 92. In support of this argument, Novartis relies primarily on State ex rel. Grupp v. DHL Exp. (USA), Inc., 19 N.Y.3d 278, 286-87 (N.Y. 2012). There, the Court of Appeals observed that "rather than redressing the harm actually suffered, the [New York FCA's] imposition of civil penalties and treble damages evinces a broader punitive goal of deterring fraudulent conduct against the State." Id. at 286. Novartis argues that "[g]iven the FCA's draconian sanctions [including treble damages] and the New York Court of Appeals' own conclusion that the NY FCA 'evinces a broader punitive goal,' it is clear . . . that the NY FCA is indeed punitive. . . . [such that] under the basic principles of the Constitution's Ex Post Facto clause, the State cannot apply this statute . . . to conduct that preceded its enactment." (Def. MTD-N.Y. Reply Br. (Dkt. No. 86) at 10 & n.9)

In Grupp, however, the New York Court of Appeals was not addressing an Ex Post Facto challenge. Rather, the court was considering "whether plaintiffs' claims on behalf of the State of New York, pursuant to the New York False Claims Act[,] . . . [were] federally preempted by the Airline Deregulation Act of 1978 . . . and the Federal Aviation Administration Authorization Act." Grupp, 19 N.Y.3d at 281 (citations omitted). In deciding the preemption issue, the court considered the applicability of the "market participant doctrine exception" to preemption. Id. Because that exception does not apply "when government entities seek to advance general societal goals rather than narrow proprietary interests through the use of their contracting power," the court considered whether, in enacting the New York FCA, the legislature

was seeking to advance "general societal goals." See id. at 286-87 (internal citation and quotation omitted). The Court of Appeals concluded that, "instead of compensating the State for damages caused by [defendant's] purported fraudulent scheme and addressing its narrow proprietary interests, the FCA would punish and consequently deter such future conduct, thereby promoting a general policy." Id. at 286-87. The court did not consider, however, whether the civil penalties provided for in the New York FCA are "so punitive" as to bar retroactive application of the Act. Accordingly, Grupp is not dispositive here. See Schneiderman, 41 Misc. 3d at 522 ("[Grupp] is unavailing as . . . [t]he Court did not consider whether the New York False Claims Act constitutes retroactive punishment forbidden by the Ex Post Facto Clause.").

"[W]hether a sanction intended as regulatory or nonpunitive is 'so punitive in fact' as to violate the ex post facto prohibition is a highly context specific matter." Doe v. Pataki, 120 F.3d 1263, 1275 (2d Cir. 1997), as amended on denial of reh'g, (Sept. 25, 1997) (citing Flemming v. Nestor, 363 U.S. 603, 616 (1960)).

In the context of the federal FCA – which "New York courts rely on . . . when interpreting the NYFCA," New York Soc., 2014 WL 3905742, at *11 – the majority of federal courts have concluded that retroactive application of the federal Act and, more recently, its 2009 amendments – does not violate the Ex Post Facto Clause. See Sanders v. Allison Engine Co., 703 F.3d 930, 948 (6th Cir. 2012) ("[R]etroactive application of the FCA does not violate the Ex Post Facto Clause's prohibition on retroactive punishments."); U.S. ex rel. Miller v. Bill Harbert Int'l Const., Inc., 608 F.3d 871, 878 (D.C. Cir. 2010) ("The defendants' arguments that the amended [federal FCA] cannot constitutionally be applied to this case are unpersuasive. The Ex Post Facto Clause of the Constitution applies only to penal legislation. The FCA is not penal.") (citations omitted); U.S. ex rel. Cannon v. Rescare, Inc., No. Civ. 09-3068, 2014 WL 4638715, at

*6 (E.D. Pa. Sept. 16, 2014) ("[A]s numerous Courts have concluded, 'the [Mendoza-Martinez] . . . factors fail to demonstrate a sufficiently punitive purpose or effect' to characterize the FCA penalty provision as criminal." (quoting Sanders, 703 F.3d at 948)); U.S. ex rel. Int'l Bhd. of Elec. Workers, Local Union No. 98 v. Farfield Co., No. Civ. A. 09-4230, 2013 WL 3327505, at *8 (E.D. Pa. July 2, 2013) ("Defendant argues that a number of courts have refused to apply the changes to [the FCA] retroactively on the ground that it would violate the Ex Post Facto Clause of the Constitution. I disagree."); U.S. ex rel. Drake v. NSI, Inc., 736 F. Supp. 2d 489, 502 (D. Conn. 2010) ("[T]he Court finds that the FCA is not sufficiently punitive in nature and effect so as to warrant application of the Ex Post Facto Clause. There is not present in this case the 'clearest proof' to defeat Congress's intention to create a civil framework to prevent fraud against the government."). These courts have concluded that although "some aspects of the FCA weigh in favor of finding a punitive purpose or effect" – such as "the deterrent function of the FCA, and the availability of treble damages" – that is "not enough alone" to render the FCA punitive. See Sanders, 703 F.3d at 945-48; see also Drake, 736 F. Supp. 2d at 500-02. Rather, those penal aspects of the FCA are outweighed by, inter alia, the remedial purpose served by the FCA, the "historically civil" monetary remedies that it provides, and the unique compensatory purpose that treble damages serve in the qui tam context – specifically, to encourage relators to pursue FCA claims. See Sanders, 703 F.3d at 945-48; see also Drake, 736 F. Supp. 2d at 500-02.

The Supreme Court has identified seven factors "traditionally applied to determine whether a[ ] [statute] is penal or regulatory in character." Kennedy v. Mendoza-Martinez, 372 U.S. 144, 168 (1963). These factors are

> [w]hether the sanction involves an affirmative disability or restraint, whether it has historically been regarded as a punishment, whether it comes into play only

> on a finding of scienter, whether its operation will promote the traditional aims of punishment – retribution and deterrence, whether the behavior to which it applies is already a crime, whether an alternative purpose to which it may rationally be connected is assignable for it, and whether it appears excessive in relation to the alternative purpose assigned. . . .

Id. at 168-69; cf. Hudson v. United States, 522 U.S. 93, 99 (1997) ("Even in those cases where the legislature 'has indicated an intention to establish a civil penalty, we have inquired further whether the statutory scheme was so punitive either in purpose or effect,' as to 'transfor[m] what was clearly intended as a civil remedy into a criminal penalty.' In making this . . . determination, the factors listed in Kennedy v. Mendoza–Martinez . . . provide useful guideposts.") (internal citations omitted). "Sometimes one factor will be considered nearly dispositive of punitiveness 'in fact,' while sometimes another factor will be crucial to a finding of nonpunitiveness." Pataki, 120 F.3d at 1275.

Here, the first factor – "[w]hether the sanction involves an affirmative disability or restraint," Kennedy, 372 U.S. at 168 – weighs against a finding that the New York FCA is punitive. "The Act imposes no physical restraint, and so does not resemble the punishment of imprisonment, which is the paradigmatic affirmative disability or restraint." See Smith, 538 U.S. at 100. Defendant points to no affirmative disability or restraint that compels a different conclusion. See Schneiderman, 41 Misc. 3d at 521 ("[The New York FCA] imposes no physical restraint, and so does not resemble the punishment of imprisonment, which is the paradigmatic affirmative disability or restraint. Therefore, this factor weighs in favor of finding a civil purpose."); see also U.S. ex rel. Bergman v. Abbot Labs., 995 F. Supp. 2d 357, 384 (E.D. Pa. 2014) (first factor weighs in favor of finding Wisconsin and Tennessee FCAs civil because "the monetary penalties authorized by each state, although substantial, do not approach the punitive nature of imprisonment"); Massachusetts v. Schering-Plough Corp., 779 F. Supp. 2d 224, 236

(D. Mass. 2011) ("Because the sanctions under the [Massachusetts False Claims Act] do not approach imprisonment, [the first Kennedy] factor weighs in favor of a finding that the MFCA sanctions are civil and regulatory in purpose or effect."); cf. Sanders, 703 F.3d at 945 ("The first Mendoza-Martinez factor clearly favors the conclusion that the [federal] FCA has a civil purpose or effect. The sanctions under the FCA do not involve an affirmative disability or restraint."); Drake, 736 F. Supp. 2d at 500 ("The sanctions under [the federal] FCA do not approach imprisonment. Therefore, this factor weighs in favor of finding a civil purpose.").

Under the second Kennedy factor, the Court must consider whether the New York FCA's penalties have "historically been regarded as a punishment." Kennedy, 372 U.S. at 168. The Act provides for "a civil penalty of not less than six thousand dollars and not more than twelve thousand dollars, plus three times the amount of all damages, including consequential damages, which the state or local government sustains because of the act of th[e] person." N.Y. State Fin. Law § 189(1). "[M]oney penalties have [not] historically been viewed as punishment. Rather, the 'payment of fixed or variable sums of money' is a sanction that has long been recognized as civil." S.E.C. v. Palmisano, 135 F.3d 860, 866 (2d Cir. 1998) (quoting Hudson, 522 U.S. at 104); see also Bergman, 995 F. Supp. 2d at 385 ("[T]his court does not consider the monetary penalties [imposed by the Wisconsin and Tennessee FCAs, including treble damages,] to be historically regarded as punishment."); Schneiderman, 41 Misc. 3d at 521-22 (concluding that this factor weighs in favor of finding that the New York FCA is civil). Accordingly, the second factor indicates that the New York FCA is civil in nature.

The third factor – whether the Act comes into play only on a finding of scienter – also weighs against a finding that the New York FCA is punitive. The New York FCA provides that a person is liable if he or she "knowingly presents, or causes to be presented a false or

fraudulent claim for payment or approval," or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." N.Y. State Fin. Law § 189(1)(a)-(b). The New York FCA defines "knowingly" as "mean[ing] that a person, with respect to information: (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." Id. § 188(3) (emphasis added). The New York FCA, therefore, "can be violated upon either a finding of scienter ('knowingly') or recklessness. Because the current act can be violated by a lower mens rea than knowingly, this factor does not weigh in favor of finding that the effect of the act is to punish." See Sanders, 703 F.3d at 946. The New York FCA "by virtue of [its] inclusion of recklessness in [its] mens rea requirements, monetarily penalize[s] acts carried out without guilty knowledge. Therefore, th[is] statute[] do[es] not intend to punish behavior that [New York] consider[s] criminal because [it] do[es] not require guilty knowledge." See Bergman, 995 F. Supp. 2d at 385.[16]

As to the fourth factor – whether the operation of the statute will promote the traditional aims of punishment, retribution and deterrence – the enhanced penalties of the New York FCA, which include treble and consequential damages, appear to serve these purposes, as the Grupp court acknowledged. See Grupp, 19 N.Y.3d at 286-87.

In discussing the federal FCA, however – which also provides for treble damages – the United States Supreme Court has noted that a treble damages remedy has both punitive and compensatory components. In Cook Cnty., Ill. v. U.S. ex rel. Chandler, 538 U.S. 119, 130

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[16] The Drake court concluded – in the context of the federal FCA – that "[s]cienter is an element of an FCA violation." Drake, 736 F. Supp. 2d at 500. The cases that Drake relied on for this proposition, however, pre-date the 2009 amendments to the federal FCA, which lowered the intent standard. See Sanders, 703 F.3d at 946 ("[T]he pre-[Fraud Enforcement and Recovery Act of 2009 ("FERA")] version of the FCA did not include a lowered intent standard (it did not premise liability on reckless conduct).").

(2003), the Court observed that "treble damages have a compensatory side, serving remedial purposes in addition to punitive objectives":

> There is no question that some liability beyond the amount of the fraud is usually necessary to compensate the Government completely for the costs, delays, and inconveniences occasioned by fraudulent claims. The most obvious indication that the treble damages ceiling has a remedial place under this statute is its qui tam feature with its possibility of diverting as much as 30 percent of the Government's recovery to a private relator who began the action. In qui tam cases the rough difference between double and triple damages may well serve not to punish, but to quicken the self-interest of some private plaintiff who can spot violations and start litigating to compensate the Government, while benefiting himself as well. The treble feature thus leaves the remaining double damages to provide elements of make-whole recovery beyond mere recoupment of the fraud. . . . [In addition,] [t]he FCA has no separate provision for prejudgment interest, which is usually thought essential to compensation, and might well be substantial given the FCA's long statute of limitations. Nor does the FCA expressly provide for the consequential damages that typically come with recovery for fraud.

Id. at 130-31 (internal citations and quotations omitted).

Accordingly, although the New York "FCA does have deterrent effects, . . . those effects are not dispositive in determining whether [the] statute's penalties serve both civil and criminal goals." Bergman, 995 F. Supp. 2d at 385. The New York FCA's provision for "treble damages can be both compensatory and punitive in nature." See id. at 386. "Given the Supreme Court's analysis of the FCA's treble damages provision, an alternative purpose may be assigned [to the New York FCA] – that of compensating, or making whole, the government for its losses suffered due to fraud." See Sanders, 703 F.3d at 947; cf. U.S. ex rel. Colucci v. Beth Israel Med. Ctr., 603 F. Supp. 2d 677, 683 (S.D.N.Y. 2009) ("Chandler holds that the punitive nature of [federal] FCA damages does not outweigh the statute's compensatory goals."); U.S. ex rel. Estate of Botnick v. Cathedral Healthcare Sys., Inc., 352 F. Supp. 2d 530, 532 (D.N.J. 2005) ("[The] [Supreme Court's] most recent interpretation of the [federal] FCA [in Chandler], as well as legislative history indicat[e] a strong intent . . . to create incentives for relators . . . to come

forward."). Accordingly, although the availability of triple damages indicates that the New York FCA "may have some punitive character," Bergman, 995 F. Supp. 2d at 386, it does not compel a conclusion that the statute is penal.[17]

The fifth Kennedy factor is whether the behavior to which the New York FCA applies is already a crime. The New York anti-kickback statute makes the type of conduct alleged here punishable as a crime. See N.Y. Soc. Serv. Law § 366-d(3) ("Any medical assistance provider who violates the provisions of this section is guilty of a misdemeanor."). While this factor thus weighs in favor of finding that the New York FCA is punitive, U.S. Supreme Court decisions indicate that this factor should be given little weight. See United States v. One Assortment of 89 Firearms, 465 U.S. 354, 365 (1984) ("[O]ne of the Mendoza-Martinez factors – whether or not the proscribed behavior is already a crime – lends . . . support to Mulcahey's position that § 924(d) imposes a criminal penalty. The fact that actions giving rise to forfeiture proceedings under § 924(d) may also entail the criminal penalties of § 922(a)(1) admittedly suggests that § 924(d) is criminal in nature. But that indication is not as strong as it might seem at first blush. Clearly Congress may impose both a criminal and a civil sanction in respect to the same act or omission.") (internal citations and quotations omitted); United States v. Ward, 448 U.S. 242, 249-50 (1980) ("Without setting forth here our assessment of each of the seven Mendoza-Martinez factors, we think only one, the fifth, aids respondent. That is a consideration of whether the behavior to which [the penalty] applies is already a crime. . . . While we agree that this consideration seems to point toward a finding that [the statute] is criminal in nature, that indication is not as strong as it seems at first blush. We

[17] This Court acknowledges that the New York FCA provides for consequential damages, and that pre-judgment interest may be an available remedy under New York law. Novartis has not demonstrated, however, that these remedies are "so punitive" as to trigger application of the Ex Post Facto Clause.

have noted on a number of occasions that Congress may impose both a criminal and a civil sanction in respect to the same act or omission.") (internal citations and quotations omitted).

The sixth factor asks whether the New York FCA's penalties may be rationally connected to an alternative, non-punitive purpose. As the Supreme Court observed in Chandler, treble damages – particularly in the qui tam context – may serve non-punitive purposes such as compensating the "private relator who began the action" while still allowing the Government to be made whole, and "quicken[ing] the self-interest of some private plaintiff who can spot violations and start litigating." 538 U.S. at 130-31. The New York FCA's remedies could be construed as rationally connected to these purposes. This factor therefore weighs "in favor of finding a civil purpose for the law." Schneiderman, 41 Misc. 3d at 524.

Consideration of the seventh factor – whether the FCA's penalties appear excessive in relation to the alternative purpose assigned – does not yield a clear answer. As the Chandler court noted, in the qui tam context, a treble damage remedy both permits governments to handsomely compensate the relator – thus incentivizing others to bring lawsuits disclosing fraud in government programs – and provides a mechanism to make the government whole. 538 U.S. at 130-31.

Analysis of the Kennedy factors – while providing some support for the notion that the New York FCA is punitive – does not meet the U.S. Supreme Court standard for overriding a legislature's stated intent. The Supreme Court has stated that "only the 'clearest proof' will suffice" to "transform what has been denominated a civil remedy into a criminal penalty." Smith, 538 U.S. at 92. Here, the factors cut both ways. "[A]ssessing all aspects and consequences of the [New York FCA], and applying the constitutional standards as . . . the Supreme Court has enunciated them to the aggregate of these consequences, [the Court]

conclude[s] that [Novartis] ha[s] not provided 'the clearest proof' that the burdens attendant to these provisions are 'so punitive in form and effect,' as to transform them into punitive sanctions." See Pataki, 120 F.3d at 1284 (citation omitted) (emphasis added). Accordingly, this Court holds that retroactive application of the New York FCA does not violate the Ex Post Facto clause, and New York's FCA claims pre-dating April 1, 2007 are not barred. Novartis's motion to dismiss these claims will be denied.

3. Executive Law § 63(12) and Social Services Law § 145-b Claims Related to Conduct Prior to August 2010 Are Time-Barred

Novartis argues that New York's claims under Social Services Law § 145-b and Executive Law § 63(12) must be dismissed to the extent they relate to violations that occurred prior to August 2010, because such claims are barred by the applicable statute of limitations. (Def. MTD-N.Y. Br. (Dkt. No. 82) at 23) Neither statute sets forth a limitations period, but Novartis argues (id.) that claims under these statutes are governed by the three-year statute of limitations set forth in N.Y. C.P.L.R. § 214(2). This provision applies to "an action to recover upon a liability, penalty or forfeiture created or imposed by statute except as provided in [C.P.L.R. §§] 213 and 215." N.Y. C.P.L.R. § 214(2). New York contends, however, that the six-year statute of limitations set forth in C.P.L.R. § 213(1) applies. (N.Y. Br. (Dkt. No. 89) at 19-21) Section 213(1) applies to "action[s] for which no limitation is specifically prescribed by law." N.Y. C.P.L.R. § 213(1).

The New York Court of Appeals has held that "CPLR 214[(2)] is . . . applicable to actions for wrongs not recognized in the common or decisional law." State v. Cortelle Corp., 38 N.Y.2d 83, 86 (N.Y. 1975). "[T]he statute . . . only governs liabilities which would not exist but for a statute. It does not apply to liabilities existing at common law which have been

recognized or implemented by statute." Aetna Life & Cas. Co. v. Nelson, 67 N.Y.2d 169, 174 (N.Y. 1986).

A cause of action falls within C.P.L.R. § 213 when "analysis of the challenged causes of action reveals that they seek essentially to redress wrongs previously known to the law, . . . before the enactment of the statutes discussed." Cortelle Corp., 38 N.Y.2d at 89. Such "causes of action . . . do not depend upon liabilities, penalties, or forfeitures created or imposed by statute within the meaning of CPLR 214[(2)]. Put another way, [C.P.L.R. § 213(1) applies where] a statute in regulating a substantive right or the procedure for its enforcement does not create or impose a liability, penalty or forfeiture." Id.

In explaining the distinction, the New York Court of Appeals has contrasted

> "(1) claims which, although provided for in a statute, merely codify or implement an existing common-law liability, which are not governed by CPLR 214(2) but by the Statute of Limitations applicable to their common-law sources; with (2) claims which, although akin to common-law causes, would not exist but for the statute . . . in which case CPLR 214(2) applies."

Gaidon v. Guardian Life Ins. Co. of Am., 96 N.Y.2d 201, 209 (N.Y. 2001) (quoting Motor Vehicle Acc. Indemnification Corp. v. Aetna Cas. & Sur. Co., 89 N.Y.2d 214, 220-21 (N.Y. 1996)) (emphasis in Gaidon).

Executive Law § 63(12) provides that

> [w]henever any person shall engage in repeated fraudulent or illegal acts or otherwise demonstrate persistent fraud or illegality in the carrying on, conducting or transaction of business, the attorney general may apply, in the name of the people of the state of New York, to the supreme court of the state of New York, on notice of five days, for an order enjoining the continuance of such business activity or of any fraudulent or illegal acts, directing restitution and damages and, in an appropriate case, cancelling any certificate filed under and by virtue of the provisions of section four hundred forty of the former penal law or section one hundred thirty of the general business law, and the court may award the relief applied for or so much thereof as it may deem proper. . . .

N.Y. Exec. Law § 63(12).

Social Services Law § 145-b makes it

> unlawful for any person, firm or corporation knowingly by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of himself or others, to attempt to obtain or to obtain payment from public funds for services or supplies furnished or purportedly furnished pursuant to [the Social Services Law].

N.Y. Social Services Law § 145-b(1).

"In applying a Statute of Limitations[,] it is basic that one look to the essence of plaintiff's claim and not to the form in which it is pleaded." Cortelle Corp., 38 N.Y.2d at 86 (citing Brick v. Cohn-Hall-Marx Co., 276 N.Y. 259, 263-64 (N.Y. 1937) ("Whether the defendant deliberately refused to make payment, thus breaching its contract, or whether through neglect it made false statements, or whether it deliberately made false statements, the action of the plaintiffs is founded and based upon the contract, without which they would have no claim at all. . . . To say that the complaint is framed in fraud and not upon contract may be true in theory, but in applying the Statute of Limitations we look for the reality, and the essence of the action and not its mere name. Whatever we may call this action, it is, so far as the Statute of Limitations is concerned, an action upon the contract and within the six-year statute.")) (emphasis added).

In Cortelle, the New York Court of Appeals concluded that C.P.L.R. § 213 applied to the Executive Law § 63(12) claim brought in that case. See Cortelle Corp., 38 N.Y.2d at 86-87. The court found that "[w]hile [Executive Law 63(12)] may in part expand the definition of fraud so as to create a new liability in some instances, it also incorporates already existing standards applied to fraudulent behavior always recognized as such." Id. at 87 (emphasis added). The fact that the statute "authorize[es] the Attorney-General to bring [the] action . . . is not dispositive" in determining whether the cause of action is "new." Id. at 86.

Where, "[a]s applied to the allegations in th[e] case, [Executive Law § 63(12)] create[s] no new claims but only provide[s] particular remedies and standing in a public officer to seek redress on behalf of the State and others[,] . . . [and] the kind of wrong the Attorney-General seeks to redress is not a new one to the decisional law," C.P.L.R. § 213 provides the applicable statute of limitations. See id. at 86-87, 89 (emphasis added).

In Cortelle, plaintiff alleged that defendants had induced distressed owners of residences whose mortgages were about to be foreclosed to enter into sale-leaseback agreements by making "representations [that] were willfully false and part of a scheme to obtain the permanent ownership of distressed properties by fraud." Id. at 85-86, 89. The court applied C.P.L.R. § 213's six-year statute of limitations to plaintiff's claim under Executive Law § 63(12), concluding that the "wrong . . . [sought to be] redress[ed] . . . is not a new one to the decisional law but a now old and common type of fraud." Id. at 86.

Here, New York argues that the six-year statute of limitations of C.P.L.R. § 213 applies to its claims under Executive Law § 63(12) and Social Services Law § 145-b, because "claims brought under [Section 62(12)] are grounded in fraud" and claims under Section 145-b "against a defendant for wrongfully obtaining Medicaid reimbursement . . . are actionable under common law doctrines, including fraud." (See N.Y. Br. (Dkt. No. 89) at 19-21) While it may be true that these statutes "incorporate[ ] already existing standards applied to fraudulent behavior always recognized as such," this factor is not dispositive, because these statutes "may in part expand the definition of fraud so as to create a new liability in some instances," such that C.P.L.R. § 213 applies instead. Cortelle Corp., 38 N.Y.2d at 87 (emphasis added). Accordingly, instead of considering these statutes in the abstract, this Court must look to the "essence" of New York's claims under these statutes "[a]s applied to the allegations in this case." See id. at 86

(emphasis added); cf. Gaidon, 96 N.Y.2d at 209-10 ("General Business Law § 349, as invoked in this case, falls in the . . . category [of claims that would not exist but for the statute]. . . . The substantive differences between the claims under General Business Law § 349 here and common-law fraud were most pointedly demonstrated by our disposition of those respective causes of action in Gaidon I. There, we held that, because of the disclaimers in the promotional illustrations Guardian Life used in selling its vanishing premium policies, the misrepresentations in those materials and by sales agents did not rise to the level necessary to establish a common-law fraud claim. Yet we also held that the disclaimers were not sufficient to dispel the deceptiveness of Guardian Life's sales practices with respect to the same illustrations for purposes of alleging violation of General Business Law § 349. . . . [This is because] section 349 encompasses a significantly wider range of deceptive business practices that were never previously condemned by decisional law. . . . [W]e hold that the three-year period of limitations for statutory causes of action under CPLR 214(2) applies to the instant General Business Law § 349 claims.") (emphasis added).

Here, New York alleges – in essence – that Novartis violated Executive Law § 63(12) and Social Services Law § 145-b by knowingly bribing doctors to cause claims for reimbursement to be submitted to Medicaid in violation of law. (See N.Y. Cmplt. (Dkt. No. 61) ¶¶ 154-58, 161) Unlike the facts in Cortelle, these allegations do not sound in common law fraud.

Under New York law,

> [i]n order to sustain a cause of action for common law fraud, the plaintiff must establish with sufficient particularity that the defendant "(1) made a material false statement; (2) knowing that the statement was false; (3) acting with intent to defraud; that plaintiff (4) reasonably relied on the false representation and (5) suffered damage proximately caused by the defendant's actions."

N.B. Garments (PVT), Ltd. v. Kids Int'l Corp., No. 03 Civ. 8041 (HB), 2004 WL 444555, at *2 (S.D.N.Y. Mar. 10, 2004) (quoting Morris v. Castle Rock Entm't, Inc., 246 F. Supp. 2d 290, 296 (S.D.N.Y. 2003)).

Here, the theory of New York's Complaint is not that Novartis made false statements. Instead, New York contends that Novartis bribed doctors to cause claims to be submitted to Medicaid that were not eligible for reimbursement. Assuming arguendo that such conduct provides the basis for a claim under Executive Law § 63(12) or Social Services Law § 145-b, such a claim does not sound in common law fraud. See People, ex rel. Spitzer v. Pharmacia Corp., 27 Misc. 3d 368, 369-74 (N.Y. Sup. Ct. Albany Cnty. 2010) (holding that three-year statute of limitations applied to a claim brought under Executive Law § 63(12), where plaintiff alleged that defendant "violated General Business Law ('GBL') § 349 and Executive Law § 63(12) by causing false and inflated prices for its prescription drugs to be published and relied upon as a basis for reimbursement under certain government health programs"; because "this [was] not a case in which the State simply [was] relying upon the generous remedies made available to the Attorney General under Executive Law § 63(12), but rather one in which the State seeks to establish a liability that arises solely from statute."); cf. State ex rel. Spitzer v. Daicel Chem. Indus., Ltd., 42 A.D.3d 301, 301-02, 303 (1st Dep't 2007) (defendants allegedly engaged in an illegal conspiracy to fix and inflate prices; the court concluded that "Plaintiff's second and third causes of action, under Executive Law § 63(12) and General Business Law § 349, were properly found to be time-barred by the three-year statute of limitations (CPLR 214[2]). These claims rely on allegations of conduct made illegal by statute. . . .").

New York argues, however, that "[c]laims brought pursuant to N.Y. Soc. Serv. Law § 145-b against a defendant for wrongfully obtained Medicaid reimbursement also are

"actionable under [other] common law doctrines, including . . . unjust enrichment[ ] and payment by mistake of fact." (See N.Y. Br. (Dkt. No. 89) at 20) These argument are unavailing. To the extent that New York argues that its claims sound in unjust enrichment, "New York courts have held that [unjust enrichment] claims are governed by . . . a three-year statute of limitations when monetary relief is sought." Grynberg v. Eni S.p.A., No. 06 Civ. 6495 (RLC), 2007 WL 2584727, at *3 (S.D.N.Y. Sept. 5, 2007). It would be anomalous to hold that a six-year statute of limitations applies – because New York's claim sounds in unjust enrichment – when an unjust enrichment claim itself would be subject to a three-year statute of limitations.

As to payment by mistake of fact, the "essence" of the action here is not equitable recovery of amounts that New York paid to Novartis by mistake. Cf. Island Fed. Credit Union v. Smith, 60 A.D.3d 730, 732 (2d Dep't 2009) ("'The principle that a party who pays money, under a mistake of fact, to one who is not entitled to it should, in equity and good conscience, be permitted to recover it back is long standing and well recognized.'" (quoting Mfrs. Hanover Trust Co. v. Chem. Bank, 160 A.D.2d 113, 117 (1st Dep't 1990))); Collins v. HSBC Bank USA, 305 A.D.2d 361, 362 (2d Dep't 2003) ("Generally, if a payor pays money based upon the erroneous assumption that it is indebted to the payee, the payee is not entitled to retain the money acquired by the mistake of the payor, even if the mistake is the result of negligence."). Instead, the essence of New York's claims is that Novartis is liable for its conduct in bribing doctors to cause claims for reimbursement to be submitted to New York Medicaid, in violation of law. Such a claim does not "merely codify or implement an existing common-law liability." Gaidon, 96 N.Y.2d at 209 (internal quotations and citation omitted). Rather, this claim "would not exist but for the statute." Id. (emphasis omitted).

Accordingly, the three-year statute of limitations under C.P.L.R. § 214(2) applies

to New York's Executive Law § 63(12) and Social Services Law § 145-b claims. Defendants' motion to dismiss these claims is granted to the extent that these claims are premised on conduct that occurred prior to August 26, 2010.[18]

IV. OFF-LABEL PROMOTION CLAIMS

Novartis has moved to dismiss the off-label promotion claims alleged in Relator's Third Amended Complaint. Novartis argues, inter alia, that Relator has not pled these false claims with the particularity required by Fed. R. Civ. P. 9(b). (Def. MTD-Relator Br. (Dkt. No. 99) at 19-22)

As discussed above, in order to sufficiently plead a violation of the FCA, Relator is required to allege false claims with sufficient particularity. See New York Soc., 2014 WL 3905742, at *15; Kester, 88 Fed. R. Serv. 3d 1261, at *11-12; Polansky, 2009 WL 1456582, at *4-5. Here, however, Relator's TAC does not identify a single false claim that was submitted in connection with the alleged off-label promotion scheme.

In response to Novartis's argument that his off-label promotion claims should be dismissed for failing to plead the alleged false claims with sufficient particularity, Relator relies on Grubbs and similar authority from outside the Second Circuit. (Relator Br. (Dkt. No. 105) at 23-24) Given that (1) this Court has found that Grubbs is not persuasive in light of contrary authority from courts in this Circuit, and (2) Relator has not pled the false claims that were submitted in connection with the alleged off-label promotion scheme with sufficient particularity, Relator's off-label promotion claims under the federal FCA will be dismissed.

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[18] New York has not challenged Novartis's contention that the relevant date for determining the expiration of the statute of limitations is the date that New York filed its Complaint-in-Intervention – August 26, 2013 (Dkt. No. 61). (See N.Y. Br. (Dkt. No. 89) 19-21)

V. RELATOR'S STATE LAW CLAIMS

A. Off-Label Promotion Claims

Under 28 U.S.C. § 1367(c), a district court may decline to exercise supplemental jurisdiction if it has dismissed all claims over which it has original jurisdiction. See Schaefer v. Town of Victor, 457 F.3d 188, 210 (2d Cir. 2006) (citing Carnegie-Mellon Univ. v. Cohill, 484 U.S. 343, 350 (1988)). "When all federal claims are eliminated in the early stages of litigation, the balance of factors generally favors declining to exercise pendent jurisdiction over remaining state law claims and dismissing them without prejudice." Tops Mkts., Inc. v. Quality Mkts., Inc., 142 F.3d 90, 103 (2d Cir. 1998) (citing Carnegie-Mellon Univ., 484 U.S. at 350). There is no reason to deviate from this rule here. Given that Relator's federal off-label promotion claims under the FCA have been dismissed, the court declines to exercise supplemental jurisdiction over Relator's state law off-label promotion claims. Accordingly, these claims will be dismissed.

B. Kickback Claims

The parties have not addressed the effect of the United States' intervention on Relator's state law claims related to the kickback allegations. Novartis contends that the United States' intervention on the federal FCA kickback claim supersedes all claims related to the kickback scheme. (See Def. MTD-Relator Br. (Dkt. No. 99) at 7 ("Relator may proceed only with allegations relating to off-label promotion of Valturna.")) Relator argues that Novartis's argument "pertains only to the federal kickback allegations," however. (Relator Br. (Dkt. No. 105) at 6 (emphasis added)) The parties have not briefed this issue. Accordingly, Defendant's motion to dismiss Relator's state law claims arising out of the alleged kickback scheme is denied without prejudice.

VI. RELATOR'S REQUEST FOR LEAVE TO AMEND

Relator requests that – should the Court dismiss any of his claims – he be granted leave to amend the TAC. (Relator Br. (Dkt. No. 105) at 25 n.17) This application is denied. Relator has already filed four complaints in this action. Moreover, Relator was present at the July 18, 2013 pre-motion conference in this action, at which the Court discussed at length its concerns about the sufficiency of the pleading concerning false claims. (July 18, 2013 Tr. (Dkt. No. 53) at 3-19) The Court discussed at that time the same cases that are cited in this opinion concerning the obligation to plead false claims with sufficient particularity under Fed. R. Civ. P. 9(b). (Id.) The United States chose to amend its complaint; Relator did not. This Court concludes that Relator's failure to adequately plead false claims in four complaints reflects an inability to do so, such that granting leave to amend would be futile. Relator's federal off-label promotion claims will be dismissed with prejudice.

CONCLUSION

For the reasons set forth above, Novartis's motion to dismiss the United States' Amended Complaint is denied.

Novartis's motion to dismiss New York's Complaint is granted as to New York's claims under Social Services Law § 145-b and Executive Law § 63(12), to the extent that they relate to conduct occurring prior to August 26, 2010. In all other respects, Novartis's motion to dismiss New York's Complaint is denied.

Novartis's motion to dismiss Relator's (1) federal FCA kickback claims in the Third Amended Complaint is denied as moot; (2) state law kickback claims is denied without prejudice; (3) federal off-label promotion claim under the FCA is granted with prejudice; and (4) state law off-label promotion claim is granted.

The Clerk of the Court is directed to terminate the motions (Dkt. Nos. 79, 81, 98).

Dated: New York, New York
September 30, 2014

SO ORDERED.

Paul G. Gardephe
United States District Judge