**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF NEW YORK**

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| UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WASHINGTON, and WISCONSIN; the DISTRICT OF COLUMBIA, and the CITY OF CHICAGO, *ex rel*. OSWALD BILOTTA,<br><br>Plaintiffs and Relator,<br><br>-against-<br><br>NOVARTIS PHARMACEUTICALS CORPORATION,<br><br>Defendant. | **11 Civ. 00071 (PGG)** |

**NOVARTIS PHARMACEUTICALS CORPORATION'S REPLY MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS THE COMPLAINT IN INTERVENTION OF THE STATE OF NEW YORK**

Evan R. Chesler
Rachel G. Skaistis
Benjamin Gruenstein
CRAVATH, SWAINE & MOORE LLP
Worldwide Plaza
825 Eighth Avenue
New York, NY 10019
(212) 474-1000

Michael A. Rogoff
Manvin S. Mayell
KAYE SCHOLER LLP
425 Park Avenue
New York, NY 10022
(212) 836-8000

*Attorneys for Defendant*
*Novartis Pharmaceuticals Corporation*

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Defendant Novartis Pharmaceuticals Corporation ("NPC" or the "Company") respectfully submits this Reply Memorandum of Law in support of its motion to dismiss the State of New York's Complaint in Intervention ("Complaint" or "NY Complaint").

## PRELIMINARY STATEMENT

The State claims in its Complaint that, over the course of nearly a decade, NPC "instituted and operated" a "vast" "scheme" to use "sham" speaker programs to induce physicians to increase their prescriptions of NPC cardiovascular drugs. As NPC demonstrated in its opening brief ("NPC NY Mem."), however, this broadly alleged kickback scheme is pleaded in wholly conclusory fashion and does not meet the requirements of Federal Rule of Civil Procedure 9(b). Among other things, the State identifies only seven of the "over 4,500" doctors it alleges participated in the purported scheme, fails adequately to plead a violation of the anti-kickback statute ("AKS"), fails to link the alleged kickbacks to false claims, and fails to plead the contours of the scheme pursuant to which the sham programs were supposedly held.

In its opposition ("NY Opp."), the State insists that its allegations are sufficient. That view, however, is largely based on cases that have no application here because they involve private plaintiffs, not the government, or are from other jurisdictions. Because the State has had access to extensive pre-suit discovery, the State is required to support its allegations with particularized details such that, at a minimum, NPC has sufficient notice and information to prepare its defense. For the reasons stated in NPC's opening brief and herein, the State's fraud allegations fall well short of this standard. In addition, certain of the State's claims should be dismissed for the independent reasons discussed in NPC's opening brief and set forth below. (See infra Sections II-V).

## ARGUMENT

I. THE COMPLAINT SHOULD BE DISMISSED FOR FAILURE TO PLEAD FRAUD WITH PARTICULARITY UNDER RULE 9(b).

Claims under the New York False Claims Act ("NY FCA") must be pleaded with particularity under Rule 9(b). (See NPC NY Mem. at 5-8.) The State does not dispute this, but rather contends that its allegations are sufficient because they "meet[] the key purpose of Rule 9(b)—to 'discourage the filing of complaints as a pretext for discovery of unknown wrongs' and 'to ensure that the complaint provides a defendant with fair notice of a plaintiff's claim and with adequate information to frame a response'". (NY Opp. at 4 (citations omitted).) The State is wrong for the following reasons.[1]

A. The Complaint Fails To Allege Predicate AKS Violations.

As an initial matter, the State's assertion that "Novartis does not seriously dispute the facts described in many of the State's allegations" (NY Opp. at 5) is specious: for purposes of this motion, NPC is, of course, required to accept those allegations as true.

The State's FCA claims are predicated on alleged violations of the AKS, namely NPC's supposed scheme to use honoraria and meals associated with its speaker programs as a way to induce doctors to increase their prescriptions of NPC drugs. As noted in NPC's opening brief, speaker programs serve a legitimate purpose (id. at 9-10): "Healthcare professionals participate in company-sponsored speaker programs in order to help educate and inform other healthcare professionals about the benefits, risks and appropriate uses of company medicines." (2009 PhRMA Code at 9, attached as Exhibit E to the Declaration of Nina M. Dillon, Esq., of

[1] To the extent the State relies on cases outside the Second Circuit that apply a relaxed pleading standard (see, e.g., NY Opp. at 10 (citing United States ex rel. Grubbs v. Kanneganti, 565 F.3d 180 (5th Cir. 2009))), those cases are inconsistent with Second Circuit precedent and should be rejected. See United States v. Wells Fargo Bank, N.A., No. 12-cv-7527, --- F. Supp. 2d. ---, 2013 WL 5312564, at *18 n.17 (S.D.N.Y. Sept. 24, 2013) (declining to apply Grubbs standard). (See also NPC NY Mem. at 6-8.)

October 24, 2013 ("Dillon Decl.").) Paying fair market value to a doctor for his or her services is not a kickback. United States ex rel. Fair Lab. Practices Assocs. v. Quest Diagnostics Inc., No. 05-cv-5393, 2011 WL 1330542, at *2 (S.D.N.Y. Apr. 5, 2011). Accordingly, to survive a motion to dismiss, the State must distinguish between legitimate and illegitimate speaker programs, something it fails to do.

First, the State insists that it has provided sufficient examples, each of which describes "a remarkably similar pattern of illegitimate and fraudulent conduct surrounding the operation of Novartis' speaker programs". (NY Opp. at 6-7.) However, claiming that "many thousands" of speaker programs were tainted and then providing only a handful of conclusory references to speaker programs held at Nobu and the Mandarin Oriental Hotel or speaker programs involving repeat attendees provides no basis on which Novartis can distinguish (and defend) challenged speaker events from events the State does not seek to challenge. (NPC NY Mem. at 9-11, 15-18; infra Section I.C.) In short, by alleging, without specificity, that NPC engaged in a statewide kickback scheme involving thousands of doctors, events and claims, the State is attempting to condemn the entirety of NPC's speaker programs (a standard industry practice) since 2002.

Second, the State claims that the Complaint also clearly sets forth numerous facts indicating that Novartis "instituted" a company-wide scheme to defraud the government, or at the very least "condoned" New York and Federal AKS violations and "recklessly disregarded" (or "turned a blind eye to") the risk that it was causing the submission of false claims for the drugs at issue. (NY Opp. at 8-9.) This statement is telling, because it makes clear that the State is not itself clear on the nature of the scheme it is alleging. Indeed, the Complaint is bereft of any details about how the purported scheme was "instituted", including such fundamentals as

when the alleged scheme commenced and who was involved. Again, the State must allege particulars to meet Rule 9(b) including facts that give rise to a "strong inference" of fraudulent intent; a "strong inference" must be "more than merely 'reasonable' or 'permissible'—it must be cogent and compelling, thus strong in light of other explanations". Glidepath Holding B.V. v. Spherion Corp., 590 F. Supp. 2d 435, 451 (S.D.N.Y. 2007).

This is particularly true in the instant case, where specific allegations of knowledge or participation by senior management are critical in order to connect what are otherwise random events over the course of nearly a decade. The sole allegations of management involvement in the alleged kickback scheme are that (1) in 2009—seven years after the "scheme" allegedly began—the Ethics & Compliance ("E&C") Department presented findings to the NPC board of directors related to non-compliant speaker programs that it monitored; (2) the E&C Department made a second presentation to management in 2011; and (3) management's response was inadequate. (NY Cmpl. ¶¶ 128-132.)[2] These allegations simply do not create a "strong inference" that Company management was intentionally using its speaker programs statewide as a vehicle to pay inducements to doctors.[3]

B. The Complaint Fails To Link the Alleged AKS Violations to False Claims.

The State has not identified a single false claim for payment. (See NPC NY Mem. at 11-15.) The Complaint attempts to link the alleged fraud to actual false claims by

[2] Of course, allegations that certain speaker programs may have violated an internal NPC policy do not suffice under Rule 9(b) to allege that those programs, let alone "many thousands" of other speaker programs, violated the AKS and resulted in false claims.

[3] United States ex rel. Winslow v. Pepsico, Inc., No. 05-cv-9275, 2007 WL 1584197, at *7-8 (S.D.N.Y. May 31, 2007), is inapposite. (NY Opp. at 9.) Unlike the State's allegations here, the relator-complaint in Winslow contained numerous specific allegations that the court found supported an inference that management purposefully stayed aloof from alleged misclassification of imports. See Winslow, 2007 WL 1584197, at *3, *8.

attaching the prescribing histories for a subset of the seven doctors (identified only by initials) and asserting that the prescribing habits of those doctors changed after the receipt of honoraria. These allegations, however, are deficient for the reasons discussed in NPC's memorandum. (Id. at 13-14.) The State's opposition simply glosses over the factual disconnects highlighted by NPC and argues—again based on inferences and extrapolation—that because five doctors participated in a handful of allegedly illegitimate speaker programs for three drugs, all of the prescriptions written by those doctors (over the course of a decade for ten drugs) must have resulted in false claims. (Id. at 10-12.) Among other issues with this argument, the State's Complaint acknowledges that doctors were writing prescriptions before they ever attended a speaker program or received honoraria (NY Cmpl. ¶¶ 107, 113, 119), and thus it is unclear how the State can now claim that every prescription, for ten drugs, written by a doctor after participating in any speaker program (legitimate or not), over the course of a decade, was induced by a kickback.[4] The "must have" allegations pleaded by the State here are exactly what Rule 9(b) is designed to prevent. See, e.g., United States ex rel. Piacentile v. Novartis AG, No. 04-cv-4265, slip op. at 15 (E.D.N.Y. Feb. 7, 2010) (Dillon Decl. Exh. D) ("[A] simple recital of government programs to which Plaintiffs merely believe Novartis-linked physicians submitted false claims—even alongside specific and detailed allegations of the supposed fraud—cannot be enough to sustain these FCA counts under Rule 9(b)."); United States ex rel. Smith v. Yale Univ., 415 F. Supp. 2d 58, 88 (D. Conn. 2006) (dismissing case involving "allegations of a general scheme of fraud that might have resulted in the submission of false claims").

[4] The State's inclusion of claims that are clearly released under the terms of the 2010 EDPA Settlement further undermines its novel assertion that all of the claims in its Exhibit A are false.

C. The "Examples" in the Complaint Are an Insufficient Basis From Which To Extrapolate a Statewide Scheme.

Even assuming that the examples related to the five doctors pleaded in the Amended Complaint are sufficient under Rule 9(b) (which they are not), the State's attempt to use those "examples" to support the conclusory allegations of a statewide scheme involving "many thousands" of speaker programs must be rejected. As the State acknowledges, in order to extrapolate from specific examples, the examples provided must be "representative samples". See United States ex rel. Bledsoe v. Cmty. Health Sys, Inc., 501 F.3d 493, 501-11 (6th Cir. 2007); United States ex rel. Mooney v. Americare, Inc., No. 06-cv-1806, 2013 WL 1346022, at *7 (E.D.N.Y. Apr. 3, 2013). Here, the State has not defined any sort of discernible subset of representative samples.[5] The State admits speaker programs are not inherently fraudulent, and it does not allege any direction by NPC to hold fraudulent programs. Instead, at most, the State has identified a handful of speaker programs that may have violated NPC policy in disparate and unique ways regarding venue, cost or attendees (which is not the same as alleging an AKS violation) and asks the Court to presume that other programs with these characteristics must have occurred, and then to infer that these programs were shams. But the State has not alleged sufficient facts to show that a "random draw" out of the "many thousands" of NPC speaker

[5] The State's reliance on Carey v. Berisford Metals Corp., No. 90-cv-1045, 1991 WL 44843 (S.D.N.Y. Mar. 28, 1991) (NY Opp. at 7) is misplaced. In Carey, the finding that the examples pleaded were sufficient was based upon the court's conclusion that "[h]ere, the fraudulent scheme is strictly limited to easily identifiable items appearing on [the party's] foreign expense reports so as to give [the party] fair notice of the claim asserted against him." Carey, 1991 WL 44843, at *5 (emphasis added). In stark contrast, the State's alleged examples lack a fraudulent scheme, let alone one that is "strictly limited", and the items (false claims) are not "easily identifiable". The other decisions cited by the State (NY Opp. at 7 n.6) are similarly inapposite. Among other things, they are decisions from outside the Second Circuit and/or involve a relator-plaintiff, not the government. As previously noted, the State has had access to substantial pre-suit discovery, and consequently must be required to do more here. See, e.g., Wells Fargo, 2013 WL 5312564, at *18 n.17.

programs would yield "a materially similar set" of programs. Bledsoe, 501 F.3d at 510-11.[6]

II. MEDICAID CLAIMS PRIOR TO 2010 FAIL UNDER RULE 12(b)(6).

The State continues to assert that Medicaid providers violated the NY FCA by making false certifications about their compliance with "applicable federal and state laws and regulations". (NY Opp. at 14-18.) Although the State fails to specify whether its argument is predicated on purported express or implied certifications, both theories are unavailing. The principal case cited by the State holds that FCA liability under an express false certification theory "cannot be premised on anything as broad and vague" as a general certification of compliance with Medicaid laws and regulations, such as the one that appears in the New York certification statement. See United States ex rel. Feldman v. City of New York, 808 F. Supp. 2d 641, 652 (S.D.N.Y. 2011). Nor does the State's implied certification theory—also based on Feldman—have merit. The implied certifications at issue in Feldman involved affirmative state requirements that the City of New York must undertake to submit Medicaid claims; those affirmative requirements did not include compliance with the AKS. See id.

Furthermore, the State's reliance on New York v. Amgen Inc., 652 F.3d 103 (1st Cir. 2011), ignores the fact that the First Circuit subscribes to a false certification theory entirely different than the controlling law in this Circuit. See Amgen, 652 F.3d at 109-110 (describing First Circuit's rejection of prevailing Second Circuit FCA standards). The Second Circuit's implied certification standard requires more than a general statement of compliance; it necessitates an "underlying statute or regulation upon which the plaintiff relies [that] expressly states the provider must comply in order to be paid". Mikes v. Straus, 274 F.3d 687, 700 (2d Cir.

[6] The State's effort to distinguish United States ex rel. Dhawan v. New York City Health & Hospital Corp., No. 95-cv-7649, 2000 WL 1610802 (S.D.N.Y. Oct. 27, 2000), aff'd, 252 F.3d 118 (2d Cir. 2001), fails. (NY Opp. at 6 n.2.) In Dhawan, as here, the plaintiff attempted to infer false claims based solely on similarities between a physician's relationship with its customers.

2001). As set forth in NPC's opening papers, the Medicaid regulations relied on by the State do not explicitly condition payment upon compliance with its terms. (NPC NY Mem. at 18-20.) Rather, Title 18 delineates specific regulatory requirements that providers must meet in order to participate in the Medicaid program. (Id.) See also United States ex rel. Blundell v. Dialysis Clinic, Inc., No. 09-cv-00710, 2011 WL 167246, at *15-20 (N.D.N.Y. Jan. 19, 2011).[7]

III. THE STATE'S THIRD, FOURTH, FIFTH AND SIXTH CLAIMS FAIL UNDER RULE 12(b)(6).

Contrary to the State's assertion, NPC does not claim that counts three through six of the Complaint are dependent upon the successful pleading of a NY FCA claim. (NY Opp. at 18.) NPC argues that these Counts should be dismissed because they do not sufficiently allege that NPC engaged in and benefitted from a fraudulent action—a requirement for each of the underlying claims.[8] (See NPC NY Mem. at 20.)

[7] In addition, the State's argument that "holding that claims resulting from kickbacks do not constitute false claims" would require the State to improperly fund purported kickbacks—or, in the alternative, turn to expensive criminal prosecution as its only financial recourse—is disingenuous. (See NY Opp. at 16-17.) The FCA focuses specifically on false claims, not on the wide variety of unlawful conduct that may give rise to them. See United States v. Rivera, 55 F.3d 703, 709 (1st Cir. 1995). In this case, moreover, the FCA is not the only means for the government to seek reimbursement for claims resulting from kickbacks. See, e.g., N.Y. Comp. Codes R. & Regs. tit. 18, § 515.3 (providing for variety of sanctions, including recoupment of overpayments). If the State were able to do what it has failed to in this litigation—identify a single prescription that resulted from an allegedly sham speaker event—an administrative remedy would exist apart from the FCA.

[8] While a plaintiff can pursue an unjust enrichment claim independent of a fraud claim, the State has not articulated how NPC was unlawfully enriched. Assuming the State is trying to claim that violations of the AKS resulted in NPC's unjust enrichment, then the State is required to make a showing that NPC violated the AKS. See LaCroix v. U.S. Bank, N.A., No. 11-cv-3236, 2012 WL 2357602, at *7 (D. Minn. June 20, 2012).

## IV. THE STATE'S EXECUTIVE AND SOCIAL SERVICES LAW CLAIMS ARE UNTIMELY.

As noted in NPC's opening brief (NPC NY Mem. at 23), the three-year limitation period set forth in N.Y. C.P.L.R. § 214(2) applies "where liability 'would not exist but for a statute'". In re Estate of Meyer, 876 N.Y.S.2d 7, 11-12 (App. Div. 2009). (In contrast, the six-year period set forth in N.Y. C.P.L.R. § 213(1) applies where a statute merely provides a new remedy to a substantive claim but does not create or impose new obligations. Id.)

The State makes the bare assertion that a six-year limitations period applies to its fraud claims under N.Y. Exec. Law § 63(12) and N.Y. Soc. Serv. Law § 145-b. (NY Opp. at 19.) However, because N.Y. Exec. Law § 63(12) and N.Y. Soc. Serv. Law § 145-b expand the definition of common law fraud, both statutes apply to fraudulent conduct for which liability arises solely from statutes. People v. Pharmacia Corp., 895 N.Y.S.2d 682, 685-86 (N.Y. Sup. Ct. 2010); see generally In re Pharm. Indus. Average Wholesale Price Litig., 685 F. Supp. 2d 186, 201-07, 209 (D. Mass. 2010).

## V. RETROACTIVE APPLICATION OF THE NY FCA VIOLATES THE EX POST FACTO CLAUSE BECAUSE ITS SANCTIONS ARE PUNITIVE IN NATURE.

The State relies exclusively on legislative intent to support its view that the NY FCA is not a punitive statute. (NY Opp. at 21-24.) Yet, legislative intent is not the determinative factor, even in the cases cited by the State. See, e.g., Hudson v. United States, 522 U.S. 93, 99-100 (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.'"); Smith v. Doe, 538 U.S. 84, 96-97 (2003) (applying seven-factored Kennedy test after determining legislative intent was to "create a civil, nonpunitive regime"). Therefore,

even a finding that the Legislature intended the NY FCA to be civil and for it to apply retroactively does not end the inquiry.

Instead, the proper inquiry in determining whether a statute is punitive is to apply the Supreme Court's seven-factor Kennedy test. See Kennedy v. Mendoza-Martinez, 372 U.S. 144, 168-69 (1963).[9] Given the NY FCA's draconian sanctions and the New York Court of Appeals' own conclusion that the NY FCA "evinces a broader punitive goal", State ex rel. Grupp v. DHL Express (USA), Inc., 970 N.E.2d 391, 397 (N.Y. 2012), it is clear under the Kennedy test that the NY FCA is indeed punitive. Therefore, regardless of the New York State Legislature's intent, under the basic principles of the Constitution's Ex Post Facto clause, the State cannot apply this statute, with its punitive goal and punitive effects, to conduct that preceded its enactment.[10]

[9] The State's reliance on a state trial court's application of the Kennedy factors (NY Opp. 24 (citing State ex rel. Empire State Ventures, LLC v. Sprint Nextel Corp., 970 N.Y.S.2d 164 (N.Y. Sup. Ct. 2013)), which is not binding on this Court, is unavailing. First, the court ignored extensive jurisprudence holding that the type of sanctions provided by the NY FCA, such as treble damages, promotes the aims of retribution and deterrence. Second, the court improperly concluded that when the same behavior addressed by the NY FCA is already a crime, this weighs in favor of the NY FCA being a civil statute. See Massachusetts v. Schering-Plough Corp., 779 F. Supp. 2d 224, 237 (D. Mass. 2011) ("Kennedy suggests that if behavior is already criminalized, then a sanction that addresses the same behavior in a civil statute may in fact be punitive."). Third, the court improperly made one factor dispositive—whether the sanction has historically been regarded as a punishment—by considering it when addressing other factors that suggest the NY FCA is punitive. Sprint Nextel is also distinguishable because it did not involve allegations, such as here, that false claims resulted from alleged violations of the AKS, a criminal statute.

[10] Having already had the benefit of extensive pre-suit discovery, as well as specific guidance from this Court at the pre-motion conference, the State's request for leave to amend should be denied as futile and the complaint dismissed with prejudice. See Chen ex rel. United States v. EMSL Analytical, Inc., No. 10-cv-7504, --- F. Supp. 2d. ---, 2013 WL 4441509, at *19 (S.D.N.Y. Aug. 16, 2013).

## CONCLUSION

For the foregoing reasons, the Court should grant NPC's motion and dismiss the Complaint in Intervention of the State of New York, in its entirety, with prejudice.

Dated: December 23, 2013

Respectfully submitted,

CRAVATH, SWAINE & MOORE LLP,

by

s/ Rachel G. Skaistis

Evan R. Chesler
Rachel G. Skaistis
Benjamin Gruenstein
Members of the Firm

Worldwide Plaza
825 Eighth Avenue
New York, NY 10019
(212) 474-1000
rskaistis@cravath.com

KAYE SCHOLER LLP
Michael A. Rogoff
Manvin S. Mayell
Members of the Firm
425 Park Avenue
New York, NY 10022
(212) 836-8000

*Attorneys for Defendant*
*Novartis Pharmaceuticals Corporation*