UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA; the States of 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, WISCONSIN; the DISTRICT OF COLUMBIA, the CITY OF CHICAGO, and the CITY OF NEW YORK, *ex rel*. OSWALD BILOTTA, Plaintiffs, -against- NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	**11 CIV. 0071 (PGG)** **NOTICE OF MOTION TO DISMISS AMENDED COMPLAINT IN INTERVENTION OF THE UNITED STATES OF AMERICA**

PLEASE TAKE NOTICE that, upon the Amended Complaint in Intervention of the United States of America filed August 26, 2013, the accompanying Memorandum of Law and the supporting declaration of Nina M. Dillon, executed October 24, 2013, with exhibits thereto, Defendant Novartis Pharmaceuticals Corporation hereby moves this Court before the Honorable Paul G. Gardephe, United States District Court, Southern District of New York, 40 Foley Square, New York, New York, for an order, pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b), dismissing the Amended Complaint in Intervention of the United States of America, and granting such other and further relief as the Court deems just and proper.

Dated: October 24, 2013

CRAVATH, SWAINE & MOORE LLP,

by

s/ Rachel G. Skaistis

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

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

PRELIMINARY STATEMENT

On April 26, 2013, the Government filed its original Complaint in Intervention ("Initial Complaint") pursuant to the False Claims Act, 31 U.S.C. § 3729 et seq., ("FCA") after electing to intervene in a qui tam lawsuit filed by Relator Oswald Bilotta ("Relator" or "Bilotta"), a former NPC sales representative.[1] The Initial Complaint alleged that during the time period from 2002 through 2011, NPC violated the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b, by paying doctors "kickbacks" through purportedly sham speaker programs in order to induce them to prescribe NPC cardiovascular ("CV") pharmaceutical products. The Initial Complaint further alleged that NPC's purported AKS violations "caused the submission of thousands of false claims for payment to federal health care programs" in violation of the FCA. (Init. Cmpl. ¶ 6.)

In a letter dated June 27, 3013, NPC notified the Court of its intention to move to dismiss the Initial Complaint. At the July 18, 2013 premotion conference to address NPC's anticipated motion, the Court expressed concern about whether the Initial Complaint was properly pleaded pursuant to Federal Rule of Civil Procedure 9(b). The Court noted, among other things, that FCA pleadings are inadequate unless they are linked to particularized

[1] The Government declined to intervene with respect to Bilotta's claims related to pricing and off-label promotion of Valturna. Following the Government's intervention decision, Relator filed a second amended complaint, which included his original pricing and off-label claims. Relator subsequently filed a third amended complaint, which abandoned the pricing allegations. In a letter dated July 29, 2013, NPC notified the Court that it intends to file a motion to dismiss Relator's third amended complaint.

allegations of actual false claims submitted to the government. (Tr. of Premot. Conf. at 8, July 18, 2013 (Dillon Decl. Exh. A).) The Court observed that the Initial Complaint, which included charts of all prescriptions written by several unnamed doctors, and all claims resulting from those prescriptions, failed to identify which of those claims were allegedly fraudulent. (Id. at 12.) The Court acknowledged that there are circumstances in which the heightened pleading standard set forth in Rule 9(b) may be relaxed, but stated that even under a relaxed pleading standard, a plaintiff must adduce specific facts to support a strong inference of fraud. (Id. at 14.) The Court gave the Government thirty days to attempt to address these concerns in an amended pleading.

On August 26, 2013, the Government filed an Amended Complaint. Like the Initial Complaint, the Amended Complaint alleges that between January 2002 and November 2011, NPC violated the AKS by paying "kickbacks" to doctors through purportedly sham speaker programs and that these alleged violations caused the submission of "many thousands" of false claims to federal health care programs for reimbursement. Also like the Initial Complaint, the Amended Complaint fails to plead the purported fraudulent kickback scheme, false claims and a link between the two with the requisite particularity.

Despite extensive discovery prior to intervention (which included interviews of doctors who participated in the challenged speaker programs), the Government's far-reaching Amended Complaint continues to assert only a handful of allegedly sham speaker events and, even as to those, includes only generalized and conclusory assertions of "lavish" wining and dining at "high-end" venues as part of a supposed nationwide kickback scheme. In fact, rather than citing to documents provided in discovery or interviews with doctors, the Government

quotes restaurant reviews from Zagat in an apparent effort to demonstrate that the locations selected for certain NPC-sponsored events were "decadent".

The Amended Complaint also does not address adequately the concerns raised by the Court, namely the Government's failure to specify the allegedly false claims resulting from NPC's purported scheme. Although the Amended Complaint now identifies (by their initials) fifteen doctors and attaches spreadsheets of each doctor's total prescriptions of the NPC drugs at issue during the challenged time period, it makes no attempt to tie those prescriptions (and the resulting allegedly false claims) to an allegedly sham speaker event—something it clearly must do in order to meet the requirements of Rule 9(b). In fact, with respect to nine of the fifteen identified doctors, there is a disconnect between the timing and subject matter of the allegedly sham speaker programs they participated in and a change in prescribing of NPC products. And with respect to two more of the fifteen doctors, the Amended Complaint does not allege that they even attended a speaker program.

In short, the Amended Complaint makes sweeping and conclusory allegations of a decade-long, nationwide fraudulent scheme based on just fifteen doctors who purportedly prescribed NPC drugs based on their participation in speaker programs, and of those fifteen examples, eleven are deficient on their face. That type of pleading simply cannot satisfy the requirements of Rule 9(b). Nor can it form the basis for the type of broad-based "extrapolated" claims the Government attempts to bring. Again, the Government had a significant advantage: it engaged in far-reaching discovery, including both document production and interviews, before filing its Initial and Amended Complaints. It also had the benefit of this Court's very specific guidance and more than a month to cure the deficiencies noted. In light of this, the Government's continued failure to put forth particularized allegations linking allegedly sham

programs to allegedly false claims warrants dismissal of the Amended Complaint in its entirety and with prejudice.

Certain of the Government's claims should be dismissed for the following additional reasons.

First, claims based on Medicaid submissions made prior to 2010 fail under Federal Rule of Civil Procedure 12(b)(6). Before the enactment of the Patient Protection and Affordable Care Act ("PPACA") in 2010, the broad certifications the Government alleges were falsely submitted in connection with Medicaid claims were (and therefore are now) insufficient to establish an FCA violation as a matter of law. (See infra Part II.)

Second, the Government's claim for the equitable remedy of unjust enrichment fails because the Government has not adequately alleged that NPC violated the AKS or was otherwise unjustly enriched. (See infra Part III.)[2]

FACTUAL BACKGROUND[3]

I. THE EDPA SETTLEMENT.

On September 30, 2010, the United States Department of Justice ("DOJ") announced that it had reached a settlement with NPC regarding an ongoing investigation conducted by the Eastern District of Pennsylvania ("EDPA").[4] As one component of the

[2] To the extent the Government's Initial Complaint was not filed within the time permitted by law, its complaints are barred by the statute of limitations. NPC reserves the right to assert a statute of limitations defense in this action.

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

[4] On the same day that the EDPA settlement was publicly announced, four related qui tam complaints were unsealed. One of them, filed by relator Jeremy Garrity (the "Garrity Complaint"), who was represented by the same counsel retained by Relator here, alleged "unlawful promotional practices by the Cardiovascular Diseases (CD) Division" of NPC—the

settlement (the "EDPA Settlement"), NPC agreed to pay $36.5 million to settle civil claims that it paid illegal kickbacks to health care professionals to induce them to prescribe Diovan, Exforge and Tekturna (all CV drugs), as well as two other NPC drugs, Zelnorm and Sandostatin.[5] NPC also entered into a separate Corporate Integrity Agreement ("CIA") with the Office of Inspector General of the Department of Health and Human Services at the time the settlement was announced. (Am. Cmpl. ¶ 64.)

II. THE PRESENT SUIT.

Relator filed his initial complaint under seal on January 5, 2011.[6] On November 18, 2011, the Government served a subpoena on the Company, which was followed by a number of informal document requests, all seeking information related to NPC's speaker programs, and specifically to speaker programs sponsored by NPC's CV Division. In response, NPC produced to the Government over 90,000 documents comprising more than 2.5 million pages. Additionally, the Government interviewed a number of NPC employees, as well as doctors who prescribed NPC's CV and metabolic drugs.

On August 26, 2013, the Government filed its Amended Complaint. The Amended Complaint asserts that NPC conducted "many thousands" of sham speaker programs between January 2002 and November 2011, which were effectively vehicles to pay "kickbacks"

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very same division of NPC that is central to the Government's and Bilotta's current complaints. (Garrity Cmpl. ¶ 5 (Dillon Decl. Exh. B).) The Garrity Complaint alleged, among other things, that NPC induced physicians to write prescriptions for Diovan, Exforge and Tekturna by paying them kickbacks "through a panoply of kickback schemes" including "hiring and paying physicians as 'consultants' as part of a Speakers Bureau". (Id.) The Garrity Complaint was originally filed in 2008 and was dismissed by the court on August 2, 2011.

[5] Zelnorm (a drug that treats gastrointestinal conditions) and Sandostatin (an oncology drug) are not drugs within NPC's CV division.

[6] Relator filed a second amended complaint on March 21, 2013 and a third amended complaint on July 9, 2013.

to "tens of thousands" of doctors who participated in the events in order to induce them to write prescriptions for Lotrel, Valturna, Starlix and "other CV division drugs" that were later reimbursed by federal health care programs in violation of the AKS and the FCA. (Am. Cmpl. ¶ 175.) The Amended Complaint, however, identifies only fifteen doctors and attaches as exhibits spreadsheets listing their prescriptions for the NPC drugs mentioned in the Amended Complaint.

ARGUMENT

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

The FCA prohibits the submission of false claims to the government for payment, and making false statements material to such a claim. See 31 U.S.C. § 3729(a)(1)(A)-(B). To state a claim under 31 U.S.C. § 3729(a)(1)(A), the Government must plead that NPC "knowingly present[ed], or caus[ed] to be presented, a false or fraudulent claim for payment or approval". 31 U.S.C. § 3729(a)(1)(A). To state a claim under 31 U.S.C. § 3729(a)(1)(B), the Government must plead that NPC "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim". 31 U.S.C. § 3729(a)(1)(B).

Claims asserting fraud—such as claims brought under the FCA—are governed by the heightened pleading standard set forth in Rule 9(b). See Gold v. Morrison-Knudsen Co., 68 F.3d 1475, 1477 (2d Cir. 1995). The purposes of Rule 9(b) are to provide defendants with fair notice of the claims against them so they can prepare a defense, to protect defendants from harm to their reputations and goodwill, and to reduce the number of strike suits. See O'Brien v. Nat'l Prop. Analysts Partners, 936 F.2d 674, 676 (2d Cir. 1991); DiVittorio v. Equidyne Extractive Indus., Inc., 822 F.2d 1242, 1247 (2d Cir. 1987). To satisfy Rule 9(b), a plaintiff alleging fraud must "1) specify the statements that the plaintiff contends were fraudulent; 2) identify the

speaker; 3) state where and when the statements were made; and 4) explain why the statements were fraudulent". United States ex rel. Polansky v. Pfizer, Inc., No. 04-cv-0704, 2009 WL 1456582, at *4 (E.D.N.Y. May 22, 2009) (quoting Rombach v. Chang, 355 F.3d 164, 170 (2d Cir. 2004)). "In other words, 'Rule 9(b) requires that a plaintiff set forth the who, what, when, where and how of the alleged fraud.'" Id. (citation omitted). Pleadings of fraud cannot be based on conclusory allegations or speculation. See, e.g., Segal v. Gordon, 467 F.2d 602, 606-08 (2d Cir. 1972).

In the FCA context, because evidence of an actual false claim is "the sine qua non of a False Claims Act [violation]", an FCA plaintiff must plead the particulars of the alleged false claims. Polansky, 2009 WL 1456582, at *5 (quoting United States ex rel. Clausen v. Lab. Corp. of Am., Inc., 290 F.3d 1301, 1311 (11th Cir. 2002)). Accordingly, an FCA plaintiff "must provide details that identify particular false claims for payment that were submitted to the government". Id. at *4 (quoting United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 232 (1st Cir. 2004)); see also United States ex rel. SNAPP, Inc. v. Ford Motor Co., 532 F.3d 496, 505-06 (6th Cir. 2008); United States ex rel. Sikkenga v. Regence BlueCross BlueShield of Utah, 472 F.3d 702, 727-28 (10th Cir. 2006); Corsello v. Lincare, Inc., 428 F.3d 1008, 1012-14 (11th Cir. 2005). In other words, Rule 9(b) requires an FCA complaint to allege "with particularity" "the actual false claims submitted to the government" in addition to the "[u]nderlying schemes and other wrongful activities that result[ed] in the submission of fraudulent claims". Karvelas, 360 F.3d at 232; United States ex rel. Moore v. Glaxosmithkline, LLC, No. 06-cv-6047, slip op. at 7-8 (E.D.N.Y. Oct. 16, 2013) (holding that the alleged false claims and underlying schemes must be pleaded with particularity) (Dillon Decl. Exh. C). Failure to identify the underlying scheme, the alleged false claims and the link between them is

fatal to an FCA claim. Karvelas, 360 F.3d at 232; United States ex rel. Chen v. EMSL Analytical, Inc., No. 10-cv-7504, --- F. Supp. 2d ---, 2013 WL 4441509, at *18 (S.D.N.Y. Aug. 16, 2013) ("[G]iven that . . . the Complaint does not provide any details as to the who, when or why of the false claims themselves, the precise manner in which Defendants' 'fake' samples and 'false' testing reports are linked to the 'false reports and invoices' allegedly submitted to the government remains unclear (not to mention what false statements those reports and invoices actually contained)."); United States ex rel. Mooney v. Americare, Inc., 06-cv-1806, 2013 WL 1346022, at *3-4 (E.D.N.Y. Apr. 3, 2013) (finding allegations of fraudulent scheme "vague and unconnected to specific claims"); see also United States ex rel. Foster v. Bristol-Myers Squibb Co., 587 F. Supp. 2d 805, 821-25 (E.D. Tex. 2008).

Moreover, in evaluating a motion to dismiss pursuant to Rule 9(b), "[t]he degree of particularity required should be determined in light of such circumstances as whether the plaintiff has had an opportunity to take discovery of those who may possess knowledge of the pertinent facts". Devaney v. Chester, 813 F.2d 566, 569 (2d Cir. 1987); see also United States ex rel. Monda v. Sikorsky Aircraft Corp., No. 99-cv-1026, 2005 WL 1925903, at *5-6 (D. Conn. Aug. 11, 2005) (applying strict interpretation of Rule 9(b) to relator who had three months to examine defendant's records and interview its personnel), aff'd, 207 F. App'x 28 (2d Cir. 2006). The Government, which has already received voluminous discovery from NPC and has access to data regarding the prescriptions it paid for, has no basis to claim that it lacks the information necessary to put NPC on notice of precisely what NPC did wrong, when such wrongdoing happened, where, under what circumstances, the amount of any resulting kickbacks and the amount of any resulting false claims. United States ex rel. Wood v. Applied Research Assocs., Inc., 328 F. App'x 744, 747 (2d Cir. 2009) ("One of the further purposes of Rule 9(b) is to

discourage the filing of complaints as a pretext for discovery of unknown wrongs. A relator's contention, that discovery will unearth information tending to prove his contention of fraud, is precisely what Rule 9(b) attempts to discourage."); United States ex rel. Smith v. N.Y. Presbyterian Hosp., 06-cv-4056, 2007 WL 2142312, at *6 (S.D.N.Y. July 18, 2007) ("Rule 9(b) fails in its purpose if conclusory generalizations permit a plaintiff to set off on a long and expensive discovery process in the hope of uncovering some sort of wrongdoing.") (quotations omitted). As detailed below, the requisite particulars are not provided by the Government here—an omission that is conspicuous considering it has access to all the information necessary to do so.

A. The Amended Complaint Fails To Allege Predicate AKS Violations.

Pursuant to the AKS, it is unlawful to "knowingly and willfully offer[] or pay[] any remuneration . . . to any person to induce such person to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program". 42 U.S.C. § 1320a-7b(b)(2)(A). The Government's FCA claims are predicated on alleged violations of the AKS; specifically, the Government contends that NPC paid certain doctors thousands of dollars in honoraria to act as "speakers" at sham events in order to induce these doctors to increase their prescriptions of NPC CV drugs. As set forth below, however, the Amended Complaint does not sufficiently plead underlying AKS violations, which warrants dismissal of the Government's FCA claims under both Rules 12(b)(6) and 9(b). See, e.g., United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc., 543 F.3d 1211, 1223-24 (10th Cir. 2008) (affirming dismissal of FCA claims predicated on AKS where allegations failed to allege AKS violation); United States ex rel. Obert-Hong v. Advocate Health Care, 211 F. Supp. 2d 1045 (N.D. Ill. 2002) (dismissing FCA claim under Rules 12(b)(6) and 9(b) because, among other things, allegations failed to establish underlying

AKS violation); United States ex rel. Piacentile v. Novartis AG, No. 04-cv-4265, slip op. at 18-19 (E.D.N.Y. Feb. 7, 2011) (dismissing FCA claim under Rule 9(b) for failure to sufficiently plead predicate AKS violations) (Dillon Decl. Exh. D).[7]

The Government asserts that NPC knowingly and willfully hosted "many thousands" of fraudulent speaker programs over a ten-year period, but it identifies only a handful of these allegedly sham events. As to that handful, the Government alleges—in conclusory fashion—that they were sham programs (and that the associated speaker honoraria were "kickbacks") because few or no presentational slides were shown or some dinners were too "lavish" (based on restaurant reviews in Zagat). Apart from those bare allegations, however, the Government fails to explain how the programs violated the AKS.[8] The Government's attempt to rely on a handful of examples as proxies for "many thousands" of sham speaker programs is inconsistent with Rule 9(b)'s heightened pleading standard and impermissibly shifts the burden to NPC to prove that each speaker program was legitimate, when in fact it is the Government's burden to identify which programs were fraudulent. Smith, 2007 WL 2142312, at *5-7.

[7] The Amended Complaint also alleges that certain doctors attended the same or similar speaker programs on a repeat basis, which, under the Government's theory, purportedly evidences that such programs were shams. (See, e.g., Am. Cmplt. ¶ 84.) Putting aside the questionable nature of that theory, the Amended Complaint does not identify these repeat attendees, nor does it allege (let alone with the required particularity) that these repeat attendees changed their prescribing habits as a result of their participation in the programs. Finally, the Amended Complaint makes no attempt to tie false claims for reimbursement to repeat attendance at speaker programs.

[8] The Government further alleges (presumably for shock value) that certain programs were held at Hooters. But, as with the repeat attendee claims (see supra note 7), the Government makes no effort to tie the Hooters programs to any speaker honoraria, any change in prescribing habits or any associated false claims, making these allegations ineligible as predicates for the Government's FCA claims.

The Government does attempt to rely upon two sources as evidence of what a proper speaker program should entail, but neither establishes that any of NPC's speaker programs (let alone "many thousands") violated the AKS.

First, the Government cites NPC's own policies. (Am. Cmpl. ¶¶ 57-58, 60, 62.) However, violations of internal corporate policies are not violations of the AKS and FCA. See Johnson v. Univ. of Rochester Med. Ctr., 686 F. Supp. 2d 259, 264-68 (W.D.N.Y. 2010) (FCA complaint dismissed despite violations of internal hospital policy). Indeed, the existence of these policies supports a positive inference that NPC in fact took significant steps at the highest levels of the Company to avoid violations of the AKS and FCA. See Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 323 (2007) (when a plaintiff relies on inferences to support the allegations in a complaint, "the court must take into account plausible opposing inferences").

Second, the Government cites the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals (the "PhRMA Code"), of which Novartis is a signatory. (Am. Cmpl. ¶¶ 59, 61.) The PhRMA Code expressly acknowledges that speaker programs play an important role in how the pharmaceutical industry conveys information about medical care to healthcare professionals ("HCPs") because they educate HCPs through presentations made not by sales representatives, but by medical peers: "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 (Dillon Decl. Exh. E).) The PhRMA Code includes a high-level statement concerning how to execute optimal speaker programs: "Speaker programs may include modest meals offered to attendees and should occur in a venue and manner conducive to informational communication." (Id. at 10.) Notably, the PhRMA Code does not

direct how the medical discussion at a speaker program should be conducted or conveyed, or how many slides (if any) should be used. Nor does it set a cost limit or describe what venues are "conducive to informational communication". That no such specifics are provided is not surprising, considering that there is no single blueprint on how to conduct a compliant speaker program and they can take various forms.

Most critically, even assuming that the Government has adequately pleaded that a few dozen speaker programs (over approximately a decade) were sham or fraudulent, there is no basis for the Government's conclusion that the "many thousands" of other speaker programs NPC arranged during that time frame also were fraudulent. As set forth infra Part I.C., extrapolation under these circumstances—especially where speaker programs are not only permissible but also serve a legitimate purpose—is both inappropriate and inconsistent with Rule 9(b).

Finally, the Amended Complaint does not (and cannot) allege that NPC knowingly and willfully sought to defraud the government, an essential element of an AKS violation. 42 U.S.C. § 1320a-7b(b)(2)(A). The Second Circuit has made clear that to serve the purposes of Rule 9(b), plaintiffs must allege facts that give rise to a "strong inference" of fraudulent intent. Mooney, 2013 WL 1346022, at *3 (emphasis added); Shields v. Citytrust Bancorp, Inc., 25 F.3d 1124, 1128 (2d Cir. 1994); Wood, 328 F. App'x. at 747; see also Tr. of Premot. Conf. at 14, July 18, 2013 (Dillon Decl. A). Among other things, and despite extensive discovery and interviews, the Government does not assert that NPC's senior management instituted a company-wide scheme to defraud the government, that senior management (which put in place the internal policies governing speaker programs cited in the Amended Complaint) condoned any of the purported violations identified by the Government or even that a small

group of lower-level employees had the ability to institute a widespread and pervasive system of fraud. Again, the Government identifies a small number of supposedly sham events and from that infers that "many thousands" of speaker programs and honoraria were fraudulent, and that they resulted in the submission of "many thousands" of false claims. This does not sufficiently demonstrate a strong inference of fraudulent intent to violate the AKS (let alone on a national level), and therefore, the Amended Complaint cannot stand. Wood, 328 F. App'x. at 747-48; see also Rombach, 355 F.3d at 174 ("To succeed [under Rule 9(b)], plaintiffs must do more than say that the statements . . . were false and misleading; they must demonstrate with specificity why and how that is so."); Segal, 467 F.2d at 607 ("Mere conclusory allegations to the effect that defendant's conduct was fraudulent or in violation of [a statute] are insufficient . . . there must be allegations of facts . . . amounting to deception in one form or another; conclusory allegations of deception or fraud will not suffice.") (internal quotations and citations omitted); Piacentile, No. 04-cv-4265 at 17-18 (dismissing FCA claim for failure to adequately plead scienter for the predicate AKS violation, which requires showing that defendant acted "knowingly" and with "willfulness . . . with the intent to do something that the law forbids") (Dillon Decl. Exh. D).

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

Even assuming that the examples of sham speaker programs and honoraria set forth in the Amended Complaint adequately plead predicate violations of the AKS (which they do not), the Amended Complaint independently fails because it does not sufficiently link NPC's alleged wrongdoing to the submission of false claims.[9] Pleadings that detail "[u]nderlying

[9] The Government has not alleged that NPC itself submitted false claims. It therefore must plead with sufficient particularity that NPC "knowingly . . . cause[d] to be presented, a false or fraudulent claim for payment" or "knowingly . . . cause[d] to be made or used, a false record or statement material to a false or fraudulent claim". 31 U.S.C. § 3729(a)(1)(A)-(B).

schemes and other wrongful activities that result in the submission of fraudulent claims" are "invariably . . . inadequate unless they are linked to allegations, stated with particularity, of the actual false claims submitted to the government that constitute the essential element of an FCA qui tam action". Polansky, 2009 WL 1456582, at *5 (emphasis added) (quoting Karvelas, 360 F.3d at 232). "Thus, a relator cannot circumscribe the Rule 9(b) pleading requirements by alleging a fraudulent scheme in detail and concluding, that as a result of the fraudulent scheme, false claims must have been submitted." Polansky, 2009 WL 1456582, at *5 (citing cases); see also Smith, 2007 WL 2142312, at *6 ("Although [Relator] 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 that theory or about any specific fraudulent claim.").

In an effort to address the Initial Complaint's failure to link the underlying alleged AKS violations to the alleged submission of false claims (as noted by the Court), the Amended Complaint identifies fifteen doctors as "examples" of health care providers who were purportedly induced via sham honoraria to increase their prescriptions of NPC CV drugs. However, even as to these fifteen doctors, the Government does not in fact connect the alleged wrongdoing to the alleged submission of false claims; instead, these examples illustrate exactly why the Amended Complaint remains deficient.

To begin, by providing details about the prescribing habits of fifteen doctors in one part of the Amended Complaint (see, e.g., ¶¶ 151-157), and details about allegedly sham speaker programs in a separate part of the pleading (see, e.g., ¶¶ 97-120), the Government has obscured the fact that it is unable to establish a causal link between the allegedly sham speaker programs and any specific false claims. Critically, nowhere does the Amended Complaint attempt to connect an allegedly sham program to a fraudulently induced prescription (or resulting

false claim). Such piecemeal pleading fails causally to link sham speaker programs to specific false claims, and this failure is a fundamental and incurable defect.[10] See Mason v. Medline Indus., Inc., No. 07-cv-5615, 2009 WL 1438096, at *3-5 (N.D. Ill. May 22, 2009); Polansky, 2009 WL 1456582, at *5.

For example, Dr. S.D.2's prescribing levels are featured prominently in the opening paragraphs of the Amended Complaint. (Am. Cmpl. ¶ 3, see also ¶ 151.) However, no allegation in the Amended Complaint subsequently connects Dr. S.D.2 to even one allegedly sham speaker program. In other words, the Government contends that Dr. S.D.2 was induced by sham speaker programs to write more prescriptions, but then fails to identify any speaker programs (whether legitimate or not) at which he spoke or attended. The same is true for Dr. L.M., whose prescribing habits are discussed in paragraphs 155-56 of the Amended Complaint, but who is not associated with any of the alleged sham speaker events contained in the Amended Complaint.

A disconnect likewise exists in at least nine other of the Government's fifteen examples:

(1) Dr. B.A. is alleged to have repeatedly attended and/or spoken at multiple Valturna speaker programs (id. ¶ 98), yet the Amended Complaint contains no allegations related to changes in his Valturna prescribing levels;

[10] Again, the Government's failure to establish requisite causal links is conspicuous in light of the substantial discovery it obtained prior to its intervention. Among other things, the Government interviewed numerous NPC employees, physicians and employees of the third-party administrator of NPC's speaker programs, and reviewed tens of thousands of NPC documents—documents that were collected and produced based on Government requests designed for the express purpose of uncovering wrongdoing related to the specific allegations in this case. Notably, the Amended Complaint fails to allege that even one doctor admitted that he or she was inappropriately induced by NPC to prescribe NPC CV drugs. Nor does it reference any document that suggests such inducement.

(2) Dr. D.S.1 is alleged to have repeatedly attended and/or spoken at multiple Valturna speaker programs (id. ¶ 113), yet the Amended Complaint contains no allegations related to changes in his Valturna prescribing levels;

(3) Dr. N.D. is alleged to have repeatedly attended and/or spoken at Valturna and Lotrel speaker programs (id. ¶¶ 108-110), yet the Amended Complaint contains no allegations related to changes in his Valturna or Lotrel prescribing levels;

(4) Dr. S.D.1 is alleged to have repeatedly attended and/or spoken at Valturna speaker programs (id. ¶ 120), yet the Amended Complaint contains no allegations related to changes in his Valturna prescribing levels;

(5) Dr. S.G. is alleged to have repeatedly attended and/or spoken at Lotrel speaker programs (id. ¶ 117), yet the Amended Complaint contains no allegations related to changes in his Lotrel prescribing levels, other than the obscure allegation that Dr. S.G.'s "participation in Novartis's speaker programs influenced his prescription writing" (id. ¶ 158);

(6) Dr. S.M.1 is alleged to have repeatedly attended and/or spoken at multiple Lotrel speaker programs (id. ¶ 97), yet the Amended Complaint contains no allegations related to changes in her Lotrel prescribing levels;

(7) Dr. S.Z. is alleged to have repeatedly attended and/or spoken at multiple Valturna speaker programs (id. ¶¶ 126-127), yet the Amended Complaint contains no allegations related to changes in his Valturna prescribing levels;

(8) Dr. T.M. is alleged to have repeatedly attended and/or spoken at multiple Valturna events (id. ¶ 120), yet the Amended Complaint contains no allegations related to changes in his Valturna prescribing levels; and

(9) Dr. C.V.S. is alleged to have repeatedly attended and/or spoken at multiple Lotrel speaker programs (id. ¶¶ 100-103), yet the Amended Complaint contains no allegations related to changes in his Lotrel prescribing levels, other than the vague claim that Dr. C.V.S.'s speaker fees "increased the likelihood that he would prescribe that company's drugs". (Id. ¶ 158.)

Similarly, although the Amended Complaint alleges that doctors received kickbacks in exchange for writing prescriptions of Lotrel, Valturna, Starlix, Tekamlo, Exforge and its HCT form, Diovan and its HCT form, and Tekturna and its HCT form, it describes allegedly sham speaker programs for only Lotrel, Valturna and Starlix (and only a few even as to those). The other drugs are simply ignored. The Government cannot fail to plead details

concerning sham speaker programs related to Tekamlo, Exforge, Diovan and Tekturna and then reasonably claim kickbacks induced doctors to prescribe these drugs. Mooney, 2013 WL 1346022, at *6 (dismissing claims related to Medicaid where no examples of Medicaid false claims were included in the complaint). The Government also fails to allege changes in doctors' prescribing histories for most of the drugs mentioned in the Amended Complaint. Although the Government alleges that fraudulent claims were submitted in connection with Lotrel, Starlix, Valturna and "other CV division drugs" (Am. Cmpl. ¶¶ 66, 172, 175), among the thirteen doctors for whom specific changes in prescribing histories are alleged, only three examples are provided for Valturna and only one for Starlix; the rest relate to Lotrel. (Id. ¶¶ 151-157.) The Amended Complaint contains no specific allegations relating to any doctor's prescribing of any of the unidentified "other CV division drugs"[11] as a result of a sham speaker program.

Of course, the Government's inability to link the doctors' prescribing habits to specific allegedly sham speaker programs also makes it impossible for the Government to specify actual false claims—another fatal flaw. United States ex rel. Sasaki v. N.Y. Univ. Med. Ctr., No. 05-cv-6163, 2012 WL 220219, at *6 (S.D.N.Y. Jan. 25, 2012) ("The central question under the False Claims Act is whether the defendant actually presented a 'false or fraudulent claim' to the government.") (quoting Johnson, 686 F. Supp. 2d at 265). The data attached to the Amended Complaint is no more informative than the chart of prescribing data included in the

[11] Although not entirely clear from the Amended Complaint, the references to "other CV division drugs" presumably refer to Diovan and its HCT form, Exforge and its HCT form, Tekturna and its HCT form, and Tekamlo. (See Am. Cmpl. ¶¶ 172-174.) As noted, however, there are no specific allegations of allegedly sham speaker programs or corresponding increases in prescription levels with respect to these drugs. More troubling, the Amended Complaint alleges that "the fact that doctors were paid in connection with Novartis' speaker programs influenced their prescription writing with respect to Novartis drugs generally". (Id. ¶ 174.) There is no basis in the Amended Complaint to understand which drugs the Government contends fall within this allegation.

Initial Complaint (see Init. Cmpl. ¶ 152), the adequacy of which was questioned by the Court at the premotion hearing. (Tr. of Premot. Conf. at 12, July 18, 2013 (Dillon Decl. A).) The raw data of all federally-reimbursed prescriptions written by 15 doctors that is attached to the Amended Complaint plainly "does not make clear which of these claims were allegedly fraudulent". Id.; see also Piacentile, No. 04-cv-4265 at 15 ("[A] simple recital of government programs to which Plaintiff 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)") (Dillon Decl. Exh. D).

The Government simply has not demonstrated an inference of fraud, let alone a strong inference. Mooney, 2013 WL 1346022, at *3. The lack of precision with which its claims are pleaded[12] also renders it impossible for NPC to determine, for example, which doctors (other than the 15 identified) were allegedly induced, when within the nearly ten-year time frame doctors were allegedly induced, and the value of any resulting prescriptions. Id. at *7; Polansky, 2009 WL 1456582, at *5; see also United States ex rel. Smith v. Yale Univ., 415 F. Supp. 2d 58,

[12] Some of the claims enumerated in the Government's exhibits to the Amended Complaint are clearly released under the terms of the EDPA Settlement. When counsel for NPC brought this to the Government's attention, the Government indicated that "[t]o the extent any such prescriptions were included in the exhibits attached to the amended complaint, it was an oversight". (See 9/12/13 Ltr. from C. Harwood to J. Gardephe at 3-4 n.1.) In addition to its "oversight" in the exhibits, the Government relies on the same error in its Amended Complaint, by including the prescribing history for a doctor ("Dr. T.M.") who was specifically named in the Garrity Complaint. (See Garrity Cmpl. ¶ 55 (Dillon Decl. Exh. B).) The Amended Complaint not only counts Dr. T.M. as one of its 15 examples, it specifically includes Dr. T.M.'s prescribing history for the time period directly covered by the EDPA Settlement. (Am. Cmpl. ¶ 176) ("[F]rom February 2003 through June 2007 and October 2009 through November 2010, Dr. T.M. wrote prescriptions for Diovan, Diovan HCT, Tekturna, Exforge and Exforge HCT. These prescriptions were paid for by a Part D Medicare Plan. Attached as Exhibit K is a spreadsheet with additional information regarding these prescriptions.").

88 (D. Conn. 2006) (finding that case involving "allegations of a general scheme of fraud that might have resulted in the submission of false claims" failed to satisfy Rule 9(b)).

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

Assuming for purposes of argument only that the Government provided enough detail to satisfy Rule 9(b) with respect to the fifteen doctors actually identified in the Amended Complaint, these "examples" do not, as a matter of law, support the Government's claims that "tens of thousands" of doctors received kickbacks; "many thousands" of speaker programs were shams; and "many thousands" of false claims were submitted. (Am. Cmpl. at 31, ¶ 175.) Although, under certain circumstances, false claims can be pleaded by example, such extrapolation is only appropriate where the properly pleaded false claims are "representative samples of the broader class of claims", something that is not the case here. Mooney, 2013 WL 1346022, at *7 (quoting United States ex rel. Bledsoe v. Cmty. Health Sys., Inc., 501 F.3d 493, 510 (6th Cir. 2007)); see also United States v. Bank of N.Y. Mellon, No. 11-cv-6969, 2013 WL 1749418, at *30 (S.D.N.Y. Apr. 24, 2013) (dismissing on 9(b) grounds the government's allegations regarding misrepresentations made to ERISA clients because "an example of a non-ERISA client is not 'representative' of ERISA clients when that distinction is essential to a finding of fraud"); United States ex rel. Thomas v. Bailey, No. 06-cv-0465, 2008 WL 4853630, at *6 (E.D. Ark. Nov. 6, 2008) (dismissing allegation of a national corporate policy of kickbacks because the complaint only offered five anecdotal examples). In Bledsoe, the Sixth Circuit Court of Appeals explained:

> "[T]he claims that are pled with specificity must be 'characteristic example[s]' that are 'illustrative of [the] class' of all claims covered by the fraudulent scheme. Webster's Third New International Dictionary of the English Language Unabridged, 1926 (1993) ('representative' definition 4). The examples of false claims pled with specificity should, in all material respects, including general time frame, substantive content, and relation to the allegedly fraudulent scheme, be

> such that a materially similar set of claims could have been produced with a reasonable probability by a random draw from the total pool of all claims."

501 F.3d at 510-11. The claims pleaded by the Government—a handful of allegedly sham speaker events, concerning different drugs, held at different time periods, in different cities and resulting in unidentified false claims—are not illustrative of anything at all, let alone a class of illegitimate claims. Including a few examples of doctors who allegedly participated in speaker programs on different topics with different alleged issues (for example, inappropriate venue versus lack of sufficient medical content) does not provide NPC notice concerning which of the thousands of other speaker programs (also on different topics, for different drugs, hosted by different NPC employees, throughout different periods of time) were allegedly shams or what precisely made them shams. Nor does it provide NPC notice concerning which of the other thousands of doctors were allegedly paid kickbacks; and, most importantly, it does not provide NPC notice concerning what false claims actually resulted from the (unspecified) wrongdoing or how the wrongdoing caused the alleged false claims. Unlike Bledsoe, the Government could not, "by a random draw" of all NPC speaker programs, pull out only shams, pull out only doctors who allegedly accepted kickbacks, or pull out only false claims.

Rule 9(b) does not permit the Government to point to a few (or, in the cases of the "other CV division drugs", zero) examples of potential wrongdoing, and from those narrow instances, extrapolate that pervasive fraud was occurring across the country over the course of a decade, particularly where there is no allegation of a fraudulent scheme by senior management or even a group of lower-level employees. United States ex rel. Dhawan v. N.Y.C. Health & Hosp. Corp., No. 95-cv-7649, 2000 WL 1610802, at *3 (S.D.N.Y. Oct. 27, 2000) (dismissing qui tam in part because details provided about an allegedly fraudulent arrangement between the defendants and several hospitals did not permit relator to "then make[] an unjustified quantum

leap" that because other hospitals had similar contracts with the defendants, the same fraudulent conduct must have occurred); U.S. ex rel. Fox Rx Inc. v. Omnicare, Inc., No. 11-962, 2013 WL 2303768, at *7 (N.D. Ga. May 17, 2013) (dismissing on Rule 9(b) grounds allegations that a broader scheme—involving claims in other years or that were submitted through other PDP sponsors—could not be "inferred from the conduct for which Relator alleges actual information"). Such extrapolation also is inappropriate where it is recognized (including by the Government) that speaker programs serve a legitimate purpose and NPC established policies to ensure that programs were conducted appropriately, and where there is a presumption that health care providers make prescribing decisions based on their medical judgment.

As set forth above, "in determining whether the pleaded facts give rise to a 'strong' inference of scienter, the court must take into account plausible opposing inferences". Tellabs, 551 U.S. at 323; Chen, 2013 WL 4441509, at *18 (dismissing FCA claim after finding that fact relied upon by Plaintiff to establish fraud "no more compels an inference of fraudulent activity than it does an inference [in favor of defendant] . . . . [Plaintiff] asks the Court to entertain his conclusory assertion . . . . The Court is not permitted, in the context of a fraud pleading, to take such a leap of faith."). The most obvious inference in favor of NPC is a legal one. On-label prescriptions written by doctors are presumptively reimbursable. See Ironworkers Local Union 68 v. AstraZeneca Pharm., LP, 634 F.3d 1352, 1362 (11th Cir. 2011) ("[W]hen a doctor prescribes a drug, he presumably does so only if, in the exercise of his independent medical judgment, he believes the drug will benefit his patient."); see also UFCW Local 1776 v. Eli Lilly & Co., 620 F.3d 121, 135 (2d Cir. 2010) ("The nature of prescriptions . . . means that [plaintiff's] theory of causation is interrupted by the independent actions of prescribing physicians."). As noted by the Court, there are many reasons why a doctor chooses to prescribe

certain products. Tr. of Premot. Conf. at 12, July 18, 2013 (Dillon Decl. A); Polansky, 2009 WL 1456582, at *9-10. The Amended Complaint, by condemning many thousands of speaker programs and prescribing decisions based on fifteen supposed examples, does not allow for the possibility that doctors would have prescribed Novartis drugs even if they had not attended allegedly sham events. See UFCW Local 1776, 620 F.3d. at 135. Although the Government dismisses this possibility as "immaterial" (9/12/13 Ltr. from C. Harwood to J. Gardephe at 3), caselaw from the Second Circuit (cited by this Court at the premotion hearing) holds otherwise. See, e.g., Polansky, 2009 WL 1456582, at *9-10. Moreover, numerous allegations in the Amended Complaint acknowledge that the identified doctors did, in fact, prescribe the products at issue prior to receiving honoraria or attending allegedly sham speaker programs. (Am. Cmpl. ¶¶ 151-157.)

The Amended Complaint's continued reliance on inferences and extrapolation is inappropriate under the circumstances here and should be rejected. See Dhawan, 2000 WL 1610802, at *3; Fox Rx Inc., 2013 WL 2303768, at *7; Bank of N.Y. Mellon, 2013 WL 1749418, at *30; Thomas, 2008 WL 4853630, at *6.

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

Under the FCA, a claim is false or fraudulent if it "is aimed at extracting money the Government otherwise would not have paid". United States ex rel. Colucci v. Beth Israel Med. Ctr., 785 F. Supp. 2d 303, 310 (S.D.N.Y. 2011) (quoting Mikes v. Straus, 274 F.3d 687, 696 (2d Cir. 2001)). Courts have recognized three theories of false claims: a "factually false" theory and two "legally false" theories. Id. at 311. A claim is "factually false" if it sets forth "an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided". Mikes, 274 F.3d at 697. The two "legally false" theories are express false certification and implied false certification. An express false certification is "a claim that

falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment". Id. at 698-99. An implied false certification (which is viable only in "limited circumstances") "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 699-700.

The Government's FCA allegations are premised on the false certification theory of liability—that by allegedly providing kickbacks to physicians to induce them to prescribe certain of Novartis's pharmaceutical products, NPC caused Medicaid providers to submit false certifications in their submissions for payment in violation of the FCA. However, the broad certifications the Government alleges were submitted in connection with Medicaid claims are insufficient to state a claim here. None of the sources cited in or attached to the Amended Complaint contains an express certification of compliance with the AKS as a prerequisite for payment. The Government solely alleges that "in many states, Medicaid 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". (Am. Cmpl. ¶ 43.) Prior to the enactment of PPACA in 2010,[13] such broad language requiring compliance with "all applicable state and federal laws" was insufficient to constitute an express or implied[14]

[13] Under the Patient Protection and Affordable Care Act, "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]". 42 U.S.C. § 1320a-7b(g) (2010). However, prior to the 2010 enactment of PPACA, a violation of the AKS was not a per se violation of the FCA. Thus, in order to state a claim pre-PPACA, the relied upon certification must contain an express certification of compliance with the AKS. See Mikes, 274 F.3d at 697.

[14] See Mikes, 274 F.3d at 700-02; Colucci, 785 F. Supp. 2d at 315; Conner, 543 F.3d at 1218-19; United States ex rel. Kennedy v. Aventis Pharm., Inc., 610 F. Supp. 2d 938, 946 (N.D. Ill. 2009) ("This Court agrees with the Second Circuit, however, that this [implied false certification theory] is viable in the Medicare context only when the underlying statute upon which the FCA

certification of compliance with anti-kickback statutes. Because the PPACA is not retroactive, see Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson, 559 U.S. 280, 283 n.1 (2010), such broad language is still insufficient to constitute an express or implied certification of compliance, warranting dismissal of the Government's pre-2010 Medicaid claims.[15]

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

The Government's unjust enrichment claim (Am. Cmpl. ¶¶ 191-192) should be dismissed because it fails to articulate how NPC was unlawfully enriched. To properly plead such a claim, the Government must show that, "(1) the defendant benefitted, (2) at the plaintiff's expense; and (3) equity and good conscience require restitution". Fed. Treasury Enter. Sojuzplodoimport v. Spirits Int'l N.V., 400 F. App'x 611, 613-14 (2d Cir. 2010). Assuming, for the purposes of this motion only, that the Government has premised its unjust enrichment claim on the theory that NPC violated the AKS (something that is not in fact articulated in the Amended Complaint), then the claim should be dismissed for the same reason as the FCA claim.

As discussed supra, the Amended Complaint fails to sufficiently allege that NPC violated the AKS. See Section I.A.; Piacentile, No. 04-cv-4265 at 17-19 (Dillon Exh. D). Moreover, it does not allege any link between any specific sham speaker programs and specific false claims. Polansky, 2009 WL 1456582, at *5. Accordingly, the Government has no basis to

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relator relies expressly states that the provider must comply in order to be paid. That is not true of the anti-kickback statute.").

[15] Furthermore, while the Government avers 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 AKS" (Am. Cmpl. ¶ 42), courts have distinguished between a defendant's certification of compliance with conditions of participation and conditions of payment. See Mikes, 274 F.3d at 700-02; United States ex rel. Blundell v. Dialysis Clinic, Inc., . 09-cv-0710, 2011 WL 167246, at *19 (N.D.N.Y. Jan. 19, 2011).

assert unjust enrichment, and the claim cannot stand. LaCroix v. U.S. Bank, N.A., No. 11-cv-3236, 2012 WL 2357602, at *7 (D. Minn. June 20, 2012) (dismissing unjust enrichment claim that was premised on an alleged kickback scheme after determining kickback scheme was not adequately pleaded); Bonner v. Redwood Mortg. Corp., No. 10-cv-0479, 2010 WL 1267069, at *6 (N.D. Cal. Mar. 29, 2010) (same); see also In re Pfizer Inc. S'holder Derivative Litig., 722 F. Supp. 2d 453, 465-66 (S.D.N.Y. 2010) (dismissing unjust enrichment claim where underlying allegation of illegal marketing by pharmaceutical company failed to state a claim for relief).

CONCLUSION

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

Dated: October 24, 2013

Respectfully submitted,

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