UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, *et al.*, Plaintiffs and Relator, v. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	ECF CASE 11 CIV. 0071 (PGG)
UNITED STATES OF AMERICA, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	

THE UNITED STATES OF AMERICA'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

PREET BHARARA
United States Attorney for the
Southern District of New York
Attorney for United States of America
86 Chambers Street, 3rd Floor
New York, New York 10007

JEANNETTE A. VARGAS,
CHRISTOPHER B. HARWOOD
Assistant United States Attorneys
-Of Counsel-

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES **PAGE**

STATUTES

OTHER AUTHORITIES

The United States of America, through its attorney, Preet Bharara, the United States Attorney for the Southern District of New York, respectfully submits this memorandum of law in opposition to Defendant Novartis Pharmaceuticals Corporation's ("Novartis") motion to dismiss the First Amended Complaint (the "Complaint" or "Compl.").

This is a civil action brought by the United States pursuant to the False Claims Act, 31 U.S.C. §§ 3729-33 (the "FCA") and the common law to recover damages based upon Novartis's violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (the "AKS"). As set forth in the Complaint, from January 2002 through at least November 2011, Novartis engaged in a nationwide kickback scheme to induce physicians to increase the number of prescriptions they wrote for Novartis cardiovascular ("CV") drugs. Specifically, under the guise of compensating physicians for their participation in educational sessions regarding Novartis drugs, Novartis systematically provided doctors with remuneration in the form of substantial honoraria, lavish dinners costing hundreds, if not thousands, of dollars per person, and other entertainment. Yet these purported speaker events contained little or no educational content, and instead served as a mechanism for Novartis to unlawfully influence doctors' prescribing habits. These sham speaker events were intended to cause, and did cause, doctors to increase the prescriptions they wrote for Novartis CV drugs, which were then reimbursed by federal health care programs. The claims submitted to federal health care programs, tainted by the kickbacks, are false claims within the meaning of the FCA.

Novartis nonetheless argues that the Complaint — which gives hundreds of specific examples of sham speaker events and thousands of examples of false claims that were tainted by kickbacks and reimbursed by federal health care programs — should be dismissed for failing to plead fraud with particularity. The Complaint more than satisfies the pleading requirements of

Federal Rule of Civil Procedure 9(b), however, and Novartis's remaining arguments are similarly unavailing. Accordingly, the motion to dismiss should be denied.

BACKGROUND

According to the Complaint, Novartis engaged in a nationwide kickback scheme, whereby it provided remuneration to physicians in the form of honoraria, dinners, and other entertainment through so-called "speaker programs." Compl. ¶¶ 1-2. Speaker programs are events at which a doctor is paid supposedly to educate other doctors about the company's drugs. *Id.* ¶ 2. From January 2002 through at least November 2011, Novartis promoted the CV drugs Lotrel, Valturna, Starlix, Diovan, Diovan HCT, Tekturna, Tekturna HCT, Tekamlo, Exforge, and Exforge HCT (the "Covered Drugs") through purported speaker programs. *Id.* ¶¶ 1, 66, 172-73.

In reality, however, thousands of these speaker programs were shams. *Id.* ¶¶ 2, 175. For example, despite the fact that doctors were purportedly being paid to present educational materials regarding Novartis CV drugs to their fellow doctors, at many of the programs there was little or no discussion of the relevant drug, and the speaker did not bother to show the required slides. *E.g., id*. ¶¶ 2, 95, 98, 105-07, 110, 115-16, 119, 133-37. Moreover, doctors around the country were paid to speak repeatedly to the same attendees on exactly the same topics. *See id.* ¶¶ 97-120. The doctors in these clusters took turns assuming the roles of speaker and attendee, with doctors repeatedly attending the same lecture they had just been paid to teach. *E.g., id.* ¶¶ 95, 97-98, 101. In addition, some of the programs for which speakers were paid either did not occur at all or did not have the attendees Novartis claims were present. *Id.* ¶¶ 138-44.

Novartis sales representatives, who were compensated in part based on the number of prescriptions written by doctors on their call lists, used these sham events as a mechanism to induce the doctors to write prescriptions for the Covered Drugs. *E.g., id.* ¶¶ 1, 77, 75, 149, 159.

Doctors selected to speak at these programs were generally paid between $750 and $1,500 for each program, with some speakers earning as much as $3,000 per program. *Id.* ¶ 79. Moreover, while the attendees did not receive cash, they (and the speakers) received substantial in-kind benefits in the form of dinners at high-end restaurants (such as a program on December 12, 2005, for two attendees and a speaker at Nobu in Dallas, Texas, that had a meal cost of $3,250 per person, *id.* ¶ 132), as well as other entertainment (such as fishing trips and evenings out at sports bars and Hooters restaurants, *id.* ¶¶ 121-24).

Sham speaker events were not limited temporally to any particular year or geographically to a specific territory or region. Rather, such programs all across the country over the course of nearly a decade. *Id.* ¶¶ 97-120, 122-33, 139-44.

Novartis tracked its "return on investment" for its speaker programs, and concluded that doctors who participated in the programs increased the number of prescriptions they wrote for CV drugs. *Id.* ¶¶ 145-49. For example, in May 2006, Novartis found that speaker programs in 2005 for Lotrel had a return on investment of more than 1.39, meaning that for every dollar spent on the programs, Novartis made more than $1.39 in revenue on the increase in prescriptions written by the doctors who participated as compared to a control group of doctors who did not participate. *Id.* ¶ 148. Moreover, doctors were required to maintain or increase high levels of prescriptions in order to be invited to present programs, and thereby receive honoraria. *Id.* ¶ 149. The speaker programs ultimately had their intended effect; they induced doctors to write prescriptions for the Covered Drugs, and thereby led to thousands of tainted claims for reimbursement from Medicare, Medicaid, TRICARE and the Department of Veterans Affairs ("VA"). *Id.* ¶¶ 150-58, 176-77 & Exs. A-O.

ARGUMENT

I. APPLICABLE LEGAL STANDARD

Rule 9(b) provides that, "in 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." Courts have recognized that "'Rule 9(b)'s ultimate meaning is context-specific' . . . . Depending on the claim, a plaintiff may sufficiently 'state with particularity the circumstances constituting fraud or mistake' without including all the details of any single court-articulated standard — it depends on the elements of the claim at hand." *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 188 (5th Cir. 2009). Thus, "claims under the FCA need only show the specifics of a fraudulent scheme and provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme." *United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1172 (10th Cir. 2010); *see Grubbs*, 565 F.3d at 190 (FCA plaintiff need only allege "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted"); *United States v. Huron Consulting Group, Inc.*, No. 09 Civ. 1800, 2011 WL 253259, at *2 (S.D.N.Y. Jan. 24, 2011) (approvingly citing to *Grubbs*, 565 F.3d at 190); *see generally United States ex rel. Longest v. Dyncorp*, No. 03-816, 2006 WL 47791, at *2 (M.D. Fla. Jan. 9, 2006) (Rule 9(b)'s requirements "may not . . . abrogate the concept of notice pleading.").

II. THE COMPLAINT MEETS THE PARTICULARIZED PLEADING STANDARDS OF RULE 9(B)

Novartis's primary challenge to the Complaint is that it fails to plead fraud with particularity pursuant to Rule 9(b). The Complaint, however, provides extensive detail regarding the nationwide fraudulent kickback scheme, describing hundreds of sham speaker events and

providing specific information regarding thousands of tainted claims. These allegations more than satisfy Rule 9(b).

A. The Complaint Provides Extensive Detail Regarding the Kickback Scheme

The AKS makes it illegal for individuals or entities to "knowingly and willfully offer[] or pay[] remuneration (including any kickback, bribe, or rebate) . . . to any person to induce such person . . . to purchase, . . . order, . . . or recommend purchasing . . . or ordering any good . . . or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). Novartis does not dispute that cash payments, dinners, and fishing trips constitute "remuneration" within the meaning of the AKS, *see, e.g.*, *United States ex rel. Gale v. Omnicore, Inc.*, No. 10-127, 2013 WL 3822152, at *6 n.67 (N.D. Ohio July 23, 2013) (remuneration includes "anything of value in any form whatsoever"), nor that Novartis provided such remuneration to physicians through its speaker programs. Novartis instead contends that the Government has not plead with particularity facts establishing the sham nature of speaker events, and thus has not shown a violation of the AKS. Novartis Brief ("Br.") at 9-10. Novartis's argument plainly fails. As this Court previously recognized at the pretrial conference held on July 18, 2013, "the Complaint contains substantial details about the alleged kickback scheme." Tr. at 18 (attached as Ex. A to Dillon Decl. dated Oct. 24, 2013).

Under Rule 9(b), "[t]o plead FCA liability predicated on AKS violations, [the Government] need only allege the particular details of a scheme to offer kickbacks in order to induce [doctors to prescribe Novartis drugs], coupled with reliable indicia leading to a strong inference that claims based on such [prescriptions] were actually submitted to Medicare or Medicaid." *United States ex rel. Parikh v. Citizens Medical Center*, No. 10-64, 2013 WL 5304057, at *9 (S.D. Tex. Sept. 20, 2013). The Government has more than met that standard.

Novartis suggests that the Complaint identifies only a "handful" of sham speaker events. Br. at 10. In fact, the Complaint describes hundreds of sham speaker events that had little or no educational value (the nominal purpose of the speaker programs), took place at inappropriate locations, and/or simply did not occur. Compl. ¶¶ 95-144. The Complaint provides such details as the dates of speaker programs, *e.g.*, *id*. ¶¶ 102, 123-32, 139-44, the identity of the speakers, *e.g.*, *id*. ¶¶ 97-103, 108-10, 113, 115, 117-18, 120, 126-29, the locations, *e.g., id.* ¶¶ 123-33, 139-43, the nominal topics, *id.* ¶¶ 97-120, the amounts of honoraria paid, *e.g., id*. ¶¶ 99, 101, 104, 110, 113, 125-29, 131-33, 139-40, 144, the cost of the dinners, *e.g., id*. ¶¶ 129-32, and descriptions of what rendered these speaker programs shams, *id.* ¶¶ 95-144.

Novartis further argues that as to those events, "the Government alleges — in conclusory fashion — that they were sham programs . . . because few or no presentational slides were shown and some dinners were too 'lavish' (based on reviews in Zagat)." Br. at 10. Contrary to Novartis's assertions, the Complaint does not merely allege that these speaker events were shams because of a failure to show slides or because they were held at highly-rated restaurants, although these facts further evidence the sham nature of the programs. Rather, the Complaint describes how doctors were paid thousands of dollars in honoraria for events that never took place, that they never attended, at which they did not speak, or at which there was little or no medical discussion. *E.g., id*. ¶¶ 107, 113, 117, 119, 131, 139-40, 144. The Complaint further details how the same group of doctors would take turns purportedly presenting to each other the same lecture over and over again in a period of weeks or months. *Id.* ¶¶ 97-120. The Complaint also alleges that doctors went on fishing trips, *id.* ¶¶ 122-23, went to sports bars and Hooters, *id*. ¶¶ 124, 128, and had dinners that routinely cost hundreds of dollars and as much as $3,250 per person, *id.* ¶¶ 129-32. In addition, the Complaint alleges that Novartis falsified its records to

conceal the fact that these speaker programs were shams. *Id*. ¶¶ 138-43.

Novartis halfheartedly attempts to defend the remuneration received by doctors as legitimate compensation for participation in an educational program, although Novartis does not begin to explain the pedagogical purpose of conducting educational programs with little or no educational content or on fishing trips or at Hooters. Instead, Novartis can only note that the PhRMA Code "does not direct how medical discussions 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.'" Br. at 11-12. Novartis's attempt to characterize this suit as a dispute about how educational information should be conveyed at a speaker program is disingenuous, given the explicit allegations regarding the lack of educational information being conveyed at many of these purported speaker programs. *E.g., id*. ¶¶ 105, 107, 110, 112, 117, 119, 131, 135-37, 139-40.

More fundamentally, however, Novartis's argument misses the point entirely. To make out a claim under the AKS, the Government is not required to allege violations of internal policies or industry standards[1] — nor is it even required to allege that the speaker programs are shams.[2] Rather, the Government need only demonstrate that the remuneration was provided with the unlawful intent to induce physicians to write prescriptions for Novartis drugs. *See, e.g.*,

[1] Novartis suggests that the Government relies upon the PhRMA Code and Novartis's internal policies as the benchmarks by which to measure the legitimacy of speaker programs. Br. at 10-11. Although these do provide indicia of industry standards with respect to speaker programs, the Complaint is not premised upon a violation of some fixed set of standards. The existence of such standards, and Novartis's complete failure to abide by them, is probative of Novartis's knowledge and intent, however. Compl. ¶¶ 57-62.

[2] Even payments made in exchange for the provision of legitimate services can run afoul of the AKS if such remuneration was provided with the unlawful purpose of inducing the recipient to prescribe particular medications. *See, e.g.*, *United States v. Bay State Ambulance & Hosp. Rental Service, Inc.*, 874 F.2d 20, 29-30 (1st Cir. 1989); *United States v. Greber*, 760 F.2d 68, 71-72 (3d Cir. 1985).

Bay State, 874 F.2d at 29-30. Alleging that the speaker programs served as a vehicle for Novartis to ply doctors with honoraria and entertainment to induce them to write prescriptions for the Covered Drugs sufficiently states a violation of the AKS.

B. The Complaint Adequately Alleges Scienter

Novartis also argues that the Complaint fails to allege that Novartis "knowingly and willfully sought to defraud the government," as required to establish a violation of the AKS. Br. at 12. Novartis ignores entirely that Rule 9 allows scienter to be plead generally, Fed. R. Civ. P. 9(b), and that the Government is therefore required only to "'provide some minimal factual basis for conclusory allegations of scienter that give rise to a strong inference' of fraudulent intent." *Powers v. British Vita, P.L.C.*, 57 F.3d 176, 184 (2d Cir. 1995) (citation omitted). To meet this standard, the Government is required only to allege facts which demonstrate "a motive for committing fraud and a clear opportunity for doing so" or, alternatively, to "identify[] circumstances indicating conscious behavior by the defendant." *Id.* (citation omitted); *see United States ex rel. Taylor v. Gabelli*, 345 F. Supp. 2d 313, 326 (S.D.N.Y. 2004). Motive, in this context, "entail[s] concrete benefits that could be realized" by the fraudulent conduct, while opportunity "entail[s] the means and likely prospect of achieving concrete benefits by the means alleged." *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1130 (2d Cir. 1994).

The Complaint plainly alleges that Novartis had a motive for the kickback scheme — to drive up the number of prescriptions and thereby increase company profits. Compl. ¶¶ 3, 77, 145-49. Indeed, according to the Complaint, Novartis specifically analyzed the "return on investment" of its speaker programs, which it measured by the increase in the participants' prescription writing. *Id.* ¶¶ 145-49. Moreover, Novartis knew and intended that the more incentives doctors received in the form of honoraria, meals and other entertainment, the more

prescriptions they would write for Novartis drugs, and that "offering an honorarium" was the top factor driving "return on investment." *Id.* Novartis sales representatives also had a strong motive to provide kickbacks to medical providers, as they were compensated in part based on the number of prescriptions written by doctors on their call lists. *Id.* ¶¶ 75, 159.

With respect to opportunity, the Complaint alleges that Novartis created the means by which the kickback scheme could function and flourish by spending tens of millions of dollars on speaker programs for the Covered Drugs, *id.* ¶ 71; compensating sales representatives in part based on the number of prescriptions written by doctors on their call lists, *id.* ¶¶ 75, 159; allowing sales representatives virtually unfettered discretion to select the speaker and venue for programs, *id.* ¶¶ 72-73, 82; making those same sales representatives responsible for determining whether any educational content would be presented at programs, *id.* ¶¶ 98, 107, 110; and placing no limit on the number of events a doctor could attend on the same topic, *id.* ¶ 84.

Although the Government is not required to plead that senior management knowingly and willfully participated in the kickback scheme, particularly where the Complaint alleges facts from which it can be inferred that Novartis sales representatives knowingly and willfully violated the AKS, *see, e.g.*, *United States v. Incorporated Village of Island Park*, 888 F. Supp. 419, 438 (E.D.N.Y. 1995) (principles of respondeat superior apply in FCA action), such an inference can be drawn from the allegations that Novartis's senior management was aware that: a payment to a doctor for a purported service that "lacks substance" could violate the AKS, Compl. ¶ 57; speaker program dinners should be of modest amounts and incidental to a professional discussion to ensure that they do not constitute unlawful inducements, *id.* ¶¶ 60-61; in September 2010, Novartis entered into a Corporate Integrity Agreement with the Government in connection with a settlement of charges that Novartis had paid illegal remuneration through speaker

programs, *id.* ¶¶ 63-64; and Novartis's speaker programs had numerous compliance problems, including excessive meal and alcohol costs, improper venues, and inappropriate speaker conduct (such as not presenting the required slides), *id.* ¶¶ 163-71. The Complaint further alleges that, despite this knowledge, senior management failed to take reasonable steps to address the compliance problems. *Id.* ¶¶ 165-71. A reasonable inference can be drawn that the senior management intended the natural consequences of their actions — that speaker programs would be used as a mechanism to pay kickbacks to doctors.

C. The Complaint Adequately Pleads the Submission of False Claims

To plead FCA claims based on an AKS violation, the Government "need not identify particular claims resulting from the kickback scheme." *Parikh*, 2013 WL 5304057, at *7. Rather, Rule 9(b) requires only that the Government "plead with particularity that [Novartis] made kickbacks with the intent of inducing [prescriptions], and . . . plead 'particular details of a scheme . . . paired with reliable indicia that lead to a strong inference that claims were actually submitted.'" *Id.* (quoting *Grubbs*, 565 F.3d at 190); *see United States ex rel. Simpson v. Bayer Corp.*, No. 05-3895, 2013 WL 4710587, at *13-14 (D.N.J. Aug. 30, 2013). Here, the Government has gone farther. The Complaint describes the details of hundreds of sham speaker events, *see supra* Part II.A; shows that the sham events were intended to induce the participants to prescribe Novartis drugs, in violation of the AKS, *see supra* Part II.B; cites evidence, including Novartis's own "return on investment" analyses and prescription data, indicating that the participants in fact wrote prescriptions for the Covered Drugs, *see* Compl. ¶¶ 145-48, 157, 176; and identifies thousands of tainted prescriptions that were submitted for reimbursement and resulted in false claims, *see id.* ¶ 176 & Exs. A-O. Nothing more is required to satisfy Rule 9(b).

Although Novartis contends that the Complaint must connect a particular sham event

with a particular fraudulently induced prescription to satisfy Rule 9(b), Br. at 14-15, this argument is without merit.[3] As an initial matter, as discussed in detail *infra* at Part III, compliance with the AKS is "a condition of payment" of any claim for reimbursement. *See, e.g.*, *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 313 (3d Cir. 2011). Accordingly, once the Government shows that a doctor received remuneration in violation of the AKS during a particular period, all claims for reimbursement from federal health care programs associated with that doctor during that period are false because payment by the Government is contingent upon the doctor's continued compliance with the AKS. *See id.* at 314 ("Compliance . . . does require a participant in a federal health care program to refrain from offering or entering into payment arrangements which violated the AKS, while making claims for payment to the Government."); *United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 55-56 (D. Mass. 2011) (holding that "compliance with the [AKS] is a precondition of payment"). Thus, the Government is not required to prove, much less plead, that a particular prescription was fraudulently induced by a particular sham event.

Even if the Government were required to establish a causal link between particular sham events and particular prescriptions — which it is not — the Government would not have to plead such a link. To the contrary, courts have concluded that "[a plaintiff] need not allege a relationship between the alleged AKS violations and the claims . . . submitted to the Government." *Simpson*, 2013 WL 4710587, at *14 (quoting *Wilkins*, 659 F.3d at 313); *see*

[3] The cases on which Novartis relies to support its position are inapposite, as they did not involve alleged violations of the AKS and/or lacked particularized allegations of a fraudulent scheme that were paired with reliable indicia supporting a strong inference that false claims were actually submitted. For example, in *United States ex rel. Polansky v. Pfizer, Inc.*, No. 04-704, 2009 WL 1456582 (E.D.N.Y. May 22, 2009), the complaint alleged an off-label marketing scheme, *id.* at *2, and lacked particularized allegations to suggest that the scheme caused false claims to be submitted, *see id.* at *3, *5.

Parikh, 2013 WL 5304057, at *7.

Indeed, in AKS cases, plaintiffs do not even need to plead the details of specific claims, as "[t]he addition of specific identifying information of each claim adds little to complete the description of the scheme since the fraudulent conduct at issue does not rely on any specific claim." *United States ex rel. Singh v. Bradford Reg'l Med. Ctr.*, No. 04-186, 2006 WL 2642518, at *7 (W.D. Pa. Sept. 13, 2006). *United States ex rel. Simpson v. Bayer Corporation* is particularly instructive in this regard. The plaintiff in *Simpson* had "describ[ed] Bayer's broad scheme of illegal kickbacks to medical providers," but had not identified any false claims actually submitted to the Government. 2013 WL 4710587, at *13-14. The court nonetheless held that the complaint "sufficiently allege[d] causation in light of [the plaintiff's] allegations, particularly those regarding Bayer's illegal kickback scheme engineered to induce medical providers to prescribe [the drugs at issue], which would inevitably cause false claims to be submitted to the government." *Id.* at *14 (holding, in AKS context, the Complaint "need not identify a particular false claim submitted to the Government to withstand a motion to dismiss").

Here, the Complaint's allegations go well beyond what was deemed sufficient in *Simpson* and *Singh*. While not required, the Complaint includes 15 examples of doctors who were induced by honoraria to increase their prescription writing for certain of the Covered Drugs, *see* Compl. ¶¶ 151-58, and, for those 15 doctors, it identifies thousands of tainted prescriptions they wrote during the period they received kickbacks, which were reimbursed by federal health care programs and thus resulted in actionable false claims, *see id.* ¶ 176 & Exs. A-O.

Novartis does not challenge, and thereby concedes, that the Government has shown a causal link between the receipt of honoraria and increase in prescriptions for four of the 15 doctors (B.D., S.M.2, R.D. and D.S.2). *Id.* ¶¶ 153, 157. For seven of the remaining 11 doctors

(B.A., D.S.1, N.D., S.D.1, S.M.1, S.Z. and T.M.), Novartis claims that the Complaint identifies sham speaker events that these doctors attended for a particular drug, but does not allege increases in prescription writing for that drug. *See* Br. at 15-16. This argument is misleading, however, as the Complaint identifies sham events that these doctors attended in connection with *multiple* drugs, and then (as an example) goes on to show that they increased their prescription writing in connection with one of those drugs. As set forth in the Complaint:

- Drs. T.M. and S.D.1, who were paid to speak to the same attendees on the same *Lotrel* topic 18 times, Compl. ¶ 120, tripled and doubled, respectively, their prescription writing for *Lotrel* after being paid to speak on the drug, *id.* ¶ 157.[4]

- Dr. S.M.1, who was paid to speak to the same attendees on the same *Valturna* topic nine times, *id.* ¶ 97, "did not start prescribing *Valturna* until she began receiving consistent honoraria payments in connection with the drug, and thereafter her prescription writing increased as she received more honoraria," *id.* ¶ 157.

- Dr. N.D., who was paid to speak at sham Lotrel and *Starlix* events, *id.* ¶ 109, significantly increased his prescription writing for *Starlix* after being paid to speak on the drug, *id.* ¶ 157, and after he ceased speaking on *Starlix*, his prescription writing returned to his pre-honoraria levels, *id.*

- Dr. S.Z. was paid $1,000 to speak to one person about *Lotrel* at his office in October 2004 (with an additional $1,000 purportedly spent on food), *id.* ¶ 129; he was paid another $1,500 to speak about *Lotrel* at a sports bar with no private room in March 2007, *id.* ¶ 128; and his prescription writing for *Lotrel* more than doubled after he began to be paid to speak on the drug, *id.* ¶ 157.

- Dr. D.S.1 significantly increased his prescription writing for *Lotrel* between July 2006 and July 2007 when he received most of his speaker fees in connection with the drug ($27,100 out of $29,600), *id.* ¶ 157, and, within that 13-month period, "Dr. D.S.1 and [another] doctor were both paid honoraria, of $1,500 and $1,000, respectively, as the speakers at six events . . . [even though they] did not both speak at any event," *id.* ¶ 113. Although the Complaint does not specify the topics of these six events, two of them concerned *Lotrel* (the other four concerned Tekturna).

[4] The fact that Dr. T.M. was also identified as a recipient of kickbacks in a case that Novartis previously settled, Br. 18 n.12, 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.

- Similarly, Dr. B.A. substantially increased his prescription writing for *Lotrel* from March 2006 through April 2007 when he received most of his speaker fees in connection with the drug ($6,200 out of $6,750), *id.* ¶ 154, and, within that period, he was paid $500 to speak at a dinner that did not occur in a private room, at which no slides were presented, and where one of the attendees brought his girlfriend, *id.* ¶ 133. Although the Complaint does not specify the topic of this event, it was *Lotrel*.

Novartis's arguments as to the remaining four doctors (S.D.2, L.M., S.G. and C.V.S.) also lack merit. The Complaint alleges that, in the more than three years before Dr. S.D.2 began receiving honoraria in connection with Lotrel, he wrote an average of only 0.5 prescriptions per month for Lotrel, and during the approximately two years in which he then received honoraria, his average number of prescriptions per month increased by more than 115 times to 59.0. *Id.* ¶ 151. The Complaint further alleges that during the nine-month period in which Dr. S.D.2 received the bulk of his honoraria ($22,450 out of $30,200), his average prescriptions per month reached a high of 84.8. *Id.* The Complaint contains similar allegations as to Dr. L.M.[5] *See id.* ¶¶ 155-56. Such allegations plainly support a strong inference that these doctors were induced by honoraria to write prescriptions for the Covered Drugs.

Novartis's challenge to the final two doctors fails for their same reason that its challenge to the Covered Drugs other than Lotrel, Valturna and Starlix, Br. at 16-17, fails: it misapprehends the Government's theory. The remuneration received in connection with a speaker program was an inducement not just to prescribe the CV drug that was the subject of the particular program, but other CV drugs as well. Accordingly, the Complaint alleges that doctors who received kickbacks from Novartis in connection with particular drugs — such as Drs. S.G., C.V.S. and N.D., who received honoraria in connection with sham events on Lotrel, Valturna and/or Starlix, Compl. ¶¶ 100-03, 108-09, 117 — were induced to write prescriptions not only

[5] The Complaint also contains similar allegations as to the seven doctors referenced above. *See* Compl. ¶¶ 154, 157. For this reason alone, its allegations as to those doctors support a strong inference that they were induced by honoraria to write prescriptions for the Covered Drugs.

for those drugs but for Novartis drugs generally, *id.* ¶¶ 158, 174. The Complaint, moreover, provides examples to support this common-sense allegation. *See id.* ¶ 158 (alleging that Dr. N.D. "was more inclined to prescribe Diovan over comparable drugs in part because of his status as a speaker on Lotrel," that Dr. S.G.'s "participation in Novartis's speaker programs influenced his prescription writing," and that Dr. C.V.S.'s status "as a paid speaker for a pharmaceutical company increased the likelihood that he would prescribe that company's drugs"). These allegations are sufficient to support a strong inference that these doctors were induced by honoraria to write prescriptions for the Covered Drugs. They also provide adequate support for the Government's claims as to the Covered Drugs beyond Lotrel, Valturna and Starlix.

Novartis's two remaining causation arguments are similarly unavailing. *First*, Novartis argues that the Complaint is deficient because, of "the thirteen doctors for whom specific changes in prescribing histories are alleged, only three examples are provided for Valturna and only one for Starlix." Br. at 17. As an initial matter, because compliance with the AKS is a condition of payment, and because the Government is not required to identify specific claims at the pleading stage, *see infra*, the Government is not required to allege changes in prescribing histories to satisfy Rule 9(b). In any event, this breakdown is entirely logical, as Novartis held many more speaker programs — and paid much more in honoraria — in connection with Lotrel than the other drugs. *See* Compl. ¶ 71.

Second, Novartis argues that there is a "possibility that [the] doctors would have prescribed Novartis drugs even if they had not attended [the] allegedly sham events." Br. 21-22. To plead a violation of the FCA predicated on kickbacks, however, the Government need only allege that the sham events were intended to induce the doctors to write prescriptions for Novartis drugs, and that the doctors thereafter wrote prescriptions for Novartis drugs that were

paid for by a federal program. *See, e.g.*, *Simpson*, 2013 WL 4710587, at *13-14. There is no requirement that the Government plead the negative — that the prescriptions would not have been written absent the kickbacks — just as there is no requirement that the Government plead that the sole purpose of the kickbacks was to induce prescription writing, *see, e.g.*, *United States v. McLatchey*, 217 F.3d 823, 834-35 (10th Cir. 2000) (plaintiff need only show that "one purpose" of the kickback was to induce referrals).

D. The Complaint Provides Sufficient Illustrations of a Far-Reaching Scheme

Where the Government alleges a geographically and temporally wide-ranging fraudulent scheme, it can satisfy Rule 9(b)'s pleading requirements by providing illustrative examples of fraudulent conduct. *See, e.g.*, *United States ex rel. Bledsoe v. Cmty Health Sys.*, 501 F.3d 493, 510-11 (6th Cir. 2007); *United States v. Wells Fargo Bank, N.A.*, No. 12-7527, 2013 WL 5312564, at *16 (S.D.N.Y. Sept. 24, 2013); *In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318, 333 (D. Conn. 2004). A handful of examples will suffice so long as they are "sufficiently representative" of the broader scheme to give the defendant fair notice. *See Wells Fargo*, 2013 WL 5312564, at *16-17 (finding 10 examples of recklessly underwritten loans sufficient to support allegations of a scheme spanning more than five years).

Here, the Government's allegations are more than sufficient to support its claim of a wide-ranging kickback scheme spanning almost a decade. The Complaint identifies hundreds of sham speaker events that involved approximately 100 different doctors, occurred in 17 different states and the District of Columbia, and took place over the span of many years. *See* Compl. ¶¶ 97-144. The Complaint also specifically identifies 13 of those doctors, and shows that those doctors alone participated in over 100 sham speaker events in six different states in each of the following years: 2004, 2005, 2006, 2007, 2010 and 2011. *See id.* ¶¶ 97-98, 100-03, 108-09,

113, 115, 117-20, 127-29. In addition, the Complaint provides numerous examples of sham speaker events that suffered from each type of problem associated with the scheme: events with little or no medical discussion, *e.g.*, *id.* ¶¶ 107, 122, 129, 133; events with the same doctors allegedly attending the same presentation within a short time period, *e.g.*, *id.* ¶¶ 100-03, 111, 113, 118; events that were excessively expensive or held at inappropriate locations, *e.g., id.* ¶¶ 122-24, 130-32; and events that simply did not occur, *e.g.*, *id.* ¶¶ 139-40.

The Complaint thus satisfies the requirements of pleading a nationwide scheme. It includes "examples, drawn from throughout the time period the Government alleges the . . . scheme occurred, [which are representative] 'in all material respects, including general time frame, substantive content, and relation to the allegedly fraudulent scheme, . . . 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.'" *Wells Fargo*, 2013 WL 5312564, at *17 (quoting *Bledsoe*, 501 F.3d at 511).[6]

Novartis nonetheless suggests that the Government cannot satisfy Rule 9(b) unless it can establish that, "'by random draw' of all NPC speaker programs, [it could] pull out only shams, pull out only doctors who allegedly accepted kickbacks, or pull out only false claims." Br. at 20. Yet the Government is not required to demonstrate that all Novartis CV speaker programs were shams in order to satisfy Rule 9(b), nor does the Complaint allege that all such speaker programs were shams. As the Complaint alleges that a subset of Novartis speaker programs served as

[6] The cases Novartis cites rejecting efforts to plead by example are all readily distinguishable. *See, e.g.*, *United States v. Bank of N.Y. Mellon*, No. 11-6969, 2013 WL 1749418, at *30 (S.D.N.Y. Apr. 24, 2013) (finding allegations that misrepresentations were made to one group of clients insufficient to support claims that misrepresentations were made to an entirely different, and unrelated, group of clients); *United States ex rel. Thomas v. Bailey*, No. 06-0465, 2008 WL 4853630, at *6 (E.D. Ark. Nov. 6, 2008) (finding allegations of a nationwide scheme insufficient, because, among other things, the complaint included only five examples of improper conduct occurring in only three states, and identified false claims involving only two physicians).

fronts for kickbacks, the Government is only required to provide representative examples from this subset, *see, e.g.*, *Wells Fargo*, 2013 WL 5312564, at *17, which it has done.

Notwithstanding its challenge to the Government's pleading, Novartis concedes that the Government has identified allegedly sham speaker events "concerning different drugs, held at different time periods, in different cities and . . . on different topics with different alleged issues (for example, inappropriate venue versus lack of sufficient medical content)." Br. at 20. Such allegations are plainly representative, and are therefore sufficient.

III. PRE-2010 MEDICAID CLAIMS TAINTED BY KICKBACKS ARE ACTIONABLE UNDER THE FALSE CLAIMS ACT

The Complaint asserts claims against Novartis under former 31 U.S.C. § 3729(a)(1), as amended, which renders liable anyone who "knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval," and former section 3729(a)(2), as amended, which applies to 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."[7] Novartis argues that the Government cannot maintain an FCA action for Medicaid claims that were submitted prior to March 23, 2010, when the Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub.

[7] The FCA was amended in May 2009 by the Fraud Enforcement and Recovery Act of 2009 ("FERA"). Under the current version of the statute, any person who, *inter alia*, "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A) (2009), or who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," *id.* § 3729(a)(1)(B), is liable under the FCA. Although the May 2009 amendments are generally applicable only to conduct occurring on or after May 20, 2009, 31 U.S.C. § 3729(a)(1)(B), which replaced and amended former section 3729(a)(2), applies retroactively to all claims pending on or after June 7, 2008. Pub. L. 111-21, § 4(f)(1), 123 Stat. 1617, 1625 (2009); *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 267 n.1 (5th Cir. 2010).

L. No. 111-148, § 6402(f), 124 Stat. 119, amendments took effect. Br. at 23-24.[8]

The PPACA states that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g) (2010). Novartis concedes, as it must, that following the enactment of the PPACA, a claim resulting from a violation of the AKS constitutes a *per se* violation of the FCA. Br. at 23 n.13. Novartis nonetheless contends that, prior to the effective date of the PPACA, the Government must establish the "legal" falsity of any claim submitted in violation of the AKS, and that certifications from Medicaid providers are not sufficient to establish that compliance with the AKS was a precondition of payment under Medicaid prior to 2010. *Id.*

Novartis's argument is fundamentally flawed because the PPACA did not constitute a change in the law, but merely ratified existing case law that overwhelmingly held that claims resulting from illegal kickbacks are not eligible for payment under federal health care programs, including Medicaid. *See Westmoreland*, 812 F. Supp. 2d at 52-53. Furthermore, even if the Government was required to allege the legal falsity of Medicaid claims, it has done so here.

A. Claims Tainted by Kickbacks are Per Se Fraudulent and Therefore Actionable Under the FCA

The position put forth by Novartis that a claim can only be "false" within the meaning of the FCA if it falls within the categories of "legally" or "factually" false, Br. at 23-24, finds no support in either the language of the statute or in Second Circuit case law. To the contrary, Congress has made clear that the term "false or fraudulent claim" in the FCA should be construed broadly, S. Rep. No. 99-345, at 9 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5274, and the Second Circuit has held that a claim is "false" if it is "aimed at extracting money the

[8] Novartis's legal challenge is limited to Medicaid. Accordingly, Novartis has waived any legal challenge to the Government's causes of action with respect to claims submitted to Medicare, TRICARE or the VA.

government otherwise would not have paid." *Mikes v. Straus*, 274 F.3d 687, 696 (2d Cir. 2001).

The Second Circuit has recognized several species of false claims, including "factually false" claims, *i.e.*, those "which involve[] an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided," and "legally false" claims, which are predicated on a "false representation of compliance with a federal statute or regulation or a prescribed contractual term." *Id.* at 696-97. Furthermore, within the category of "legally false" claims, the Second Circuit has held that there can be both "express false certifications," which involve an explicit false certification of "compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment," *id.* at 698, and "implied false certifications," where "the act of submitting a claim for reimbursement itself implies compliance" with a precondition to payment, *id.* at 699.

But the Second Circuit never held that these are the *only* categories of false claims, and instead explicitly noted that "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.* at 697 (emphasis added) (quoting S. Rep. No. 99-345, at 9); *see United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 385-86 (1st Cir. 2011).

Accordingly, 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. *Compare United States ex rel. Marcus v. Hess*, 317 U.S. 537, 542 (1943) (collusive bid-rigging renders claims false under FCA); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 787-88 (4th Cir. 1999) (fraudulent inducement to enter contract renders subsequent claims false);

United States v. McLeod, 721 F.2d 282, 284 (9th Cir. 1983) (defendant liable under the FCA where he cashed erroneously issued check); *Murray & Sorenson v. United States*, 207 F.2d 119, 123-24 (1st Cir. 1953) (inflating bid based upon insider tip deemed fraudulent).

As discussed above, compliance with the AKS is a fundamental condition of payment under all federal health care programs, thus rendering any claims for goods or services tainted by kickbacks actionable under the FCA. *See, e.g.*, *Westmoreland*, 812 F. Supp. 2d at 54-55 (citing cases).[9] The prohibition against kickbacks is a core prerequisite for payment whose violation eviscerates the value of the service the Government has bargained for: an unbiased determination by a medical provider that a certain medical procedure, device, or drug is "reasonable and necessary" for the treatment of a patient. Indeed, it is axiomatic that the Government does not ordinarily pay for illegal goods, and the payment or receipt of kickbacks constitutes a felony. *Id.* at 55 ("[T]o submit such a claim for reimbursement is in effect to ask the government to fund criminality retroactively . . . ."). Just as lying to the Government to induce it to enter into a contract or engaging in collusive bid-rigging is inherently fraudulent, so too is paying bribes to physicians. *Cf. United States v. Stark*, 157 F.3d 833, 838 (11th Cir. 1998) ("[S]uch kickbacks are more clearly *malum in se* rather than *malum prohibitum*.").[10]

To obviate any doubt that claims tainted by kickbacks are "false" within the meaning of the FCA, Congress clarified this issue by enacting the PPACA. The legislative history of the PPACA "evinces Congress' intent to clarify, not alter, existing law that claims for payment made

---

[9] *See also United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 33 (D.D.C. 2003); *United States ex rel Pogue v. Diabetes Treatment Cntrs. of Am.*, 238 F. Supp. 2d 258, 263 (D.D.C. 2002); *United States ex rel Thompson v. Columbia HCA/Healthcare Corp.*, 20 F. Supp. 2d 1017, 1047-48 (S.D. Tex. 1999).

[10] For this same reason, claims tainted by kickbacks also fit within the rubric of factually false claims, as "the Government does not get what it bargained for when a defendant is paid by CMS for services tainted by a kickback." *See Wilkins*, 659 F.3d at 314.

pursuant to illegal kickbacks are false under the [FCA]." *Westmoreland*, 812 F. Supp. 2d at 52-53 (citing 155 Cong. Rec. S10852, S10853 (Sen. Kaufman)).[11]

B. Medicaid Claims Tainted by Kickbacks are Legally False

It is well-established that payment under the Medicaid program is conditioned upon both express and implied certifications of compliance with the AKS. *See, e.g., Wilkins*, 659 F.3d at 313; *United States ex rel. Lisitza v. Johnson & Johnson*, 765 F. Supp. 2d 112, 127-28 (D. Mass. 2011); *United States v. Health Alliance of Greater Cincinnati*, No. 03-00167, 2008 WL 5282139, at *12 (S.D. Ohio Dec. 18, 2008); *United States v. Rogan*, 459 F. Supp. 2d 692, 714 (N.D. Ill. 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008). Accordingly, Medicaid claims tainted by kickbacks are legally false within the meaning of *Mikes*, 274 F.3d at 696-99.

The Complaint alleges that reimbursement of Medicaid claims is expressly conditioned upon compliance with the AKS. As set forth in the Complaint, participants in state Medicaid programs must affirmatively sign enrollment agreements that certify compliance with state and federal Medicaid requirements generally, including the AKS. Compl. ¶ 42. The Complaint also alleges that Medicaid providers in many states must affirmatively certify, as a condition of payment for claims submitted to Medicaid for reimbursement, compliance with applicable federal and state laws and regulations. *Id.* ¶ 43. Such enrollment agreements and claim certifications suffice to establish that compliance with the AKS is an express condition of payment for federal health care programs. *See, e.g.*, *Hutcheson*, 647 F.3d at 392-94; *Mason v.*

[11] Novartis's argument that the PPACA is not retroactive, Br. at 24, is a red herring. In *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280 (2010), the Supreme Court addressed the retroactivity of PPACA's amendments to the public disclosure bar, and did not discuss the AKS provision. Moreover, because the PPACA's amendments to the AKS provision serve only to clarify existing law, it is inconsequential whether this provision is considered "retroactive" or not. *See, e.g.*, *Leshinsky v. Telvent GIT, S.A.*, 873 F. Supp. 2d 582, 590 (S.D.N.Y. 2012) ("when an amendment merely clarifies existing law, rather than effecting a substantive change to the law, then retroactivity concerns do not come into play" (citing cases)).

Medline Indus. Inc., 731 F. Supp. 2d 730, 738 (N.D. Ill. 2010); *United States ex rel. Jamison v. McKesson Corp*., No. 08-214, 2009 WL 3176168, at *12 (N.D. Miss. Sept. 29, 2009); *United States ex rel. Pogue v. Diabetes Treatment Cntrs of Am.*, 565 F. Supp. 2d 153, 159 (D.D.C. 2008); *Pogue*, 238 F. Supp. 2d at 264.

Novartis, ignoring the overwhelming authority to the contrary, nonetheless suggests that these Medicaid enrollment agreements and certifications are too general to form the basis for an express certification. Br. at 23-24. Courts routinely reject such arguments, however, and hold that certifications of compliance with generally applicable laws and regulations, such as those included in Medicaid enrollment agreements, suffice to establish an express certification of compliance. *See, e.g., United States ex rel. Schmidt v. Zimmer, Inc*., 386 F.3d 235, 243 (3d Cir. 2004); *Lisitza*, 765 F. Supp. 2d at 127-28.[12]

The Government has also adequately alleged that, because these claims for reimbursement were not eligible for payment, they were impliedly false under the standard set forth in *Mikes*. The *Mikes* court recognized that there can be an impliedly false certification under the FCA where an underlying statute or regulation expressly preconditions payment on compliance with its terms. *Mikes*, 274 F.3d at 700. Although it is not clear that this limitation on the use of the implied certification theory applies outside of the specific context in which

[12] Indeed, the principal case upon which Novartis relies, *United States ex rel. Conner v. Salina Regional Health Center, Inc*., 543 F.3d 1211 (10th Cir. 2008), explicitly reserved on the question of whether a general certification of compliance in a provider agreement could establish that compliance with the AKS constitutes a condition of payment. Taking note of the cases that answered this question in the affirmative, the *Conner* court observed that "some regulations or statutes may be so integral to the government's payment decision as to make any divide between conditions of participation and conditions of payment a 'distinction without a difference.'" *Id*. (citation omitted).

Mikes arose,[13] the Complaint nonetheless alleges that express statutory and regulatory language links the payment of Medicaid claims with compliance with the kickback laws.

First, the AKS itself recognizes that the presence of an illegal kickback bears directly on whether a claim should be paid by a federal health care program, as it makes it a crime to pay a kickback to induce a person to arrange for the purchase of an item "for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b). Thus, the AKS on its face links the prohibited activity to the payment of a claim. *Second*, the Complaint alleges that state regulatory regimes have conditioned payment of Medicaid claims on compliance with kickback laws. Compl. ¶ 41 (citing to New York regulations as an example). Such state regulations make clear that any claim tainted by a kickback contains an implied false certification. *See, e.g.*, *New York v. Amgen*, *Inc.*, 652 F.3d 103, 110-16 (1st Cir. 2011) (state regulations such as New York's sufficiently establish that compliance with kickback laws is a condition of payment).

IV. THE UNJUST ENRICHMENT CLAIM IS ADEQUATELY PLEAD

To prevail on its unjust enrichment claim, the Government need only show that Novartis obtained government money under circumstances where it would be unjust for Novartis to retain it. *See, e.g.*, *Hill v. Waxberg*, 237 F.2d 936, 939 (9th Cir. 1956); *see also Provident Life & Accident Ins. Co. v. Waller*, 906 F.2d 985, 993-94 (4th Cir. 1990); *United States ex rel. Trim v. McKean*, 31 F. Supp. 2d 1308, 1316 (W.D. Okla. 1998). The Government has alleged that

[13] *Mikes* was concerned with the use of the FCA to "federaliz[e] medical malpractice," by subjecting medical providers to fraud claims based upon the provision of negligent medical care. *Id.* at 698-700. Accordingly, at least one court in this district has noted that the *Mikes* court "restricted its holding" regarding the necessity of an express statutory or regulatory provision "to FCA claims brought against 'a medical provider.'" *United States ex rel. Feldman v. City of New York*, 808 F. Supp. 2d 641, 653 (S.D.N.Y. 2011); *cf. Hutcheson*, 647 F.3d at 388 (expressing doubt that the Second Circuit would extend *Mikes'* limitations on the use of an implied certification theory to a case involving AKS violations).

Novartis paid kickbacks to doctors that induced doctors to write prescriptions for its drugs, and that Novartis ultimately benefited at the expense of federal health care programs from those unlawfully induced prescriptions. *E.g.*, Compl. ¶¶ 1, 149-50, 192. Such allegations provide a sufficient basis for the Government's unjust enrichment claim.

Novartis asserts that the unjust enrichment claim fails if the Government's AKS and FCA claims are not sufficiently plead. Br. at 24. Yet the Government has adequately plead such violations. Further, the Government need not plead all the elements of violations of the AKS or FCA to pursue its claim for unjust enrichment, as these statutory causes of action are distinct from, and have different proof requirements than, the equitable remedy of unjust enrichment. *See, e.g.*, *United States ex rel. Roberts v. Aging Care Home Health, Inc.*, 474 F. Supp. 2d 810, 820-21 (W.D. La. 2007); *United States v. Rogan*, 459 F. Supp. 2d 692, 727-28 (N.D. Ill. 2006); *United States ex rel. Purcell v. MWI Corp.*, 254 F. Supp. 2d 69, 78 (D.D.C. 2003).

V. IF THE COURT DETERMINES THE COMPLAINT IS INADEQUATELY PLEAD, THE GOVERNMENT REQUESTS LEAVE TO AMEND

The Government respectfully requests that, in the event any of its claims are deemed deficient, the Government be given an opportunity to amend the Complaint to cure the deficiency. Rule 15(a)(2) provides that a court should "freely give leave [to amend] when justice so requires." "Complaints dismissed under Rule 9(b) are 'almost always' dismissed with leave to amend," *Luce v. Edelstein*, 802 F.2d 49, 56 (2d Cir. 1986), and dismissal of a complaint without granting an opportunity to plead fraud with greater specificity constitutes an abuse of discretion, *id.* at 57. Here, dismissal of the Government's claims with prejudice — without allowing the Government the benefit of the Court's rulings regarding the pleading requirements and after the Government addressed the concerns the Court previously raised at the pretrial conference — would be inappropriate given the liberal nature of Rule 15(a).

CONCLUSION

For the foregoing reasons, Defendant's motion to dismiss the Complaint should be denied.

Respectfully Submitted,

PREET BHARARA
UNITED STATES ATTORNEY

s/ Jeannette Vargas

Christopher B. Harwood
Jeannette A. Vargas
Assistant United States Attorneys
86 Chambers Street, 3rd Floor
New York, New York 10007
Telephone: (212) 637-2728/2748
Fax: (212) 637-2686
Email: jeannette.vargas@usdoj.gov
Email: Christopher.harwood@usdoj.gov