UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

x

UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSCHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WASHINGTON, and WISCONSIN; the DISTRICT OF COLUMBIA, THE CITY OF CHICAGO and THE CITY OF NEW YORK; *ex rel.*, CHARLES ARNSTEIN and HOSSAM SENOUSY,

Plaintiffs and Relators,

-against-

TEVA PHARMACEUTICALS USA, INC.; TEVA NEUROSCIENCE, INC.; and TEVA SALES AND MARKETING, INC.,

Defendants.

x

No. 13 Civ. 3702 (CM)

MEMORANDUM DECISION AND ORDER DENYING DEFENDANTS' MOTIONS TO DISMISS

McMahon, J.:

Plaintiff-relators Charles Arnstein and Hossam Senousy ("Relators") filed this *qui tam* action asserting claims arising under the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, and related state and local laws. The Defendants named in the complaint are Teva Pharmaceuticals USA, Inc. and two of its subsidiaries, Teva Neuroscience, Inc. and Teva Sales and Marketing, Inc. (collectively "Teva" or "Defendants"). Relators allege that Teva violated the FCA and the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), in connection with a kickback scheme.

Pending before the Court are the Defendants' motions to dismiss the Relators' Second Amended Complaint pursuant to Rules 12(b)(6) and 9(b) of the Federal Rules of Civil Procedure. For the reasons discussed below, those motions are denied. However, as was the case in a similar action before this court, *U.S. ex rel. Kester v. Novartis Pharm. Corp.*, No. 11 CIV. 8196, in which I disposed of multiple motions to dismiss on the same grounds argued here, Relators need to amend their complaint either to add specificity to their assertion that certain claims are false and fraudulent or drop those claims from this lawsuit. Relators have 30 days from the date of this Order to amend their complaint.

Relators' corresponding claims under state law (Counts II through XXXIII) will be stayed pending resolution of the federal claim; the motions to dismiss those claims are denied without prejudice to renewal.

BACKGROUND

The Parties

Pursuant to the False Claims Act ("FCA"), private persons known as "relators" may file *qui tam* actions and recover damages on behalf of the United States. *See* 31 U.S.C. § 3730(b). Plaintiffs Charles Arnstein and Hossam Senousy ("Relators") originally filed this FCA action in May 2013 on behalf of the United States, 29 states, and three cities.

The defendants, collectively "Teva," are three subsidiaries of Teva Pharmaceutical Industries, Ltd., an Israeli pharmaceutical company with a global footprint that develops, manufactures, markets and sells pharmaceutical products. (SAC ¶ 4.) Defendant Teva USA is a Pennsylvania corporation with its principal place of business in North Wales, Pennsylvania; it does business nationwide. (*Id.* at ¶ 5.) Defendant Teva Neuroscience is a division or operating unit of

Teva USA; it is headquartered in Overland Park, Kansas. (*Id.* at ¶¶ 6, 8.) Defendant Teva Sales and Marketing is another division or operating unit of Teva USA. It is headquartered in North Wales, Pennsylvania. (*Id.* at ¶¶ 7-8.)

The Relators are pharmaceutical sales representatives who were employees of Teva Neuroscience from 2002 and 2006, respectively, until January 1, 2014, when they – along with all other Teva Neuroscience employees – were transferred to Teva Sales and Marketing. (*Id.* at ¶¶ 7-8, 12-13.)

The Relators allege that the defendants are each other's alter egos or agents, and refer to all three defendants as a single entity. (*Id. passim.*)

The Relators filed a Second Amended Complaint ("SAC" or "Complaint") on November 26, 2014. (Docket #11.) They bring claims against Teva on behalf of the United States, 29 states, and three cities. The Relators assert a claim (Count 1) under two sections of the FCA: 31 U.S.C. § 3729(a)(1)(A) and 31 U.S.C. § 3729(a)(1)(B). They also assert claims (Counts 2-30) under 29 different state law analogues of the FCA, and three different local law analogues of the FCA (Counts 31-33).

The United States has declined to intervene and assume the prosecution of this case. A number of states and municipal corporations are named plaintiffs in this action; they, too, were offered the opportunity to intervene and take over the prosecution of claims brought under corresponding state and local laws that, while similar to the FCA, are not always identical to it. They, too, elected not to intervene, and none of them has appeared by its Attorney General or other legal representative. (*See* Docket #12).

The FCA outlaws the submission of a false or fraudulent "claim" for payment (*i.e.*, a request for reimbursement) to the government. *See* 31 U.S.C. § 3729(a)(1). Such claims may be

rendered "false" in a variety of ways. In this case, the Relator's FCA claims are predicated on underlying violations of the Anti-Kickback Statute ("AKS"). Under the AKS, it is illegal to offer a person "remuneration" (*i.e.*, kickbacks) in order to "induce" that person to "recommend" the purchase of a drug covered by a federal health care program. 42 U.S.C. § 1320a-7b(b)(2). It is likewise illegal to receive remuneration "in return for . . . recommending purchasing" such drugs. *Id.* at § 1320a-7b(b)(1).

Generally, the Relators allege that, from 2003 through the present, the defendants violated the AKS by bribing physicians through honoraria for sham speaker programs relating to the drugs Azilect and Copaxone ("the Drugs"), which treat serious neurological diseases. At the same time, defendants allegedly caused downstream pharmacies – which were dispensing Azilect and Copaxone, possibly because of physicians' bribe-addled judgment – to submit claims to federal, state and local healthcare programs for reimbursement of the cost of those drugs.

Relators allege that, by causing downstream entities to submit claims for reimbursement for Azilect and Copaxone while at the same time paying physicians to prescribe those drugs, Teva caused the government to pay "false" claims, in violation of federal, state and local false claims acts.

Relators further allege that, by failing to take its kickback payments into account when reporting its "Best Price" and "Average Manufacturer Price" to government healthcare programs, which reports were used to calculate rebates owed to the government and to make Teva drugs eligible for purchase by certain government entities, Teva itself submitted false claims.

The Second Amended Complaint

Copaxone and Azilect

Copaxone, approved by the FDA in 1996, is used to treat relapsing-remitting Multiple Sclerosis. (SAC ¶ 88.) Teva holds several patents relating to Copaxone. Most expired in May 2014; one will expire in September 2015. (*Id.*)

Copaxone's average annual cost for a Medicare or Medicaid patient is approximately $60,000. (*Id.*) With 40% of the market in its therapeutic class, Copaxone garnered $2.958 billion in sales for Teva in 2010, $3.570 billion in 2011, and $3,996 billion in 2012. (*Id.* ¶ 91.) It has led the market for its therapeutic class since 2008. (*Id.*)

Azilect, approved by the FDA in 2006, is used to treat symptoms of Parkinson's Disease. (SAC ¶ 89.) Teva has several patents relating to Azilect, which have expired or will expire between 2013 and 2027. (*Id.*)

Azilect's average annual cost for a Medicare or Medicaid patient is approximately $4,600. (*Id.*) The drug garnered $244 million in sales in 2010, $290 million in 2011, and $330 million in 2012. (*Id.* ¶ 92.)

Together, I will refer to Copaxone and Azilect as the "Drugs."

Plaintiffs allege that the Drugs' ever-increasing sales "are hardly a coincidence – they are the direct result of a pervasive illegal kickback scheme whereby," since 2006, "Teva paid physicians to write prescriptions for the . . . Drugs through an elaborate and widespread network of paid speaker programs." (*Id.* ¶¶ 94, 96.)

Speaker Programs

In the United States, between 250,000 and 300,000 people suffer from Multiple Sclerosis. (*Id.* ¶ 104.) Approximately 500,000 people in the United States suffer from Parkinson's Disease. (*Id.*)

To reach those patients' doctors, Teva Neuroscience employs approximately 200 pharmaceutical sales representatives, spread over three sales areas (West, Central, and East), which are divided into 22 "regions," and then subdivided into 112 "territories." (*Id.*) Each sales representative is assigned to devote his or her attention to between 50 and 80 healthcare providers, and will make an average of five "calls" on physicians' offices daily. (*Id.*)

In addition to making "calls" on physician offices, sales representatives arrange for "speaker programs." A common feature of the pharmaceutical sales industry, "Speaker programs enlist physicians, for pay, to speak to other physicians about FDA-approved drug use." *United States v. Caronia*, 703 F.3d 149, 156 (2d Cir. 2012).

In 2011, Teva representatives arranged at least 1,329 speaker programs for Azilect and Copaxone. (SAC ¶ 97.) In 2012, that number nearly quadrupled – to 5,036. (*Id.*) As of August 2013, approximately 4,600 programs had been completed or scheduled. (*Id.*)

During approximately the same time period, there were 420 "trained Copaxone speakers" – a term the Complaint does not define – and 410 "trained Azilect speakers." (*Id.* ¶ 97.) Some physicians were paid to speak at "speaker programs" several times per month. (*Id.*)

Honoraria Allegedly Dependent on the Number of Prescriptions Written by the Payee Physician

Teva paid more than $10 million annually to physicians for speaking about Azilect and Copaxone at speaker programs in 2012, 2013, and 2014. (*Id.* ¶ 97.) It pays physicians an

honorarium of between $1,500 and $2,700 for each speaker program. (*Id.* ¶ 96.) The average honorarium for a single speaker program is between $2,000 and $2,500.

Prior to 2011, Teva sales representatives were permitted to decide the amount of the honorarium, and delivered the payments in green envelopes, purportedly to emphasize the lucrative nature of serving as a speaker. (*Id.*)

Relators allege that Teva added paid speakers without completing needs-assessment or similar testing. (*Id.* ¶ 98.)

Instead, Teva allegedly added paid speakers on the basis of return on investment analysis. (*Id.*) The relevant "return" variable consisted of the number of prescriptions that the physician speaker - the one being paid the honorarium - wrote for the Drugs. (*Id.* ¶¶ 98, 152.)

Teva allegedly permits a physician to continue as a paid speaker only if he or she maintains or increases the number of prescriptions he or she writes for the relevant drug. (*Id.* ¶ 96.) If a speaker-physician failed to prescribe enough Copaxone or Azilect (what was "enough" is unclear from the SAC), then "Teva refused to give them any additional speaker programs, required them to undergo 'training' in order to be added back onto the [list of physicians from whom sales representatives could choose and pay speakers], and insisted that they write more prescriptions if they were to be included on the speakers' list for the following year." (*Id.* ¶ 108.)

The SAC provides two examples of physicians who were allegedly removed from the list of approved speakers because of their failure to increase their prescribing levels for the covered drugs. (*Id.* ¶¶ 144-145.) In one instance, Teva allegedly specifically advised a physician "that he would not be given any further speaking opportunities until he increased his Copaxone prescriptions." (*Id.* ¶ 145.) The SAC does not identify who at Teva sent that particular message.

The SAC provides the initials and locations of some 30 physicians situated throughout the United States who are allegedly complicit in the kickback scheme. (*Id.* ¶ 103.) Of these, one Detroit physician is a particularly prized speaker. He allegedly earns approximately $216,000 in honoraria per year, not including payments he receives from Teva for research and other consulting. (*Id.* ¶ 109.) Plaintiffs allege that Teva has gone so far as to remove that physician's name and other information from a website that tracks speakers, in order to shield him from scrutiny. (*Id.* ¶ 109.) Or perhaps his absence from the relevant database is the result of his having formed a limited liability corporation to insulate his name from scrutiny of just such payments. (*Id.*) In exchange for this largess and protection, the Detroit physician prescribes Copaxone for approximately 80% of the 5,000 patients at his clinic, meaning that he is personally responsible for $200 million of Copaxone sales annually. (*Id.*)

The SAC goes on to identify the number of claims reimbursed by Medicare Part D relating to prescriptions written by the Detroit physician as well as the 30 other physicians whose initials are used in the complaint, doing so by year. (*Id.* ¶ 110.) Those claims reach into the tens of millions of dollars. (*Id.*)

The Questionable Value of the Speaker Services Physicians Receive Honoraria to Perform

Next, Relators question the value of the speaker services that physicians provide.

Neither of the Drugs is new to the market, having been on the scene for 18 and 8 years respectively – "and there have been little, if any changes in the indications appropriate for" them. (*Id.* ¶ 100.) Teva allegedly "has not provided the sales force with any new materials to present at the programs in a number of years. Nevertheless, Teva continues to impress upon the sales force [the need] to set up more and more of these programs in order to drive the sales of the . . . Drugs." (*Id.* ¶ 150.)

The speaker programs include "Journal Clubs," in which the same "journal presentations" – I assume that plaintiffs are referring to presentations that reference articles in medical journals – "occurred again and again to the same attendees." (*Id.* ¶ 99.) More recently, the majority of Teva's speaker programs have been "Peer-to-Peer Programs" and "Patient Programs" that allegedly "had few to no attendees, lacked little, if any, educational value, discussed dated and/or redundant topics, were conducted by multiple speakers from the same medical groups, and were often attended by the same physicians, patients and their families." (*Id.* ¶ 100.)

There are not a large number of canned presentations: two for Copaxone and four for Azilect. (*Id.* ¶ 100.)

It is allegedly common for physicians to alternate between giving presentations and then attending the very same canned presentation as given by another physician – allegedly because it was well nigh impossible to convince any "non-corrupt" physician to attend the same presentation more than once. (*Id.* ¶ 101.)

The SAC provides several examples of allegedly sham programs, including one in which four physicians met monthly with one another and Teva sales representatives, and rotated the duty of giving a 15 minute presentation to each other on one of a set number of rote topics. The doctors were paid $1500 each time they presented. (*Id.* ¶ 112.) In a different "program" two physicians and two Teva employees sat down to dinner; no presentation was made and no new material discussed, but each physician received $2,000 for the "program." (*Id.* ¶ 113.) On another occasion, a physician sat down to dinner with a single Teva representative, presented no medical materials, and was paid $2,000. (*Id.* ¶ 114.) The Complaint provides several more examples of such generosity. (*Id.* ¶¶ 115-118.)

Teva's Efforts to Disguise the Kickback Scheme

Teva allegedly tried to "disguise the fact that the same presentations were being given against and again to the same attendees by (a) changing the titles of the programs slightly without changing the substance of the presentations, (b) changing the wording in the presentations without making any material substantive changes to the presentations, and (c) shuffling the 'slide deck' so that the presentation appeared somewhat different – even though the substance was the same." (*Id.* ¶ 100; *see also* ¶ 102 (describing the content of the presentations); ¶¶ 119-139 (offering many specific examples of speaker programs with no physician attendees, no educational content, and/or rotating speakers and attendees).)

But no one was fooling the attendees. Programs for Copaxone "typically attract the same patients and their family members, who are already familiar with Copaxone and . . . who will often leave once dinner is done but prior to the completion of the program." (*Id.* ¶ 143.)

Plaintiffs allege that Teva began to use speaker programs with more regularity in 2008 or 2009, when it became clear that a previous scheme to compensate physicians for prescribing Teva drugs was under scrutiny. Specifically, from approximately 2003 through 2008, Teva used "preceptorship" programs, "in which physicians were paid to allow a Teva sales representative to spend time observing their practice when, in fact, the sole purpose of the payments was to compensate physicians" for prescribing Teva drugs. (*Id.* ¶ 99.) Plaintiffs allege that Teva's paid speaker programs – as they have existed since approximately 2006 – are less blatantly fraudulent, but nonetheless are simply successors to those preceptorship programs. (*Id.*)

Teva Management's Role in Orchestrating and Promoting the Kickback Scheme

This pay-to-play scheme allegedly was the result of Teva management's express direction. (*Id.* ¶ 108.)

Teva's corporate policy allegedly encouraged the kickback scheme by, *inter alia*, "evaluat[ing] and reward[ing] the sales force based on the number of speaker programs" they arranged and completed – not on the quality of those programs. (*Id.* ¶ 149.)

Moreover, managers throughout Teva allegedly encouraged sales representatives to use honoraria to incentivize physicians to write more prescriptions, stating, *inter alia:*

- In January 2008: "We have committed as a group to try to use as many of the [speaker] programs as possible and develop our regional advocates [i.e., paid physician speakers] for outside programs." (*Id.* ¶ 147.)
- In September 2011: "AHMs [(speaker programs)], AHMS, AHMs – this is the closest thing I have to a silver bullet." (*Id.* ¶ 148.) "Invest wisely – who are your advocates? Who do you want to be your advocates?" (*Id.*)
- Intermittently, statements such as "I would like to see us [be the] #1 region in regards to using our programs." (*Id.* ¶ 149.)
- At a regional sales meeting in October 2013, an Area director stated that 80% of all Azilect prescriptions were then being written by Azilect paid speakers. (*Id.* ¶ 96.) He "stress[ed] the need to continue paying physicians to speak (since it results in the physicians themselves writing more prescriptions) . . . [and] reinforced Teva's intent to increase its use of payments to speakers as a way to drive even greater sales in 2014." (*Id.* ¶ 97.)

At the highest levels of management, Teva devised "Best Practices: Regional Approaches Seminar" – a seminar for sales associates – in which the "overarching message to Teva's leadership team [i.e., mid-level managers] was the more speaking opportunities you create to pay doctors, the

more prescriptions they will write for Teva, and the more financial rewards you will receive." (*Id.* ¶ 148.)

Effect on Prescribing Habits

The SAC alleges that "the fact that doctors were paid in connection with Teva's speaker programs influenced their prescription writing with respect to the Covered Drugs." (*Id.* ¶ 153.) In Exhibit A to the SAC, the Relators provide 89 examples of physicians whose prescription-writing increased as their receipt of honoraria increased. The Relators also allege that some doctors who were kicked out of the speaker programs for failure to write an adequate number of prescriptions took the hint, and increased their prescription writing to bring themselves back into the fold. (*Id.* ¶ 145).

Teva allegedly "caused many thousands of prescriptions to be written as a result of payments and/or other remuneration made in connection with speaker programs that were kickbacks to doctors. Teva paid tens of millions of dollars in kickbacks to physicians in the form of honoraria and/or other remuneration in connection with speaker programs concerning the Covered Drugs between 2006 and to date. On average each of these doctors wrote many hundreds of thousands of dollars' worth of prescriptions for the Covered Drugs that were paid for by the Government Healthcare Programs." (*Id.* ¶ 154.)

Kickback-Tainted Claims for Reimbursement

Generally, when a physician prescribes a drug, a patient is provided with a prescription, which is then filled at a pharmacy. (*Id.* ¶ 34.) The pharmacy then submits the claim for payment to the relevant Government Healthcare Program(s) for reimbursement. (*Id.*) For Copaxone in particular,

> TEVA generally first works with an MS patient to (a) establish coverage by a Government Healthcare Program or other insurance scheme, (b) ensure that the

> prescription is filled by a pharmacy (and delivered to the patient – usually by mail), and (c) provide training and instruction on how Copaxone should be self-administered by injection by the patient. Once the patient is able to self-administer the drug by way of injection, Copaxone prescriptions are then filled by traditional and other pharmacies.
>
> In certain circumstances, a Government Healthcare Program may also have pharmacy facilities that directly dispense prescription drugs. In such cases, the Government Healthcare Program purchases the drug directly rather than reimbursing the pharmacy.

(*Id.* ¶¶ 34-35.)

As explained in further detail below, Relators allege that certifications and attestations signed by those seeking reimbursement from certain government healthcare programs certified compliance with the federal Anti-Kickback Statute, and that the honoraria paid to physicians prescribing the Drugs rendered those certifications and attestations false. (*Id.* ¶ 158.)

Medicare Part D

Over 50% of all patients suffering from Parkinson's Disease are on Medicare. (*Id.* ¶ 86.) Approximately 25-30% of all patients suffering from Multiple Sclerosis are on Medicare. (*Id.* ¶ 85.)

Medicare beneficiaries receive prescription drug benefits through, *inter alia*, Part D of the Medicare Program, which, through The Centers for Medicare and Medicaid Services ("CMS"), contracts with private companies known as "Part D sponsors" in order to administer prescription drug plans. (*Id.* ¶ 36.)

In turn, Part D sponsors administer the prescription drug plans through subcontracts with a variety of pharmacies. (*Id.*) "Pharmacy benefit managers" or "PBM"s – who appear to work for the Part D sponsors – facilitate interactions between pharmacies and Part D sponsors. (*Id.* ¶¶ 37-38.)

When a pharmacy dispenses drugs to a Medicare beneficiary (pursuant to a physician's prescription), the pharmacy submits an electronic claim to the beneficiary's Part D sponsor. After the pharmacy submits the electronic claim, the Part D sponsor or its PBM will reimburse the pharmacy for the "gross drug cost" of the drug dispensed – the portion of the drug cost not paid by the beneficiary, the pharmacy's dispensing fee, and any applicable sales taxes. (*Id.* ¶ 37.)

Pursuant to CMS regulations, Part D plan sponsors must agree to comply with "Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. 3729 et seq.), and the *anti-kickback statute* (section 1128B(b) of the Act)." 42 C.F.R. § 423.505(h)(1) (emphasis added). Further, 42 C.F.R. § 423.505(i)(4)(iv) states: "Each and every contract must specify that the related entity, contractor, or subcontractor must comply with all applicable Federal laws, regulations, and CMS instructions."

The AKS is unquestionably one of the "applicable Federal laws" governing Medicare Part D that is cited in the contractor certification. CMS regulations specifically identify the AKS as one of the "Federal laws and regulations designed to prevent fraud, waste, and abuse" that apply to Medicare Part D. 42 C.F.R. § 423.505(h)(1). Moreover, the AKS itself states that it applies to any "Federal health care program," which includes Medicare Part D. 42 U.S.C. § 1320a–7b(f).

Accordingly, downstream entities who certify compliance "with all applicable Federal laws, regulations, and CMS instructions" certify compliance with the AKS. 42 C.F.R. § 423.505(i)(4)(iv).

In Exhibit A to their Complaint, Relators provide what they describe as a "representative sample of false claims tainted by kickbacks for which reimbursement was obtained from the Medicare Part D program in 2010 and 2011. . . based upon this sample . . . alone . . . Medicare Part

D . . . paid over $63 million dollars in claims that were tainted by Teva's paid-speaker scheme." (*Id.* ¶ 155.)

Exhibit A is a four-page spreadsheet listing more than 100 physicians, showing each physician's speaking engagements for Azilect or Copaxone in the years 2009, 2010, and 2011, and showing the number of Medicare Part D claims associated with each physician's prescriptions of the relevant drug during 2010 and 2011 (but not 2009). (Docket #13-2.) It shows that at least some physicians increased the number of prescriptions written for the relevant drug as their speaker engagements (and corresponding fees) increased.

Medicaid

Medicaid is a joint federal-state program that provides health care benefits for groups including the poor and disabled. (*Id.* ¶ 57.) Each state administers a state Medicaid program that includes reimbursement for prescription drugs. (*Id.*) The federal government provides a portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"). (*Id.* ¶ 58.)

The Relators' allegations regarding "false" certifications made in connection with Medicaid vary in their specificity.

The SAC identifies New York as an example of a state whose regulatory regime explicitly forbids payment to those claims resulting from "bribes and kickbacks." N.Y. Comp. Codes R. & Regs. Title 18 §§ 518.1(c), 515.2(b)(5); SAC ¶ 60. It implies that all states have such provisions. (*See* SAC ¶ 60.) In Counts 2-30, the Relators allege that each of the states named as co-plaintiffs have similar regulatory regimes, and that in each, compliance with an anti-kickback statute was an express condition of payment of claims. (*See id.* at, *e.g.*, ¶¶ 175, 187, 199.)

The SAC further alleges that "providers who participate in the Medicaid program must sign enrollment agreements with their states that certify compliance with the state and federal Medicaid requirements, including the AKS. Although there are variations among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies furnished." (SAC ¶ 61.)

Finally, the Relators allege that, "in many states, Medicaid providers, including both physicians and pharmacies, must affirmatively certify, as a condition of payment of the claims submitted for reimbursement by Medicaid, compliance with applicable federal and state laws and regulations." (SAC ¶ 62.) The Complaint cites nothing for that proposition, and only provides an exemplar certification from New York State.

TRICARE (formerly CHAMPUS)

TRICARE, formerly known as CHAMPUS, is part of the United States military's health care system. (*Id.* ¶ 64.) It is administered by the Department of Defense ("DOD"). (*Id.*) TRICARE provides prescription drug benefits through military treatment facility outpatient pharmacies, TRICARE network retail pharmacies, and TRICARE's mail order service. (*Id.* ¶ 65.) TRICARE contracts with a PBM to administer its retail and mail order pharmacy programs. (*Id.*) TRICARE beneficiaries can also pay for prescriptions out of their own pockets and then submit a claim for reimbursement to TRICARE's PBM. (*Id.*) The claims process differs for each program. (*Id.*)

Pursuant to 38 U.S.C. § 8126, pharmaceutical manufacturers are required to enter into national contracts with the DOD and to make certain drugs (I presume these to include Copaxone and Azilect) available to the DOD at the Federal Ceiling Price, which is defined as no more than 76% of the manufacturer's average price for the drug. 38 U.S.C. § 8126(a)(2). (SAC ¶ 69.)

All providers that offer services to TRICARE beneficiaries, whether network providers or non-participating providers, are required to comply with TRICARE's program requirements, including its anti-abuse provisions. Kickback arrangements are included within the definition of abusive situations that constitute program fraud. 32 C.F.R. §§ 199.2(b), 199.9(a)(4), 199.9(b), 199.9(c)(12). (SAC ¶ 72.)

Additionally, while any licensed and otherwise accredited physician may provide services to TRICARE beneficiaries, some enroll in the TRICARE program as participating providers. (*Id.*) Relators allege that participating providers must expressly certify their compliance with TRICARE regulations (*id.*), but point to no program requirement of any express certification, nor do they provide any sample express certification.

Veterans Administration Health Care

The Department of Veterans Affairs ("VA") maintains a system of medical facilities from which all pharmaceutical supplies, including prescription drugs, are procured directly by the VA. (*Id.* ¶ 73.) Pursuant to 38 U.S.C. § 8126, the VA purchases the pharmaceuticals that it dispenses at the Federal Ceiling Price. (*Id.* ¶ 74.) A VA facility that requires a particular medication submits a purchase order to the VA's pharmaceutical prime vendor ("PPV"), which fills the order for the facility, then submits an invoice to the VA for payment. (*Id.*)

Relators allege that Teva entered into a contract with the VA that requires Teva to comply with all applicable federal, state and local laws. (SAC ¶ 75.)

The Claims for Reimbursement Alleged to Be False

The SAC does not identify any particular claim that is alleged to be false. Instead, it identifies (in Exhibit A), the initials of 121 physicians who wrote prescriptions for the Drugs that caused downstream entities (*i.e.*, pharmacies) to submit claims to Medicare Part D for

reimbursement, which claims were submitted during a year that the physicians were receiving allegedly sham "honoraria" from Teva. Exhibit A provides the number of such claims for each physician, as well as the amount that Medicare Part D paid out for such claims during 2010 and 2011. It further provides a personal identifying number relating to each physician, and offers to provide each physician's full name if the court so instructs.

The SAC does not provide any equivalent to Exhibit A for Medicaid, TRICARE, or the VA healthcare system. Instead, it identifies the claims alleged to be false as claims listed in Exhibit A (which relates only to Medicare Part D) and "all other claims submitted to the Government Healthcare Programs for prescriptions written by these physicians for the Covered Drugs beginning from the time they began receiving honoraria payments or other remuneration and continuing to date, because the claims were the result of prescriptions induced by honoraria or other remuneration." (SAC ¶ 156.) It appears that the physicians listed in Exhibit A are not exhaustive of those who received honoraria, but are allegedly a "representative sample" of the same. (*Id.* ¶ 155.)

Pricing Violations

In addition to alleging that Teva's kickback scheme caused downstream entities' certifications to be "false," the Relators allege that Teva itself made false statements to government healthcare programs that wrongly enriched Teva at the public's expense.

Pharmaceutical manufacturers who wish to participate in various government healthcare programs, described below, are periodically required to report the "Average Manufacturer Price" ("AMP") for a drug, and also the "Best Price" ("BP") for a drug to various government entities.

Alleged Avoidance of Rebate Payments Owed to State Medicaid Programs Through Failure to Exclude Kickback Payments from Calculations of Teva's "Best Price" and "Average Manufacturer Price" for the Drugs.

First, pharmaceutical manufacturers participating in Medicaid programs must rebate to the States a certain statutorily prescribed portion of the price of the drugs purchased by each Medicaid program in each state. (*Id.* ¶ 76.) The amount of the rebate is calculated, in part, using the pharmaceutical manufacturer's report of its BP and AMP. (*Id.* ¶ 77.) Thus, to participate in Medicaid, Teva entered into rebate agreements with the Department of Health and Human Services ("HHS"), in which it agreed to comply with 42 U.S.C. § 1396r-8, and therefore:

a. Agreed to report its Best Price, inclusive of cash discounts, free goods contingent upon any purchase requirements, volume discounts and rebates, etc.;

b. Agreed that it would determine its Best Price based upon its AMP, calculated as "net sales divided by numbers of units sold, excluding free goods (*i.e.*, drugs or any other items given away, but not contingent on any purchase requirements)" and that it would include in the calculation, cash discounts and all other price reductions "which would reduce the actual price paid"; and

c. Agreed that the Best Price would not take into account nominal prices, defined as prices that are less than 10% of the AMP in that quarter, so long as the sale of product at a nominal price was not contingent on any other sale.

(*Id.* ¶ 78.)

Teva made quarterly reports of its AMP and/or BP to the Medicaid Program in an electronic form, Form CMS-367. (*Id.* ¶ 79.)

The Relators allege that, when reporting its Best Price on Form CMS-367 over the last six years, Teva failed to take into account the kickbacks it paid – thereby artificially inflating its Best

Price. (*Id.* ¶ 81.) That inflation of its Best Price allegedly reduced the rebate amount that Teva paid to each State Medicaid program. (*Id.*)

The SAC does not include examples of any CMS-367 form, but I take it that the Relators wish to pursue claims based on each and every allegedly undersized rebate Teva paid to State Medicaid programs based on the allegedly inaccurate CMS-367 forms submitted in the six years prior to the filing of the SAC.

The Veterans Healthcare Act

The Federal Supply Schedule ("FSS") is a price list containing more than 20,000 pharmaceutical products; the VA and other government healthcare programs depend on the FSS for most of their drug purchases. (*Id.* ¶ 83.) For a drug to be listed on the FSS, and therefore available for purchase by the patients who use the VA and other government healthcare programs, the drug's manufacturer is "required to enter a pricing agreement with HHS for the section 340B Drug Pricing Program, and with the VA and other DOD programs." (*Id.* ¶ 82.) The SAC does not define "the section 340B Drug Pricing Program."

Under the Veterans Healthcare Act of 1992 ("VHCA"), drug manufacturers must comply with 38 U.S.C. § 8126, which is entitled "Limitation on prices of drugs procured by Department and certain other Federal agencies." Subsection (a)(2) of that Section requires that "the price charged during the one-year period beginning on the date on which the agreement takes effect may not exceed 76% of the non-Federal average manufacturer price (less the amount of any additional discount required under subsection (c)) . . ." (*Id.* ¶ 84.)

Subsection (4) of § 8126 provides that,

> **unless the manufacturer meets the requirements of paragraphs (1), (2), and (3), the manufacturer may not receive payment** for the purchase of drugs or biologicals from (A) a State plan under title XIX of the Social Security Act, except as authorized under section 1927(a)(3) of such Act,

> (B) any Federal agency described in subsection (b) [i.e., the VA, the Department of Defense, the Public Health Service, including the Indian Health Service, and the Coast Guard];
> (C) any entity that receives funds under the Public Health Service Act.

38 U.S.C. § 8126(4) (emphasis added).

The Relators appear to argue that, by artificially inflating its Average Manufacturer Price with the cost of its kickback scheme, Teva failed to comply with the requirement that Azilect and Copaxone's pricing for the relevant government agencies "not exceed 76% of the non-Federal average manufacturer price" and therefore made it ineligible to "receive payment for the purchase of drugs" from the government entities referenced in Subsection (4). (SAC ¶ 84.)

The Relators' Causes of Action

Count 1 asserts that Teva violated two FCA subsections by: (a) "knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A); and (b) "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to a false or fraudulent claim," *id.* § 3729(a)(1)(B). That Count relates to two broad theories: (1) that Teva's kickback scheme tainted downstream entities' express and/or implied certifications of compliance with the anti-kickback statute, or that Teva's kickback scheme rendered downstream claims for reimbursement false regardless of whether there was an express or implied certification; and (2) that Teva itself made false claims by failing to account for its kickback payments when reporting the Drugs' respective "Best Prices" to various government healthcare programs – where accurate reporting was required for it to receive any payments at all under 38 U.S.C. § 8126(4), and inaccurate reporting permitted it to avoid paying the full rebates it allegedly owed to State Medicaid programs.

The Relator also asserts claims (Counts 2-30) under 29 state analogues of the FCA, and claims (Counts 31-33) under three local analogues of the FCA. These state and local claims pertain to claims for repayment submitted to state and local Medicaid programs.

Procedural History

The seal on this matter was lifted on March 12, 2015, after the United States government, state governments and local governments all declined to intervene. (Docket #22.)

Teva filed the present motions to dismiss the action under Federal Rules of Civil Procedure 9(b) and 12(b)(6) on June 5, 2015.

In addition to briefing by Teva and the Relators, this Court received a "Statement of Interest" from the United States, in which the United States disputed Teva's positions on two points of law relevant to the motion. (Docket #43.) Teva objects to the Court's consideration of such a Statement of Interest in light of the United States' decision not to intervene. (*See* Docket #44.)

The Court has reviewed the statement of interest, but is of the mind that Relators are masters of their complaint and control what issues will and will not be pursued here. If the United States wished to pursue issues the Relators are not intending on pursuing, it should have intervened. I will not force Relators to make arguments that they did not intend on making.

DISCUSSION

I. Standard of Review

In deciding a motion to dismiss pursuant to Rule 12(b)(6), the Court must liberally construe all claims, accept all factual allegations in the complaint as true, and draw all reasonable inferences

in favor of the plaintiff. *See Cargo Partner AG v. Albatrans, Inc.*, 352 F.3d 41, 44 (2d Cir. 2003); *see also Roth v. Jennings*, 489 F.3d 499, 510 (2d Cir. 2007).

However, to survive a motion to dismiss pursuant to Rule 12(b)(6), "a complaint must contain sufficient factual matter . . . to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (internal quotations, citations, and alterations omitted). Thus, unless a plaintiff's well-pleaded allegations have "nudged [its] claims across the line from conceivable to plausible, [the plaintiff's] complaint must be dismissed." *Id.* at 570; *see also Iqbal*, 556 U.S. at 680.

This liberal pleading standard is modified by Rule 9(b), which requires a plaintiff asserting fraud claims to meet a heightened pleading standard. While Rule 8(a) usually requires only a "short and plain statement of the claim showing that the pleader is entitled to relief," Fed. R. Civ. P. 8(a), a plaintiff asserting fraud must "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Rule 9(b) applies to claims brought under the FCA and its state law analogues. *See Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1476-77 (2d Cir. 1995); *U.S. ex rel. Polansky v. Pfizer, Inc.*, No. 04 Civ. 704, 2009 WL 1456582, at *4 (E.D.N.Y. May 22, 2009).

II. The Relators Have Pled Their Claims with Sufficient Particularity.[1]

A. The Complaint Sufficiently Alleges the Relationship Among the Defendants and the Role of Each in the Alleged Kickback Scheme.

First, Defendants argue that the SAC's refusal to differentiate between them – instead referring to all three defendants collectively as "Teva" – violates Federal Rule of Civil Procedure 9(b). (Docket #33 at 9 (citing, *e.g.*, *Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1175 (2d Cir. 1993).)

"Rule 9(b) is not satisfied where the complaint vaguely attributes the alleged fraudulent [acts] to 'defendants.' " *Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1175 (2d Cir. 1993). Thus, "Where multiple defendants are asked to respond to allegations of fraud, the complaint should inform each defendant of the nature of his alleged participation in the fraud." *DiVittorio v. Equidyne Extractive Indus.*, 822 F.2d 1242, 1247 (2d Cir. 1987). The Relators contend that the SAC does just that – by alleging that each defendant "participated" insofar as each is an agent and alter ego of the other, that all operated as a single joint entity and integrated enterprise, and that, therefore, the act of one is attributable to all. (SAC ¶-8.)

Where a complaint alleges a legal relationship between fraud defendants that makes the acts of one attributable to each, "Rule 9(b) does not require Plaintiffs to allege a "specific connection between fraudulent representations . . . and particular defendants . . ." *Id.* (quoting *Luce v. Edelstein,* 802 F.2d 49, 55 (2d Cir. 1986)) (discussing "insiders and affiliates" who all participated in alleged fraud).

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[1] In addition to the two arguments discussed below, Defendants' opening 9(b) memorandum briefly complains that the Relators have failed to identify certifications by physicians themselves. (Docket #33 at 17.) This contention has no merit. Defendants flesh out this argument further in their 12(b)(6) memoranda, (*see* Docket # 31 at 8-9, Docket #38 at 3-4), and I therefore address (and reject) it in greater detail below. *See infra* at 45-48.

"[A] bare allegation of an individual defendant's affiliation with entities allegedly committing fraudulent acts is not enough to satisfy Rule 9(b)." *Angermeir v. Cohen*, 14 F. Supp. 3d 134, 147 (S.D.N.Y. 2014). Thus, "Although it is a well-established principle that '[t]he fraudulent statements of an agent, when made within the scope of its agency, are attributable to the principal'," a complaint sounding in fraud against multiple defendants on an agency theory still must "plead . . . facts supporting the existence of an agency relationship . . ." *Woods v. Maytag Co.*, 807 F. Supp. 2d 112, 121 (E.D.N.Y. 2011) (quoting *Aetna Cas. & Sur. Co. v. Aniero Concrete Co.*, 404 F.3d 566, 581 (2d Cir. 2005)). So too, a naked allegation that one defendant was an "affiliate" of another defendant "alone is insufficient to link [the defendant] to [the alleged fraud]" for purposes of Rule 9(b). *Ouaknine v. MacFarlane,* 897 F.2d 75, 80 (2d Cir. 1990).

However, as for the Relators' allegation that the defendants are each others' alter egos, "Whether Fed. R. Civ. P. 9(b) applies to veil-piercing claims has been characterized as a 'knotty question.'" *United Feature Syndicate, Inc. v. Miller Features Syndicate, Inc.,* 216 F.Supp.2d 198, 222–23 (S.D.N.Y.2002) (quoting *Farley v. Davis,* 1992 WL 110753, at *6 (S.D.N.Y. May 8, 1992)). A "veil-piercing claim [that] rests on allegations of fraud" is required to satisfy the requirements of Rule 9(b). *Id.* (citing cases). However, "Rule 9(b) does not come into play where fraud is not" the basis of a claim for piercing the corporate veil. *Network Enters., Inc. v. APBA Offshore Prods., Inc.,* 2002 WL 31050846, at *5 (S.D.N.Y. Sept. 12, 2002); *see also Dist. Council No. 9 v. APC Painting, Inc.*, 272 F. Supp. 2d 229, 241 (S.D.N.Y. 2003).

Here, the alleged fraud is the filing of false claims, not the affiliation among the named defendants. As a result, the Rule 8 pleading standard, not the heightened standard of Rule 9(b), applies.

Under Rule 8(a), I must determine if the complaint contains "sufficient factual matter," which, if accepted as true, makes allegations regarding an agency, joint enterprise, or alter ego relationship that are "plausible on [their] face." *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544, 570 (2007). "Threadbare recitals of the elements of a clause" or "labels and conclusions" do not suffice. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Where "the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct," a complaint is insufficient under Fed. R. Civ. P. 8(a) because it fails to "show . . . that the pleader is entitled to relief." *Id.* at 679.

Defendants' opening memorandum does not challenge the sufficiency of the Relators' allegations regarding the relationships between them. In their reply brief, Defendants argue that the SAC contains nothing more than a "cursory, kitchen sink-like list of alternative possible legal relationships between Defendants." (Docket #39 at 3 (citing SAC ¶ 8)).

Even if that objection were timely, it is inaccurate. The SAC alleges the following regarding the relationship between the three defendants, Teva USA, Teva Neuroscience, and Teva Sales and Marketing:

- All three defendants are subsidiaries of non-party Teva Pharmaceutical Industries, Ltd., an Israeli corporation with a global footprint. (SAC ¶ 4.)
- Teva USA is a Pennsylvania corporation that does business throughout the United States. (SAC ¶ 5.)
- "Defendant Teva Neuroscience is a division or operating unit of [defendant] Teva USA." (SAC ¶ 6.)
- "Teva Sales and Marketing is a new legal entity created at the direction of Teva USA and also is a division of Teva USA. Effective January 1, 2014, all Teva

Neuroscience employees [including the Relators] were transferred to Teva Sales and Marketing." (SAC ¶ 7.)

- The Relators "are currently considered to be employees of Teva Sales and Marketing and take direction from Teva Sales and Marketing [yet] . . . are compensated and have their expenses paid by Teva Neuroscience in its capacity as an operating unit of Teva USA." (SAC ¶ 7.)
- "At all pertinent times, Teva USA controlled, directed and supervised the sales and marketing activities of Teva Neuroscience and Teva Sales and Marketing, as well as their employees . . ." (SAC ¶ 8.)
- "At all pertinent times, the employee and labor relations, as well as the compensation and benefit activities and the sales and marketing policies and procedures of TEVA have operated from and through the centralized control of Teva USA, which has established employee and labor relations, compensation and benefits and sales and marketing policies and procedures for Teva Neuroscience and Teva Sales and Marketing." (SAC ¶ 8.)

Thus, the Relators have pleaded that the two entities that have employed them – Teva Neuroscience ("TN") and Teva Sales and Marketing ("TSM") – both function at the behest of Teva USA ("TUSA"). The Relators currently work for TSM yet are paid and reimbursed by TN (presumably including reimbursements for expenditures on speaker programs), and allege that the very sales and marketing policies that create the alleged kickback scheme, and the compensation policies that reinforce them (*i.e.*, rewarding sales representatives based, in part, on the number of speaker programs orchestrated), are created and controlled by TUSA.

These allegations are sufficient to satisfy the liberal notice pleading standard of rule 8(a).

B. The Relators Have Sufficiently Identified the False Claims at Issue.

Next, the defendants argue that the SAC fails to identify the "sine qua non" of a False Claims Act action: the false claims. *U.S. ex rel. Bilotta v. Novartis Pharm. Corp.*, 50 F. Supp. 3d 497, 510-11 (S.D.N.Y. 2014) (quoting *United States ex rel. Clausen v. Laboratory Corporation of America, Inc.*, 290 F.3d 1301, 1311 (11th Cir.2002) (emphasis in original)).

The FCA "was enacted in 1863 with the principal goal of stopping the massive frauds perpetrated by large [private] contractors during the Civil War." *Vt. Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 781 (2000). "[T]he statute attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the 'claim for payment.' " *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995). "Underlying schemes and other wrongful activities that result in the submission of fraudulent claims are included in the 'circumstances constituting fraud or mistake' that must be pled with particularity pursuant to Rule 9(b). However, such pleadings invariably are 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." *U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir. 2004); *see also Polansky*, 2009 WL 1456582, at *5 (collecting cases). "As such, Rule 9(b)'s directive that 'the circumstances constituting fraud or mistake shall be stated with particularity' does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government.... [I]f Rule 9(b) is to be adhered to, some indicia of reliability must be given

in the complaint to support the allegation of an *actual false claim* for payment being made to the Government." *Bilotta,* 50 F. Supp. 3d at 510 (quoting *Clausen*, 290 F.3d at 1311).

"In line with the weight of authority in this Circuit," this Court already has "adopt[ed] the *Karvelas* standard—plaintiffs asserting subsection (a)(1)(A) and (a)(1)(B) claims must plead the submission of a false claim with a high enough degree of particularity that defendants can reasonably 'identify particular false claims for payment that were submitted to the government.' " *U.S. ex rel. Kester v. Novartis Pharm. Corp.,* 23 F. Supp. 3d 242, 257-58 (S.D.N.Y. 2014) ("*Novartis I*") (quoting *Karvelas,* 360 F.3d at 232). Thus, "the plaintiff must provide a detailed factual basis to support his allegation that the defendant submitted a false claim in this specific instance, not just that the defendant had a custom of submitting claims." *Id.*, 23 at 255 (emphasis in original). This specificity must "provide the defendant with enough details to be able to reasonably discern which of the claims it submitted are at issue." *Id.* at 258.

This Court has cited *Karvelas* with respect to the "kind of identifying information that a plaintiff can provide in order to satisfy Rule 9(b)," which includes "dates of claims, contents of claims, identification numbers, reimbursement amounts, goods or services provided, and individuals involved in the billing." *Novartis I*, 23 F. Supp. 3d at 258. In *Karvelas*, the First Circuit held that "a relator must provide details," which, although not a formulaic list, could include "the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices." *Karvelas*, 360 F.3d at 233. As this Court has recognized, "In the health care fraud context, courts also note the usefulness of data such as the name of the patient who received the good or service,

the name of the medical professional who provided the good or service, the date on which the good or service was delivered, the name of the employee who submitted the claim, and the government entity that reimbursed the claim." *Novartis I*, 23 F. Supp. 3d at 258. For complaints alleging extensive schemes, plaintiffs may satisfy these requirements in two ways: (1) by providing sufficient identifying information about all the false claims; or (2) by providing examples of specific false claims. *Id.* at 258.

Defendants argue that the Relators have failed to provide either examples of specific false claims or sufficient identifying information about all the false claims. In this, they argue that, "To the extent any effort is made in the SAC to specify false claims, it is in Paragraph 110 and Exhibit A," and complain that those portions of the SAC "merely set forth, in summary fashion, the number of 'Medicare Part D Claims for Drug' and cost of total 'Medicare Reimbursement' for 2010 and 2011 for each identified practitioner." (Docket #33 at 15.) Thus, the defendants argue, "This case is fundamentally different from *Novartis I*, where the government alleged that 'every single claim' for certain drugs submitted during a particular time period involved a kickback and was therefore false." *Id.* (quoting *Novartis I*, 23 F. Supp. 3d at 265).

Actually, this case is more similar to the Novartis case than the Defendants care to admit. In *Novartis I*, the United States Government, which had intervened and taken over prosecution of the action, did not identify any particular claim that was allegedly false. 23 F. Supp. 3d at 250. Rather, the Government alleged that every claim in a few "narrowly defined pools" was false. The complaint defined those pools as claims (1) for two specific drugs, (2) that were submitted by certain identified pharmacies to certain government programs, (3) during a specified time period. *Id.* at 265. The pleading was held to be sufficient under Rule 9(b).

Here, Relators have alleged that all claims in a similarly defined pool are false. The pool is comprised of all claims for reimbursement (1) relating to prescriptions of Copaxone and Azilect, (2) prescribed by doctors who participated in the allegedly "sham" speaker programs, (3) that were submitted for reimbursement to certain specified government programs, (4) from 2003[2] to the present. Relators have even identified some 30 doctors who participated in the speaker programs (SAC ¶ 103), as well as 121 speaker program participants whose prescriptions of the Drugs resulted in claims to Medicare Part D (*see* SAC Ex. A), thereby further refining the second prong of the definition.[3] Claims alleged to be false as part of that pool include claims submitted for reimbursement to four federal programs – Medicare, Medicaid, TRICARE, and the VA. There are also claims for pricing violations of the FCA, which Relators bring on the ground that Teva falsely certified information about Best Price and Average Manufacturer Price for Copaxone and Azilect.

All in all, Relators have pleaded "the submission of a false claim with a high enough degree of particularity that defendants can reasonably identify particular false claims for payment that were submitted to the government." *Novartis I,* 23 F. Supp. at 258 (internal quotation marks and citation omitted). The information in the Amended Complaint sufficiently alleges that Teva caused false claims for reimbursement related to Copaxone and Azilect to be submitted to the government. As I held in *U.S. ex rel. Kester v. Novartis Pharm. Corp.*, No. 11 CIV. 8196 CM, 2015 WL 109934, (S.D.N.Y. Jan. 6, 2015) ("*Novartis VII*"), Relators need not submit sample claims for *each government program* on behalf of which they have brought suit. *Id.* at 23. Providing sample claim information for one program with respect to the drugs at issue is a

[2] Relators allege that Teva has knowingly and willfully violated the FCA "from 2003 to the present" (SAC ¶ 163), though they note that sham speaker programs became more prevalent in 2008 and 2009 (SAC ¶ 99).

[3] These lists do not purport to be exhaustive; there may come a time when they will be deemed exhaustive, however.

sufficient basis for the Court to infer that similar claims were submitted to the other named government programs. "Such a[n] assumption does not expose the … defendants to baseless or speculative fraud allegations – the problem Rule 9(b) is intended to protect against." *Id.* at *24.

Thus, the allegations in the Complaint provide a basis for the allegation that false claims were actually submitted to the government programs named in the Complaint and are sufficient for Teva to identify those false claims. Teva's motion to dismiss the Complaint for failure to sufficiently identify the false claims at issue is denied.

III. The Relators Have Sufficiently Alleged a Plausible Kickback Scheme in Violation of the AKS.

A. The Scheme Generally

"Because the False Claims Act is an anti-fraud statute, 'claims brought under the FCA fall within the express scope of Rule 9(b).'" *United States v. New York Soc. for the Relief of the Ruptured & Crippled, Maintaining the Hosp. for Special Surgery*, No. 07 civ. 292 (PKC), 2014 WL 3905742, at *7 (S.D.N.Y. Aug. 7, 2014) (quoting *Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1477 (2d Cir. 1995)). "Rule 9(b) does not impose a 'one size fits all' list of facts that must be included in every FCA complaint." *Novartis I*, 23 F. Supp. 3d at 258 (quoting *In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318, 337-38 (D. Conn. 2004)). "Ultimately, whether a complaint satisfies Rule 9(b) 'depends upon the nature of the case, the complexity or simplicity of the transaction or occurrence, the relationship of the parties and the determination of how much circumstantial detail is necessary to give notice to the adverse party and enable him to prepare a responsive pleading.'" *Id.* (quoting *United States v. Wells Fargo Bank, N.A.*, 972 F. Supp. 2d 593, 616 (S.D.N.Y. 2013)). This "is a fact-specific inquiry." *Id.*

Where an FCA claim is premised on violations of the anti-kickback statute, plaintiff must "plead with particularity the 'who, what, when, where and how' of the fraudulent . . . scheme."

U.S. ex rel. Mooney v. Americare, Inc., No. 06 Civ. 1806, 2013 WL 1346022 (E.D.N.Y. Apr. 3, 2013).

"The [federal Anti–Kickback Statute] makes it illegal to 'knowingly and willfully offer[ ] or pay[ ] any remuneration (including any kickback, bribe, or rebate) . . . to any person to induce such person' to 'purchase or ... recommend purchasing' a drug that is covered by a federal health care program." *Novartis I*, 23 F.Supp.3d at 262 (quoting 42 U.S.C. § 1320a–7b(b)(2)). "The [Statute] defines 'remuneration' as including 'transfers of items or services for free or for other than fair market value.' " *U.S. ex rel. Fair Lab. Practices Assocs. v. Quest Diagnostics Inc.*, No. 05 Civ. 5393 (RPP), 2011 WL 1330542, at *2 (S.D.N.Y. Apr. 5, 2011), *aff'd sub nom.*, *United States v. Quest Diagnostics Inc.*, 734 F.3d 154 (2d Cir. 2013) (quoting 42 U.S.C. § 1320a–7a(i)(6)). "[T]he AKS [also] outlaws 'knowingly and willfully solicit[ing] or receiv[ing] any remuneration (including any kickback, bribe, or rebate)' 'in return for purchasing ... or recommending purchasing' a drug covered by a federal health care program." *Novartis I*, 23 F.Supp.3d at 262 (quoting 42 U.S.C. § 1320a–7b(b)(1)). "Thus, the AKS forbids offering, paying, soliciting, or receiving kickbacks in exchange for recommending drugs covered by [federal health care programs]." *Id.*

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

Relators – who were themselves pharmaceutical sales representatives at Teva – have alleged that the most important sales tool available to them was the capacity to purchase doctors' loyalty by offering them "honoraria" for speaker programs that have plausibly been alleged to be shams.

Their allegations are strikingly similar to those in a complaint Judge Gardephe found sufficient under Rule 9(b) in *U.S. ex rel Bilotta v. Novartis Pharmaceuticals Corp.*, 50 F. Supp. 3d 497 (S.D.N.Y. Sept. 30, 2014). In that case, Novartis allegedly

> hosted lavish events that—while ostensibly intended to "educate" attendees about Novartis cardiovascular division drugs—actually provided little to no information about the drugs. Instead, the events constituted upscale, all-expense paid social outings for the doctors, as evidenced by the fact that (1) Novartis sales representatives repeatedly invited the same participants and "speakers" to attend events concerning the same drug or topic in a short span of time; (2) Novartis spent exorbitant amounts of money on these events, both at the macro level and at the individual event level; (3) doctors were paid thousands of dollars to "speak" at these events, even when Novartis drugs were not discussed or the events did not take place; . . .

Id. at 515.

So too here. As alleged, the speaker programs – while educational in some abstract sense – were not educational for anyone providing or attending the programs, in that they offered no new content, and were given to the same attendees repeatedly – even sometimes given to no one at all outside of Teva itself.

As in *Bilotta*, physicians were continually recruited to be speakers and therefore receive generous honoraria even though allegedly Teva did no needs-assessment or similar analyses of whether it needed any more speakers to be able to staff its presentations, though it is easy to see why: it apparently had trouble finding *attendees*. *See id.*

Furthermore, as in *Bilotta*, the ability to make thousands of dollars in honoraria was allegedly contingent on the number of prescriptions that the physician-speaker wrote. *See id.*

B. There is no Requirement that the Bribes Be "But-for" Causes of Prescriptions

Defendants argue that the SAC fails to state a claim for a violation of the AKS in that it fails to "allege a factual nexus between the improper conduct and the resulting submission of a

false claim to the government." (Docket #33 at 10 (quoting *Johnson v. Univ. of Rochester Med. Ctr.*, 686 F. Supp. 2d 259, 266 (W.D.N.Y. 2010).) In other words, Teva asks the Court to dismiss this suit unless the plaintiffs plead facts sufficient to support the inference that the physicians would not have prescribed the drugs "but for" the fact that they were being paid pursuant to the sham speaker scheme. (*Id.*)

As this Court has already found, however, "the AKS does not require a kick-back scheme to succeed in generating new business (*i.e.*, new patient prescriptions) in order for a violation to have occurred." *Novartis I* at 263. Indeed, I have expressly rejected the argument that the AKS contains a "but for" causation requirement on a claim-by-claim basis. *See U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 41 F. Supp. 3d 323, 332-35 (S.D.N.Y. 2014) ("*Novartis IV*"). More recently, my colleague Judge Gardephe reached the same conclusion, holding, "At the pleading stage, it is not necessary for the Government [] to demonstrate with precision that every prescription written by every doctor was written in exchange for a kickback." *Bilotta*, 50 F. Supp. 3d at 523.

This is because the focus of the AKS is not the success of the bribe, but the bribe itself. Thus, this Court and others within this District follow the rule of the Third, Fifth, Seventh, Ninth, and Tenth Circuits: that "the [Relator] need only prove that 'one purpose' of remuneration is to induce a person to use a service for which payment is made under a federal health care program." *U.S. v. Narco Freedom, Inc.*, No. 14-cv-8593 JGK, 2015 WL 1499265, at *10 (S.D.N.Y. Apr. 2, 2015), *U.S. v. Borrasi*, 639 F.3d 774, 781–82 (7th Cir. 2011); *U.S. v. McClatchey*, 217 F.3d 823, 834–35 (10th Cir. 2000); *U.S. v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); *U.S. v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989) (per curiam); *U.S. v. Greber*, 760 F.2d 68, 71–72 (3d Cir. 1985).

Defendants argue that the Relators have failed to allege that the speaker program had any single *universal* purpose of remuneration. (Docket #39 at 7-8.) But taking all of the SAC's factual allegations as true and drawing all inferences in favor of the nonmoving party, a universal purpose of remuneration is precisely what the Relators allege for these speaker programs. The Relators have pleaded that these speaking programs were sham, provided useless information, and that the few persons in attendance were both familiar with the material already (indeed, most of them are alleged to have been presenters) and were paid to be there. By pleading facts tending to show that the speaking programs and engagements were nothing more than a means to provide money to doctors who prescribed large amounts of the Drugs, in a corporation where centralized management both oversaw the operations of a nationwide sales force and allegedly devised the scheme to defraud, Relators have done all they must at the pleading stage to advance a theory that the speaker program had a universal and improper purpose. We shall see if they can prove their case.

C. The Allegedly Sham Honoraria – If Indeed They Are Shams – Are Not Shielded by the AKS' Personal Services Safe Harbor.

The AKS exempts certain conduct covered by statutory and regulatory safe harbors. 42 U.S.C.A. § 1320a-7b(b). Among them is a safe harbor for personal services contracts. *See* 42 C.F.R. § 1001.952(d). Defendants argue that the Relators' pleading fails to place their conduct outside of this regulatory safe harbor. (Docket #31 at 18.)

The SAC clearly alleges facts inconsistent with the personal services safe harbor.[4]

[4] Because the SAC, if believed, precludes application of the personal services safe harbor, I need not decide the question whether it is a plaintiff's burden to allege facts that remove a defendant's conduct from all possible safe harbors, or instead a defendant's burden to prove entitlement to a safe harbor as an affirmative defense after the pleadings stage.

A personal services contract must meet several conditions to qualify under the safe harbor provision. *See* 42 C.F.R. § 1001.952(d). Among them:

> The aggregate compensation paid to the [physician] over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.

42 C.F.R. § 1001.952(d)(5).

As I have explained, shot through the *entire complaint* are allegations of fact supporting the inference that the compensation paid to the physician was not "consistent with fair market value," in that the speaker programs often had no "market value" at all, and were indeed "determined in a manner that t[ook] into account the volume or value of any referrals or business otherwise generated between the parties" insofar as physicians could only *become* speakers and *remain* speakers if they generated sufficient prescriptions.

IV. The Relators Have Sufficiently Alleged the "Falsity" of Some Claims, but Are Ordered to Amend Their Pleading with Respect to Other Claims.

The Relators' federal claims arise under two subsections of the FCA, "one for *causing* false claims related to the submission of false . . . certifications, in violation of Title 31, United States Code, Section 3729(a)(1)(A) . . . and a second for the *use* of false statements related to the submission of . . . certifications, in violation of Title 31, United States Code, Section 3729(a)(1)(B)." *United States v. Movtady*, 13 F. Supp. 3d 325, 330 (S.D.N.Y. 2014); (*see* SAC ¶¶ 163-64).

Subsection (a)(1)(A) provides for liability where the defendant "knowingly presents, or causes to be presented, a *false or fraudulent claim* for payment or approval." 31 U.S.C.

§ 3729(a)(1)(A) (emphasis added). To prove a claim under this subsection, a plaintiff must show that: (1) there was a false or fraudulent claim, (2) the defendant knew it was false or fraudulent, (3) the defendant presented the claim, or caused it to be presented, to the United States, and (4) it did so to seek payment from the federal treasury. *See Mikes v. Straus*, 274 F.3d 687, 695 (2d Cir. 2001); *U.S. ex rel. Pervez v. Beth Israel Med. Ctr.*, 736 F. Supp. 2d 804, 811 (S.D.N.Y. 2010).

Subsection (a)(1)(B) provides for liability where the defendant "knowingly makes, uses, or causes to be made or used, a false record or statement material to a *false or fraudulent claim*." 31 U.S.C. § 3729(a)(1)(B) (emphasis added). To prove a claim under this subsection, a plaintiff must show that: (1) the defendant made (or caused to be made) a false statement, (2) the defendant knew it to be false, and (3) the statement was material to a false or fraudulent claim. *See Pervez*, 736 F. Supp. 2d at 811.

Both subsections of the FCA at issue in this case require the existence of "false or fraudulent" claims.

A. Definition of False or Fraudulent Claims

In *Mikes v. Straus*, 274 F.3d 687, 696 (2d Cir. 2001), the Second Circuit established the definition of a "false or fraudulent" claim in this Circuit: it is any claim "aimed at extracting money the government otherwise would not have paid." *Id.* at 696. The Second Circuit recognized two types of "falsity"—*i.e.*, two reasons that the government would not pay the claim if it knew the true facts. One is factual falsity; the other is legal falsity. *See id.* at 697.

A claim is "factually false" where the party submitting the claim supplies "an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." *Id.*; *see also Pervez*, 736 F. Supp. 2d at 812. In other words, the party "bills for

something it did not provide." *U.S. ex rel. Kirk v. Schindler Elevator Corp.*, 601 F.3d 94, 113 (2d Cir. 2010), *rev'd on other grounds*, 131 S. Ct. 1885 (2011).

In contrast, a "legally false" claim is "false" because it has been tainted by some underlying statutory, regulatory, or contractual violation made in connection with that claim, which renders the claim ineligible for reimbursement. Under *Mikes*, a violation does not render a claim "false" unless (1) compliance with the underlying statute, regulation, or contract is a "precondition" to payment of the claim, and (2) a party falsely represents (or "certifies") compliance with the provision in connection with the claim. 274 F.3d at 697-98. The *Mikes* court distinguished between preconditions to *payment* of claims and mere conditions of *participation* in a government program; in order for a statutory violation to provide a basis for legal "falsity," the government's decision to reimburse the claim must be conditioned upon compliance with the underlying statute. *See id.* at 701-02. The preconditions to payment vary by government program.

There are also two types of false certifications: express and implied.

As the name suggests, an "express false certification" occurs when the party submitting the claim expressly and "falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment." *Id.* at 698. Generally, express certifications are made when a government program requires participants to submit forms explicitly stating that they have complied with certain statutes. *See id.* Where the party certifying compliance is, in fact, violating the statute in question, that certification is "false." The claims rendered legally "false" by such false certifications include all the claims connected to the underlying statutory violation.

Legal "falsity" can also arise on a theory of "implied false certification." The implied false certification theory 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. In *Mikes*, the Second Circuit stated that this theory "is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid." *Id.* at 700 (emphasis in original). "Liability under the Act may properly be found . . . when a defendant submits a claim for reimbursement while knowing . . . that payment expressly is precluded because of some noncompliance by the defendant." *Id.*

In 2010 Congress amended the AKS to clarify that compliance with the AKS is a precondition to payment. Pursuant to the Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 111-148, 124 Stat. 119 (Mar. 23, 2010), the AKS now states that, "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act]." 42 U.S.C. § 1320a-7b(g). The AKS applies to all "Federal health care program[s]," including Medicare and Medicaid. *Id.* § 1320a-7b(f). The 2010 amendment therefore made clear that compliance with the AKS is a precondition to the payment of claims submitted to these programs, and not merely a condition of participation in the programs. "Accordingly, from and after March 2010 'the act of submitting a claim for reimbursement itself implie[d] compliance with' the AKS, *Mikes*, 274 F.3d at 699, even in the absence of any express certification of compliance." *U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 43 F. Supp. 3d 332, 364 (S.D.N.Y. 2014) ("*Novartis V*"). However, because "the AKS did not 'expressly' state that it was a precondition to payment of claims submitted to federal health care programs prior to March 2010 … it [cannot] constitute a basis for implied false certifications prior to that date." *Id.* at 365.

Relators argue that factual and legal falsity are not the only categories of false or fraudulent claims, and that, "A claim may be false or fraudulent under the FCA where it contains no certifications at all, as long as the claim is ineligible for payment, such as a claim resulting from illegal kickbacks." (Docket # 35 at 9-10). In essence, Relators argue that any claim tainted by an

illegal kickback – or for that matter, any claim submitted in violation of a statute that is a precondition to payment – is *per se* a false claim. They support this argument in two ways: they point to a statement in *Mikes* to the effect that "*a false claim may take many forms*, the most common being a claims for goods and services not provided, or provided in violation of contract terms, specification, statute or regulation." 274 F.3d at 697 (emphasis added, emphasis in original omitted); and they cite *Novartis V,* in which this court held that compliance with the AKS was a precondition to payment even prior to the 2010 Amendment to the AKS. 43 F. Supp. 3d at 362-364.

I decline Relators' invitation to manufacture a new type of false claims. False claims jurisprudence from and after *Mikes* and its progeny rests on analyzing whether a claim submitted to the Government for reimbursement either expressly or impliedly certified compliance with the law; that analysis would be unnecessary if there were some other type of "false claim." *Mikes*, which establishes the blueprint for analyzing false claims in this Circuit, is the law that binds this court. This court most certainly did not create any third category of false claims in *Novartis V*; rather, I concluded that the Government's pleading stated a claim under the legal falsity theory that was announced in *Mikes.*

Thus, Relators may bring a claim under the FCA for violation of the AKS if (1) submission of a claim was factually false or (2) submission of a claim was legally false because a party (a) expressly certified compliance with the AKS or (b) impliedly certified compliance with the AKS. Because the world was not on notice until March 23, 2010, that a claim tainted by an implied certification of compliance with the AKS was a "false or fraudulent" claim, Relators can prevail on a theory of implied certification only with respect to claims that were submitted after March

23, 2010. Any claims arising prior to that date would have to be accompanied by express certifications in order to be actionable under the FCA.

B. The Pricing Violations

The Relators allege that Teva failed to account for its kickback scheme when reporting the Drugs' "Average Manufacturer Price" and "Best Price" to various government health programs. In their briefing on this issue, the parties treat Relators allegations as express certification claims. (Docket # 35 at 18; Docket # 38 at 7). But allegations that Teva "failed to take into accounts the kickbacks it paid when it reported its Best Price" (SAC ¶ 80) or Average Manufacturing Price (*id.* ¶ 84) are allegations of *factual* falsity, not legal falsity.

Specifically, Relators allege that, when reporting its Best Price on Form CMS-367 over the last six years, Teva reported a number that was too high, because it consisted, not only of the actual cost of the drug, but also some amount representing the fees paid to physician participants in the sham speaker series. (*Id.* ¶ 81.) According to Relator, the true "best price" and "average manufacturing price" for Copaxone and Azilect should have been reported by backing out the alleged kickback. The price at which (1) federal and state/local governments reimbursed Teva for providing the drug, or (2) Teva paid a rebate to the states of a certain statutorily-prescribed portion of the price of drugs purchased by each Medicaid program, *see* 42 U.S.C § 1396r-8(a)(1), was dependent on Best Price or Average Manufacturing Price (as the case may be). Thus, Relators allege that Teva caused the governments to subsidize its kickback program, by reducing the amount or the rebate that Teva had to pay to each State Medicaid program, pursuant to the rebate Agreement Teva was required to enter with HHS for its drugs to be available to Medicaid beneficiaries. (*Id.* ¶¶ 76-81.)

Relators further allege that, by artificially inflating its Average Manufacturer Price with the cost of its kickback scheme, Teva failed to comply with the requirement of its pricing agreement with HHS that Azilect and Copaxone's pricing "not exceed 76% of the non-Federal average manufacturer price" and therefore made Teva ineligible to "receive payment for the purchase of drugs" from the government entities referenced in Subsection (4), namely the VA and the DOD. (*Id.* ¶ 84.)

In response, Defendants argue that they were not required to include speaker fees when calculating AMP and BP because, "Speaker fees constitute bona fide services fees ("BFSFs"), which are expressly excluded from AMP calculations. *See* 42 C.F.R. § 447.504(a) and (h); 42 C.F.R. § 447.502." (Docket # 38 at 7.)

The Court is not convinced – at least, not at the motion to dismiss stage. 42 C.F.R. § 447.502 defines bona fide service fees as "fees paid by a manufacturer to an entity; that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement; and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug." The fair import of Relators' allegations is that speaker fees paid to doctors were *not* fair market value for bona fide services. Rather, the presentations for which doctors were paid allegedly were devoid of substance (SAC ¶ 101), and the "honoraria" were, in reality, kickbacks paid in exchange for writing prescriptions of Defendants' drugs (*id.* ¶ 96). Thus, for purposes of defeating a motion to dismiss, Relators have sufficiently alleged that honoraria fall outside of the BFSF exclusion from AMP calculations.

C. The Reimbursement Claims (Medicare, Medicaid, VA & TRICARE)

The Relators briefly argue that "claims tainted by kickbacks . . . 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.'" (Docket #35 at 10 (quoting *U.S. ex. Rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 314 (3d Cir. 2011).) *Wilkins*, however was not a factual falsity case but a legal falsity case; the discussion quoted above comes from an explanation of the implied certification theory. *See* 659 F.3d at 313-14. *Wilkins* simply does not stand for the premise that claims tainted by kickbacks are somehow factually, as opposed to legally, false claims.

Moreover, there is no allegation of fact in the complaint supporting an inference that the reimbursement claims contained factually inaccurate information – *i.e.*, that the claims supplied "an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." *Mikes*, 274 F.3d 697. As such, the reimbursement claims allegedly in violation of the FCA must be analyzed under the theory of legal falsity.

Because I have already determined that compliance with the AKS is a precondition of payment by federal healthcare programs, *supra* at 39, the only issue is whether Relators have sufficiently alleged express or (after the effective date of the PPACA) implied certifications. Relators argue that they have alleged express certification claims for each government program at issue. Thus, I will address whether Relators have sufficiently alleged express certification claims first and only reach the question of implied certification if necessary.

1. Medicare Part D

Teva argues that it cannot be held responsible for the express certifications identified in the Complaint with respect to Medicare Part D, because the express certifications at issue were not submitted by the physicians who allegedly received the kickbacks and because the certifications

are too broad to be deemed "express certifications." Neither argument is persuasive. Teva also argues that submission of Prescription Drug Events ("PDEs") to the government cannot be the basis of a FCA violation because PDEs contain no certifications and Relators have failed to allege factual falsity as to any PDE data. On this point, Defendants are correct.

a. Teva Can Cause an "Upstream"[5] Entity's False Certification

Relators have described in detail the order of operations by which a doctor's kickback-tainted prescription results in a false claim: (1) a Part D sponsors enter into a subcontract with a pharmacy (SAC ¶ 36), (2) the pharmacy submits a claim to the Part D sponsor (or to its Pharmacy Benefits Manager, which submits to the Part D sponsor) when it dispenses drugs to a Medicare beneficiary (*id.* ¶ 37), (3) the pharmacy receives reimbursement from the Part D sponsor (or PBM) (*id.*), and (4) the Part D sponsor receives reimbursement from CMS (*id.* ¶¶ 40-41). Relators have even provided a chart showing the number of Medicare Part D claims and the dollar reimbursement to pharmacies associated with such claims, which were made as a result of prescriptions by allegedly compromised physicians in 2010 and 2011. (*See* SAC, Ex. A.)

Defendants contend that Relators cannot prevail on a theory by which doctors receive kickbacks from Teva but pharmacies certify compliance with the AKS, arguing that the entity making the certification must know it to be false: "For example, if upstream party Z certifies that it did not violate the AKS, and Z in fact did not, the certification is true even if downstream entity

[5] Throughout this opinion, the Court has referred to all entities, such as pharmacies, that are below the Part D sponsor and "first tier entity" (*i.e.*, the party that contracts with the Part D sponsor) in the chain of claim submission as "downstream" entities, consistent with the definitions provided in 42 C.F.R. § 423.4. Pharmacies, however, are "upstream" from the physicians who allegedly received kickbacks from Teva, in that they are further up the causal chain of claim submission. I will therefore refer to such pharmacies as "upstream" to demonstrate their position in the causal chain relative to physicians and Teva, for purposes of this section only.

X did. True certifications cannot support a false certification claim." (Docket # 38 at 7). This is a clever argument, but not a successful one.

First, Relators *have* alleged that the physicians did, in fact, certify compliance with the AKS – via the CMS Form 855I. That form, which Relators allege is prerequisite to participation in the Medicare program, expressly certifies the physicians will comply with the AKS in all their dealings with Medicare. (SAC ¶ 56). Defendants argue that this form applies only to the provision of physician's services (covered by Medicare Part B) and not to the provision of prescription drugs (covered by Medicare Part D). But that is incorrect. The certification states that:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to the organization listed in Section 4A of this application. The Medicare laws, regulations, and program instructions are available through the fee-for-service contractor. I understand that *payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law)*, and on the supplier's compliance with all applicable conditions of participation in Medicare.

Medicare Enrollment Application for Physicians and Non-Physician Practitioners, CMS.gov, https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855i.pdf at 1 (last visited February 8, 2015) (emphasis added). Thus, while the form itself may be directed at a physician's services (Part B) rather than the provision of medication (Part D), the language of the certification applies to all claims made to Medicare by or at the behest of the physician. The certification under CMS Form 855I is sufficient to underpin an FCA claim for Medicare Part D reimbursement premised on a violation of the AKS.

Second, even if the physicians' CMS Form 855I did not apply to the claims at issue, Relators' argument fails because the pharmacies that filled the kickback-tainted prescriptions are alleged to have certified compliance with the AKS pursuant to 42 C.F.R. § 423.505(i)(4)(iv). Contrary to Defendants' argument, *Mikes* does not require that the party certifying compliance

with a statute also be the party with knowledge that the certification is false. *See* 274 F.3d at 697. Knowledge is, of course, required for liability under the FCA, but Relators are not seeking to hold the pharmacies liable for Teva's misdeeds; they are seeking to hold Teva liable for causing the pharmacies to make false certifications. And Teva is alleged to have known exactly what it was doing.

That the pharmacies may not have known about Teva's misconduct is not fatal to the claim against Teva, because, "It is well-established that the FCA reaches claims that are rendered false by one party, but submitted to the government by another." *U.S. ex rel. Feldman v. City of New York*, 808 F. Supp. 2d 641, 650 (S.D.N.Y. 2011) (internal quotation marks and citation omitted). Defendants concede that a downstream entity can cause an upstream entity to make a false certification. (*See* Docket #31 at 9 n.11).

The legislative history behind the 2010 amendment to the AKS, discussed at length in *Novartis IV*, makes clear that Congress took action to clarify existing law to foreclose precisely the argument Defendants make here. In enacting the amendment, Senator Ted Kaufman, the bill's sponsor, expressly disapproved of the district court's holding in *United States ex rel. Thomas v. Bailey*, No. 06 Civ. 465, 2008 WL 4853630 (E.D.Ark. Nov. 6, 2008), a case in which a medical device company and its sales representative paid kickbacks to a surgeon for using the company's device in its surgeries. The company and the sales representative escaped liability under the FCA because the hospital – an innocent party that submitted claims to the federal government for reimbursement based on the surgeon's use of the medical device – certified its *own* knowledge of compliance with the AKS. Thus, the court determined that the hospital's certification was not, strictly speaking, false, for purposes of the FCA. Congress disapproved of this interpretation of the law and, in response, sought to clarify that "*all claims* resulting from illegal kickbacks are

'false or fraudulent' even when the claims are not submitted directly by the wrongdoers themselves." *Novartis IV*, 41 F.Supp.3d at 334 (internal citation omitted). As I stated in *Novartis IV*:

> By enacting Section 1320a–7b(g), Congress made clear that the fact that the certifications were made by an innocent party submitting a claim without knowledge of an AKS violation did not remove the taint of falsity from the certifications; any claim connected in any way to an AKS violation was ineligible for reimbursement, even if the party that submitted the claim had no knowledge of the AKS violation.

Id. at 335. Congress could hardly have intended to insulate entities whose actions violate the AKS simply because upstream entities – whose claims the violators have induced – make the actual certification. Following the 2010 amendment, Senator Kaufman left little doubt as to that intent.

Thus, this case cannot be distinguished from *Novartis IV*, in which this court denied a pharmaceutical company's motion to dismiss claims predicated on express certifications relating to the Medicare Part D program. 41 F. Supp. 3d at 337. The only difference between this case and *Novartis* is that, in the latter, the FCA claims were predicated on kickbacks allegedly paid to pharmacies that certified compliance with the AKS. Here, the kickbacks were allegedly paid to doctors, who prescribed drugs that were ultimately dispensed by the pharmacies. But that is of no moment, because the kickbacks here are properly alleged to have caused doctors to prescribe the drugs, which caused pharmacies to dispense the drugs and make related claims to a Part D sponsor, which submitted claims to the federal government. The fact that there is an extra link in the causal chain does not render the claims submitted for reimbursement any less false.

b. Broad Certification Language Does Not Preclude an Express Certification Claim

Novartis IV also forecloses Defendants' argument that the certifications at issue are too "sweeping" in their language to certify compliance with the AKS. (Docket # 31 at 7-8).

Defendants argue that "generalized language, referring broadly to all applicable requirements, is insufficient to create an express certification of compliance with the AKS upon which government payment is conditioned." (*Id.*)

In *Novartis IV*, this Court held that because, "The AKS is unquestionably one of the 'applicable Federal laws' governing Medicare Part D that is cited in the subcontract certification . . . subcontracting pharmacies who certify compliance 'with all applicable Federal laws, regulations, and CMS instructions' certify compliance with the AKS." 42 C.F.R. § 423.505(i)(4)(iv)." 41 F. Supp. 3d at 337. That certification is an express certification of compliance for purposes of the FCA. In that same case, I also held that a certification of compliance with "applicable federal and state laws and regulations" in a New York Medicaid billing certification was an express certification of compliance with the AKS. *Id.* at 338.

The case on which Defendants rely for the premise that broad certification language cannot support a claim for FCA liability, *U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211 (10th Cir. 2008), is easily distinguishable. In that case, the relator sought to hold a hospital liable under the FCA for failure to comply with various regulations and statutes establishing conditions of participation in the Medicare program. *Id.* at 1216. The relator argued that the following certification in the hospital's annual cost reports created an express certification for purposes of the FCA: "I . . . certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations." *Id.* at 1219. The circuit court affirmed the district court's dismissal of the express certification claim, not because the certification was too "general" to find that it attested to compliance with the Medicare regulations at issue, but because the breadth of the certification suggested that compliance with the underlying regulations *was not a*

precondition to payment. *Id.* In contrast, here, there is no question that compliance with the AKS is a precondition to payment under all federal healthcare programs. *See Novartis V,* 43 F. Supp. 3d 332, 364 (S.D.N.Y. 2014). As such, a certification of compliance with "all applicable Federal laws" is express certification of compliance with a statute – the AKS – that is a precondition to payment.

c. Relators Fail to State an Express Certification Claim Premised on the Submission of Prescription Drug Events

Finally, Teva argues that PDEs – data submitted by Part D Sponsors to CMS comprising 39 fields regarding the claim such as the prescriber, quantity and amount paid to the pharmacy (SAC ¶ 38) – cannot form the basis of a FCA claim premised on violation of the AKS because PDEs contain a certification as to the factual accuracy of the data submitted, and there is no allegation in the complaint of factual inaccuracy. (Docket #31 at 9.)

Teva is correct that there is no allegation in the Complaint that PDEs submitted to the government contained inaccurate data. Relators respond that "PDE claims for drugs tainted by kickbacks are 'false claims' for purposes of the FCA," citing *U.S. ex rel. Spay v. CVS Caremark Corp.*, 913 F. Supp. 2d 125, 171 (E.D. Pa. 2012). (Docket # 35 at 15). But *Spay* stands for the proposition that PDEs, if they are alleged to contain false or inaccurate data, are false claims for purposes of the FCA – not that PDEs containing accurate data allegedly tainted by kickbacks constitute false claims. Thus, the allegations in the Complaint as written do not state a claim for violation of the FCA based on the submission of PDEs.

Should Relators wish to proceed with a claim based on the submission of PDEs they must amend their Complaint to allege precisely what aspect of the PDE forms is inaccurate. They have 30 days to do so. If, as appears to be the case, Relators cannot identify any such factually inaccurate

data, then allegations of false certifications relating to the PDEs should be dropped from the Complaint.

2. *TRICARE (formerly known as CHAMPUS)*

Compliance with the AKS is a precondition to payment under Federal Healthcare Programs, including TRICARE. *Novartis V*, 43 F. Supp. 3d at 362-64 (S.D.N.Y. 2014). Thus, the question is whether express or implied certifications were made in connection with claims submitted to TRICARE.

Relators allege that "physicians" and "all providers that offer services to TRICARE beneficiaries" must expressly certify compliance with various "anti-abuse" provisions. (*See, e.g.*, SAC ¶ 72). In support of this allegation, Relators cite to 32 C.F.R. §§ 199.9(a)(4), 199.9(c)(12) and 199.2(b).

Section 199.9 is titled Administrative Remedies for Fraud, Abuse and Conflict of Interest. Section 199.9(a)(4) states in full: "Providers seeking payment from the Federal Government through programs such as [TRICARE] have a duty to familiarize themselves with, and comply with, the program requirements." 32 C.F.R. § 199.9. Section 199.9(c)(12) provides that "Examples of situations which. . . are presumed to be fraud [as defined by § 199.2] include, but are not limited to: … Arrangements by providers with employees, independent contractors, suppliers, or others which appear to be designed primarily to overcharge the [TRICARE] through various means (such as commissions, fee-splitting, and kickbacks) used to divert or conceal improper or unnecessary costs or profits." 32 C.F.R. § 199.9.

These sections do not require express certifications of compliance with the AKS. And there are no allegations that Teva entered into any TRICARE contracts or provider agreements

that expressly certify compliance with the AKS. Relators have not identified any express certifications – not even exemplars. Further, this Court has held in *Novartis VII* that neither § 199.9(a)(4) nor § 199.9(c)(12) requires compliance with the AKS as a condition of payment. *See Novartis VII,* 2015 WL 109934 at *18. These provisions cannot form the basis of an implied certification claim. *Id.*

In their opposition brief, Relators argue that "the SAC identifies actionable claims based upon DD Form 2642." (Docket # 35 at 18.) But reference to Form 2642 does not save Relators' claim. Form 2642 is, according to the Complaint, a form filled out by a beneficiary (that is, a patient) when filling out a prescription at a retail pharmacy outside of TRICARE's Network. The beneficiary pays the full amount for the prescription, and then submits the Form 2642 to a Pharmacy Benefit Manager, which submits a claim to TRICARE. (SAC ¶ 67). But the form itself does not certify compliance with the AKS – or with any other statute or regulation that could conceivably relate to the conduct of a pharmaceutical company. As such, Form 2642 cannot serve as the basis for an express certification claim. *See* http://www.dtic.mil/whs/directives/forms/eforms/dd2642.pdf (last visited February 9, 2016).

Thus, Relators have not sufficiently alleged express certification claims relating to TRICARE. They also have not pointed to any basis for recognizing an implied certification claim for claims submitted to TRICARE before March 23, 2010. For claims submitted to TRICARE after March 23, 2010, the PPACA states that compliance with the AKS is a precondition for reimbursement, so to that extent, and that extent only, Relators have stated a claim for implied certification.

I note that Defendants argue that the PPACA "only addresses that subset of claims that '*resulted from*' the kickback." (Docket # 31 at 14). Thus, according to Defendants, Relators' must

allege that each prescription that caused a claim was the result of "improper financial influence," in order to state an implied certification claim. (*Id.* at 15). But, as discussed above with respect to the causation requirements of Rule 9(b), *supra* at 34-36, that argument has no merit – not least because I addressed and rejected it in *Novartis IV*. *See* 41 F. Supp. 3d at 332-35. The PPACA clarified that the AKS is, and has always been, a precondition of payment, and it does not create a "but for" requirement as part of that precondition.

Because Relators have failed to allege any express or implied false certifications made in connection with the claims submitted to TRICARE prior to the enactment of the PPACA on March 23, 2010, Relators' FCA claim may not go forward insofar as it relates to those claims for repayment. Relators have 30 days to replead their TRICARE claims, invoking the specific certification forms, statutes, or regulations that provide a basis upon which this Court can find that false certifications (either express or implied) rendered those claims "false."

3. Veterans Administration Healthcare

Relators allege that Defendants entered into a contract with the VA that "requires TEVA to comply with all applicable federal, state and local laws, executive orders, rules and regulations applicable to performance of TEVA's duties" under the contract. (SAC ¶ 75). Relators allege that the contract also specifically identifies seven statutes with which TEVA is required to comply. Though Relators appear to concede that the statutes specifically identified by contract have no bearing on this suit, they argue that a certification of compliance with "all applicable federal. . . laws" is an express certification of compliance with the AKS. (Docket #35 at 18.) Defendants argue that this language is too broad to be deemed an express certification.

As discussed above, because the AKS is a precondition to suit and, by its own terms, applies to federal healthcare programs, certification of compliance with all applicable laws in a contract for services under the Veterans Administration Healthcare program is express certification of compliance with the AKS. Relators have sufficiently alleged express certification claims with respect to the VA healthcare program.

4. Medicaid

Relators allege a variety of express certifications with respect to Medicaid. The SAC alleges that "providers who participate in the Medicaid program must sign enrollment agreements with their states that certify compliance with the state and federal Medicaid requirements, including the AKS." (SAC ¶ 61.) The SAC does not contain sample language from any enrollment agreement. Further, Relators allege that, "in many states, Medicaid providers, including both physicians and pharmacies, must affirmatively certify, as a condition of payment of the claims submitted for reimbursement by Medicaid, compliance with applicable federal and state laws and regulations." (SAC ¶ 62.) The Complaint provides an exemplar certification from New York State. The Complaint also alleges that Teva "caus[ed] the States to submit false claims to the United States Government on Form CMS-64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program), which falsely certified that all drugs for which federal reimbursement was sought. . . were paid for in compliance with federal law, including the AK[S]. . . " (*Id.* ¶ 165), and that Teva knowingly caused pharmacies and other healthcare providers to submit false CMS-1500 claims for payment. (*Id.* ¶ 164).

Defendants argue that (1) Relators have failed to allege express certifications for all state Medicaid programs except for New York's, (2) allegations that the states submitted false claims

to the United States Government on Form CMS-64 fail because the form's certification is "forward-looking" and too broad to constitute an express certification, and (3) Form CMS-1500 contains no express certification.

In *Novartis IV*, I held that "conclusory allegations that 'many states' require express AKS compliance certifications" were insufficient to state a claim premised on express certification. 41 F. Supp. 3d at 338-39. To state a claim, Relators must *identify* the express certification. Here, Relators here have not actually identified any express certification with respect to enrollment agreements. Nor have they identified certifications with respect to billing, with the exception of billing certifications for New York's Medicaid program. (See SAC ¶ 63).

As for the alleged express certification in form CMS-1500, neither party has provided the Court with a sample form (the link provided by Defendants in their reply brief does not lead to the form itself), but the Court endeavored to find the CMS 1500 claim form 08/05 (the form in effect during the relevant time period) itself. It appears to contain no certification as to compliance with the AKS.[6]

However, Relators have sufficiently alleged express certifications with respect to state Medicaid programs on Form CMS-64. Because Form CMS-64 contains an express certification of compliance with federal laws (Compl. ¶ 164), and Relators allege that states submitted this form in conjunction with Medicaid claims submitted to the federal government for reimbursement, Relators' FCA claim premised on express certifications with respect to Medicare withstands Defendants motion to dismiss. As discussed above, Defendants' argument that such a certification

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[6] *See https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwiTgfaGnfDKAhUW4GMKHYKkBXwQFgg2MAA&url=https%3A%2F%2Fwww.cms.gov%2FMedicare%2FCMS-Forms%2FCMS-Forms%2Fdownloads%2Fcms1500805.pdf&usg=AFQjCNE-dWVkcMSjOhJOfVjmq7ufMnZ8vQ&sig2=miL3gxD0RI4IxMaIBKkD7A&cad=rja*

is too broad, per *Conner*, fails. Further, Defendants' contention that Form CMS-64 cannot form the basis of an express certification claim because it is "forward-looking" has no merit. Neither party has provided the exact language of the CMS-64 form, but the parties seem to agree that this form contains language similar to the CMS-855I form, which says, "I agree to abide by the Medicare laws, regulations and program instructions." (*See* Docket # 31 at 13 n.16; Docket # 35 at 16.) In *Novartis VII*, I held that the phrase "I *agree* to abide by" applicable laws and regulations "does not predict future behaviors; it obligates the provider to behave in a certain manner." 2015 WL 109934, at *19. Form CMS-64 (assuming it contains the same language, as the parties suggest) is therefore an express certification of compliance with the AKS.

Should Relators wish to proceed with their Medicaid-based allegations on a certification other than that contained in Form CMS-64, they must amend their Complaint to state the express certifications from the enrollment agreement or billing certifications upon which they rely. They may do so by providing exemplar certifications for each relevant state, as they have done for New York. They have 30 days to do so.

V. The Relators Have Sufficiently Alleged That the Defendants "Willfully" and "Knowingly" Caused the Submission of False Claims.

"[T]he text of the FCA expressly states that it does not require 'proof of specific intent to defraud.' " *New York Soc.*, 2014 WL 3905742, at *8 (quoting 31 U.S.C. § 3729(b)(1)(B)). Rather, a defendant violates the FCA if it "knowingly . . . causes to be presented[ ] a false or fraudulent claim for payment or approval," or "knowingly . . . causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)-(B).

Defendants argue that, to meet this standard, a complaint must allege facts sufficient to draw the inference that a defendant had specific knowledge that he was violating the Anti-

Kickback Statute and then had specific knowledge of the submission of false claims. (*See* Docket #31 at 20-22.) That is simply not the standard.

A defendant acts knowingly within the meaning of the FCA if it "(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A) (emphasis added). " '[T]his does not conflict with Rule 9(b),' since '[m]alice, intent, knowledge, and other condition of mind of a person may be averred generally.' " *New York Soc.*, 2014 WL 3905742, at *8 (quoting *Gold*, 68 F.3d at 1477).

As Judge Gardephe found in *Bilotta*, so this Court finds that, considered together,

> the allegations raise a strong inference that [Teva] caused the submission of false claims to federal . . . healthcare programs and that it acted with actual knowledge in doing so or, at the very least, in deliberate ignorance or reckless disregard of that fact. This strong inference arises from the abundant evidence—as pled in the complaints—that the purpose of the speaker program was not to disseminate medical or scientific information to doctors, but rather to reward those who prescribed large quantities of [Teva] drugs, and to encourage other doctors to prescribe larger quantities of [Teva] drugs. This inference also arises from evidence demonstrating that [Teva] intentionally encouraged these sham speaker events . . .

Id. at 528-29 (citing 31 U.S.C. § 3729(b)(1)). Defendants' arguments to the contrary uniformly ask the Court to draw all inferences in their favor, rather than in the favor of non-movant Relators.

VI. The Relators' State and Municipal FCA Claims Are Stayed and the Motions to Dismiss Counts II Through XXXIII are Denied Without Prejudice

In addition to alleging that Defendants caused false Medicaid claims to be submitted to the federal government in violation of the FCA, Relators claim that Teva caused the submission of false Medicaid claims to state and local governments in violation of the false claims acts of 32 different states and municipalities, each of which has its own laws and regulations, not all of which are identical to the AKS.

In the interest of judicial economy and docket management, these claims (Counts II through XXXIII) are stayed until the federal FCA claims have been resolved. If the federal claims are ultimately dismissed, this Court will decline to exercise jurisdiction over the several state and local claims and they can be adjudicated in fora where local laws are well known and frequently applied. If Relators prevail on the federal claims, we will address the resolution of these pendent claims as part of an overall resolution. However, there is no reason for this Court to spend a lot of time delving into the arcana of myriad (as in, more than 30) state and local false claims laws before the factual record in this case is developed and the federal claims are resolved one way or another.

Accordingly, Teva's motions to dismiss the state and local claims are denied without prejudice to renewal after the federal claims have been resolved; Counts II through XXXIII are severed and placed on the Court's suspense calendar.

CONCLUSION

For the foregoing reasons, Defendants' motions to dismiss are denied. As I have held that certain of the certifications alleged in the complaint are an insufficient basis for FCA liability, Relators must amend their pleading with respect to those claims as directed *supra* in sections IV.C.1.c, IV.C.2, and IV.C.4. They have 30 days to do so. The Clerk of the Court is directed to remove Docket Nos. 30 and 32 from the Court's list of pending motions.

Dated: February 22, 2016

U.S.D.J.

BY ECF TO ALL COUNSEL