IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES, *et al. ex rel.* TOBY TRAVIS, **Plaintiffs,** **v.** **GILEAD SCIENCES, INC., *et al.*,** **Defendant.**	**CIVIL ACTION NO. 17-1183**

MEMORANDUM OPINION

Rufe, J. **April 1, 2022**

Relator Toby Travis, on behalf of the government of the United States and 29 jurisdictions within the United States, brings claims against Defendant Gilead Sciences, Inc. ("Gilead") and Defendant Good Health, Inc., d/b/a Premier Pharmacy Services ("Premier") under the False Claims Act[1] and under the equivalent laws of 28 states and the District of Columbia.[2] This Court has jurisdiction over Relator's federal claims under 28 U.S.C. § 1331, and supplemental jurisdiction over Relator's state law claims under 28 U.S.C. § 1367.

Gilead has moved to dismiss the claims asserted against it in the Third Amended Complaint ("TAC") in their entirety for failure to state a claim under Federal Rules of Civil Procedure 9(b) and 12(b)(6).[3] In support of this motion, Gilead has asked the Court to take judicial notice of certain guidance documents issued by the United States Department of Health

[1] 31 U.S.C. § 3729 *et seq.*

[2] The Third Amended Complaint brings claims on behalf of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Washington, Massachusetts, and Virginia, and the District of Columbia, for violation of each jurisdiction's respective false claims act.

[3] Gilead's Mot. Dismiss [Doc. No. 56].

and Human Services as well as the 2009 "Code on Interactions with Health Care Professionals" published by the Pharmaceutical Research and Manufacturers of America.[4] Premier has also filed a one-page motion seeking to join Gilead's motion, and incorporating Gilead's "Motion and Brief . . . in full by reference."[5]

For the reasons described below, Gilead's request for judicial notice is granted, Gilead's motion to dismiss is granted in part and denied in part, and Premier's motion to dismiss is granted in part and denied in part.

I. PROCEDURAL HISTORY

As this case was reassigned to this Court, and the instant motions to dismiss are the first substantive actions taken in this case, a brief review of the procedural history of this case is appropriate. This case was initially assigned to the docket of the Honorable Petrese B. Tucker on March 16, 2017. However, as Relator has filed on behalf of the United States and the governments of 28 states and the District of Columbia, the complaint remained sealed for some time while those governments evaluated whether they wished to enter the case as intervenors. The complaint was amended twice during this period. This case was unsealed and served in December 2021, and was amended for a third time on motion of Relator before Defendants responded. The TAC was filed on July 14, 2021, and the motions to dismiss were filed in response. On 6, August 2021 the case was reassigned to this Court.

[4] Gilead's Req. Judicial Not. [Doc. No. 57].

[5] Premier's Joinder Mot. Dismiss [Doc. No. 58].

II. BACKGROUND[6]

Gilead is a biopharmaceutical company headquartered in Foster City, California. Gilead owns the drugs Sovaldi and Harvoni, which are designed to treat the hepatitis C virus ("HCV").[7] Sovaldi was approved by the FDA on December 6, 2013, and Harvoni was approved on October 10, 2014.[8] Defendant Good Health, Inc., d/b/a Premier Pharmacy Services ("Premier") is a specialty pharmacy, licensed in all 50 states, which employs approximately 300 people in two pharmacy dispensing and distribution centers.[9]

Relator Toby Travis worked for Gilead between July 2013 and October 2014 as a Hepatic Therapeutic Specialist, promoting Sovaldi in southern Oregon and northern California.[10] In October 2014 Relator began working as a sales representative for Premier, assigned to the California, Oregon, and Alaska territories.[11]

A. Gilead's Marketing of Sovaldi and Harvoni

The TAC alleges that Gilead conducted pre-approval marketing of Sovaldi and Harvoni, marketed off-label uses of Sovaldi and Harvoni, made misleading, inaccurate, and false marketing statements to prescribers, paid the co-pays of patients prescribed Sovaldi and Harvoni by funneling money to patients through a third-party entity called the "PAN Foundation," and

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[6] On a motion to dismiss, the Court accepts the facts alleged in the Third Amended Complaint as true and draws all reasonable inferences in favor of Relator. *See Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 231 (3d Cir.2008).

[7] TAC [Doc. No. 49] ¶¶ 56–59.

[8] TAC [Doc. No. 49] ¶ 65.

[9] TAC [Doc. No. 49] ¶ 10.

[10] TAC [Doc. No. 49] ¶ 3.

[11] TAC [Doc. No. 49] ¶ 3.

established sham "speaker programs" to direct meals, vacations, and cash payments to high-volume prescribers.

1. The Rollout of Sovaldi

Gilead began training a team of sales representatives to promote Sovaldi approximately six months before the drug's approval.[12] Sales representatives began outreach to physicians, collecting information about their HCV patient populations and treatment practices.[13] As part of this outreach, Gilead allegedly directed sales representatives to instruct providers to perform their patients' laboratory work "prior to the drug's approval so they could prescribe Sovaldi on day one."[14] During this process, the TAC alleges that "sales representatives were instructed, in submitting their expense reports, to state the expenditures were for HCV disease state promotion, and not Sovaldi because it had not been approved."[15] The alleged goal of this early outreach was to "get as many prescriptions covered before insurance companies" realized Sovaldi's "high cost" and implemented "cost saving measures."[16]

Once Sovaldi was approved, explicit marketing began. The TAC alleges that Gilead's marketing training for Sovaldi contained multiple misrepresentations, including misleading information about Sovaldi's effectiveness in patients with previous failed treatments[17] and misleading statements about the tested viral loads in patients after treatment.[18] Gilead also

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[12] TAC [Doc. No. 49] ¶ 71.

[13] TAC [Doc. No. 49] ¶¶ 74–77.

[14] TAC [Doc. No. 49] ¶ 78.

[15] TAC [Doc. No. 49] ¶ 78.

[16] TAC [Doc. No. 49] ¶ 84.

[17] TAC [Doc. No. 49] ¶¶ 126–131.

[18] TAC [Doc. No. 49] ¶¶ 132–134.

instructed sales representatives regarding certain off-label uses of Sovaldi.[19] The training also allegedly instructed sales representatives in methods to make HCV patients appear sicker than they were to secure insurance approval for Sovaldi by manipulating their fibrosis tests, or "F-Scores."[20] During the Sovaldi training, "it was openly discussed that as long as the patient's fibrosis score was not tested using a liver biopsy, a patient who works out or fails to fast prior to the test would produce an artificially inflated fibrosis score."[21] The TAC alleges that, "although Gilead never came out and explicitly said to tell providers to manipulate their patients' F-Score results by telling them not to fast, [Gilead] provided all of the information to allow sales representatives to make this pitch to providers."[22]

2. PAN Foundation Donations

For many patients with HCV, "the copay alone" on Sovaldi and Harvoni was "thousands of dollars."[23] The PAN Foundation is a third party "patient assistance program" formed to "purportedly provide financial assistance to patients who cannot afford the cost of their medications."[24] The TAC alleges that, as part of training, Gilead instructed its sales representatives to advertise the PAN Foundation "as a way of mitigating providers' concerns regarding the cost of Sovaldi."[25] Sales representatives were told to tell providers that through "Support Path," a customer service program run by Gilead, "Gilead would work directly with the

[19] TAC [Doc. No. 49] ¶¶ 164–65.

[20] TAC [Doc. No. 49] ¶151.

[21] TAC [Doc. No. 49] ¶ 152.

[22] TAC [Doc. No. 49] ¶ 161.

[23] TAC [Doc. No. 49] ¶ 98.

[24] TAC [Doc. No. 49] ¶ 90.

[25] TAC [Doc. No. 49] ¶¶ 94–95.

patient to make sure the correct information was provided to the [PAN] Foundation to receive financial assistance."[26]

Support Path only provided assistance to patients receiving Sovaldi and Harvoni, and "almost all patients who signed up for foundation support [through Support Path] received financial assistance for their Sovaldi or Harvoni prescriptions."[27] Sales representatives were told that "Gilead spends a lot of time and energy analyzing the amount of money the [PAN] Foundation would need to provide financial assistance for Sovaldi and Harvoni until the end of the year," and "use[s] that information to determine how much to donate" to the PAN Foundation.[28] Sales staff were told to encourage prescribers "to prescribe early in the year" because the PAN Foundation was likely to "exhaust[] its funds for Sovaldi and Harvoni prescriptions by the start of the fourth quarter."[29] At a sales training session, a speaker for Gilead allegedly described these donations as "support[ing]" sales representatives "in the field."[30]

3. Speaker Programs

In support of the marketing of Sovaldi, and later Harvoni, Gilead sponsored "physician speaker programs" that were "central to Gilead's promotional campaign for Sovaldi and Harvoni."[31] Initially these programs were presented by well-known "thought leaders" with specific expertise in treating HCV, attracted large crowds of physicians, and offered continuing

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[26] TAC [Doc. No. 49] ¶ 94.

[27] TAC [Doc. No. 49] ¶ 94.

[28] TAC [Doc. No. 49] ¶ 96.

[29] TAC [Doc. No. 49] ¶ 96.

[30] TAC [Doc. No. 49] ¶ 95.

[31] TAC [Doc. No. 49] ¶ 99.

medical education credit to attendees.[32] After the FDA approved Sovaldi, however, Gilead began hiring an increasing number of lesser-known speakers, even as "attendance quickly plummeted."[33] Physician speakers traveling from out-of-town would "expect[], as Gilead promised, to be paid for two or three speaking engagements."[34] In response sales representatives were instructed to arrange catered breakfast, lunch, and dinner talks at which the physician speakers could present.[35] However, the breakfast and lunch programs were "normally very, very lightly attended," and were "largely conversational."[36]

Gilead allegedly used the speaker programs as a vehicle to provide high-prescribing doctors with honoraria and "trips to vacation destinations."[37] For example, the TAC alleges that Relator was specifically instructed by his manager to use MD1 as a speaker "because he was a high prescriber of Sovaldi."[38] MD1 was a largely unknown internal medicine practitioner from Atlanta, GA, who repeatedly drew few or no practitioners to presentations in Relator's California and Oregon territories.[39] However, MD1 "was the top Sovaldi and Harvoni prescriber in the state of Georgia."[40] From 2013 to 2015 Gilead paid more than $225,000 in honoraria and travel

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[32] TAC [Doc. No. 49] ¶¶ 99–102.

[33] TAC [Doc. No. 49] ¶ 102.

[34] TAC [Doc. No. 49] ¶¶ 104.

[35] TAC [Doc. No. 49] ¶ 103.

[36] TAC [Doc. No. 49] ¶¶ 103–04.

[37] TAC [Doc. No. 49] ¶ 117.

[38] TAC [Doc. No. 49] ¶ 110.

[39] TAC [Doc. No. 49] ¶¶ 111, 115(a).

[40] TAC [Doc. No. 49] ¶ 113.

arrangements for MD1, and MD1 requested trips to particular areas.[41] In 2014 alone MD1 submitted more than $2,000,000 worth of claims to Medicare Part D for Sovaldi and Harvoni.[42]

The TAC also alleges that Gilead compensated mid- and high-level prescribers by paying them to present to their own office staff.[43] This compensation mechanism was targeted towards prescribers "who were not influential enough to speak to other providers."[44] Gilead also allegedly used this strategy to compensate high-prescribing practitioners that Gilead wanted to compensate but expressly did *not* want speaking with other practitioners about HCV treatments. For example, the TAC alleges that NP1 was initially a speaker, and one of the highest prescribers of Sovaldi in the state of Oregon.[45] The TAC alleges that Relator's manager approached him about accommodating her request to go to Alaska.[46] When NP1 expressed concern to Relator's manager "about Sovaldi's high price and the anticipated high price of Harvoni," however, Relator's manager instructed Relator to limit NP1's speaker presentations so that she did not "spread the poison" to other prescribers,[47] and the trip to Alaska was not scheduled by Relator.[48] However, NP1 remained a high prescriber of Sovaldi, so to keep NP1 happy, Relator's manager instructed Relator to continue paying NP1 to give presentations to her own office staff.[49]

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[41] TAC [Doc. No. 49] ¶ 112.

[42] TAC [Doc. No. 49] ¶ 112.

[43] TAC [Doc. No. 49] ¶ 121.

[44] TAC [Doc. No. 49] ¶ 121.

[45] TAC [Doc. No. 49] ¶ 117.

[46] TAC [Doc. No. 49] ¶ 117.

[47] TAC [Doc. No. 49] ¶ 121.

[48] TAC [Doc. No. 49] ¶ 117.

[49] TAC [Doc. No. 49] ¶ 121.

Following this instruction NP1 was paid to conduct at least three "speaker presentations" to her office staff—some at her office and at least one at an Oregon winery.[50]

4. The Rollout of Harvoni

In September 2014, Gilead began training its sales force to promote Harvoni to physicians for the treatment of HCV.[51] Harvoni was distinguished from Sovaldi and "the rest of the HCV market by its 8-week duration, superior SVR rates, and interferon-free one pill dosing."[52] As part of the sales force training, Gilead instructed its sales force to begin holding pre-approval speaker programs "regarding a new 8-week, interferon free, treatment for HCV" ahead of the anticipated October 10, 2014 FDA approval date.[53] This advertising gimmick was required because "Gilead had already been doing HCV disease state speaker presentations for well over a year, and providers were unwilling to attend similar speaker programs on the same topic by an unknown speaker."[54] In advertising this, Relator was told by his manager to tell physicians that the program would contain new information regarding how Harvoni is different from existing medications.[55] This advertising "resulted in attendees asking questions about Harvoni during the program," without Gilead ever directing the presenters to discuss Harvoni.[56] The TAC alleges that "[t]he goal of this marketing scheme . . . was to develop Harvoni 'early

[50] TAC [Doc. No. 49] ¶ 121.

[51] TAC [Doc. No. 49] ¶ 87.

[52] TAC [Doc. No. 49] ¶ 87.

[53] TAC [Doc. No. 49] ¶ 87.

[54] TAC [Doc. No. 49] ¶ 88.

[55] TAC [Doc. No. 49] ¶ 89.

[56] TAC [Doc. No. 49] ¶ 87.

adopters' or physicians who would be ready and willing to prescribe Harvoni immediately upon its FDA approval."[57]

The TAC also alleges that, by the second quarter of 2014, due to the unexpectedly high cost of Sovaldi, most insurance providers, including Medicare, Medicaid, and Tricare, implemented strict authorization criteria that required fibrosis score testing and F-Scores of F-3 or F-4 before reimbursing either Sovaldi or Harvoni.[58] The Harvoni pre-launch training allegedly included three separate trainings on F-Scores, emphasizing how F-Scores may be boosted by eating or exercising shortly before a test.[59] In addition, the TAC alleges that, as with Sovaldi, Harvoni sales staff were trained to make intentionally false or exaggerated statements about the side effects and safety profile of Harvoni treatment.[60]

B. Gilead's Relationship with Premier

"Prior to the launch of Sovaldi, each [Gilead] sales representative was instructed to establish relationships with three specialty pharmacies to direct providers to send Sovaldi and Harvoni prescriptions to be filled."[61] The TAC alleges than an "important factor in determining which specialty pharmacy to work with was their ability and willingness to oppose therapeutic substitutions of Sovaldi or Harvoni[] for less expensive treatment options."[62] Gilead management allegedly told Relator that as Sovaldi prescriptions were highly profitable for these pharmacies,

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[57] TAC [Doc. No. 49] ¶ 87.

[58] TAC [Doc. No. 49] ¶¶ 147–48.

[59] TAC [Doc. No. 49] ¶¶ 154–60.

[60] TAC [Doc. No. 49] ¶¶ 166, 168.

[61] TAC [Doc. No. 49] ¶ 172

[62] TAC [Doc. No. 49] ¶ 178.

specialty pharmacies "will do whatever [representatives] ask to secure their Sovaldi business."[63] Relator worked with Premier and two other pharmacies.[64]

The TAC alleges that while Relator was working for Gilead, Premier "would regularly send a representative with Relator on sales calls to physicians' offices."[65] "During these sales calls, the specialty pharmacy representative would explain to the provider that if they sent the prescription to their specialty pharmacy, they would perform all of the administrative responsibilities associated with getting the prescription filled."[66] However, in the face of less expensive competitors to Sovaldi and Harvoni, Gilead began to take over this relationship to more thoroughly control the prescription recommendations.[67] Gilead pitched its Support Path program as a way of reducing the administrative burden required to obtain insurance coverage of Sovaldi and Harvoni.[68] After a physician decided to prescribe Sovaldi or Harvoni, the physician would submit a form to Support Path, "which also indicated the provider's preferred specialty pharmacy."[69] "In mid-to-late 2014, Gilead entered into a pricing contract with Premier that offered a volume-based margin on Harvoni and Sovaldi purchases" and "incentivized Premier to aggressively grow the number of Sovaldi and Harvoni prescriptions it filled each month."[70]

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[63] TAC [Doc. No. 49] ¶ 175.

[64] TAC [Doc. No. 49] ¶ 172.

[65] TAC [Doc. No. 49] ¶ 174.

[66] TAC [Doc. No. 49] ¶ 176.

[67] TAC [Doc. No. 49] ¶¶ 179–80.

[68] TAC [Doc. No. 49] ¶¶ 47–54.

[69] TAC [Doc. No. 49] ¶ 55.

[70] TAC [Doc. No. 49] ¶ 124.

The TAC alleges that, at some unspecified time after Relator left Gilead, he became Director of Marketing for a specialty pharmacy in Los Angeles.[71] In that role a Gilead Support Path representative has contacted Relator "several times," noting that many physicians submit their paperwork "without the preferred pharmacy box filled in."[72] This representative of Gilead offered that "[i]f we work together, I will make sure all the Harvoni and Sovaldi scripts get filled through you."[73] Relator understood that this representative was asking the pharmacy to "oppose therapeutic substitutions or alternative treatments" to Sovaldi and Harvoni, and that the representative was also "asking more than to oppose therapeutic substitutions."[74] The TAC does not elaborate on what "more" Relator believes was being asked or offered.

C. Premier's Solicitation of Prescriptions for Sovaldi, Harvoni, and other HCV Medications

The TAC alleges that, in addition to Premier's formal work with Gilead, in 2014 Premier began to directly pay sales representatives for pharmaceutical companies, including Gilead, in exchange for directing HVC prescriptions to Premier. Relator alleges that from June 2014 to October 2014 he was among the many pharmaceutical representatives secretly paid by Premier to direct prescriptions to Premier's pharmacy.[75]

The TAC alleges that Premier employees were instructed to keep all payments "under the table," and to route all payments to sales representatives, "including those working for

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[71] TAC [Doc. No. 49] ¶ 182.

[72] TAC [Doc. No. 49] ¶ 182.

[73] TAC [Doc. No. 49] ¶ 182.

[74] TAC [Doc. No. 49] ¶ 182.

[75] TAC [Doc. No. 49] ¶ 197–99.

pharmaceutical companies, through Happy Home Marketing,"[76] a shell company set up by Premier's Vice President of Sales.[77] Happy Home Marketing made payments in cash or by personal check to pharmaceutical representatives.[78] To aid in this deception, Premier operated what the TAC describes as a "glorified pyramid scheme."[79] The TAC describes several senior employees of Premier, including Relator himself, who recruited pharmaceutical sales representatives to direct prescriptions to Premier "in exchange for a cut of their commissions."[80]

In addition to paying pharmaceutical representatives to direct prescriptions toward Premier, Premier allegedly courted prescribers themselves by offering to host free or nearly free "FibroScan Clinics" at the clinics of health care providers who directed prescriptions towards Premier.[81] The TAC alleges that Premiere promised to "provide[] the CPT codes for billing and reimbursement of the scan and reading of the scan,"[82] and described the free clinics as "a profitable endeavor" for host practices.[83] The TAC alleges that "prior to conducting the FibroScan Clinics, the Premier sales representative would secure a commitment from the health

[76] TAC [Doc. No. 49] ¶¶ 193–95.

[77] TAC [Doc. No. 49] ¶¶ 185, 192, 194

[78] TAC [Doc. No. 49] ¶ 195.

[79] TAC [Doc. No. 49] ¶ 197.

[80] TAC [Doc. No. 49] ¶¶ 197, 202–04.

[81] TAC [Doc. No. 49] ¶¶ 219, 230. FibroScan is a non-invasive technique to measure fibrosis that generates an F-Score. TAC [Doc. No. 49] ¶¶ 149–150. These trainings are ordinarily provided only with the purchase of a $200,000 FibroScan system or at a cost of $1,800 per training. TAC [Doc. No. 49] ¶¶ 220, 224.

[82] TAC [Doc. No. 49] ¶ 265.

[83] TAC [Doc. No. 49] ¶ 231.

care provider to use Premier as their specialty pharmacy of choice for all specialty medications."[84]

III. LEGAL STANDARD

Gilead moves to dismiss these allegations under 12(b)(6) for failure to state a claim, and under Rule 9(b) for failing to meet the particularity requirement. To survive a motion to dismiss under Rule 12(b)(6), a plaintiff must plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged."[85] The Court must accept as true all factual allegations in the complaint and make all reasonable inferences in favor of the non-moving party.[86] "All relevant evidence and all reasonable inferences that can be drawn from the record are . . . viewed in the light most favorable to the non-moving party."[87]

Because a claim under the FCA sounds in fraud, "False Claims Act plaintiffs must also plead their claims with plausibility and particularity under . . . [Rule] 9(b)."[88] "Rule 9(b)'s particularity requirement requires a plaintiff to allege 'all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where, and how of the events at issue.'"[89] For Relator to satisfy Rule 9(b)'s pleading requirement, "it is sufficient for a plaintiff to allege particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually

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[84] TAC [Doc. No. 49] ¶ 239. "Premier only held FibroScan Clinics at practices that agreed to send them all of their HCV prescriptions." TAC [Doc. No. 49] ¶ 239.

[85] *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)).

[86] Fed. R. Civ. P. 12(b)(6); *McDermott v. Condalkin Group, Inc.*, 649 F. App'x 263, 266 (3d. Cir. 2016).

[87] *Jordan v. Fox Rothschild, O'Brian, & Frankel, Inc.*, 20 F.3d 1250, 1261 (3d Cir. 1994) (citation omitted).

[88] *Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 195 (2016); Fed. R. Civ. P. 9(b).

[89] *United States ex rel. Bookwalter v. UPMC*, 946 F.3d 162, 176 (3d Cir. 2019) (citation omitted).

submitted."[90] "Rule 9(b) does not require the relators to plead anything more, such as the date, time, place, or content of every single allegedly false Medicare claim."[91]

IV. DISCUSSION

A. Premier's "Joinder" to Gilead's Motion to Dismiss

As an initial matter, the Court will address Premier's purported joinder to Gilead's motion to dismiss. In response to the TAC, Premier submitted a one-page document moving to dismiss the complaint "in its entirety."[92] In lieu of presenting an argument for dismissal, Premier "joins in and relies upon the Motion to Dismiss and Brief in Support thereof . . . filed by [Gilead], which Motion and Brief are incorporated herein in full by reference."[93]

Premier's joinder is flawed because the TAC alleges largely separate claims against Gilead and Premier, and Gilead defends them as such.[94] Only one set of claims—the conspiracy claims brought under the False Claims Act[95] and related state laws—appear to be asserted against both Gilead and Premier, and this is the only claim related to Premier that is even tangentially addressed in Gilead's motion to dismiss.[96] For this reason, Premier effectively only moves to dismiss the conspiracy claims alleging a fraudulent conspiracy between Premier and Gilead. These claims are assessed below.

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[90] *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156 (3d Cir. 2014) (quotation omitted).

[91] *United States ex rel. Bookwalter v. UPMC*, 946 F.3d 162, 176 (3d Cir. 2019).

[92] Premier's Joinder Mot. Dismiss [Doc. No. 58].

[93] Premier's Joinder Mot. Dismiss [Doc. No. 58].

[94] *See* Gilead's Mot. Dismiss [Doc. No. 56].

[95] 31 U.S.C. § 3729(a)(1)(C).

[96] Gilead's Mot. Dismiss [Doc. No. 56] at ECF page 33. In fact, Gilead's motion explicitly characterizes Premier's payments to Relator as "kickbacks," and (except to the extent that the TAC alleges a conspiracy between Gilead and Premier) presents no arguments that could plausibly be adopted by Premier as a defense to the claims brought in the TAC. *Id*. at ECF page 12.

B. Gilead's Request for Judicial Notice

In support of Gilead's motion to dismiss, Gilead has asked the Court to take judicial notice of two guidance documents issued by the United States Department of Health and Human Services (together, the "OIG Guidance"), as well as the 2009 "Code on Interactions with Health Care Professionals" published by the Pharmaceutical Research and Manufacturers of America ("PhRMA").[97] When ruling on a motion to dismiss, a court may look beyond the pleadings at "documents incorporated into the complaint by reference, and matters of which a court may take judicial notice."[98] Federal Rule of Evidence 201(b) permits a court to take judicial notice of a fact not subject to reasonable dispute because it: "(1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned."[99] Although this "should be done sparingly at the pleadings stage," and "[o]nly in the clearest of cases should a district court reach outside the pleadings for facts necessary to resolve a case at that point,"[100] "[a] court must take judicial notice if a party requests it and supplies the court with the necessary information."[101]

Relator does not object to the admission of Exhibit B,[102] and does not object to the admission of Exhibit A[103] and Exhibit C[104] "to the extent that the documents are to be considered

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[97] Gilead's Req. Judicial Not. [Doc. No. 57].

[98] *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

[99] Fed. R. Evid. 201(b).

[100] *Victaulic Co. v. Tieman*, 499 F.3d 227, 236 (3d Cir. 2007), *as amended* (Nov. 20, 2007).

[101] *Sturgeon v. Pharmerica Corp.*, 438 F. Supp. 3d 246, 257 (E.D. Pa. 2020) (internal quotation marks omitted).

[102] Req. Judicial Not. Ex. B [Doc. No. 57-2].

[103] Req. Judicial Not. Ex. A [Doc. No. 57-1].

[104] Req. Judicial Not. Ex. C [Doc. No. 57-3].

'for their existence and not for their truth.'"[105] These documents are readily available guidance documents whose accuracy is not questioned.

Further, Gilead only uses these documents to argue that Relator has not pled *scienter*.[106] At this early stage of the litigation, the Court may take judicial notice of administrative and industry guidance to determine whether Relator has pled that Defendants' "were . . . on notice that certain conduct was fraudulent."[107] The request for judicial notice is granted.

C. False Claims Act Claims Against Gilead

Relator brings claims against Gilead under the False Claims Act. The False Claims Act imposes liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment" to the government.[108] To survive a motion to dismiss, a False Claims Act complaint "must plead three elements: (1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent."[109]

The "particularity" requirement of Rule 9(b) expands this analysis. The purpose of the heightened pleading requirement in Rule 9(b) is to "provide defendants with fair notice of the

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[105] Pl.'s Resp. Opp'n Def. Gilead's Mot. Dismiss [Doc. No. 60] at 12 n.10 (quoting *Sturgeon*, 438 F. Supp. 3d at 268).

[106] *See* Gilead's Mot. Dismiss [Doc. No. 56] at ECF pages 21, 26–28.

[107] *Sturgeon*, 438 F. Supp. 3d at 259; *see United States v. Allergan, Inc.*, 746 F. App'x 101, 108 (3d Cir. 2018).

[108] 31 U.S.C. § 3729(a)(1)(A).

[109] *United States ex rel. Bookwalter v. UPMC*, 946 F.3d 162, 175 (3d Cir. 2019) (quotation marks and citation omitted). To act "knowingly" under the FCA means "that a person has 'actual knowledge of the information,' 'acts in deliberate ignorance of the truth or falsity of the information,' or 'acts in reckless disregard of the truth or falsity of the information.'" *Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 182 (2016).

plaintiff['s] claims,"[110] and to "place the defendants on notice of the precise misconduct with which they are charged."[111] The TAC alleges multiple theories of misconduct and categories of conduct, each of which alleges violations of the False Claims Act and may implicate a separate set of underlying claims. On a motion to dismiss, it is necessary to address each theory, and to identify deficient *theories* rather than deficient *counts*, where the intertwined pleading of multiple theories means that "defendants are . . . left to guess" which alleged activities "were fraudulent, and most importantly, how those [activities] were fraudulent."[112] For this reason, the Court will assess which, if any, alleged categories of behavior support a sufficiently pled case under the False Claims Act.

1. Pre-Approval, Off-Label, and Misleading Marketing and F-Score Manipulation

Relator pleads a series of allegations related to the manner in which Gilead marketed Sovaldi and Harvoni, including allegations that Gilead conducted pre-approval marketing, that Gilead marketed Sovaldi for off-label uses, that Gilead made misleading statements as part of marketing pitches to prescribers, and that Gilead specifically instructed its sales representatives in how a fibrosis test could be manipulated to make a patient appear more likely to qualify for Sovaldi and Harvoni.

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[110] *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156 (3d Cir. 2014) (alteration omitted).

[111] *Grant v. Turner*, 505 F. App'x 107, 111 (3d Cir. 2012).

[112] *State Farm Mut. Auto. Ins. Co. v. Ficchi*, No. 10-555, 2012 WL 1578247, at *7 (E.D. Pa. May 4, 2012) (dismissing certain paragraphs of a complaint which alleged that certain conduct was fraudulent but failed to meet the particularity requirement of Rule 9(b)); *see Allied Med. Assocs. v. State Farm Mut. Auto. Ins. Co.*, No. 08-2434, 2009 WL 1066932, at *5 (E.D. Pa. Apr. 16, 2009) (internal quotation marks and citations omitted) (holding that alternative theories of fraud undermined the particularity requirement of 9(b), as "[r]ather than placing [defendants] on notice of the precise misconduct with which they are charged, [defendants] must defend multiple theories.").

However, while these allegations may invoke other grounds for criminal or civil liability, as pled they do not sound in the FCA. Although the TAC alleges that Gilead and its sales representatives presented this information to prescribers alongside the FDA approved information included in the medication's packaging, the TAC fails to allege a core element of an FCA claim: that the purported fraud was material to the decision of the government to pay for prescriptions.[113]

> The materiality standard is demanding. The False Claims Act is not an all-purpose antifraud statute, or a vehicle for punishing garden-variety breaches of contract or regulatory violations. A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance.[114]

In fact, the TAC contains no allegations that patients were prescribed Sovaldi or Harvoni in medically unnecessary circumstances because of Gilead's alleged illegal or misleading marketing. The TAC does claim that, as a result of Gilead's pre-approval marketing push, "some providers . . . submitted Sovaldi prescriptions prior to the drug's approval."[115] Relator provides no detail about these alleged providers, does not allege that these prescriptions were actually filled or paid for prior to FDA approval, and does not allege that Gilead knew that their pre-

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[113] *See Elliott-Lewis v. Abbott Lab'ys, Inc.*, No. 14-13155, 2016 WL 9244128, at *3 (D. Mass. Mar. 28, 2016) ("Missing from [relator's] complaint are allegations that as a result of the off label promotion, claims were submitted to the government. [Relator] has identified no specific entities who submitted claims, nor has she identified government program payers, or the times, amounts, or circumstances of such claims.").

Courts in this District have held that "the absence of off-label marketing is not a precondition of [Medicare and Medicaid] payment *per se*." *U.S. ex rel. Bergman v. Abbot Lab'ys*, 995 F. Supp. 2d 357, 368–69 (E.D. Pa. 2014).

[114] *Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 194 (2016) (quotation marks and citation omitted).

[115] TAC [Doc. No. 49] ¶ 86.

approval marketing would induce prescribers to write prescriptions before FDA approval was issued.[116] This vague statement is not enough to meet the Rule 9(b) particularity requirement.

2. Speaker Program Allegations

The TAC also alleges that Gilead's Sovaldi and Harvoni speaker programs were designed in part to funnel money to practitioners who prescribed high volumes of Sovaldi and Harvoni.[117] Such a claim sounds in the Anti-Kickback Statute ("AKS"),[118] a law designed to penalize bribery conducted with respect to a federal healthcare program. The AKS provides for criminal penalties for anyone who "knowingly and willfully offers or pays any remuneration" to induce a person to submit a claim to a federal health care program.[119] To establish an AKS violation, Relator must plead that (1) Gilead's speaker programs involved paying "remuneration," (2) at least one purpose of the speaker programs was to "induce" the remunerated parties to prescribe more Sovaldi and Harvoni, and (3) Gilead acted "knowingly and willfully" to induce such prescription.[120] A claim that is induced by bribery in violation of the AKS is inherently false or fraudulent for the purposes of applying the FCA.[121]

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[116] In fact, the TAC specifically alleges that this advertising push was made to secure "day one" prescriptions—that is, prescriptions *following* FDA approval. TAC [Doc. No. 49] ¶ 78.

[117] TAC [Doc. No. 49] at VIII(E).

[118] 42 U.S.C. § 1320a-7b(b)(2).

[119] 42 U.S.C. § 1320a-7b(b)(2).

[120] *United States ex rel. Gohil v. Sanofi U.S. Servs. Inc.*, No. 02-2964, 2020 WL 4260797, at *7 (E.D. Pa. July 24, 2020); *see* 42 U.S.C. § 1320a-7b(b)(2).

[121] 42 U.S.C.A. § 1320a-7b(g) ("In addition to the penalties provided for in [the Anti-Kickback Statute], a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for the purposes of [the False Claims Act]"); *United States ex rel. Gohil v. Sanofi U.S. Servs. Inc.*, No. 02-2964, 2020 WL 6682483 (E.D. Pa. Nov. 12, 2020) ("Claims that are tainted by kickbacks violate the AKS and are therefore automatically false.").

> Relators need not show that a *quid pro quo* exchange occurred, or that the physicians would not have prescribed Defendant's medication but for the kickbacks. It is sufficient to show that Defendant paid kickbacks to a physician for the purpose of inducing the physician to prescribe

At this stage, no party disputes that Gilead paid medical practitioners to conduct the Sovaldi and Harvoni speaker programs. In response, Gilead argues that guidance provided by the U.S. Department of Health and Human Services and the organization "Pharmaceutical Research and Manufacturers of America," ("PhRMA") endorses the use of speaker programs in some circumstances, and so Gilead was not on notice that their alleged conduct surrounding the speaker programs was illegal.[122] Gilead also argues that the TAC fails to plead that low attendance was "intentional on Gilead's part," and that it "fails to allege that these programs had systematically low attendance."[123]

The claim that Gilead did not *intend* for the events to be poorly attended is irrelevant; the AKS does not require that bribery be the *sole* purpose of a payment.[124] The TAC alleges that the Sovaldi speaker events had *systemically* low attendance,[125] and also alleges that throughout this period of low attendance Gilead continued to increase the number of speaker events and recruit and pay little-known speakers who prescribed large amounts of Sovaldi and Harvoni.[126]

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specific drugs, and that the physician then prescribed those drugs, *even if* the physician would have prescribed those drugs absent the kickback.

United States ex rel. Bawduniak v. Biogen Idec, Inc., No. 12 -10601, 2018 WL 1996829, at *3 (D. Mass. Apr. 27, 2018).

[122] Gilead's Mot. Dismiss [Doc. No. 56] at ECF pages 27–28.

[123] Gilead's Mot. Dismiss [Doc. No. 56] at ECF pages 27–28.

[124] *United States ex rel. Gohil v. Sanofi U.S. Servs. Inc.*, No. 02-2964, 2020 WL 4260797, at *9 (E.D. Pa. July 24, 2020); 42 U.S.C. § 1320a-7b(b)(2).

[125] This distinction is important. Systematic means "following a system or plan," whereas systemic means "embedded throughout a system." Whether Gilead *planned* for low attendance is irrelevant; allegations that Gilead *knew* that the speaker programs would be poorly attended and continued to increase the number of programs and speakers are highly relevant to a claim that the speaker programs were motivated by an improper purpose.

[126] TAC [Doc. No. 49] ¶¶ 102–05.

In addition, the TAC alleges that Relator's supervisor directed him to schedule two specific providers who were frequent prescribers of Sovaldi for speaking engagements that lined up with their vacation requests. Similarly, Relator alleges one specific case in which a speaker, NP1, was not allowed to present to other practitioners after she raised concerns about the high price of Sovaldi and Harvoni, so that she did not "spread the poison" to other prescribers.[127] However, to keep NP1 "happy," Relator's supervisor instructed Relator to continue paying NP1 to give presentations to her own office staff, including at a local winery.[128] This allegation, even without more, alleges a violation of the AKS and FCA that would survive a motion to dismiss.[129]

3. PAN Foundation Allegations

The TAC alleges that Gilead's contributions to and interactions with the PAN Foundation subsidized patients' copays in order to encourage them to submit insurance claims for Sovaldi and Harvoni. Where a company "knowingly and willfully" pays "a remuneration [like] Medicare coinsurance and copays, indirectly via its correlated charitable contribution funding . . . to induce patients on Medicare to purchase" that organization's products, such payment violates the AKS and the FCA.[130]

In *United States ex rel. Vitale v. MiMedx Group, Inc.*, the relator also alleged FCA fraud in relation to the PAN Foundation. In *MiMedx*, the district court held that a relator had stated an FCA violation by alleging that the defendant (1) had sales representatives identify patients who

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[127] TAC [Doc. No. 49] ¶ 121.

[128] TAC [Doc. No. 49] ¶ 121.

[129] *Compare with United States v. Novartis Pharms. Corp.*, No. 13-3700, 2020 WL 1436706, at *7 (S.D.N.Y. Mar. 24, 2020) (dismissing FCA complaint where statements about "taking care of" high-prescribing doctors were not tied to specific actions taken by the drug company or specific kickbacks that were subsequently provided).

[130] *United States of Am. ex rel. Vitale v. MiMedx Grp., Inc.*, 381 F. Supp. 3d 647, 659 (D.S.C. 2019).

would be eligible for funding by the PAN Foundation, (2) prepared forms for submission, (3) contributed the needed amount to the PAN Foundation, and then (4) immediately submitted the applications, "in essence . . . laundering money" through the PAN Foundation.[131] Here, the TAC alleges that Gilead employees, through the Support Path program, directly worked with patients to file support requests with the PAN Foundation, that Support Path only filed requests for Sovaldi and Harvoni, and that these requests were almost always successful.[132] Sales representatives were also told that specific funds were set aside for Sovaldi and Harvoni prescriptions by the PAN Foundation, although they were also told that such funds might be "exhausted" by the fourth quarter of the year.[133] Allegedly, sales representatives were told that "Gilead spends a lot of time and energy analyzing the amount of money the [PAN] Foundation would need to provide financial assistance for Sovaldi and Harvoni until the end of the year," "use[s] that information to determine how much to donate" to the PAN Foundation,[134] and that a purpose of these donations was to "support" sales representatives "in the field."[135]

Gilead again cites to guidance issued by the Department of Health and Human Services, which endorses charitable cash contributions to charitable assistance programs.[136] However, the same guidance cited by Gilead notes that such contributions do not raise kickback concerns if, among other things:

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[131] *United States of Am. ex rel. Vitale v. MiMedx Grp., Inc.*, 381 F. Supp. 3d 647, 659 (D.S.C. 2019).

[132] TAC [Doc. No. 49] ¶ 94.

[133] TAC [Doc. No. 49] ¶ 96.

[134] TAC [Doc. No. 49] ¶ 96.

[135] TAC [Doc. No. 49] ¶ 95.

[136] Gilead's Mot. Dismiss [Doc. No. 56] at ECF pages 24–25.

> The charity awards assistance in a truly independent manner that **severs any link** between the pharmaceutical manufacturer's funding and the beneficiary (i.e., **the assistance provided to the beneficiary cannot be attributed to the donating pharmaceutical manufacturer**).[137]

Here, the TAC alleges that Gilead employees work directly with patients, the beneficiaries, to secure assistance from PAN, and only provide this assistance for patients seeking financial support to buy Sovaldi and Harvoni. While the alleged coordination is less detailed than the scheme pled in *Vitale*, the allegations here are sufficiently close to the allegations in *Vitale* that they cannot be dismissed at this time.

D. Conspiracy to Violate the False Claims Act

The TAC brings claims against both Gilead and Premier under § 3729(a)(1)(c), alleging a conspiracy to violate the False Claims Act. "[A] conspiracy claim under the FCA is required to allege the underlying fraud with particularity, but the allegations of the conspiracy need only satisfy the notice pleading standards of Rule 8."[138] To allege an FCA conspiracy, a Relator must identify co-conspirators and allege a specific agreement to violate the FCA.[139] "[I]t is not enough for relators to show there was an agreement that made it *likely* there would be a violation of the FCA; they must show an agreement was made *in order to* violate the FCA."[140]

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[137] Gilead's Mot. Dismiss [Doc. No. 56] at ECF page 24 (emphasis added).

[138] *U.S. ex rel. Boise v. Cephalon, Inc.*, No. 08-287, 2015 WL 1724572, at *13 (E.D. Pa. Apr. 15, 2015) (citations omitted).

[139] *U.S. ex rel. Bates v. Dentsply Int'l, Inc.*, No. 12-7199, 2014 WL 4384503, at *9 (E.D. Pa. Sept. 4, 2014) (holding that "relators have not stated a claim for conspiracy because they failed to identify any co-conspirators in the second amended complaint and failed to allege an agreement.").

[140] *United States ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905, 917 (6th Cir. 2017) (emphasis original).

The TAC alleges a broad array of conduct involving many participants, and does not clearly lay out any specific theories of conspiracy. Therefore, the Court will address several potential FCA conspiracies explicitly invoked by the TAC.

1. Conspiracy between Gilead and PAN Foundation

The TAC alleges a series of FCA violations arising from Gilead's interactions with the PAN Foundation. For the same reasons that the TAC alleges an FCA claim with respect to these interactions, it also alleges an FCA conspiracy claim between the two. The Court can "infer the existence of an agreement" between Gilead and the PAN Foundation to violate the False Claims Act by specifically directing donations to subsidize the copays of patients who have been prescribed Sovaldi or Harvoni.[141]

2. Conspiracy between Gilead and Premier

The TAC alleges that Gilead required its sales representatives to work with Premier and similar specialty pharmacies, that Gilead put in place a volume contract with Premier that made high prescription volumes particularly profitable, and that Gilead chose specialty pharmacies who would oppose substituting cheaper therapeutics for Sovaldi and Harvoni.[142] Relator argues that this constitutes a conspiracy, as Gilead collaborated with Premier "to process the tainted claims."[143] To the extent that these claims were "tainted" by Gilead's speaker program, however, the TAC does not allege that Premier knew about or was involved with Gilead's speaker program. While the TAC alleges that Gilead chose pharmacies who opposed therapeutic

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[141] *U.S. ex rel. Gohil v. Sanofi-Aventis U.S. Inc.*, 96 F. Supp. 3d 504, 523 (E.D. Pa. 2015).

[142] TAC [Doc. No. 49] ¶ 178.

[143] Pl.'s Resp. Opp'n Def. Gilead's Mot. Dismiss [Doc. No. 60] at 19.

substitutions, it does not allege any details about these therapeutic substitutions that would allow the Court to conclude such opposition was not a legitimate medical judgment.

In addition, the TAC alleges that Premier was paying commissions to some of Gilead's workers under the table for prescriptions directed towards Premier's pharmacy.[144] The TAC also appears to allege that, while Relator was employed as the Director of Marketing for an unnamed "specialty pharmacy in Los Angeles, California," he was approached by a Gilead "Support Path" representative who attempted to solicit bribes in exchange for directing prescriptions to Relator's pharmacy.[145] However, the TAC specifically notes that it makes "no allegation that Gilead instructed its sales representatives to direct prescriptions to Premier in exchange for . . . kickbacks."[146] Further, nothing in the TAC alleges that Gilead knew Premier was bribing physicians to secure HCV prescriptions. At most, the TAC alleges that corruption was rampant among Gilead's sales staff, without Gilead's knowledge. This is not enough to plead a conspiracy between Gilead and Premier.

3. Conspiracy between Gilead and Others

The TAC alleges extensive additional wrongdoing by Gilead, some of which states a claim under the FCA and some of which does not. However, the TAC is vague as to which of this conduct, if any, is intended to represent a "conspiracy." While the TAC alleges sufficient details surrounding Gilead's operation of the speaker program to make out a theory of FCA liability against Gilead, the TAC does not plead a conspiracy between Gilead and the speakers to

[144] TAC [Doc. No. 49] ¶¶ 188–206.

[145] TAC [Doc. No. 49] ¶¶ 182–83.

[146] TAC [Doc. No. 49] ¶ 200.

solicit kickbacks through the speaker program. The TAC alleges that the Sovaldi and Harvoni prescriptions generated by the speaker program were "false" because they were induced by bribery in violation of the AKS, not that the underlying prescriptions were medically unjustified or otherwise fraudulent. Although Relator pleads that some prescribers expressed preferences about where they would be sent to speak, the TAC does not contain allegations against the speakers or plead sufficient facts to infer that the speakers were "knowingly and willfully"[147] soliciting bribes in violation of the AKS by participating in Gilead's speaker program.[148]

4. Conspiracy between Premier and Others

Although the TAC does not clearly allege an FCA conspiracy between Gilead and Premier, the TAC plainly alleges that Premier engaged in two broad conspiracies to violate the FCA, each composed of multiple agreements. First, the TAC alleges that Premier paid cash under the table to the employees of pharmaceutical companies in exchange for those employees directing HCV prescriptions to Premier's pharmacy.[149] Second, the TAC alleges that Premier provided valuable services to various medical providers in exchange for their agreement to send HCV prescriptions to Premier's pharmacy.[150] As each of these schemes, taken as true, represents an explicit agreement that Premier would provide kickbacks or bribes in exchange for directing prescriptions to Premier, and the TAC alleges many acts taken in furtherance of each conspiracy,

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[147] 42 U.S.C. § 1320a-7b(b)(1).

[148] *See U.S. ex rel. Bates v. Dentsply Int'l, Inc.*, No. 12-7199, 2014 WL 4384503, at *9 (E.D. Pa. Sept. 4, 2014) (holding that "relators have not stated a claim for conspiracy because they failed to identify any co-conspirators in the second amended complaint and failed to allege an agreement.").

[149] *See* TAC [Doc. No. 49] at VIII(J).

[150] *See* TAC [Doc. No. 49] at VIII(K).

"[t]here is therefore little ambiguity" that either theory is sufficient to state an FCA conspiracy claim against Premier.[151]

E. State Law Claims

The TAC also brings claims on behalf of 28 states and the District of Columbia, for violation of each jurisdiction's respective state false claims act.[152] Gilead has moved to dismiss 26 of these counts with respect to Gilead, arguing that Relator cannot maintain many of his state law claims against Gilead because he only alleges specific activities in a few states.[153]

A blanket pleading that alleges a "nationwide" scheme in violation of the FCA but only provides specific examples of behavior violating the FCA in one jurisdiction fails to satisfy the particularity requirement of Rule 9(b) with respect to claims brought under the laws of other jurisdictions. [154] Here Relator alleges that, as a Gilead representative, specific "speaker program" events were staged as "kickbacks" in his territory: California and Oregon.[155] Relator alleges that a prescribing physician was flown from Georgia to California as part of this "kickback" scheme, and that he was asked to send a high-prescriber on a paid speaking trip from Oregon to Alaska because she wanted "to go to Alaska."[156] Relator further alleges that these schemes were presented as part of general trainings of Gilead's Sovaldi and Harvoni sales staff from multiple regions, and encouraged or initiated by his supervisor at Gilead, who was "responsible for the

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[151] *U.S. ex rel. Boise v. Cephalon, Inc.*, No. CIV.A. 08-287, 2015 WL 1724572, at *14 (E.D. Pa. Apr. 15, 2015).

[152] TAC [Doc. No. 49] ¶¶ 287–585.

[153] Gilead's Mot. Dismiss [Doc. No. 56] at ECF pages 34–35.

[154] *Hericks v. Lincare Inc.*, No. CIV.A. 07-387, 2014 WL 1225660, at *8 (E.D. Pa. Mar. 25, 2014); *United States v. Medtronic, Inc.*, No. 15-6264, 2017 WL 2653568, at *5 (E.D. Pa. June 19, 2017).

[155] TAC [Doc. No. 49] ¶¶ 116–17.

[156] TAC [Doc. No. 49] ¶ 117.

Washington, Oregon, Idaho, Utah, Montana, Alaska, Northern California, Northern Nebraska, and Nevada sales regions."[157]

As Relator has alleged specific misconduct affecting multiple jurisdictions "around the country," and makes "allegations about [the defendant's] nationwide, systemic practices," Relator has alleged a nationwide plan with sufficient particularity, and does not need to plead specific facts in every state to state a claim under each jurisdictions FCA-equivalent statute.[158] To the extent that the TAC states FCA claims against Defendants, it also states claims under the equivalent laws of each jurisdiction pled in the TAC.[159]

V. CONCLUSION

For the reasons set forth above, Gilead's motion to dismiss is denied with respect to the TAC's allegations related to the Sovaldi and Harvoni Speaker Programs and Gilead's

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[157] TAC [Doc. No. 49] ¶ 4.

[158] *United States v. Exec. Health Res., Inc.*, 196 F. Supp. 3d 477, 496 (E.D. Pa. 2016) (citations omitted); *see also United States v. Medtronic, Inc.*, 15-6264, 2017 WL 2653568, at *5 (E.D. Pa. June 19, 2017) (holding that "mere allegation . . . that [the defendant] engaged in 'nationwide marketing' is not enough to survive dismissal of . . . state law claims" but noting that allegations of conduct in multiple states can allege a "nationwide scheme" on a motion to dismiss.).

To the extent that Premier's "joinder" is interpreted as presenting this argument, a similar analysis applies. Relator alleges that Premier provided prescription services in all fifty states, and that Premier paid kickbacks to secure prescriptions in at least Idaho, Montana, Wyoming, Utah, North Dakota, South Dakota, California, Oregon, Washington, and Alaska. TAC [Doc. No. 49] ¶¶ 10, 191, 202.

[159] Gilead also argues that the state law claims should fail for the same reasons that Gilead argues the federal claims should fail. Gilead's Mot. Dismiss [Doc. No. 56] at ECF page 34.

Where no party has alleged a material difference between the standards applicable to the FCA and equivalent state laws, on a motion to dismiss these claims succeed or fall together. *See U.S. ex rel. Petratos v. Genentech, Inc.*, 141 F. Supp. 3d 311, 322 (D.N.J. 2015); *U.S. ex rel. Bergman*, 995 F. Supp. at 377.

Relator argues that the Texas Medicaid Fraud Prevention Act ("TMFPA") does not require a "false claim" to establish materiality and encompasses a broader range of conduct than the FCA. Pl.'s Resp. Opp'n Def. Gilead's Mot. Dismiss [Doc. No. 60] at 21–22. However, Relator does not point to any allegations in the TAC that would constitute a violation of the TMFPA without satisfying the FCA's pleading requirements. Additionally, the TAC does not include any allegations specific to Texas, so the TMFPA is invoked only to the extent that the TAC pleads a national scheme.

relationship with the PAN Foundation, denied with respect to the TAC's allegations of conspiracy between Gilead and the PAN Foundation, and is otherwise granted. Premier's motion to dismiss is granted with respect to any claims alleging a conspiracy between Premier and Gilead and is otherwise denied. Gilead's request for judicial notice is granted.