****FOR PUBLICATION****

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

In re PLAVIX MARKETING, SALES PRACTICE AND PRODUCTS LIABILITY LITIGATION (NO. II)	MDL DOCKET NO. 2418 Civil Action No. 13-1039 (FLW)(LHG)
UNITED STATES OF AMERICA, *et al.*, ex rel. ELISA DICKSON, Plaintiffs, v. BRISTOL-MYERS SQUIBB CO., *et al*, Defendants.	**OPINION**

WOLFSON, United States District Judge:

Before the Court is the motion of Defendants Bristol-Myers Squibb Company ("BMS"), Sanofi-Aventis U.S. LLC, Sanofi U.S. Service Inc., and Sanofi-Synthelabo Inc. (collectively "Sanofi") (together with BMS, "Defendants") to dismiss the Fourth Amended Complaint ("4AC") of relator Elisa Dickson ("Realtor"). In the 4AC, Relator brings a *qui tam* action, a member case of the Multi-District Litigation, In re: Plavix Marketing, Sales Practices and Products Liability Litigation, involving the alleged wrongful marketing and sales of Plavix (clopidogrel bisulfate), a prescription blood thinner manufactured by Defendant BMS and marketed in the United States by BMS and Sanofi. Relator brings this case on behalf of the United States and seventeen states, asserting claims for violation of the federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729–3733 (Count I); conspiracy under the FCA, 31 U.S.C. § 3729(a) (Count II); and the False Claims Acts of twenty-four (24) states (Counts III-XXVI). Defendants

move to dismiss the 4AC in its entirety, and in the alternative to limit the temporal scope of Relator's state FCA claims under the laws of five states, the FCAs of which became effective after March 30, 2005.

For the reasons stated herein, the Defendants' Motion to Dismiss the 4AC is GRANTED, and Defendants' motion to restrict the retroactive application of the five state FCAs, which became effective after March 30, 2005, is denied as moot.

I. FACTUAL BACKGROUND

The relevant facts of this action, as set forth in the 4AC and taken as true by this Court, are as follows. Plavix® (clopidogrel bisulfate) ("Plavix") is a prescription blood thinner manufactured by BMS and comarketed in the United States by Sanofi. 4AC ¶ 1. Plavix has been approved by the United States Food and Drug Administration ("FDA") and is indicated for the treatment of Acute Coronary Syndrome and for use following a recent myocardial infarction or stroke or established peripheral artery disease. *Ibid.* Plavix costs approximately $4.00 per pill. Aspirin, an over-the-counter blood thinner, costs approximately $0.04 per pill. *Id.* at ¶ 3.

Relator claims that Defendants promoted Plavix as a superior drug to aspirin for certain indicated usages, when Plavix was no more effective than aspirin for those indicated usages and cost one hundred times more. *Id.* at ¶ 22. More than half of state Medicaid programs contain cost-based restrictions that limit coverage under Medicaid to cost-effective treatments. *Ibid.* In these states, Medicaid only pays for cost-effective drugs. *Ibid.* Where an equally effective but cheaper treatment is available for a particular course of treatment, the more expensive drug is not cost effective and cannot be reimbursed. *Ibid.* In these states, cost effectiveness is not just a requirement for participation in Medicaid, it is a condition precedent to reimbursement designed to ensure that a state's Medicaid program is a good steward of taxpayer dollars. *Ibid.*

Relator alleges that Defendants targeted their marketing efforts, misrepresenting the effectiveness of Plavix relative to aspirin, at physicians and prescribers whose patients relied upon public assistance programs such as Medicaid. *Id.* at ¶ 3. Relator claims that Defendants' marketing efforts caused physicians to submit many prescriptions for Plavix in the mistaken belief that it was a cost-effective treatment. *Ibid.*

In order for the cost of a drug to be reimbursed under Medicaid, the drug manufacturer must have entered into, and have in effect, a rebate agreement wherein the manufacturer agrees to give the applicable government payor back a percentage of the cost of the reimbursed drug. *Id.* at ¶ 92. Drugs that are covered by a rebate agreement are then statutorily divided into two distinct categories: those that require prior authorization from Medicaid prior to reimbursement and those that are reimbursed automatically when the drug is prescribed. *Ibid.* Each state maintains a preferred drug list, or formulary[1], that explicitly exempts certain Medicaid-eligible drugs from a prior authorization requirement. Medicaid is obligated to provide reimbursement for the cost of a drug on a state's formulary when the drug is prescribed by a physician for an "on-label" indication. *Ibid.* In other words, if a drug is on a state's formulary, once an "on-label" prescription for that drug is written and the prescription is filled, the cost for that prescribed drug is automatically reimbursed by the government. No other authorizations are required. *Id.* at ¶ 26.

[1] The 4AC Complaint defines the term "preferred drug list" as equivalent to or interchangeable with the term "formulary." *Id.* at ¶ 92. Defendants correctly object in their motion papers that these terms have distinct legal meanings. "Formularies" are described under 42 U.S.C. § 1396r-8(d)(4), while "preferred drug lists" ("PDL"), exempting drugs from "prior authorization programs," are described under § 1396r-8(d)(5). However, as it is clear from the 4AC that Relator is concerned with the placement of Plavix on PDLs only, and merely also refers to these lists as formularies, the legal distinction between these terms as used in the Medicaid statute does not affect the Court's decision. *See* 4AC ¶¶ 25, 100.

In addition to marketing to prescribing physicians, Relator also alleges that Defendants falsely marketed Plavix to the physicians and pharmacists on state formulary committees as a cost effective treatment eligible for listing on the states' formularies, when Plavix was not in fact so eligible, due to its lack of superior effectiveness to aspirin and significantly greater cost. *Id.* at ¶ 151. Relator claims that these marketing efforts fraudulently induced the formulary committees to include Plavix on each state's PDL/formulary, which triggered an automatic government obligation to reimburse Plavix prescriptions—even when Plavix did not meet the cost-effectiveness requirements for inclusion on the formulary. *Ibid.* Relator alleges that reimbursements for Plavix in this context constitute false claims under the FCA and under the state FCAs. *Ibid.*

II. PROCEDURAL HISTORY

On March 30, 2011, Relator filed this case in the United States District Court for the Southern District of Illinois ("the transferor court"). The United States and its co-plaintiff States declined to intervene in Relator's claims. On November 29, 2012, Relator filed a Second Amended Complaint. Defendants moved to dismiss that pleading, and the transferor court granted that motion in part and denied it in part ("*Dickson* I"). See 289 F.R.D. 271 (S.D. Ill. 2013) (Dkt. No. 54.).

The Judicial Panel on Multidistrict Litigation then transferred the case to this Court to be part of the Plavix® Multi-District Litigation. This Court then vacated *Dickson* I, in part, upon reconsideration, granted further dismissal in part, and granted Relator leave to amend her pleading ("*Dickson* II"). *See* 2013 WL 7196328 (D.N.J. Aug. 21, 2013) (Dkt. No. 88). On September 20, 2013, Relator filed a 149-page Third Amended Complaint ("3AC"). The 3AC's Prescriber Allegations and Formulary Allegations asserted that Defendants violated the federal

FCA and numerous state FCAs by causing the submission of false claims for Medicare and Medicaid payment. Defendants moved to dismiss the 3AC in its entirety. On August 20, 2015, the Court granted Defendants' motion in part and denied it in part. The Court dismissed (1) all FCA claims based on Medicare Part D; (2) federal FCA claims based on the Medicaid plans of thirty-three (33) states, including the District of Columbia; (3) all FCA claims based on Plavix's inclusion on state formularies; (4) state FCA claims raised under the law of nineteen (19) states; and (5) all federal and state FCA claims for claims made prior to March 30, 2005, pursuant to the applicable statutes of limitations. *See Dickson* III, 123 F. Supp. 3d at 619.

The active claims remaining in the case after the Court's decision were (1) federal FCA claims based on Defendants' conduct in 17 States — Connecticut, Delaware, Idaho, Kansas, Maryland, Massachusetts, Mississippi, Montana, Nebraska, North Carolina, Ohio, Oklahoma, Rhode Island, South Dakota, Utah, Washington and Wyoming — each of which imposes a cost-effectiveness requirement as a condition for the reimbursement of drugs under that state's Medicaid program ("the Cost-Imposed States"); and (2) state FCA claims under the law of the seven Cost-Imposed States that have enacted their own FCAs — Connecticut, Delaware, Massachusetts, Montana, North Carolina, Oklahoma, and Rhode Island.

On December 15, 2015, the Court stayed this case pending the Supreme Court's decision in *Universal Health Servs., Inc. v. United States and Massachusetts, ex rel. Escobar*, —— U.S. ——, 136 S. Ct. 1989, 2001, 195 L. Ed. 2d 348 (2016)) (hereinafter "*Escobar*"). On June 16, 2016, the Supreme Court decided *Escobar*. These proceedings were reopened on June 29, 2016.

On August 16, 2016, without seeking leave to amend, Relator filed her fifth pleading: the 175-page Fourth Amended Complaint ("4AC"). The 4AC asserts claims for violation of the federal FCA, 31 U.S.C. §§ 3729-3733 (Count I), and for conspiracy to violate the federal FCA,

31 U.S.C. § 3729(a) (Count II), based on allegedly false Medicaid claims submitted in thirty-six (36) states. In addition to federal FCA claims based on conduct in the 17 Cost-Imposed States that this Court previously allowed to go forward, Relator also includes claims in 19 states – Alabama, Alaska, Arizona, Arkansas, Colorado, Florida, Georgia, Hawaii, Iowa, Louisiana, Maine, Michigan, Minnesota, Nevada, New Jersey, New Mexico, Oregon, Tennessee, Wisconsin – which this Court previously dismissed. Relator claims that these states too impose cost-effectiveness requirements in their Medicaid reimbursement schema, which were simply not pleaded in the 3AC. The 4AC also asserts claims under 24 state FCAs.[2] This figure includes 17 state FCA claims, which this Court previously dismissed — California, Colorado, Florida, Georgia, Illinois, Indiana, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, Tennessee, Texas, Virginia, Wisconsin, District of Columbia. Again, Relator's rationale for

[2] *See* California FCA (Cal. Gov. Code §§ 12650-12655) (Count III); Colorado Medical FCA (C.R.S. § 25.5-4-304 *et seq.*) (Count IV); Connecticut False Claims Act (CONN. GEN. STAT. ANN. § 17b-301a et seq.) (Count V); Delaware False Claims and Reporting Act (6 DEL. CODE ANN. § 1201(a)(1) and (2)) (Count VI); Florida False Claims Act (FL. STAT. §§ 68.081-68.090) (Count VII); Georgia False Medicaid Claims Act (GA. CODE 49-4-168 et seq.) (Count VIII); Illinois Whistleblower Reward and Protection Act (740 ILCS 175, et seq.) (Count IX); Indiana State False Claims and Whistleblowers Protection Act (IND. CODE ANN. § 5-11-5.5-1 – 5-11-5.5-18) (Count X); Massachusetts False Claims Act (MASS. GEN. LAWS c.12 § 5(A)) (Count XI); Michigan Medicaid False Claims Act (Mich. Comp. Laws §§ 400.601-400.613) (Count XII); Minnesota False Claims Act (MINN. STAT. § 15.C01 et. seq) (Count XIII); Montana False Claims Act (MONT. CODE ANN. §§ 17-8-401 – 17- 8-412) (Count XIV); Nevada False Claims Act (NEV. REV. STAT. ANN. §§ 357.01-.250) (Count XV); New Jersey False Claims Act (N.J. STAT. § 2A:32C-1-17) (Count XVI); New Mexico Medicaid False Claims Act (N.M. STAT. ANN. § 27-14-1- - 27-14-15) (Count XVII); New York False Claims Act (N.Y. St. Finance Law § 187 et seq.) (Count XVIII); North Carolina False Claims Act (N.C. GEN. STAT. § 1-605 – 618, § 108A-63) (Count XIX); Oklahoma False Claims Act (63 OKLA. STAT. §§ 5053-5053.7) (Count XX); Rhode Island's State False Claims Act (R.I. GEN. LAWS §§ 9-1.1-1 – 9-1.1-8) (Count XXI); Tennessee Medicaid False Claims Act (TENN. CODE. ANN. §§ 71-5-181 to -185) (Count XXII); Texas Medicaid Fraud Prevention Act (TEX. HUM. RES. CODE ANN 36.001-.132) (Count XXIII); Virginia Fraud Against Taxpayers Act (VA CODE ANN. 8.01-2.16. 1-216.19) (Count XXIV); Wisconsin State Law Claims for Violations of the Wisconsin False Claims Act (WIS. STAT. § 20.931) (Count XXV); District of Columbia Procurement Reform Amendment Act (D.C. CODE ANN. §§ 2-308.13-.15) (Count XXVI).

resurrecting these claims is that these states also impose cost-effectiveness requirements, which were previously not pleaded. Relator's federal and state FCA claims in the 4AC incorporate this Court's previous ruling on the statutes of limitations, and do not seek recovery for false claims arising prior to March 30, 2005, except for revived previously dismissed claims under four State FCAs with longer or shorter limitations periods: New Mexico (four years), New York (10 years), Texas (four years), and Wisconsin (10 years). 4AC ¶ 51 n. 54.

On January 30, 2017, Defendants moved to dismiss the 4AC in its entirety. On May 1, 2017, the Third Circuit issued its first reported opinion interpreting the Supreme Court's decision in *Escobar*. Defendants submitted a notice of supplementary authority on May 8, 2017, contending that the Third Circuit's precedential decision in *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481 (3d Cir. 2017), compelled the dismissal of the 4AC for failure to allege that Defendants' fraud was material to any government Medicaid payor's decision to pay for Plavix. Relator opposed Defendants' arguments concerning *Petratos* on May 11, 2017.

III. LEGAL STANDARD

This Court has federal-question jurisdiction over the federal FCA claims under 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a). Supplemental jurisdiction extends to the state FCA claims under 28 U.S.C. § 1367. *See also United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 302 (3d Cir. 2011). "The law of the transferee forum applies . . . to federal questions, though the Court may give the law of the transferor forum 'close consideration.'" *In re Nazi Era Cases Against German Defendants Litig.*, 320 F. Supp. 2d 204, 214 (D.N.J. 2004), *aff'd*, 153 F. App'x 819 (3d Cir. 2005) (citing *In re Korean Air Lines Disaster*, 829 F.2d 1171 (D.C.Cir. 1987)). Accordingly, in considering the present motion to dismiss, the precedents of the Third Circuit control the merits of Relator's federal FCA claims. *In re Nazi Era Cases Against German*

Defendants Litig., 198 F.R.D. 429, 439 n.16 (D.N.J. 2000) ("When dealing with cases that have been consolidated for pretrial proceedings pursuant to an order of the MDL Panel under 28 U.S.C. § 1407, the law of the transferor forum merits close attention, but should not be read to have stare decisis effect in a transferee forum situated in another circuit. *See In re Korean Air Lines Disaster*, 829 F.2d 1171, 1176 (D.C. Cir. 1987). For this reason the Court will apply the law of the Third Circuit, with due consideration given to the rulings of other circuits.").[3] Because the Court exercises supplemental jurisdiction over the state FCA claims under the laws of twenty-four states, the Court must apply the state substantive law of each respective state to that state's FCA claim. *Silverstein v. Percudani*, 422 F. Supp. 2d 468, 471 (M.D. Pa.), *aff'd*, 207 F. App'x 238 (3d Cir. 2006) ("A federal district court exercising supplemental jurisdiction over state law causes of action must apply the substantive law of the State [providing the cause of action] as interpreted by the State's highest court.").

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[3] *See also In re Donald J. Trump Casino Sec. Litig.-Taj Mahal Litig.*, 7 F.3d 357, 368 n. 8 (3d Cir. 1993) (assuming without deciding that the district court was correct that in multidistrict transfers, the precedent of the Third Circuit as the transferee court controls on issues of federal law, while the circuit precedent of the transferor court merits close consideration); *In re Managerial, Prof'l & Tech. Employees*, No. 02-CV-2924, 2006 WL 38937, at *2 (D.N.J. Jan. 5, 2006) (quoting *Korean Air Lines*, 829 F.2d at 1174 (quoting Marcus, *Conflict Among Circuits and Transfers Within the Federal Judicial System*, 93 Yale L.J. 677, 721 (1984))) ("Where the claim arises under federal law, as is the case here, the appropriate course is to apply the law of the transferee court. In considering the issue, the D.C. Circuit Court of Appeals recognized that the pretrial nature of multidistrict transfers suggests that the law of the origin circuit should apply, while the presumed uniformity of federal law across circuits suggests that doing so would be unnecessary. After considering these competing views, the court decided that ''the transferee court [should] be free to decide a federal claim in the manner it views as correct without deferring to the interpretation of the transferor circuit.'"); *In re National Century Financial Enterprises, Inc., Inv. Litigation*, 323 F. Supp. 2d 861, 876 (S.D. Ohio 2004) ("the rule in multidistrict litigation is that the transferee court, in interpreting federal law, should apply the law of its own circuit rather than the law of the transferor court's circuit."); *In re StarLink Corn Prod. Liab. Litig.*, 211 F. Supp. 2d 1060, 1063 (N.D. Ill. 2002) (applying *Korean Air Lines* and *McMasters v. United States*, 260 F.3d 814, 819 (7th Cir. 2001) to find that, on questions of federal law, circuit precedent from the transferee court applies unless the federal law is specifically intended to be geographically non-uniform).

When considering a motion to dismiss a complaint for failure to state a claim upon which relief can be granted, pursuant to Fed. R. Civ. P. 12(b)(6), a court must accept all well-pleaded allegations in the complaint as true and view them in the light most favorable to the plaintiff. *Evancho v. Fisher*, 423 F.3d 347, 351 (3d Cir. 2005). It is well settled that a pleading is sufficient if it contains "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). However, "[a]lthough the Federal Rules of Civil Procedure do not require a claimant to set forth an intricately detailed description of the asserted basis for relief, they do require that the pleadings give defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." *Baldwin Cnty. Welcome Ctr. v. Brown*, 466 U.S. 147, 149–50 n. 3 (1984) (quotation and citation omitted). A district court, in weighing a motion to dismiss, asks "'not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claim.'" *Bell Atlantic v. Twombly*, 550 U.S. 544, 583 (2007) (quoting *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 684 (2009) ("Our decision in *Twombly* expounded the pleading standard for all civil actions.") (internal citations omitted); *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) ("*Iqbal* ... provides the final nail-in-the-coffin for the 'no set of facts' standard that applied to federal complaints before *Twombly*.").

Following the *Twombly/Iqbal* standard, the Third Circuit applies a two-part analysis in reviewing a complaint under Rule 12(b)(6). First, a district court must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions. *Fowler*, 578 F.3d at 210. Second, a district court must determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a "plausible claim for relief." *Id.* A complaint must do more than allege the plaintiff's entitlement to relief. *Id.* However, this standard "'does not

impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary element.'" *Phillips v. Cnty. of Allegheny,* 515 F.3d 224, 234 (3d Cir. 2008) (quoting *Twombly,* 127 S. Ct. at 1965); *see also Covington v. Int'l Ass'n of Approved Basketball Officials*, 710 F.3d 114, 118 (3d Cir. 2013) ("[A] claimant does not have to set out in detail the facts upon which he bases his claim. . . . The pleading standard is not akin to a probability requirement, . . . to survive a motion to dismiss, a complaint merely has to state a plausible claim for relief." (citations omitted)). Nonetheless, a court need not credit either "bald assertions" or "legal conclusions" in a complaint when deciding a motion to dismiss. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1429–30 (3d Cir. 1997). The defendant bears the burden of showing that no claim has been presented. *Hedges v. U.S.*, 404 F.3d 744, 750 (3d Cir. 2005) (citing *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1409 (3d Cir. 1991)).

Finally, a court in reviewing a Rule 12(b)(6) motion must only consider the facts alleged in the pleadings, the documents attached thereto as exhibits, and matters of judicial notice. *Southern Cross Overseas Agencies, Inc. v. Kwong Shipping Grp. Ltd.,* 181 F.3d 410, 426 (3d Cir. 1999).

Because FCA claims allege fraud, they are subject to the heightened pleading requirements of Federal Rule of Civil Procedure 9(b). *Wilkins*, 659 F.3d at 301 n. 9; *Frederico v. Home Depot*, 507 F.3d 188, 202–03 (3d Cir. 2007). In order to satisfy Rule 9(b), a complaint must provide "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." *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) (quoting *Burlington Coat Factory*, 114 F.3d at 1422). In order to satisfy the standards of 9(b) in the FCA

context Relator "must provide particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted. Describing a mere opportunity for fraud will not suffice. Sufficient facts to establish a plausible ground for relief must be alleged." *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 157–58 (3d Cir. 2014) (quotations omitted). *See also id.* at 156 (In *United States ex Rel. Wilkins* . . ., we noted that we had never "held that a plaintiff must identify a specific claim for payment *at the pleading stage* of the case to state a claim for relief.").

IV. ANALYSIS

"[T]he FCA makes it unlawful to knowingly submit a fraudulent claim to the government."[4] *U.S. ex rel. Schumann v. Astrazeneca Pharm. L.P.*, 769 F.3d 837, 840 (3d Cir. 2014). "The primary purpose of the FCA is to indemnify the government-through its restitutionary penalty provisions-against losses caused by a defendant's fraud." *Wilkins*, 659 F.3d at 304 (quotation omitted). To that end, the Act contains a *qui tam* provision that permits private parties (known as "relators") to bring suit "on behalf of the United States against anyone submitting a false claim to the Government." *Schumann*, 769 F.3d at 840 (internal quotation marks omitted) (quoting *Hughes Aircraft Co. v. U.S. ex rel. Schumer*, 520 U.S. 939, 941 (1997)). If a *qui tam* suit is successful, the relator has the opportunity to share in the recovery.

The Third Circuit has recognized that "[t]here are two categories of false claims" that may form the basis of an FCA *qui tam* suit: (1) factually false claims; and (2) legally false

[4] The FCA as FERA has amended it, now imposes liability on:
[A]ny person who—
(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
(B) 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); *Wilkins*, 659 F.3d at 303.

claims. *Wilkins*, 659 F.3d at 305. "'A claim is factually false when the claimant [knowingly] misrepresents what goods or services that it provided to the Government.' '[A] claim is legally false when the claimant knowingly falsely certifies that it has complied with' a material statute, regulation, or contractual provision. Such certification may be express or implied. 'Under the 'express false certification' theory, [a claimant] is liable under the FCA for falsely certifying that it is in compliance with' a material statute, regulation, or contractual provision." *United States v. Eastwick Coll.*, 657 F. App'x 89, 93–94 (3d Cir. 2016) (quoting *Wilkins*, 659 F.3d at 305). "By contrast, implied false certification liability attaches when a claimant 'makes specific representations about the goods or services provided' and the claimant's 'failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.'" *Id.* (quoting *Escobar*, 136 S. Ct. at 2001).[5] "[T]he implied certification theory of liability should not be applied expansively, particularly when advanced on the basis of FCA allegations arising from the Government's payment of claims under federally funded health care programs." *Wilkins*, 659 F.3d at 307. "Thus, under this theory a plaintiff must show that if the Government had been aware of the defendant's violations of the Medicare [or Medicaid] laws and regulations that are the bases of a plaintiff's FCA claims, it would not have paid the defendant's claims." *Ibid.*

In addition to factually false and legally false claims, the federal courts have recognized a narrow, third category of false claims obtained by "fraud-in-the-inducement." "[A] fraudulently induced contract may create liability under the False Claims Act when that contract later results in payment thereunder by the government, whether to the wrongdoer or someone else." *United*

[5] "The FCA defines 'material' as 'having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.'" *Wilkins*, 659 F.3d at 303 (quoting 31 U.S.C. § 3729(b)(4)).

States v. Veneziale, 268 F.2d 504, 505 (3d Cir. 1959) (citing *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943) (superseded by statute)). *See also U.S. ex rel. Thomas v. Siemens AG*, 593 F. App'x 139, 143 (3d Cir. 2014) ("Although the focus of the False Claims Act is on false 'claims,' courts have employed a fraudulent inducement theory to establish liability under the Act for each claim submitted to the government under a contract which was procured by fraud, even in the absence of evidence that the claims were fraudulent in themselves.").

In the 4AC, Relator pursues her federal and state FCA claims under both implied false certification and fraud-in-the-inducement theories of liability. First, Relator contends that Defendants caused physicians to submit prescriptions to Medicaid for payment by fraudulently marketing Plavix to those physicians as more effective than aspirin, despite Plavix being one-hundred times more expensive and no more effective. Relator contends that the claims to Medicaid, submitted by physicians who were subjected to Defendants' marketing efforts, contained an implied false certification that Plavix complied with state Medicaid program requirements that all prescriptions submitted for payment be for drugs that are cost-effective treatments. Because Plavix costs one-hundred times more than aspirin, but Relator alleges it to be no more effective, Relator contends that Plavix was not cost-effective and was not eligible for reimbursement under the laws of the thirty-six states imposing cost-effectiveness requirements in their Medicaid program. The Court shall refer to this category of claims as the "Prescriber Allegations."

Second, relying explicitly on the fraud-in-the-inducement theory enunciated by the Third Circuit in the context of a fraudulently induced contract in the unreported decision in *Thomas*, Relator contends that Defendants fraudulently induced state Medicaid formulary committees to place Plavix on their respective state PDLs — or formularies — by marketing Plavix to those

committees as more effective than aspirin, when Plavix was not in fact more effective than aspirin. 4AC ¶ 98, n. 140 (incorporating *Thomas* into fraud-in-the-inducement theory). Relator again contends that Plavix therefore did not meet the state-law requirements for cost-effectiveness, a prerequisite to being included on the formularies of the thirty-six states imposing such requirements. The court shall refer to this category of claims as the "Formulary Allegations."

Defendants move to dismiss all of Relator's federal FCA claims in both categories. Specifically, Defendants argue that the Prescriber Allegations must be dismissed because (1) the law of the case bars Relator from reviving federal FCA claims based on alleged implied false certifications submitted in the 19 states and state FCA claims under the statutes of 17 states that this Court dismissed in its decision concerning the 3AC; (2) the Prescriber Allegations are deficient under Fed. R. Civ. P. 9(b); and (3) the Prescriber Allegations fail to meet the heightened pleading standard for materiality established by the Supreme Court in *Escobar*. Defendants argue that the Formulary Allegations must be dismissed because (1) the law of the case bars Relator from reviving the Formulary Allegations, which were dismissed in this Court's decision concerning the 3AC; and (2) the Formulary Allegations fail to state a claim under *Thomas*, or any other identified authority. Additionally, Defendants move, in the alternative, to dismiss Relator's state FCA claims to the extent based on the retroactive application of the state FCA statutes in five states which became effective after March 30, 2005. I will address each of Defendants' arguments in turn.

A. The Prescriber Allegations

1. Law of the Case

"The law of the case doctrine directs courts to refrain from re-deciding issues that were resolved earlier in the litigation." *Pub. Interest Research Grp. of New Jersey, Inc. v. Magnesium Elektron, Inc.*, 123 F.3d 111, 116 (3d Cir. 1997). The rule was developed "to maintain consistency and avoid reconsideration of matters once decided during the course of a single continuing lawsuit." *In re Pharmacy Benefit Managers Antitrust Litig.*, 582 F.3d 432, 439 (3d Cir. 2009) (internal quotation marks and citation omitted). Law of the case is a matter of a court's discretion, but a court faced with revisiting a prior decision in the case "should be loathe to do so in the absence of extraordinary circumstances such as where the initial decision was clearly erroneous and would make a manifest injustice." *Id.* (quoting *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 816 (1988)). In addition, a court may revisit its own decisions or one of a coordinate court where (1) new evidence is available; (2) "a supervening new law has been announced"; or (3) "whenever it appears that a previous ruling, even if unambiguous, might lead to an unjust result." *Id.* The law of the case doctrine, however, only applies "to issues that the court actually decided, whether expressly or by implication." *Coca–Cola Bottling Co. of Shreveport v. Coca–Cola Co.*, 988 F.2d 414, 429 (3d Cir. 1993).

Here, Defendants contend that this Court's dismissal of federal FCA claims based on false certifications of compliance with the law of non-Cost Imposed States in *Dickson* III, acts to bar federal FCA claims based on the law of those states in the 4AC. I disagree. "A False Claims Act violation includes four elements: falsity, causation, knowledge, and materiality." *Petratos*, 855 F.3d at 487. In *Dickson* III, this Court dismissed federal FCA claims based on alleged false certifications of compliance with the law of all states except the Cost-Imposed States on the ground that Relator had failed to plead falsity in connection with the non-Cost-Imposed States. Specifically, the 3AC alleged that Plavix was not "medically necessary" and thus was ineligible

for reimbursement under the Medicaid plans of various states. With regard to the Cost-Imposed States, Relator had successfully pleaded that in their legal definitions of medical necessity, "the Cost–Imposed States have included not only a cost-based restriction, but rather, . . . have also mandated that the cheaper alternative must be equally effective as Plavix." *In re Plavix Mktg., Sales Practices & Prod. Liab. Litig.*, 123 F. Supp. 3d 584, 611 (D.N.J. 2015). This Court found such restrictions to be consistent with the limitations authorized by Medicaid, and found Relator to have pleaded that Plavix was not an equally cost-effective treatment to aspirin. Accordingly, although Relator had failed to plead falsity on the basis of "medical necessity," this Court held that Relator had adequately alleged, in the Cost-Imposed States, that physicians submitted claims with the implied false certifications that Plavix met state Medicaid cost-effectiveness requirements for reimbursement. For the same reasons, this Court then dismissed the Prescriber Allegations under the state FCAs of every state except the seven that were also Cost-Imposed states.

With regard to the non-Cost-Imposed states, however, the Court found merely that Relator had failed to allege "how those states have defined 'medical necessity'; in other words, there are no allegations relating to the types of restrictions by a state." *Id.* at 610. Accordingly, this Court did not find that the non-Cost-Imposed states did not impose cost-effectiveness requirements as a prerequisite to Medicaid reimbursement, but rather only that there was a total lack of allegations as to the content of the state statutory requirements for reimbursement in those states.

Relator now seeks to raise federal FCA claims on the basis of certifications of compliance with the laws of nineteen (19) of these previously dismissed states on the grounds that their statutory definitions of medical necessity, or other prerequisites to reimbursement, do

indeed contain cost-effectiveness requirements, which Relator simply failed to plead in the 3AC. Relator also presents claims under seventeen (17) more state FCAs for states that allegedly also impose cost-effectiveness requirements for Medicaid reimbursement. It is clear that Relator should have sought leave to amend in order to bring such claims. Allowing Relator to bring federal claims for false certifications of compliance with the law of the nineteen previously dismissed states and state claims under the laws of seventeen previously dismissed states, however, does not require this Court to revisit or overturn the reasoning of its previous decision. In reviewing the 3AC, the Court found that only the Cost-Imposed states included allegations that cost-effectiveness was a precondition for Medicaid reimbursement, and the other states lacked any such allegations. In the 4AC, Relator now seeks to supply such allegations for nineteen additional states under the FCA and seventeen additional states under the state FCAs.

"Generally, Rule 15 motions should be granted." *United States ex rel. Customs Fraud Investigations, LLC. v. Victaulic Co.*, 839 F.3d 242, 249 (3d Cir. 2016). In its most recent precedential FCA decision, the Third Circuit reversed a district court's denial of leave to amend, invoking well-settled Supreme Court precedent. "In *Foman v. Davis*, the Supreme Court held that the fundamental purpose of Rule 15 is to allow a plaintiff 'an opportunity to test his claim on the merits,' and although 'the grant or denial of an opportunity to amend is within the discretion of the District Court,' that discretion is abused if it is exercised without giving the plaintiff sufficient opportunity to make her case." *Ibid.* (quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962)). Here, Plaintiff's proposed additional allegations are consistent with the Court's decision in *Dickson* III, and there is no possibility of prejudice to Defendants in considering such allegations as they are equally subject to Defendants' legal challenges under 9(b) and 12(b)(6) as are the allegations concerning the Cost-Imposed States. Moreover, while this Court has certainly

afforded Relator ample opportunities to make her case, as demonstrated by its previous grant of leave to amend in *Dickson* II, the Court finds in its discretion that it would not be in the interest of justice or the parties to deny Relator the opportunity to test the legal sufficiency of her claims in the present motion. Defendants' motion to dismiss the federal and state FCA Prescriber Allegations under the law of the case is denied.

2. Rule 9(b)

Defendants next seek reconsideration of their own previously denied motions to dismiss the Prescriber Allegations under Fed. R. Civ. P. 9(b). As this Court observed in *Dickson* III, Chief Judge Herndon, hearing this case in the transferor court prior to its transfer here, denied Defendants' Motion to Dismiss under Rule 9(b). *See* January 2013 Memorandum and Order. With regard to Defendants' assertions that the Second Amended Complaint was insufficient under Rule 9(b), Chief Judge Herndon stated that "Relator's instant allegations are sufficient to comport with the requirements of Rule 9(b) in this instance," and that "[a]s to which specific physicians such misrepresentations were allegedly made, and further which specific employees of defendants' instructed relator to make such misrepresentations, such details can be fleshed out in discovery." *Id.* at 8–9. In response to Defendants' arguments that "relator is required at this stage in the proceedings to identify specific claims actually submitted which relator alleges were false," the court stated that it "does not feel such specificity is required in this instance." *Id.* at 9 n. 6.

In response to Defendants' renewed motion to dismiss under 9(b) in *Dickson* III, this Court observed that "[w]hile the Third Amended Complaint has added significant details as to the states' limitations on Medicaid and Medicare, . . ., and as to the states' formulary programs, . . ., the factual allegations otherwise remain the same as alleged in the Second Amended

Complaint. Thus, with the exception of the Defendants' new arguments regarding the formulary allegations, Chief Judge Herndon's decision regarding the adequacy of Relator's pleading remains the law of the case." *In re Plavix Mktg., Sales Practices & Prod. Liab. Litig.*, 123 F. Supp. 3d 584, 614 (D.N.J. 2015). I next found that none of the extraordinary circumstances warranting reconsideration of the transferor Court's prior decision were applicable and left undisturbed Chief Judge Herndon's decision that Relator's Prescriber Allegations were adequate under Rule 9(b). *Ibid.* I also noted that

> when applying the standard of Rule 9(b) to claims under the FCA, the Third Circuit, like the First, Fifth, and Ninth Circuits, uses a "nuanced" version of the heightened pleading standard. *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 157 (3d Cir.2014). Under this reading "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 submitted." *Id.* at 156. The court also repeated the statement from *Wilkins* that "we ha[ve] never held that a plaintiff must identify a specific claim for payment at the pleading stage of the case to state a claim for relief." *Id.* Thus, Defendants' argument that the Complaint must identify specific false claims is misplaced.

Dickson III, 123 F. Supp. 3d at 614 n. 19.

Looking now to Defendants' present motion, the allegations of the 4AC are substantially similar to the allegations in the 3AC concerning the Prescriber Allegations. Defendants do not dispute this, and instead argue that reconsideration is appropriate because the Supreme Court's decision in *Escobar* constitutes a supervening change in the law governing 9(b) pleading standards for particularity. In *Escobar*, the Supreme Court imposed a heightened pleading standard to allege the element of materiality in implied false certification cases under the FCA. *Escobar*, 136 S. Ct. at 1996. As discussed, *infra*, the decision indisputably states an intervening change of law in the standard to plead materiality under FCA, whether under Fed. R. Civ. P. 8(a) or 9(b). *Escobar*, 136 S. Ct. at 2004 n. 6 ("We reject Universal Health's assertion that materiality is too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss or at

summary judgment. The standard for materiality that we have outlined is a familiar and rigorous one. And False Claims Act plaintiffs must also plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b) by, for instance, pleading facts to support allegations of materiality."). *Escobar* is silent, however, whether the general standard for particularity under Rule 9(b) has been affected in the pleading of other FCA elements.

Defendants extrapolate that *Escobar* altered the Rule 9(b) standard for particularity for other FCA elements on the basis of a single line in the decision. *See Escobar*, 136 S. Ct. at 2001 ("we hold that the implied certification theory can be a basis for liability, at least where two conditions are satisfied: first, the claim does not merely request payment, *but also makes specific representations about the goods or services provided*; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements *makes those representations misleading half-truths*") (emphasis added). Defendants contend that *Escobar*'s requirement of allegations concerning "specific representations about the goods or services provided" and how those representations became "misleading half-truths" changes the particularity pleading requirement of 9(b) for implied certification FCA claims and reopens the inquiry previously decided by the transferor court.

Here, as discussed below, the Court finds the imposition by the Supreme Court in *Escobar* of a heightened pleading standard for materiality under the FCA to be dispositive of Relator's allegations in the 4AC. As such, other than observing that the *Escobar* decision constitutes a supervening change in law with regard to the materiality element, this Court need

not decide whether the pleading standard for other elements of the FCA[6] or for pleading fraud with particularity under 9(b) have been affected by that decision.[7]

3. Materiality under *Escobar*

As noted above, "[a] False Claims Act violation includes four elements: falsity, causation, knowledge, and materiality." *Petratos*, 855 F.3d at 487. In *Dickson* III, Defendants moved to dismiss, and this Court dismissed the Prescriber Allegations for failure to plead *falsity*, except to the extent raised for implied false certifications of compliance with the law of the 17 Cost-Imposed States. I held:

> The allegations based on the Medicaid plans of the Cost–Imposed States stand on a different footing. Relator alleges that the Cost–Imposed States have included in their Medicaid statutes a cost effective requirement. In that connection, Relator alleges that Plavix is no more effective than aspirin, which is significantly less costly. *See* TAC at ¶¶ 115–120. Because, as Relator avers, "Plavix was regularly and systematically presented

[6] "Rule 9(b)'s heightened pleading standard applies to state law fraud claims asserted in federal court." *N. Am. Catholic Educ. Programming Found., Inc. v. Cardinale*, 567 F.3d 8, 13 (1st Cir. 2009). Accordingly, any change in the general standard for pleading fraud with particularity would affect the state law FCA claims as well.

[7] This Court's position is supported by the Third Circuit's only decision applying Rule 9(b) to an FCA claim post-*Escobar*. In an unreported decision, the Third Circuit enunciated the heightened pleading standard for implied false certification cases following *Escobar*. "By contrast, implied false certification liability attaches when a claimant '*makes specific representations about the goods or services provided*' and the claimant's 'failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.'" *United States v. Eastwick Coll.*, 657 F. App'x 89, 94 (3d Cir. 2016) (quoting *Escobar*, 136 S. Ct. at 2001) (emphasis added)). The Third Circuit, then, however, went on to apply the pre-*Escobar* 9(b) pleading standard for particularity to the allegations before it. "In order to satisfy Rule 9(b), a complaint must provide '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.'" *United States v. Eastwick Coll.*, 657 F. App'x 89, 93 (3d Cir. 2016) (quoting *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1422 (3d Cir. 1997))). The Third Circuit also affirmed the continued vitality, post-*Escobar*, of *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 158 (3d Cir. 2014), one of the cases upon which this Court previously relied in denying Defendants' motion for reconsideration of the transferor court's 9(b) ruling in *Dickson* III, applying *Foglia* to the question of whether claims were made with the requisite particularity. *Eastwick*, 657 F. App'x at 95.

> to physicians as superior to aspirin for [certain] patients," *see id.* at ¶ 152, Defendants caused these physicians to submit false claims. At this stage of this litigation, I find that Relator has stated plausible claims under the Cost–Imposed States' Medicaid regime. Relator alleges that cost-effectiveness is a "condition[ ] of Government payment"—that is, a condition "which, if the government knew they were not being followed, might cause it to actually refuse payment." *Wilkins,* 659 F.3d at 309. Indeed, the state statutes and regulations cited by Relator, on their face, indicate that services and treatments must be cost-effective in order to be covered by Medicaid.

Dickson III, 123 F. Supp. 3d at 611. The Court's judgment was rendered with the caveat that "Relator's claims in this context may not survive scrutiny should, for example, evidence show that Plavix was placed on certain states' Preferred Drug Lists," because, as courts in other circuits had observed, prescriptions for drugs on state PDLs may be submitted to and paid by Medicaid without the prescribing physician having to obtain prior authorization from the state — that is, the state payor might not have the opportunity to deny reimbursement for the prescription. *Ibid.* In other words, this Court noted that while on the face of the 3AC, Relator had adequately alleged that *false* certifications of cost-effectiveness had been submitted, it remained to be determined whether those false certifications were *material* to a government payor's reimbursement decision, in light of the exemption of some drugs from the prior authorization process altogether.

In the 4AC, Relator now affirmatively alleges that every state imposing a cost-effectiveness requirement for reimbursement under Medicaid also placed Plavix on its PDL or formulary, exempting Plavix from all prior authorization requirements, and obligating state Medicaid payors to reimburse claims for Plavix automatically. *See* 4AC ¶¶ 26, 47, 99-150. Defendants contend that, in doing so, Relator has pleaded herself out of court by alleging facts showing that implied false certifications by prescribing physicians necessarily could not have been material to Medicaid's decision to pay for Plavix prescriptions. In short, Defendants contend that Relator has alleged that state Medicaid agencies would reimburse Plavix

prescriptions automatically upon receipt because Plavix was included on each state's PDL, regardless of whatever representations were made by the prescribing physician. Defendants contend that these allegations fail the heightened pleading standard for materiality set forth by the Supreme Court in *Escobar*. I agree.

In *Escobar*, the Supreme Court reaffirmed the well-established requirement that "[a] misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act," and sought to "clarify . . . how that *rigorous* materiality requirement should be enforced." 136 S. Ct. at 1996 (emphasis added). The *Escobar* Court explained:

> 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. Materiality, in addition, cannot be found where noncompliance is minor or insubstantial.

Id. at 2003 (quoting *Allison Engine*, 553 U.S., at 672). The Court later concluded:

> In sum, when evaluating materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. Likewise, proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Id. at 2003–04. The Supreme Court also explained that failure to plead materiality was a proper basis for a motion to dismiss. *Id.* at 2004 n. 6 ("We reject Universal Health's assertion that materiality is too fact intensive for courts to dismiss False Claims Act cases on a motion to

dismiss or at summary judgment. The standard for materiality that we have outlined is a familiar and rigorous one."). After offering such guidance on how the materiality standard should be applied, the Court declined to apply it to the facts before it and remanded to the court of appeals for application. *Id.* at 2004.

Signifcantly, the Third Circuit has recently applied *Escobar* in circumstances which control the outcome in this case. In *Petratos*, the Third Circuit found that *Escobar* imposed a "heightened materiality standard" to plead a violation of the FCA, and applied that standard to affirm the dismissal of a relator's implied false certification complaint. *Id.* at 492–93.[8] The relator in *Petratos* alleged that the defendants, the makers of the widely prescribed cancer drug Avastin, had engaged in a marketing campaign which systematically suppressed information about Avastin's health risks, and "[a]s a consequence of [defendants'] data-suppression strategy, [relator] claimed the company caused physicians to submit Medicare claims that were not 'reasonable and necessary.'" *Petratos*, 855 F.3d at 485–86. The relator further alleged:

> If Roche/Genentech had revealed true and complete clinical, safety, and epidemiological information about Avastin to government regulatory agencies or the public, a significant number of doctors (if not all) would have more carefully evaluated their patients in order to determine which patients should receive lower doses of the drug, or discontinue use of the drug altogether. Similarly, had Roche/Genentech been truthful and forthcoming with reporting this information, third party payers (including federal and state government programs) would have reimbursed for fewer Avastin indications or for lower dosages, or conceivably would not have reimbursed for Avastin treatment at all.

United States ex rel. Petratos v. Genentech, Inc., No. 2:11-CV-03691, First Amended Complaint filed 04/16/15, Dkt. No. 77, ¶ 19. The Third Circuit found that the relator's allegations did not meet the "high standard" for pleading materiality post-*Escobar*.

[8] The district court below in *Petratos* dismissed the relator's complaint for failure to plead falsity. The Third Circuit disagreed with the district court's analysis, but affirmed on the alternative basis that the complaint failed to plead materiality, in light of the Supreme Court's intervening decision in *Escobar*. *Petratos*, 855 F.3d at 489.

> Petratos's allegations do not meet this high standard. As the District Court noted: "there are no factual allegations showing that CMS would not have reimbursed these claims had these [alleged reporting] deficiencies been cured." Petratos does not dispute this finding, which dooms his case. Simply put, a misrepresentation is not "material to the *Government's payment decision*," when the relator concedes that the Government would have paid the claims with full knowledge of the alleged noncompliance. . . . Similarly, we think that where a relator does not plead that knowledge of the violation could influence the Government's decision to pay, the misrepresentation likely does not "have[ ] a natural tendency to influence ... payment," as required by the statute. *See* 31 U.S.C. § 3729(b)(4). At a minimum, this would be "very strong evidence" that the misrepresentation was not material.

Petratos, 855 F.3d at 490 (citations omitted) (emphasis in original). In further support of its finding that the relator failed to plead materiality, the Third Circuit also noted that (i) the mere fact that a drug being "reasonable and necessary" was a condition of payment, without more, does not establish materiality; (ii) relator failed to plead that CMS "consistently refuses to pay" claims like those alleged; (iii) relator essentially conceded that CMS would consistently reimburse those claims with full knowledge of the purported noncompliance; and (iv) relator failed to cite to a single successful claim under the "reasonable and necessary" provision involving drugs prescribed for their on-label uses or a court decision upholding such a theory. *Id.* at 490.

Here, in the 4AC, Relator baldly alleges that government payors would not have reimbursed for Plavix had they been aware of the alleged false certification of cost-effectiveness,[9] but Relator's other, more specific allegations, belie these conclusory facts because Relator concedes that Plavix was listed on each state's PDL and that a PDL-listing alone was sufficient to compel government Medicaid payors *automatically* to reimburse claims for

[9] *See, e.g.*, 4AC ¶ 196 ("Had the United States known that BMS/Sanofi were knowingly causing physicians and pharmacists to submit such false claims for payment, the United States would not have provided reimbursement for such prescriptions under Government Payors' programs."); ¶ 208 (same for California); ¶ 222 (same for Colorado); ¶ 234 (same for Connecticut); etc.

Plavix. Specifically, Relator first alleges that Plavix was listed on the PDL of every state imposing a cost-effectiveness requirement for reimbursement. *See* 4AC ¶¶ 99-150. Next, Relator alleges that once a claim for Plavix was received by a government payor, it had to be paid automatically because of Plavix's listing on the state PDLs/formularies. *Id.* at ¶ 26 ("For drugs that are on the formulary, Medicaid programs are required to reimburse the cost of a drug on a state's formulary when the drug is prescribed by a physician for an indication for which the drug is on the formulary. Thus, if a drug is on a state's formulary, once an "on-label" prescription for that drug is written and the prescription is filled, the cost for that prescribed drug is automatically reimbursed by Government Payors. No other authorizations are required."); ¶ 47 ("But because of BMS/Sanofi's fraudulent conduct, prescribing physicians were misled into prescribing Plavix for Medicaid subscribers—which prescriptions certified to the Cost-Imposed States that Plavix met the requirements for Medicaid reimbursement—namely that the drug was medically necessary and cost effective for each patient receiving a prescription for Plavix. Where Plavix is on the formulary, these false certifications resulted in the automatic reimbursement of Plavix.").

Accordingly, the Prescriber Allegations in the 4AC clearly allege that once Plavix was placed on a state PDL, the government payor was obligated to reimburse on-label claims for the drug automatically, without consideration of what certifications the prescribing physicians might or might not have been making about the drug. Accordingly, while the Prescriber Allegations may suggest that Defendants' alleged fraudulent marketing of Plavix to prescribing physicians *caused* allegedly legally false claims to be submitted to Medicaid government payors, the Prescriber Allegations clearly state that the government payors' decision *to pay* the claims was based solely upon Plavix's inclusion on the state PDL.

In the 4AC Relator contends that these allegations are sufficient to establish causation. 4AC ¶ 27 ("A false implied certification by a doctor that a particular drug is medically necessary and cost effective for a particular patient (i.e., a prescription) is not just material to the Government Payor's payment decision, it is determinative because that prescription results in Government Payor reimbursement despite its falsity."). The relator in *Petratos* made a similar argument, which the Third Circuit explicitly rejected. In *Petratos*, as here, the relator argued that because defendants' fraudulent marketing practices to prescribing physicians were a "but for" cause of the submission of claims including implied false certifications to government payors, in other words that the defendants' misrepresentations to physicians about the drug were material to the physicians' decision to prescribe the drug and submit a claim to Medicare or Medicaid, the defendants' fraud was material to the government payors' decision to reimburse the claims. The Third Circuit succinctly noted that relator's "argument conflates materiality with causation, a separate element of a False Claims Act cause of action." *Petratos*, 855 F.3d at 491. The Third Circuit explained that in the FCA specific context, *the government* is always the "ultimate recipient of the misrepresentation" about compliance with a statutory, regulatory, or contractual requirement," and materiality is judged exclusively in relation to the government's payment decision. *Petratos*, 855 F.3d at 491. The Third Circuit concluded:

> By attempting to focus our inquiry solely on the physician's materiality determination, [relator] again tries to pass off restyled causation arguments as proof of materiality. The alleged fraud's effect on physicians is relevant to the extent that it caused claims eventually to reach CMS. *That is, evidence of how the claim makes its way to the government should be considered under the causation analysis, while the materiality analysis begins after a claim has been submitted.* The materiality inquiry, in asking whether the government's payment decision is affected, assumes that the claim has in fact reached the government.

Id. at 492 (emphasis added). Applied here, the prescribing physicians' alleged belief that Plavix was cost-effective on the basis of Defendants' allegedly fraudulent marketing campaign, is

relevant only to the extent that is shows that Defendants induced or caused claims containing implied false certifications of cost-effectiveness to reach the government Medicaid payors. For the Prescriber Allegations to state a claim under the FCA, Relator needed also to allege that the prescribers' implied false certification of cost-effectiveness affected the government Medicaid payors' decision to pay the claims for Plavix. This Relator failed to do, and indeed could not do, instead clearly alleging that once the claims for Plavix were submitted to Medicaid, they were paid automatically by virtue of Plavix's inclusion on state PDLs, without consideration by a government payor of the prescribers' implied certification of cost-effectiveness.

Returning to the language of *Petratos*, the Prescriber Allegations' claims about Defendants' conduct in marketing Plavix to physicians in a fraudulent of misleading manner, allegedly inducing those physicians to submit prescriptions for Plavix to Medicaid, go to "how the [allegedly false] claim makes its way to the government" and therefore are "considered under the causation analysis." *Id.* at 492. "*Materiality analysis begins after a claim has been submitted*," and the only fact alleged to have influenced the government payors' decision to reimburse claims for Plavix in this case is the inclusion of Plavix on the PDLs for all relevant states. *Ibid*. (emphasis added). Once Plavix was listed on the PDLs, the Complaint alleges that prescriptions for Plavix were reimbursed "automatically," regardless of whatever certifications were being made by the prescribing physicians. 4AC ¶ 26.

As was the Court in *Petratos*, this Court is further convinced in its finding that Relator has failed to plead materiality in this case because (i) the mere fact that a drug being "cost-effective" was a condition of payment, without more, does not establish materiality; (ii) Relator failed to plead that government Medicaid payors in fact consistently refuse to pay claims like those alleged; (iii) Relator's automatic reimbursement allegations essentially concede that

government Medicaid payors would consistently reimburse claims for Plavix with full knowledge of the purported false certification of physicians that Plavix was cost-effective (*i.e.* because Plavix prescriptions were automatically reimbursed without being considered for approval by the Medicaid payor once Plavix was placed on the state PDL); and (iv) Relator failed to cite to a single successful claim under the "cost-effectiveness" provisions of the relevant state statutes involving drugs prescribed for their *on-label* uses or a court decision upholding such a theory. *Petratos*, 855 F.3d at 490.

Accordingly, the Prescriber Allegations fail to plead materiality, and therefore do not state a cause of action under the federal FCA. Count I (for substantive violations of the FCA) and Count II (for conspiracy to violate the FCA), to the extent grounded in the Prescriber Allegations, and are therefore dismissed.[10] For the same reasons, the state FCA Prescriber Allegations will also be dismissed as discussed, *infra*.

B. The Formulary Allegations

1. Law of the Case

In *Dickson* III, based on Relator's failure to plead falsity, this Court dismissed Relator's Formulary Allegations, then premised on claims that Defendants had misrepresented Plavix to formulary committees as "medically necessary." *Dickson* III, 123 F. Supp. 3d at 612 ("Relator

[10] Under section 3729(a)(1)(C), the FCA's conspiracy provision, raised in Count II of the 4AC, liability attaches to any person who "conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)" of that section. Here, as explained, *supra*, the Court has dismissed Relator's substantive FCA claims under the other subsections of Section 3729(a)(1), and therefore Relator's Section 3729(a)(1)(C) conspiracy claim, premised on a conspiracy to violate those other subsections must be dismissed also. *United States ex rel. Petras v. Simparel, Inc.*, 857 F.3d 497, 507 (3d Cir. 2017) (reasons for the dismissal of relator's substantive FCA claim "appl[y] with equal force to the dismissal of [relator's] conspiracy claim); *id* at 507 n. 53 (quoting *Pencheng Si v. Laogai Research Found.*, 71 F. Supp. 3d 73, 89 (D.D.C. 2014) ("'[T]here can be no liability for conspiracy where there is no underlying violation of the FCA.")).

cannot identify any false certification which actually was a prerequisite to payment. Equally deficient, Relator's speculative allegations with respect to Medicaid P & T Committees also do not state a claim. There are simply no allegations how any of Defendants' allegedly false promotional statements were material to, or had any bearing on, the decisions made by these committees."); *id.* at 612-13 (allegations that Defendants' scheme caused states to include Plavix on their state's Medicaid formularies for indications for which Plavix is not medically necessary failed to plead falsity). In their present motion, Defendants contend that this Court's prior dismissal of the Formulary Allegations is law of the case, and bars Relator from bringing its modified Formulary Allegations in the 4AC. I disagree for two reasons.

Firstly, as was the case with the Prescriber Allegations, the Formulary Allegations in the 4AC are based on Defendants' alleged inducement of state formulary committees to include Plavix on their PDLs through misrepresentations about Plavix's cost-effectiveness, not its medical necessity. As such, Relator's Formulary Allegations in the 4AC do not contradict or otherwise require reconsideration of this Court's previous dismissal of the Formulary Allegations in the 3AC based on Plavix's medical necessity. Although, again, it would have been appropriate for Relator to request leave to amend to conform her Formulary Allegations to this Court's prior decision, the Court grants such leave now in the interest of allowing Plaintiff an opportunity for her claims to be considered fully and because of the absence of prejudice to Defendants. As with the Prescriber Allegations, Defendants have had an opportunity to move to dismiss the Formulary Allegations as presently drafted, and indeed have done so.

Secondly, the 4AC makes clear, for the first time, that Relator's formulary allegations are intended to state a claim under a fraud-in-the-inducement theory of liability under the FCA, as embodied in the Third Circuit's unreported decision in *Thomas*. 4AC ¶ 98, n. 140. Because a

fraud-in-the-inducement theory of liability was not before this Court in *Dickson* III, and the Court did not have the benefit of the parties' briefing on the issue, the Court, in its discretion, declines to hold that the Court's prior dismissal of the Formulary Allegations encompassed Relator's new theory. Accordingly, Defendants' motion to dismiss the Formulary Allegations as law of the case is denied, and I will now turn to the merits of the claim.

2. Rule 12(b)(6) Failure to State a Claim

As discussed, *supra*, the Prescriber Allegations in the 4AC fail because they allege that state formulary committees' decisions to include Plavix on their state PDLs, and not the implied false certifications of prescribers submitting claims to Medicaid, were actually material to government Medicaid payors' decisions to reimburse claims for Plavix. In other words, the allegedly fraudulent inclusion of Plavix on a PDL by a formulary committee, not the submission of a false claim by a physician, is the operative act affecting each Medicaid payment decision in this case. The question before the Court on Relator's Formulary Allegations, therefore, is whether the FCA recognizes such a cause of action for "fraud on the formulary committee." Relator, in the 4AC, and in her opposition briefing on the present motion, contends that the FCA does provide for such actions under the theory of fraud in the inducement enunciated in *Thomas*.

"[T]he focus of the False Claims Act is on false 'claims.'" *Thomas*, 593 F. App'x at 143. "The conception of a claim against the government normally connotes a demand for money or for some transfer of public property." *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 183 (3d Cir. 2001) (quotation omitted). *See also id.* (quoting *United States v. McNinch*, 356 U.S. 595, 599 (1958) ("the False Claims Act was not designed to reach every kind of fraud practiced on the Government"). In *Thomas*, however, relying upon older, reported precedent, the Third Circuit held that "[a]lthough the focus of the False Claims Act is on false 'claims,' courts have

employed a fraudulent inducement theory to establish liability under the Act for each claim submitted to the government under a contract which was procured by fraud, even in the absence of evidence that the claims were fraudulent in themselves." *Thomas*, 593 F. App'x at 143. This theory dates back to the decision of the Supreme Court in *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943) (superseded by statute). *See id.* at 542–44 (recognizing fraudulent inducement theory). *Hess* involved collusive bidding on federally assisted state contracts. The United States later made payments by disbursing federal grants into a joint fund to aid the local government in paying its obligations under the collusively obtained contracts. The Supreme Court noted that although the wrongdoing in *Hess* did not involve the submission or inducement of a false claim in the strictest sense, the conduct of the defendants in inducing the underlying contracts by fraud nevertheless fell within the prohibition of the FCA.

> The government's money would never have been placed in the joint fund for payment to respondents had its agents known the bids were collusive. By their conduct, the respondents thus caused the government to pay claims of the local sponsors in order that they might in turn pay respondents under contracts found to have been executed as the result of the fraudulent bidding. This fraud did not spend itself with the execution of the contract. Its taint entered into every swollen estimate which was the basic cause for payment of every dollar paid by the P.W.A. into the joint fund for the benefit of respondents. The initial fraudulent action and every step thereafter taken, pressed ever to the ultimate goal—payment of government money to persons who had caused it to be defrauded.

Hess, 317 U.S. at 543–44. The Third Circuit has long applied *Hess*'s holding. *See United States v. Veneziale*, 268 F.2d 504, 505 (3d Cir. 1959) ("[I]t has long since been settled that a fraudulently induced contract may create liability under the False Claims Act when that contract later results in payment thereunder by the government...."). Furthermore, when Congress amended the FCA in 1986, it recognized that fraudulently induced contract claims were actionable under the statute. S. Rep. No. 99–345, at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 5266, 5274 ("[E]ach and every claim submitted under a contract, loan guarantee, or other

agreement which was originally obtained by means of false statements or other corrupt or fraudulent conduct, . . . constitutes a false claim.").[11] Since the 1986 Amendments, numerous federal Courts of Appeals have recognized the "fraud-in-the-inducement" theory of FCA liability in the context of *contracts* induced by fraud.[12]

a) The Third Circuit Has Not Recognized Relator's Theory of FCA Liability

Here, Relator argues that the fraud-in-the-inducement theory in *Thomas* may be extended to support Relator's fraud-on-the-formulary-committee theory in this case. I disagree. Firstly, none of the Supreme Court or circuit court precedents recognizing the fraud-in-the-inducement theory, including those binding decisions of the Third Circuit, has ever recognized Relator's novel fraud-on-the-formulary-committee theory. Fraud-in-the-inducement began in the Supreme Court's *Hess* decision as a doctrine applicable to contracts induced by fraud. It was reaffirmed by Congress in the legislative history of the 1986 Amendments to the FCA as a doctrine limited to

[11] The district court below in Thomas relied in part on the legislative history of the 1986 Amendments in finding an actionable "fraud-in-the-inducement" claim in that contract case. *U.S. ex rel. Thomas v. Siemens AG*, 991 F. Supp. 2d 540, 567–68 (E.D. Pa.), *aff'd*, 593 F. App'x 139 (3d Cir. 2014).

[12] *See, e.g., In re Baycol Prod. Litig.*, 732 F.3d 869, 876 (8th Cir. 2013) ("when a relator alleges liability under a theory of fraud-in-the inducement, claims for payment subsequently submitted under a contract initially induced by fraud do not have to be false or fraudulent in and of themselves in order to state a cause of action under the FCA"); *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458, 467–68 (5th Cir. 2009) (where a contract was procured by fraud, even when subsequent claims for payment under the contract were not literally false, they became actionable FCA claims because they "derived from the original fraudulent misrepresentation"); *Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376 (4th Cir. 2008) (recognizing a fraudulent inducement claim under the FCA based on obtaining a government contract through false statements) (citing *Harrison I*, 176 F.3d at 787); *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1173 (9th Cir. 2006) ("liability will attach to each claim submitted to the government under a contract, when the contract ... was originally obtained through false statements or fraudulent conduct"); *United States ex rel. Bettis v. Odebrecht Contractors of Cal., Inc.*, 393 F.3d 1321, 1326 (D.C. Cir. 2005) ("[C]ourts have employed a 'fraud-in-the-inducement' theory to establish liability under the Act for each claim submitted to the Government under a contract which was procured by fraud, even in the absence of evidence that the claims were fraudulent in themselves.") (citation omitted).

claims "under a contract, loan guarantee, or other agreement." S. Rep. No. 99–345, at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 5266, 5274. And it has only ever been applied by the Courts of the Third Circuit, including in *Thomas* itself, to contracts induced by fraud. *Thomas*, 593 F. App'x at 143 (allegations that defendants fraudulently induced the VA to enter into the contracts); *States v. Veneziale*, 268 F.2d 504, 505 (3d Cir. 1959) (allegations that defendants fraudulently induced government guaranteed bank loan agreement). In the absence of any binding or persuasive authority suggesting that a theory of liability formed in the context of contracts should be applied equally in the context of non-contract interactions with government regulatory bodies, as in this case, marketing statements to formulary committees, this Court will not craft a fraud-on-the-formulary theory for Relator out of whole cloth.

Secondly, even were the Court inclined to reason by analogy from the contract context, *Thomas* would still not offer Relator a cause of action here. In *Thomas* and the earlier fraud-in-the-inducement cases going back to *Hess*, the fraudulently obtained contract was alleged to give rise to the claims submitted for payment to the government. *See, e.g.*, *Hess*, 317 U.S. at 543 (award of contracts induced local government sponsors to submit claims to the federal government in order to pay defendants under the contracts). Here, Relator cannot allege in the same way that Plavix's listing on state PDLs gave rise to the later claims submitted for payment to the government. Instead, Relator attempts to establish the connection between the fraud on the formulary committee and the payment by the government of false claims through Defendants' alleged separate fraud — although a part of an overall fraudulent scheme — to falsely market Plavix to prescribing physicians, who were thereby induced to submit false claims to Medicaid. The absence of the same direct causal connection between Defendants' alleged fraud on the formulary committee, and the submission of false claims that is present between contracts

induced by fraud and claims submitted under those contracts, gives the Court pause because it suggests that embracing Relator's theory would be a step toward bringing all misrepresentations to government bodies within the purview of the FCA. The Supreme Court and the Third Circuit have always made it clear that the FCA was not designed to have so expansive a scope. *See, e.g.*, *Escobar*, 136 S. Ct. at 2003 (quoting *Allison Engine*, 553 U.S., at 672) ("The False Claims Act is not 'an all-purpose antifraud statute'"); *Petratos*, 855 F.3d at 490 (quoting *Wilkins*, 659 F.3d at 307 (citation omitted)) ("the False Claims Act is not 'a blunt instrument to enforce compliance with all . . . regulations.'"); *Wilkins*, 659 F.3d at 307 ("the implied certification theory of liability should not be applied expansively, particularly when advanced on the basis of FCA allegations arising from the Government's payment of claims under federally funded health care programs. In particular . . . the rationale . . . does not fit comfortably into the health care context because the [FCA] was not designed for use as a blunt instrument to enforce compliance with all medical regulations—but rather only those regulations that are a precondition to payment." (citation omitted)). Accordingly, this Court will not extend the Third Circuit's recognized fraud-in-the-inducement theory of FCA liability beyond the realm of contracts induced by fraud.

b) The *Solvay* Decision is Unpersuasive

In opposition, Relator cites to a single reported case for the proposition that *Thomas* may be extended to encompass a fraud-on-formulary-committee theory of liability.[13] Relator contends

[13] Relator also cites two additional unreported cases in support of her position. Both are irrelevant to the Court's analysis. In addition to being a non-binding decision, *United States v. Pfizer, Inc.*, No. 05-CV-6795, 2016 WL 807363, at *10 (E.D. Pa. Mar. 1, 2016), is factually and legally inapplicable to the present case. Firstly, it was not a fraud-in-the-inducement case; the Relator in *Pfizer* proceeded under an implied false certification theory that doctors were caused by Defendants to submit prescriptions for off-label uses that were not medically accepted or medically necessary. Secondly, *Pfizer* dealt with an alleged scheme for off-label promotion of a drug to *hospital* formulary decision-makers. Simply put, *Pfizer* offers no guidance as to whether Relator has stated a *fraud-in-the-inducement* cause of action for *on-label* promotion to *state*

that in *U.S. ex rel. King v. Solvay S.A.*, 823 F. Supp. 2d 472 (S.D. Tex. 2011) *order vacated in part on reconsideration*, No. 06-CV-2662, 2012 WL 1067228 (S.D. Tex. Mar. 28, 2012), the Sothern District of Texas applied a *Thomas*-like theory to find fraudulent marketing of a drug to a state formulary committee actionable under the FCA. Opp. 26-27.[14]

In *Solvay*, the relators alleged that defendants had marketed three drugs — Luvox, Aceon, and AndroGel — for conditions other than conditions for which the drugs were approved by the FDA ("off-label") and had offered kickbacks to physicians who prescribed the drugs. *Solvay*, 823 F. Supp. 2d at 480-81. The relators in *Solvay* pursued a false certification theory of liability under the FCA, along with claims under the Anti-Kickback Statute. *Solvay*, 823 F. Supp. 2d at 488. In ruling on defendants' motion to dismiss the realtors' FCA claims pursuant to Fed. R. Civ. P. 12(b)(6), the *Solvay* Court first found that for at least some of the drugs, relators had shown off-label claims had knowingly been submitted for payment to the government. *Id.* at 509. The Court then proceeded to consider whether the relators' false certification FCA claims satisfied the elements of falsity and materiality. Turning to materiality first, the court concluded, without reasoning or supporting law, that relators' false certification claims for off-label promotion satisfied the FCA's materiality requirement.[15] *Id.* at 509. The court then launched into

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formulary committees. Similarly, in *U.S. ex rel. Brown v. Celgene Corp.*, No. 10-CV-3165, 2014 WL 3605896, at *6 (C.D. Cal. July 10, 2014), the district court found, *inter alia*, a defendant's attempt to improperly influence drug compendia by bribing physicians who worked on the compendia committee to give rise to a plausible inference that the defendant was promoting off-label uses of its drug that were not supported by the compendia. Here, the only uses of Plavix alleged to have been promoted were on label and there are no allegations of bribery.

[14] The Court devotes significant attention to the otherwise only marginally relevant opinion of *Solvay*, because it is the only case that Relator has identified, and that this Court has been able to discover, that may even arguably be said to have adopted Relator's theory of FCA liability. Relator thus relies heavily upon *Solvay* in her Opposition and supplementary briefing.

[15] It is worth noting that the *Solvay* Court employs confused and vague language, which makes it impossible for this Court to determine the basis on which materiality was initially found. For example the Court, referencing its discussion of Rule 9(b) particularity wrote "the court found

an extensive analysis of the falsity element, focused on whether the drugs which had been marketed off-label were nevertheless marketed for a medically accepted use listed in the DrugDex compendium. The *Solvay* Court concluded that the realtors had alleged falsity.

After addressing these two elements, the *Solvay* court moved on to a new subsection of its opinion, confusingly titled "Alternative Ways of Showing Falsity/Materiality." I so characterize the title because, the federal courts have not recognized "alternative ways" to demonstrate falsity or materiality than those reflected in the Medicare and Medicaid statutes and case law that the *Solvay* court had already addressed, and secondly, because falsity and materiality are distinct elements of an FCA claim, which cannot be used and should not be referred to interchangeably. Tellingly, it is this section of the Solvay court's opinion upon which the Relator in this case relies. The *Solvay* court first concluded, without citation to supporting law, that:

> Linking the off-label promotion to materially false claims with claims data is not the only way in which the 4AC could allege that the prescriptions resulting from the off-label promotion had a natural tendency to influence the government's decision regarding payment of claims. Relators argue that . . . [defendant's] specific targeting of P & T committee members to gain favorable treatment on state formularies demonstrate that the

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above that the alleged off-label promotion was material to off-label claims, under subsection 3729(a)(1)." *Id.* at 509. As the Third Circuit made clear in *Petratos*, however, the inquiry in FCA false certification cases is not whether defendants' marketing efforts are material to the submission of claims, but rather whether the ultimate false certification that reaches the government is material to the government's payment decision. Moreover, the *Solvay* court's opinion is unclear whether materiality was ever really at issue on defendants' motion. The *Solvay* Court first wrote that "[defendant] SPI moves to dismiss the 4AC under Rule 12(b)(6) because it fails to plead falsity or materiality as to the alleged FCA violations based on off-label promotion." *Id* at 509. Just sentences later, however, the court wrote "[defendant] SPI's argument here, though, is not that the alleged scheme was not material to off-label claims. Rather, SPI argues that Relators fail to allege facts demonstrating that off-label claims stemming from the alleged off-label promotion were non-reimbursable, and therefore false, claims." *Ibid.* In short, immediately after stating that materiality was at issue, the *Solvay* court stated that the defendant's motion really sounded in falsity.

> off-label promotion campaign had a natural tendency to influence the government's decision regarding payment of claims.

Solvay, 823 F. Supp. 2d at 514.

The *Solvay* court then discussed the allegations in the realtors' complaint supporting this "alternative" theory of materiality:

> The 4AC additionally alleges that Solvay specifically geared its off-label promotion towards members of state P & T committees in a [sic] attempt to influence which drugs were included on the states' Medicaid formularies. The 4AC alleges that "[w]ooing P & T committee members was discussed openly and earnestly on periodic conference calls with upper management." A Solvay sales representative allegedly argued for the inclusion of Aceon on the Preferred Drug List in a meeting with the West Virginia P & T Committee. She allegedly relied on the PROGRESS study, which the 4AC alleges does not support the use of Aceon at all.

Id. at 515 (citations omitted).

Then, once again without the discussion of any law, the *Solvay* court summarily concluded that "the alleged wooing of P & T committee members plausibly influenced which drugs were placed on state formularies and thus had a natural tendency to influence the states' decision, and in turn the federal government's, decision with regard to payment. Accordingly, the 4AC plausibly satisfies the materiality element." *Ibid.* Finally, after another brief discussion about falsity, the court concluded "[i]n sum, the court finds that the 4AC plausibly pleads that the claims resulting from off-label promotion were false *or* material." *Ibid.* (emphasis added). I am particularly troubled by this conclusion because, to state an FCA claim, the alleged false certification must be both false *and* material.

As a threshold matter, I note that *Solvay* is an out-of-circuit, district court decision which is not binding on this Court. I further find that I cannot place any reliance upon it as persuasive authority due to the gaps in its reasoning identified, *supra*, and its complete failure to cite any law in reaching the holding for which Relator offers it to this Court. The *Solvay* Court did not adequately distinguish between falsity and materiality, nor did it appropriately address the

principle that materiality is judged from the perspective of the government payor, not the physician submitting an allegedly false claim. Moreover, *Solvay*, as every other case cited by Relator in support of her Formulary Allegations, involved the *off-label* marketing of drugs. *Solvay*, 823 F. Supp. 2d at 515 ("specifically geared its off-label promotion towards members of state P & T committees"). The 4AC alleges, and there is no dispute in this case, that Defendants' alleged marketing efforts to state formulary committees, to the extent they existed at all, were strictly for on-label, FDA-approved indications of Plavix. An open question thus remains whether *Solvay* and Relator's other off-label cases have any import here at all. *See, e.g.*, *Petratos*, 855 F.3d at 490 (observing in dismissing relator's claim, "[n]or has he cited to a single successful claim under [Medicare's exclusions from coverage] involving drugs prescribed for their on-label uses or a court decision upholding such a theory."). Based upon the foregoing, I find that *Solvay* provides no persuasive support for Relator's position here.

There are further reasons that *Solvay* does not assist Relator's case. Firstly, *Solvay* is not, as Relator argued, a fraud-in-the-inducement case like *Thomas*. Instead, it appears that the court, after proceeding through the elements of an FCA claim on defendants' motion to dismiss, hypothesized about other "alternative" ways in which the relators in that case could have established the elements of falsity and materiality in their false certification claim. The court then, concluded, without legal citation, that allegations of a fraud on state formulary committees satisfied the materiality element in a false certification FCA case. One possible explanation for this result can be found in the legal standard the *Solvay* court identified earlier in its opinion. There, the court indicated that it considered the realtors' claims under the framework set forth by the Fifth Circuit in *United States ex rel. Longhi v. United States*, 575 F.3d 458, 470 (5th Cir. 2009). *Longhi*, a *pre-Escobar* case, established a "natural tendency" test for materiality in the

Fifth Circuit. "The 'natural tendency' test requires 'that the false or fraudulent statements either (1) make the government prone to a particular impression, thereby producing some sort of effect, or (2) have the ability to effect the government's actions, even if this is the result of indirect or intangible actions on the part of the Defendants.' Thus, the statements must 'have the potential to influence the government's decisions.'" *Solvay*, 823 F. Supp. at 489–90 (quoting *Longhi*, 575 F.3d at 470). This test for materiality is significantly more permissive and expansive of the FCA's scope than the materiality test established in *Escobar* and applied in *Petratos*.

Although the Fifth Circuit has yet to explain whether *Escobar* overturned *Longhi*, in a recent reported decision, the Court of Appeals cited *Longhi* for the elements of an FCA claim, but applied *Escobar*'s heightened pleading standard for materiality. *See Abbott v. BP Expl. & Prod., Inc.*, 851 F.3d 384, 387–88 (5th Cir. 2017) (referencing *Longhi*, but applying *Escobar* instead of the "natural tendency" test). At least one circuit court of appeals has specifically considered the issue, and has concluded that *Longhi* and its equivalents in other circuits are not good law after *Escobar*.[16] Although this Court need not decide the issue, having already determined that *Solvay* is not entitled to any persuasive weight, the very fact that *Solvay* is not based on current law further undercuts its relevance to Relator's proposed legal theory.

c) Comparable Fraud-on-the-FDA Claims Have Been Rejected

[16] *See Johnson v. D.C.*, 144 A.3d 1120, 1136-1138 (D.C. 2016) (seven circuits, including the Fifth Circuit in *Longhi*, adopted the less burdensome "natural tendency" test for materiality in FCA cases; the Eighth Circuit adopted an "outcome materiality test" holding that there can be no false claim if the government would have made payments regardless of the defendant's actions; in *Escobar* "the Court announced a new approach to materiality closer to the outcome test than to the less stringent one followed by a majority of the federal circuits. . . . The statutory test for 'materiality,' therefore, as 'having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property,' appears to be 'the effect on the *likely or actual* behavior of the recipient of the alleged misrepresentation' upon learning about it, not on its mere potential to affect the recipient's decision.").

Finally, I note that, although not discussed by the parties, Relator's Formulary Allegations more closely resemble unsuccessful FCA actions for "fraud-on-the-FDA," which have, on rare occasions, been raised in this and other federal district courts. Relator fares no better under the reasoning of those cases. Relators there alleged that 1) defendants committed fraud in obtaining FDA approval for their drugs, through deceptive statements or the withholding of relevant information, 2) claims for those drugs were submitted to and paid by government payors, 3) government payors relied upon the drugs' FDA approval in making their decision to pay, and therefore 4) all claims paid by the government payors were converted to false claims by virtue of the fact that FDA approval was obtained by fraud.[17] Here, the Formulary Allegations state an analogous case, namely that Defendants fraudulently induced state formulary committees to place Plavix on their respective state PDLs, which resulted in the automatic reimbursement by government payors of false claims for Plavix submitted by prescribers.

In the wake of *Escobar*, the First Circuit Court of Appeals in *D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016), became the first federal appellate court to consider a "fraud-on-the-FDA" FCA theory on the merits, and soundly rejected it as outside the scope of the statute.[18] I find the

[17] *See, e.g., U.S. ex rel. Feldstein v. Organon, Inc.*, No. CIVA.07-CV-2690(DMC), 2009 WL 961267, at *11 (D.N.J. Apr. 7, 2009), *aff'd*, 364 F. App'x 738 (3d Cir. 2010) ("Nonetheless, Relator's claim is that Defendants committed fraud when it obtained approval of Raplon® and as a result, all claims for payments from the Government for Raplon® were illegitimate. The fraud at issue allegedly took place when Organon obtained approval for Raplon® and not when claims were submitted to the Government."); *United States ex rel. D'Agostino v. EV3, Inc.*, 153 F. Supp. 3d 519, 538–39 (D. Mass. 2015), *aff'd sub nom. D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016) ("In broad generalizations, D'Agostino alleges that all Axium devices on the market were defective and therefore, any claim for Medicare reimbursement involving Axium was false. With regard to Onyx, D'Agostino returns repeatedly to the theme that, but for defendants' misrepresentations, the FDA would not have approved Onyx in the first instance. In another iteration of this argument, D'Agostino speculates that, had the FDA known of all of the alleged hidden defects, it would have withdrawn its approval of Onyx or ordered its recall.").

[18] The Third Circuit in *U.S. ex rel. Feldstein v. Organon, Inc.*, 364 F. App'x 738 (3d Cir. 2010), was presented with the dismissal of a fraud-on-the-FDA theory by the district court below for

First Circuit's opinion persuasive that Relator's fraud-on-the-formulary-committee theory similarly fails and should be dismissed. In *D'Agostino*, the relator claimed that defendants made fraudulent representations to the FDA in seeking approval for their medical device, the device was approved, and Medicare later made payments reimbursing the cost of the device in reliance upon the device's FDA approval. *Id.* at 7. The First Circuit observed that because CMS and not the FDA actually paid all claims in the case and FCA liability attaches to "false or fraudulent claims for payment," relator was required to allege a causal link between the CMS payments and the alleged fraudulent representations made to the FDA. *Id.* at 7. The relator alleged that FDA approval is a precondition to CMS reimbursement for medical devices and that the misrepresentations to the FDA "could have" influenced the FDA to grant approval that it otherwise would not have. *Ibid.*

The First Circuit rejected the relator's allegations as insufficient to plead a violation of the FCA on three grounds, with the third playing the decisive role in the Court's decision. First, the Court noted that the relator's complaint failed to plead causation on its face because the allegations that defendants' fraudulent representations "could have" influenced the FDA were plainly not the same as alleging that the representations *did* influence the FDA and thereby cause the FDA to grant approval and cause CMS to pay false claims on the basis on that approval. *Ibid.* This facial deficiency is not an issue in the 4AC, because Relator has included at least conclusory allegations that the state formulary committees *would not* have listed Plavix on their PDLs had they been aware of Defendants' alleged misrepresentations about Plavix's efficacy relative to aspirin.

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failure to plead fraud under Rule 9(b), but affirmed dismissal on other grounds without considering the theory's viability under the FCA.

Second, the First Circuit noted that the relator argued, relying on 31 U.S.C. § 3729(b)(4), that the fraudulent misrepresentations to the FDA were nevertheless material to CMS's payment decision because they had a "natural tendency to influence" or were "capable of influencing, the payment or receipt of money or property." *Id.* The First Circuit observed that the relator's argument likely misconstrued the FCA's "demanding" materiality standard after *Escobar*. The court then went on to note that "[m]oreover, the FCA requires that the fraudulent representation be material to the government's payment decision itself. The fact that CMS has not denied reimbursement for Onyx in the wake of D'Agostino's allegations casts serious doubt on the materiality of the fraudulent representations that D'Agostino alleges." *D'Agostino*, 845 F.3d at 7 (citing *Escobar* 136 S. Ct. 2003-04 ("[I]f the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.")). The same concerns about materiality arise in this case because of the 4AC's failure to plead that any government Medicaid payor actually stopped reimbursing for Plavix or took other remedial action in the wake of gaining actual knowledge of the allegations of fraud-on-the-formulary committees[19] in this very-well-publicized, high-profile litigation.[20]

[19] The Seventh Circuit, the circuit of the transferor court in this case, recently came to a similar conclusion. *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445, 447–48 (7th Cir. 2016) (explaining, on remand from *Escobar*, that materiality looks to the effect on the *likely* or *actual* behavior of the recipient of the alleged misrepresentation, and affirming the grant of summary judgment to defendants where Relator alleged only that the government was legally entitled to deny payment on the basis of defendants' regulatory noncompliance, but failed to show that the government in fact administered penalties or terminated payment upon receiving actual knowledge of the alleged fraud (quotations omitted) (emphasis in original)).

[20] Relator's arguments that government payors and state formulary committees might lack actual knowledge of the alleged fraud are unconvincing, particularly as the Relator admits, roughly half of all state attorney general offices are active participants in the litigation.

Third and finally, however, the First Circuit in *D'Agostino* found that while materiality might have been lacking, the separate FCA element of causation could not be alleged in the relator's fraud-on-the-FDA theory as a matter of law. *D'Agostino*, 845 F.3d at 8 ("The defect in D'Agostino's claim is not a mere flaw in the complaint's choice of words."). The First Circuit found that the relator's complaint failed to allege that in the six years since the relator first revealed the alleged fraud the FDA had undertaken any action to revoke or reconsider the approval of defendants' device. *Ibid.* The court concluded that

> [t]he FDA's failure actually to withdraw its approval of Onyx in the face of D'Agostino's allegations precludes D'Agostino from resting his claims on a contention that the FDA's approval was fraudulently obtained. To rule otherwise would be to turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval . . . . The FCA exists to protect the government from paying fraudulent claims, not to second-guess agencies' judgments about whether to rescind regulatory rulings.

D'Agostino, 845 F.3d at 8. In short, the court found that the regulatory agency's real-world conduct after having obtained actual knowledge of the fraud must be alleged as evidence in any FCA fraud-on-the-agency style claim because failure to do so would require the court to reconsider and potentially reverse the agency's regulatory ruling on a basis that the agency itself explicitly has chosen not to act upon. The First Circuit was also persuaded in its position by problems in the implementation of any alternative standard for FCA causation in such cases.

> Practical problems of proof also inform our conclusion. How would a relator prove that the FDA would not have granted approval but for the fraudulent representations made by the applicant? Would competing experts read someone's mind? Whose? What if former officials no longer in government were of one view, and current officials of another? These and similar questions all support our position that the absence of some official agency action confirming its position and judgment in accordance with the law renders D'Agostino's fraud-on-the-FDA theory futile.

Id. at 9.

The same considerations arise in this case in the context of Relator's attempt to have this Court second guess the decisions of state formulary committees to list Plavix on their respective

states' PDLs. The 4AC does not allege that any state formulary has delisted Plavix in the wake of this litigation. Were Relator ultimately to prevail on her Formulary Allegations in this case, the jury would have to have find that defendants' alleged misrepresentations to formulary committees *caused* those committees to list Plavix and that the committees would not have listed Plavix on their state PDLs in the absence of those misrepresentations, despite the fact that once the formulary committees themselves actually became aware of the alleged misrepresentations, they took no action to reverse their prior decision. The problems of proof also weigh heavily upon this Court. In the only specific incident of alleged misrepresentations to formularies in the Complaint, a representative from Sanofi is alleged to have spoken during the public comment period during an Idaho formulary committee meeting and misrepresented the results of a clinical trial. 4AC ¶¶ 94, 95. Relator alleges, without specific factual support that "[b]ased on this information, the committee approved Plavix for inclusion on the formulary." 4AC ¶ 96. As in *D'Agostino*, questions arise as to whether present and former formulary committee members who made the Plavix PDL listing determination in Idaho, and every state, would need to be deposed and brought to testify at trial, or competing experts would hypothesize about what an objective physician or pharmacist member of a formulary committee schooled in the applicable state of the art at the time Plavix was considered for listing would have done with knowledge of the alleged fraud, or even which committee members from which time periods opinions should be afforded decisive weight, given that Plavix could have been listed or delisted at any time between its entry into the market and the revelation by Relator of the alleged fraud. In short, although it is sufficient for this Court to observe that Relator's fraud-on-the-formulary committee (or fraud-in-the-inducement) claim does not conform to any theory of FCA liability recognized by the Third Circuit, the Court is persuaded that the analogy to the First Circuit's rejection of

"fraud-on-the-FDA" theories of FCA liability for failure to plead causation in the absence of some agency action, provides further support for this conclusion.

Accordingly, Relator's Formulary Allegations in the 4AC do not state a claim for fraud-in-the-inducement or other cause of action under the federal FCA, and Counts I and II of the 4AC are dismissed. For the same reasons, the state FCA Prescriber Allegations will also be dismissed as discussed, *infra*.

C. State FCA Claims

In *Dickson* III, this Court dismissed the state FCA Prescriber and Formulary Allegations in parallel with their federal counterparts. In their present motion to dismiss the 4AC, Defendants argue that "Relator's claims under . . . the false claims and Medicaid claims statutes of the 24 Participating States are substantively similar to and/or track the language of the federal FCA[,] [and that] [t]hese claims must be dismissed, as they were before, for all the reasons set forth above." Mot. 17. Relator acknowledges that her claims under the state FCAs are subject to the same reasoning as those under the federal FCA, and opposes on the same grounds. Opp. 34 ("Defendants incorporate their FCA arguments in moving for dismissal of Relator's state-law claims. These claims survive for the reasons stated above [in the context of the federal FCA]."). In light of the briefing of the parties applying their arguments under the federal FCA to the twenty-four state FCAs, this Court concludes that the same reasons stated above for the dismissal of Counts I and II — under both the Prescriber and Formulary Allegations — compel dismissal of the state FCA claims, Counts III through XXVI.

Finally, in their Motion, Defendants identify five state false claims acts under which Relator brings suit which became effective after March 30, 2005, the date to which the Court found Relator's claims to extend under the applicable statutes of limitations, and move to limit

these claims to conduct taking place after the statutes' effective dates. The Court having dismissed the state FCA claims, Defendants' motion to restrict the retroactive effect of these five statutes is denied as moot.[21]

V. CONCLUSION

For the reasons stated above, the Defendants' Motion to Dismiss the 4AC is GRANTED, and Defendants' motion to restrict the retroactive application of the five state FCAs, which became effective after March 30, 2005, is denied as moot.

Dated: 6/27/2017

/s/ Freda L. Wolfson
The Honorable Freda L. Wolfson
United States District Judge

[21] In any event, Relator consented to the relief requested in Defendants' non-retroactivity motion. Opp. 35 n. 51.