NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, et al., Plaintiffs, v. JOHNSON & JOHNSON, et al., Defendants.	Civil Action No. 12-7758 (MAS) (LHG) **MEMORANDUM OPINION**

SHIPP, District Judge

This matter comes before the Court on Defendant Johnson & Johnson's Motion to Dismiss (ECF No. 57) and Janssen Products, L.P.'s ("Janssen Products") (collectively, "Defendants") Motion to Dismiss (ECF No. 58) the First Amended Complaint ("Amended Complaint"). Relators Jessica Penelow and Christine Brancaccio (collectively, "Relators") filed opposition (ECF No. 64) and Defendants replied (ECF Nos. 70, 71). Relators filed a Motion for Leave to File a Sur-Reply. (ECF No. 73.) Janssen Products filed opposition to Relators' Motion.[1] (ECF No. 74.) The United States of America (the "Government") filed a Statement of Interest (ECF No. 75), and Janssen Products filed a response (ECF No. 77). Finally, Relators filed two Notices of Supplemental Authority (ECF Nos. 78, 82) and Janssen Products filed responses (ECF Nos. 79, 84).

The Court has carefully considered the parties' submissions and heard oral argument on May 23, 2017. For the reasons stated below, Janssen Products's Motion to Dismiss is GRANTED in part and DENIED in part, and Johnson & Johnson's Motion to Dismiss is GRANTED.

[1] As set forth on the record during the May 23, 2017 oral argument, the Court denies Relators' Motion for Leave to file a Sur-Reply. (ECF No. 73; May 23, 2017 Oral Argument Tr. 1:25-2:5.)

I. Background

Relators filed the instant action on behalf of the Government, twenty-seven states, and the District of Columbia against Defendants, alleging fifty-eight counts under the Federal False Claims Act ("FCA"), Federal Anti-Kickback Statute ("AKS"), and the false claims acts of various states. The claims arise from Defendants' purported misconduct in connection with two HIV/AIDS drugs: Prezista and Intelence. (*See* Am. Compl. ¶¶ 107-61, ECF No. 41.)

With respect to Prezista, Relators allege that Defendants' sales representatives and managers falsely promoted the drug as "lipid neutral," which means that "the drug would *not* affect or increase a patient's cholesterol or triglyceride levels, contrary to Prezista's label." (*Id.* ¶ 108.) Relators further plead that because Prezista actually increases lipids in patients, it presents a serious risk of cardiovascular disease for patients. (*Id.* ¶ 109.) Relators allege numerous instances where Defendants' sales representatives and managers have misrepresented Prezista's effect on lipids. (*Id.* ¶¶ 110-27.) Additionally, Relators allege that Defendants misrepresented Prezista as having superior "binding affinity," which relates to the drug's ability to prevent HIV from replicating. (*Id.* ¶¶ 128-35.) The Amended Complaint reports that Prezista's worldwide sales increased substantially due to Defendants' misrepresentations. (*Id.* ¶ 140.)

As to the second drug, Intelence, Relators allege that Defendants improperly promoted and marketed the drug for unapproved once-daily dosage and treatment-naïve patients. (*Id.* ¶¶ 141-61.) Intelence, according to Relators, was actually intended for twice-daily dosing to patients who were treatment-experienced in that they had "viral strains resistant to an NNRTI[2] and other antiretroviral agents." (*Id.* ¶ 141.)

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[2] Non-nucleoside reverse-transcriptase inhibitors. (Am. Compl. ¶ 13.)

According to the Amended Complaint, Defendants utilized their nationwide sales force to implement a broad scheme to mislead physicians. (*Id.* ¶¶ 162-92.) Defendants also allegedly implemented a kickback scheme, used dinner programs with planted audience members to ask off-label questions, and paid for speaking engagements to falsely promote Prezista and Intelence as having certain characteristics. (*Id.* ¶¶ 193-207.) As a result of Defendants' misleading marketing and kickback schemes, Relators allege that false claims for reimbursement were submitted to the Government under Medicaid and Medicare programs. (*Id.* ¶¶ 212-19.)

II. Legal Standard

When analyzing a Rule 12(b)(6) motion, district courts conduct a three-part analysis. First, the court must "tak[e] note of the elements a plaintiff must plead to state a claim." *Ashcroft v. Iqbal*, 556 U.S. 662, 675 (2009). Second, the court must accept as true all of a plaintiff's well-pleaded factual allegations and construe the complaint in the light most favorable to the plaintiff. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). The court, however, must disregard any conclusory allegations proffered in the complaint. *Id.* at 210-11. Finally, once the well-pleaded facts have been identified and the conclusory allegations ignored, a court must determine whether the "facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Fowler*, 578 F.3d at 211 (quoting *Iqbal*, 556 U.S. at 679).

Further, a plaintiff pleading fraud "must meet a heightened pleading standard under Federal Rule of Civil Procedure 9(b)." *Zuniga v. Am. Home Mortg.*, No 14-2973, 2016 WL 6647932, at *2 (D.N.J. Nov. 8, 2016). "In alleging fraud . . . , a party must state with particularity the circumstances constituting fraud . . . ." Fed. R. Civ. P. 9(b). "A plaintiff alleging fraud must therefore support [her] allegations 'with 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.'" *U.S. ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 307 (3d Cir. 2016) (quoting *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002)). In the Third Circuit, a viable FCA claim must 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." *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156-57 (3d Cir. 2014) (citations omitted). The Third Circuit does not require a plaintiff to "identify a specific claim for payment *at the pleading stage* of the case to state a claim for relief." *Id.* at 156 (citing *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 308 (3d Cir. 2011)).

III. Parties' Positions[3]

A. Motion to Dismiss: Janssen Products

First, Janssen Products argues that merely alleging that Defendants falsely certified Prezista as "reasonable and necessary" for the treatment of patients fails to state a viable claim under the FCA. (Janssen Prods.'s Moving Br. 8-12, ECF No. 58-1.) According to Janssen Products, the Amended Complaint concedes that Prezista was prescribed for its FDA-approved use and that FDA approval inherently renders the drug "reasonable and necessary." (*Id.*; Janssen Prods.'s Reply Br. 1-5, ECF No. 71.) Janssen Products further argues that the Amended Complaint's allegations of misbranding are conclusory and cannot, therefore, give rise to FCA liability. (Janssen Prods.'s Moving Br. 13-15; Janssen Prods.'s Reply Br. 5-7.)

Second, with respect to both Prezista and Intelence, Janssen Products argues that the heightened pleading standard of Federal Rule of Civil Procedure 9(b) applies and that Relators

[3] The Court summarizes the parties' arguments as set forth in their written submissions. The Court recognizes that the arguments have evolved over the course of the briefing schedule, due to supplemental authorities, substantive correspondence from the parties, and further elaboration at oral argument. The Court does not set forth all of those arguments here, but has considered all of the parties' arguments and addresses the material issues in the Discussion section below.

have failed to plead with sufficient particularity a "scheme to induce the submission of false claims for government reimbursement using misleading or off-label promotion" or "how that alleged scheme actually caused such claims to be submitted to Medicare and Medicaid." (Janssen Prods.'s Moving Br. 15-22; Janssen Prods.'s Reply Br. 7-11.)

Finally, Janssen Products asserts that Relators' state claims should be dismissed for: (1) the same reasons as the federal claims; (2) failure to mention any conduct that occurred in many of the states; and (3) miscellaneous reasons specific to certain states. (Janssen Prods.'s Moving Br. 22-25; Janssen Prods.'s Reply Br. 11-12.)

In opposition, Relators argue that they have adequately pled Defendants' use of fraud by deliberate suppression of material information about Prezista and unlawful payment for speeches and other financial incentives to prescribing physicians in violation of the AKS. (Relators' Opp'n Br. 9, ECF No. 64.) Relators further note that Defendants have failed to dispute the viability of Relators' FCA claims regarding illegal off-label marketing of Intelence. (*Id.* at 10.) In response to Janssen Products's characterization as to what constitutes "reasonable and necessary," Relators argue that a viable FCA claim persists even where the prescriptions at issue were FDA-approved. (*Id.* at 10-23.)

Next, Relators clarify that their "claims do not arise from the misbranding itself, but from the *submission of claims* for uncovered, misrepresented (and therefore, misbranded), and medically unnecessary drugs, induced by Defendants' deceptive conduct." (*Id.* at 24-28.) Relators additionally argue that they have adequately pled their claims with detail pursuant to Rule 9(b). (*Id.* at 28-44.) Finally, Relators argue that they have sufficiently pled a nationwide scheme such that identification of state-specific conduct is unnecessary, and additionally respond to Janssen Products's miscellaneous state-specific arguments. (*Id.* at 44-47.)

With regard to Janssen Products's contention as to whether on-label use is always "reasonable and necessary," the Government submitted a Statement of Interest, arguing that "a drug is not per se 'reasonable and necessary' simply because it was prescribed for a FDA-approved indication." (Gov't's Statement of Interest 5, ECF No. 75.) Rather, the Government asserts, other factors are relevant to the "reasonable and necessary" determination, such as "whether a physician prescribed the drug." (*Id.*) Additionally, the Government argues that "[f]raud directed at physicians may . . . establish FCA liability if government reimbursement was a reasonably foreseeable result." (*Id.* at 6-8.) The Government does not take a position as to whether Relators have adequately pled under this theory. (*Id.* at 8.)

In response to the Government's Statement of Interest, Janssen Products clarifies that it is not advocating a per se rule for FDA-approved drugs. (Janssen Prods.'s Resp. to Gov't's Statement of Interest 1, ECF No. 77.)

B. Motion to Dismiss: Johnson & Johnson

Johnson & Johnson argues that Relators' claims against it are solely based on Janssen Products's conduct. (Johnson & Johnson's Moving Br. 5, ECF No. 57-1.) Accordingly, Johnson & Johnson asserts that its parent corporation status is insufficient to support claims arising entirely from claims against Janssen Products. (*Id.* at 4-6; Johnson & Johnson's Reply Br. 2-5, ECF No. 70.) Johnson & Johnson further argues that Relators fail to satisfy Rule 9(b)'s pleading standard because the Amended Complaint does not differentiate the factual allegations with respect to each Defendant. (Johnson & Johnson's Moving Br. 6-8; Johnson & Johnson's Reply Br. 5-6.)

In their opposition brief, Relators argue that they have adequately pled their claims against Johnson & Johnson.[4] First, Relators assert that Johnson & Johnson was involved in the purportedly fraudulent schemes due to its control over Janssen Products. (Relators' Opp'n Br. 48-50.) Relators, otherwise, do not describe any other allegations in the Amended Complaint specific to Johnson & Johnson, but simply argue that "[a] parent company can be held liable under the FCA because of its involvement in its subsidiary's FCA violations." (*Id.* at 48.) Relators further argue that Johnson & Johnson "may be held liable under an agency theory of liability." (*Id.* at 48-49.)

IV. Discussion

A. Motion to Dismiss: Janssen Products

1. Count One: FCA – For Misbranded and Off-Label Prescriptions of Prezista and Intelence

Relators bring their federal claims under 31 U.S.C. § 3729(a)(1)(A), (B), of the FCA. (Am. Compl. ¶¶ 220-27.) The relevant provisions of the FCA prohibit any person from: (1) "knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval"; and (2) "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A), (B). To establish a prima facie case pursuant to these provisions, a plaintiff must plead that: "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." *United States ex rel. Wilkins*, 659 F.3d at 305 (quoting *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 (3d Cir. 2004)). "A claim is legally false when it does not comply 'with a statute or regulation the

[4] The Court notes that during oral argument, however, Relators conceded to their inadequate pleading with respect to Johnson & Johnson. (*See* May 23, 2017 Oral Argument Tr. 19:10-12 ("Your Honor, our complaint is thin as to Johnson & Johnson. We admit that. And if Your Honor chooses to dismiss [the allegations with respect to Johnson & Johnson], we can understand that.").)

compliance with which is a condition for Government payment.'" *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 486 (3d Cir. 2017) (quoting *United States ex rel. Wilkins*, 659 F.3d at 305).

Relators' claims arise under the Medicare and Medicaid programs. (Am. Compl. ¶¶ 81-94.) Under the Medicare statute, "no payment may be made . . . for any expenses incurred for items or services . . . [that] are not reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395w-102(e)(3); 42 U.S.C. § 1395y(a)(1)(A). Relators allege that Medicaid similarly "only reimburses for 'reasonable and necessary' medical services, including drugs."[5] (Am. Compl. ¶ 88.) Accordingly, Relators can adequately plead a false claim with respect to Prezista and Intelence if the drugs were not medically "reasonable and necessary." *United States ex rel. Petratos*, 855 F.3d at 487. As Janssen Products concedes that Relators have adequately pled the off-label use of Intelence,[6] the Court focuses its analysis on Prezista.

According to the Third Circuit, "the 'reasonable and necessary' determination is a process involving the FDA,[7] CMS,[8] *and* individual doctors." *Id.* FDA approval does not per se render a drug "reasonable and necessary," but rather a drug "must also be 'reasonable and necessary for [the] *individual patient*' based on 'accepted standards of medical practice and the medical

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[5] The Court recognizes the separate statutory schemes for Medicare and Medicaid. *See In re Plavix Mktg., Sales Practices & Prods. Liab. Litig.* ("*Dickson*"), 123 F. Supp. 3d 584, 606-10 (D.N.J. 2015). Nonetheless, because the parties group the Medicare and Medicaid allegations in making their arguments with respect to the definition of "reasonable and necessary," the Court will not separately analyze each state's specific Medicaid restrictions at this stage of the litigation.

[6] May 23, 2017 Oral Argument Tr. 7:18-21 ("For Intelence, . . . there are clearly defined off-label allegations for off-label uses, absolutely.").

[7] The Food and Drug Administration.

[8] The Centers for Medicare & Medicaid Services.

circumstances of the *individual case*.'" *Id.* at 488 (alteration in original). In light of the guidance from *Petratos*, Relators have adequately pled that despite FDA approval, Prezista was not "reasonable and necessary" for certain patients.

Janssen Products argues that *Petratos* did not specifically address the analysis in *In re Plavix Marketing, Sales Practices and Products Liability Litigation* ("*Dickson*"), 123 F. Supp. 3d 584, 600-11 (D.N.J. 2015), and that *Petratos* concerned reimbursements under Medicare Parts A and B, as opposed to *Dickson*'s analysis under Part D. (Janssen Prods.'s May 17, 2017 Letter 1, ECF No. 84.) Although the present case arises under Part D and the Court recognizes the differences between Parts A, B, and D under the Medicare program, the Court finds persuasive the Third Circuit's recent decision in *Petratos*. *Petratos* interpreted "reasonable and necessary" in Section 1395y(a)(1)(A)—which Part D incorporates by explicit reference—to include the determinations of individual doctors. 855 F.3d at 487-89; 42 U.S.C. § 1395w-102(e)(3).

In *Dickson*, the district court determined that "a FDA approved drug that has been prescribed for its on-label use is necessarily covered under Medicare Part D," but qualified its conclusion by stating: "[o]f course, if a doctor were to give a prescription to a patient who did not require medication at all, such a prescription would not be 'reasonable and necessary.'" *Dickson*, 123 F. Supp. 3d at 605 n.12. The court further found that the plaintiff did "not allege[] that [the] [d]efendants' marketing caused [the drug] to be prescribed to patients who did not need such a drug." *Id.* Accordingly, *Dickson* recognized, as the Third Circuit later set forth in *Petratos*, that an individualized assessment of a particular patient's medical circumstances is relevant to whether a drug is "reasonable and necessary." Applying the definition of "reasonable and necessary," with the benefit of the recent, additional guidance from *Petratos*, the Court finds that the Amended Complaint has adequately pled the FCA claims with respect to Prezista.

Janssen Products further argues that the Amended Complaint fails to plead adequate materiality. (Janssen Prods.'s May 17, 2017 Letter 2.) To state a valid FCA claim, a pleading must allege a "misrepresentation about compliance with a statutory, regulatory, or contractual requirement [that is] material to the Government's payment decision." *United States ex rel. Petratos*, 855 F.3d at 489 (quoting *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016)). Under the FCA, "materiality" is defined as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). "The materiality standard is demanding." *United States ex rel. Escobar*, 136 S. Ct. at 2003. "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." *Id.* "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." *Id.*

Janssen Products argues that the Amended Complaint fails to plead materiality with respect to Prezista because "there are no factual allegations showing that the Part D sponsor would not have reimbursed claims for on-label prescriptions of Prezista." (Janssen Prods.'s May 17, 2017 Letter 2.) To the contrary, however, the Amended Complaint pleads that: (1) each of Defendants' claims for government reimbursement, in connection with Prezista and Intelence, included false certifications rendering the claims "ineligible for reimbursement"; and (2) Defendants' "claims for prescriptions caused by [their] misconduct are not reimbursable." (Am. Compl. ¶¶ 213-14.) Moreover, the Court notes that in *Petratos*, the relator failed to "plead that knowledge of the violation could influence the Government's decision to pay," and, therefore, found that the relator did not adequately plead materiality. *United States ex rel. Petratos*, 855 F.3d at 490. In contrast,

Relators have adequately pled that Defendants' misconduct would have caused the Government to refuse reimbursement.

2. Particularity under Rule 9(b) re: Counts One & Two

Janssen Products argues that Relators have generally failed to comply with Rule 9(b)'s heightened pleading requirements, especially because "they do not identify even one physician who wrote a prescription that was reimbursed by a government payor based on the[] allegedly false statements or when any such prescription was written." (Janssen Prods.'s Moving Br. 17-18 (emphasis removed).) To satisfy Rule 9(b) for a FCA claim, a plaintiff must 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." *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156 (3d Cir. 2014) (adopting the pleading requirements set forth by the First, Fifth, and Ninth Circuits). Under this standard, a plaintiff need not identify a specific claim for payment to survive a motion to dismiss. *United States ex rel. Walker v. Loving Care Agency, Inc.*, No. 11-6142, 2016 WL 7408848, at *2 (D.N.J. Dec. 22, 2016) (citations omitted). In other words, "[t]he fact that Relators did not identify a single reimbursement is not fatal to their claims at this stage of the proceedings." *United States ex rel. Brown v. Pfizer, Inc.*, No. 05-6795, 2016 WL 807363, at *11 (E.D. Pa. Mar. 1, 2016); *see also United States v. Medco Health Sys., Inc.*, No. 12-522, 2014 WL 4798637, at *11 (D.N.J. Sept. 26, 2014) (stating that a plaintiff need not identify specific claims submitted for reimbursement because "such specific proofs are usually inaccessible to a *qui tam* plaintiff").

For the proposition that the Amended Complaint pleads inadequate particularity, Janssen Products relies on two district court cases that were decided prior to the controlling Third Circuit authority in *Foglia v. Renal Ventures Management, LLC*, 754 F.3d 153 (3d Cir. 2014): *United States ex rel. Lampkin v. Johnson & Johnson, Inc.*, No. 08-5362, 2013 WL 2404238 (D.N.J. May

31, 2013), and *United States ex rel. Piacentile v. Sanofi Synthelabo, Inc.*, No. 05-2927, 2010 WL 5466043 (D.N.J. Dec. 30 2010). Janssen Products attempts to reconcile *Foglia* with these two cases by stating that they applied the more lenient *Foglia* standard. (May 23, 2017 Oral Argument Tr. 12:14-16.) The *Lampkin* and *Piacentile* courts, however, did not apply the *Foglia* standard. In *Foglia*, the Third Circuit specifically refused to require plaintiffs to show "representative samples" of the alleged misconduct because it would be "one small step shy of requiring production of actual documentation with the complaint." *Foglia*, 754 F.3d at 156. In contrast, the *Lampkin* court specifically dismissed the complaint because, *inter alia*, the plaintiff failed to "identify any examples of specific false claims that were made to the government." *United States ex rel. Lampkin*, 2013 WL 2404238, at *5. Similarly, the *Piacentile* court dismissed a FCA claim because the "allegations of the claims that were submitted to the government [were] conclusory." *United States ex rel. Piacentile*, 2010 WL 5466043, at *8.

Here, the Court finds that Relators have adequately pled the submission of false claims under the pleading standard set forth in *Foglia*. First, the Amended Complaint alleges that "Defendants caused false claims to be submitted to the Government Health Care Programs for reimbursement." (Am. Compl. ¶¶ 213, 215, 217.) The Amended Complaint further alleges that Defendants utilized a nationwide scheme of misbranding and kickbacks to cause physicians to prescribe Prezista and Intelence, which resulted in substantial financial success for Defendants. (*Id.* ¶¶ 107-219); *see United States ex rel. Brown*, 2016 WL 807363, at *11 (finding that the plaintiff's allegation of the defendant's "incredible success of [its] marketing efforts in increasing the sale of [its product] and gaining an edge over competitors in the antifungal drug market . . . , coupled with the marketing efforts targeted at hospitals, physicians, and pharmacists, to prescribe [the defendant's drug] for off-label use, gives rise to a strong inference that [the] [d]efendant's off-

label marketing scheme caused the submission of false claims to government health care providers"). Accordingly, the Court finds that Relators have adequately pled Counts One and Two as they relate to Janssen Products.

3. State Claims

With respect to Relators' state claims, the Court first dismisses Relators' Maryland claims in light of Relators' concession that they should be dismissed. (Relators' Opp'n Br. 47, ECF No. 64.) Relators further seek leave to amend incorrect statutory references with regard to their Washington and Connecticut claims. (*Id.*) Accordingly, the Court dismisses these claims as well, and grants Relators' request to amend their pleading as it relates to these claims.

As to Relators' Michigan claims, Janssen Products cites the *Merck Sharp* case for the proposition that Relators' claims constitute products liability claims that are barred under state law. (Janssen Prods.'s Moving Br. 24-25 (citing *Attorney Gen. v. Merck Sharp & Dohme Corp.*, 807 N.W.2d 343, 345-46 (Mich. Ct. App. 2011)).) The *Merck Sharp* case, however, dealt specifically with on-label, FDA-approved uses, whereas here, Relators allege "off-label promotion of . . . prescription drug[s] for uses beyond the FDA's approval." *United States ex rel. Brown v. Pfizer, Inc.*, No. 05-6795, 2016 WL 807363, at *14 (E.D. Pa. Mar. 1, 2016). Here, Relators plead off-label use with respect to Intelence and plead that Defendants marketed Prezista in direct contradiction to the label as to the drug's effect on lipids. (May 23, 2017 Oral Argument Tr. 7:18-21; Am. Compl. ¶¶ 108-09, 113-15, 141-61.) Based on the parties' limited briefing on this issue, the Court finds that Relators have adequately pled their Michigan claims at this stage of the litigation.

With respect to the remaining state claims, the Court finds that the Amended Complaint has adequately pled a nationwide scheme of misbranding and the utilization of kickbacks to

survive a motion to dismiss. *See United States ex rel. Polansky v. Exec. Health Res., Inc.*, 196 F. Supp. 3d 477, 496 (E.D. Pa. 2016) ("Certainly, [the] [p]laintiff cannot be expected to plead with particularity each and every false claim nationwide without the benefit of at least some discovery, as such information rests solely within [the] [d]efendants' control." (quoting *United States ex rel. Spay v. CVS Caremark Corp.*, 913 F. Supp. 2d 125, 177 (E.D. Pa. 2012))).

B. Johnson & Johnson

Finally, the Court agrees with Johnson & Johnson's argument that Relators fail to plead specific allegations against it with sufficient particularity. By defining "J & J" as referencing both Defendants, Relators fail to provide Johnson & Johnson with the requisite notice as to what specifically is being alleged against Johnson & Johnson. (Am. Compl. at 1); *see Foglia*, 754 F.3d at 156 (recognizing that "the purpose of Rule 9(b) is to provide[] defendants with fair notice of the plaintiffs' claims") (alteration in original) (internal quotations omitted). Additionally, Relators have not identified allegations in the Amended Complaint that set forth agency liability in adequate detail, and the Court does not consider factual allegations set forth in Relators' briefs or oral argument where absent from the pleading itself. *In re Burlington Coat Factory Sec. Litig.*, 114 F. 3d 1410, 1426 (3d Cir. 1997) ("As a general matter, a district court ruling on a motion to dismiss may not consider matters extraneous to the pleadings.") (citation omitted). As "mere ownership of a subsidiary does not justify the imposition of liability on the parent,"[9] the Court dismisses Relators' claims against Johnson & Johnson under Rule 9(b) of the Federal Rules of Civil Procedure.

[9] *Pearson v. Component Tech. Corp.*, 247 F.3d 471, 484 (3d Cir. 2001) (citing *United States v. Bestfoods*, 524 U.S. 51, 69 (1998)).

V. Conclusion

For the reasons set forth above, Janssen Products's Motion to Dismiss is GRANTED in part and DENIED in part, and Johnson & Johnson's Motion to Dismiss is GRANTED. An order consistent with this Memorandum Opinion will be entered.

s/ Michael A. Shipp
MICHAEL A. SHIPP
UNITED STATES DISTRICT JUDGE

Dated: May 31, 2017