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

UNITED STATES OF AMERICA, *ex rel.* STEPHEN A. KRAHLING AND JOAN A. WLOCHOWSKI,	:	CIVIL ACTION
Relators,	:	NO. 10-4374 & NO. 12-3555
v.	:	
MERCK & CO., INC.,	:	
Defendant.	:	

AMENDED MEMORANDUM

Jones, II, J. **September 5, 2014**

In Civil Action No. 10-4374, Relators Stephen A. Krahling and Joan A. Wlochowski ("Plaintiffs") bring this *qui tam* action in accordance with the False Claims Act ("FCA"), pursuant to 31 U.S.C. §§ 3729-33. Relators allege that their former employer, Defendant Merck & Co., Inc. ("Merck") fraudulently misled the government and omitted, concealed, and adulterated material information regarding the efficacy of its mumps vaccine in violation of the FCA. The United States declined to intervene in this action, filing a Notice of Election to Decline Intervention before this Court on April 27, 2012. (Dkt. No. 14). Defendant moves to dismiss the Amended Complaint pursuant to Federal Rules of Civil Procedure 12(b)(6), 8(a)and 9(b). (Dkt. No. 45).

In Civil Action No. 12-3555, Chatom Primary Care, P.C., Andrew Klein, M.D., John I. Sutter, M.D. (the "Plaintiffs") bring this putative class action alleging monopolization in violation of the Sherman Act under 15 U.S.C. § 2 and violations of various state laws. (Dkt. No.

26.) Defendant moves to dismiss the Amended Complaint pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b). (Dkt. No. 40).

For purposes of deciding the Motions to Dismiss, this memorandum takes as true facts as alleged in the Amended Complaints. *See Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008). For the reasons that follow, Defendant's Motions regarding all claims for both cases are granted in part and denied in part.

I. BACKGROUND

A. The Parties

Stephen A. Krahling and Joan A. Wlochowski (the "Relators") bring this *qui tam* action against Merck & Co., Inc. ("Defendant"). Relators were employed as virologists in the Merck lab and allegedly witnessed first-hand the allegedly fraudulent efficacy testing. (Dkt. No. 12 ¶ 3, 8-9.)

Chatom Primary Care, P.C., Andrew Klein, M.D., John I. Sutter, M.D. (the "Plaintiffs") bring this putative class action alleging monopolization in violation of the Sherman Act under 15 U.S.C. § 2 and violations of various state laws. (Dkt. No. 26.)

Defendant is a New Jersey corporation with its vaccine division based in West Point, Pennsylvania. (Dkt. No. 12 ¶ 10.) Defendant is the sole manufacturer licensed by the FDA to sell Mumps Vaccine (M-MR®II and ProQuad®) ("Mumps Vaccine") in the United States. (Dkt. No. 12 ¶ 11.)

B. Relators' and Plaintiffs' Alleged Facts

The Court recites the facts in the light most favorable to the nonmoving parties and draws all reasonable inferences in their favor. According to Relators' Amended Complaint, in 1999, Defendant initiated new efficacy testing of its Mumps Vaccine. (Dkt. No. 12 ¶¶ 22, 25.) Relators allege that Defendant first tested their vaccine with a Mumps Plaque Reduction Neutralization assay comparing pre and post vaccinated blood to test whether the vaccine neutralized the virus. (Dkt. No. 12 ¶ 25-29). Relators note that rather than using the "gold standard" approach and testing the vaccine against a "wild-type mumps virus," Defendant tested it against the attenuated

virus strain that had created the vaccine in the 1960s. (Dkt. No. 12 ¶ 29). Relators allege that comparing a vaccine to its originator virus strain would likely overstate the vaccine's effectiveness. (Dkt. No. 12 ¶ 29.) According to the Amended Complaint, the results of this first test did not result in the "desired 95 percent threshold," so Defendant abandoned this methodology in subsequent tests. (Dkt. No. 12 ¶¶ 30-32.)

Defendant created a second testing methodology: Enhanced Mumps Plaque Reduction Neutralization Assay. (Dkt. No. 12 ¶ 33.) Defendant allegedly told Relators that the "objective" of this new methodology was to "[i]dentify a mumps neutralization assay format…that permits measurement of a ≥ 95% seroconversion rate in MMR®II vaccines." (Dkt. No. 12 ¶ 34.) Defendant continued to test the vaccine against the virus strain that originated the vaccine. (Dkt. No. 12 ¶ 35.) In addition, Defendant added animal antibodies to pre and post vaccinated blood samples. (Dkt. No. 12 ¶ 35.) Relators allege that this addition was "for the singular purpose of altering the outcome of the test by boosting the amount of virus neutralization counted in the lab." (Dkt. No. 12 ¶¶ 35-39.) Relators claim that the use of animal antibodies created a high number of pre-vaccinated positive results, which Defendant systemically destroyed or falsified in order to legitimize the use of animal antibodies. (Dkt. No. 12 ¶¶ 40-51.) Relators also allege that senior management was aware, complicit, and in charge of this testing. (Dkt. No. 12 ¶¶ 52-58.)

Relators reported these alleged infractions to the FDA, leading to an FDA visit. (Dkt. No. 12 ¶¶ 59-64.) After the FDA visit, Relators were barred from participating in the mumps vaccine testing. (Dkt. No. 12 ¶ 66.) Relators assert that Defendant continued to make the false representations of its inflated 95 percent efficacy rate to the government, while deliberately covering up the results of the tests showing a diminished efficacy.

C. Relators' Allegations

Relators allege two overall counts of violations of the FCA. First, Plaintiffs allege that Defendant billed the CDC for purchase of its mump vaccines when Defendant knew of the vaccine's diminished efficacy. (Dkt. No. 12 ¶ 152.) Plaintiffs' theory is that because the vaccine's efficacy was diminished, the vaccine was mislabeled and was not the product for which the government paid. (Dkt. No. 12 ¶ 152.) As such, Plaintiffs allege that Defendant knowingly presented a fraudulent claim for payment to the U.S. government in violation of 31 U.S.C. § 3729(a)(1)(A).

Second, Plaintiffs allege that Defendant falsified, abandoned, and manipulated testing data that should have been shared with the government in order to fraudulently mislead the government into purchasing the mumps vaccine. (Dkt. No. 12 ¶ 155.) As such, Plaintiffs allege that Defendant knowingly incorporated falsified records material to their fraudulent claims for payment for the vaccine. 31 U.S.C. § 3729(a)(1)(B).[1]

D. Plaintiffs' Allegations

Plaintiffs based their Complaint on the *qui tam* action filed by the Relators. (Dkt. No. 26, p. 5.) Based on the same allegations, Plaintiffs allege that Defendant's manipulation and misrepresentation of the seroconversion rate of the Mumps Vaccine to the United States government , led to Defendant's monopoly of the relevant market in violation of the Sherman Act and violations of various state laws. Plaintiffs allege six counts:

1. **Count I**: Monopolization in violation of the Sherman Act. 15 U.S.C. § 2. (Dkt. No. 26 ¶¶ 151-55.) In this Count, Plaintiffs allege that Defendant falsified the seroconversion rate of its Mumps Vaccine in its products and to the FDA. (Dkt.

[1] The Amended Complaint refers to these sections under their pre-2009 codification as 3729(a)(1)-(2).

No. 26 ¶ 152.) Plaintiffs argue that because of this falsification, Defendant was effectively excluding competition from the relevant market. (Dkt. No. 26 ¶ 154.)

2. **Count II**: Violation of state consumer protection laws in twenty-four states. (Dkt. No. 26 ¶ 156-69.) Plaintiffs state that Defendant engaged in false or deceptive conduct in making statements about the efficacy of the Mumps Vaccine with the intention of misleading consumers. (Dkt. No. 26 ¶¶ 163-66.)

3. **Count III**: Breach of contract. (Dkt. No. 26 ¶¶ 170-75.) Plaintiffs allege that Defendant entered a contract to provide Mump Vaccine to Plaintiffs and the Class and that part of this standardized contract included the falsified representation of the inflated efficacy rate. (Dkt. No. ¶¶ 171-74.) Plaintiffs allege suffering for the purchase price they paid for the Mumps Vaccine because of this alleged breach of contract. (Dkt. No. ¶ 174.)

4. **Count IV**: Violation of Pennsylvania's Express Warranty Law. Pa. Stat. Ann. Tit. 13 § 2313. (Dkt. No. 26 ¶¶ 176-87.) Plaintiffs allege that Defendant acted as a Merchant under the Pennsylvania Uniform Commercial Code, made a contract with Plaintiffs and class members to sell the Mumps Vaccine. (Dkt. No. 26 ¶¶ 177-80.) Plaintiffs allege that because the vaccine did not have an efficacy rate of 95, as represented by Defendant, Defendant breached an express warranty. (Dkt. No. 26 ¶¶ 181-87.)

5. **Count V**: Violation of Pennsylvania's Implied Warranty Law. Pa. Stat. Ann. Tit. 13 § 2315. (Dkt. No. 26 ¶¶ 188-97.) Plaintiffs allege that Defendant violated the warrant of merchantability at the time of the Mumps Vaccine's sale to Plaintiffs because the Vaccine was not 95 percent efficacious as represented by Defendant. (Dkt. No. 26 ¶¶ 188-97.)

6. **Count VI**: Unjust enrichment. (Dkt. No. 26 ¶¶ 198-205.) Plaintiffs allege that Defendant has benefitted financially because of its "deceptive and wrongful conduct" in misrepresenting the efficacy of the Mumps Vaccine at the expense of Plaintiffs. (Dkt. No. 26 ¶¶ 199-203.) Plaintiffs request compensatory and punitive damage. (Dkt. No. 26 ¶ 204.)

E. Procedural Posture

Relators first filed this Complaint under seal on August 27, 2010. (Dkt. No. 20.) The Compliant, docket entries, and related filings were kept under seal until June 20, 2012 during the period to intervene requested by the United States. On April 27, 2012, the United States declined to intervene in the Relators' case. (Dkt. No. 54 at 3.) Relators filed an amended complaint and

request for jury trial on April 27, 2012, unsealed on June 21, 2012. (Dkt. No. 12.) The original, unredacted complaint remains under seal. On August 31, 2012, Defendant moved to dismiss Relators' Amended Complaint with prejudice. (Dkt. No. 45.)

On September 20, 2012, Plaintiffs filed a Consolidated Amended Class Action Complaint against Defendant. (Dkt. No. 26.)

II. LEGAL STANDARDS

This Court has jurisdiction pursuant to 28 U.S. § 1331 and 31 U.S.C. § 3732(a).

A. 12(b)(6)

In deciding a motion to dismiss pursuant to Rule 12(b)(6), courts must accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief. *Id.* (internal quotation and citation omitted). Complaints that contain only "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (citing *Twombly*, 550 U.S. 544, 555 (2007)). The facts must demonstrate that the Plaintiff is entitled to relief, not just show a "mere possibility of misconduct." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir. 2009) (quoting *Iqbal* at 679). This standard asks that the complaint "'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of

entitlement to relief.'" *Iqbal*, 556 U.S. at 679 (quoting *Twombly*, 550 U.S. at 557). In *Ashcroft v. Iqbal*, the Supreme Court clarified that this standard applies to all civil cases. *Iqbal*, 129 S. Ct. at 1949.

When deciding a motion to dismiss under 12(b)(6), the "court must consider only the complaint, exhibits attached to the complaint, matters of public record, as well as undisputedly authentic documents if the complainant's claims are based upon these documents." *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010). Assessing the sufficiency of a complaint is "a context-dependent exercise" because "[s]ome claims require more factual explication than others to state a plausible claim for relief." *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 98 (3d Cir. 2010) (cited in *United States ex rel. Galmines v. Novartis Pharms. Corp.*, 2013 U.S. Dist. LEXIS 120672 (E.D. Pa. Aug. 23, 2013)) (citations omitted).

B. 9 (b)

Fed. R. Civ. P. 9(b) states "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed .R. Civ. P. 9(b). The aim of this heightened pleading standard is "to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral and fraudulent behavior." *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir.1984). This standard "requires, at a minimum, that plaintiffs support their allegations of . . . fraud with all of the essential factual background . . . that is, the who, what, when, where and how of the events at issue." *United States of America ex rel. Ronald J. Streck v.*

Allergan, Inc., 894 F. Supp.2d 584, 601 (E.D. Pa. 2012) (citing *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002)).[2]

III. DISCUSSION

Defendants seek dismissal pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6) on the grounds that Relators have failed to plead fraud with the requisite particularity and failed to state a claim upon which relief can be granted.

A. Relators' Claims (Case No. 10-4374)

Relators make out two counts for violations of the FCA. Relators' Complaint alleges that Defendants submitted test results to the government that contained falsifications, or omissions, of

[2] In some False Claims Act (FCA) cases, the Third Circuit has generally sought to relax this pleading standard, explaining that Relators need not "plead the date, place or time of the fraud, so long as they use an alternative means of injecting precision and some measure of substantiation into their allegations of fraud." *U.S. ex rel. John Underwood v. Genentech, Inc.*, 720 F. Supp. 2d 671, 676 (E.D. Pa. 2010) (quoting *Rolo v. City Investing Co. Liquidating Trust*, 155 F.3d 644, 658 (3d Cir.1998)); *see also City Investing Co. Liquidating Trust*, 155 F.3d 644, 658 (3d Cir. 1998) (citations omitted), *abrogation on other grounds recognized*, *Forbes v. Eagleson*, 228 F.3d 471 (3d Cir. 2000).

In other FCA cases, however, the Third Circuit has cited approvingly – but has not formally adopted –the heightened standard used by the Eleventh Circuit whereby a Relator cannot "describe a private scheme in detail" and then allege fraud simply by assuming that "requesting illegal payments must have submitted, were likely submitted or should have been submitted to the Government." *United States ex rel. Quinn v. Omnicare, Inc.*, 382 F.3d 432, 439-40 (3d Cir.2004) (citing *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002)). The District Courts within the Third Circuit have been split on this issue with some courts dismissing complaints that do not refer to a specific false claim for payment and others allowing more general complaints to proceed. *See Underwood*, 720 F. Supp. 2d at 677 (citing *United States ex rel. Bartlett v. Tyrone Hosp., Inc.*, 234 F.R.D. 113, 120 (W.D. Pa. 2006); and *United States ex rel. Schmidt v. Zimmer, Inc.*, No. 00-1044, 2005 U.S. Dist. LEXIS 15648, at *1, *7-*8 (E.D. Pa. July 29, 2005) for granting dismissals; and *United States ex rel. Singh v. Bradford Reg'l Med. Ctr.*, No. 04-186, 2006 U.S. Dist. LEXIS 65268 (W.D. Pa. Sept. 13, 2006); *United States ex rel. Landsberg v. Levinson*, No. 03-1429, 2006 U.S. Dist. LEXIS 66689 (W.D. Pa. 2006); *Gibbons ex rel. United States v. Kvaerner Phila. Shipyard, Inc.*, No. 05-685, 2006 U.S. Dist. LEXIS 5172 (E.D. Pa. Feb. 10, 2006) for denying dismissals.). Looking at other circuits, however, the Eastern District of Pennsylvania has noted that the availability of evidence of fraud from the Government, as opposed to evidence being solely in the hands of the Defendant is a crucial factor in determining whether an FCA complaint should contain evidence of an actual claim in order to survive Rule 9(b). *See Underwood*, 720 F. Supp. 2d at 677; *United States ex rel. Streck v. Allergan, Inc.*, 894 F. Supp. 2d 584, *601 (E.D. Pa. July 3, 2012).

relevant testing data. These omissions and falsifications were reflected in their labeling, their submissions for approvals, and their requests for payment for purchase of the medications.

Defendant argues that the Relators' claim is dependent upon a finding that the MMR Product label is false, representing a 95 percent efficacy rate. (Dkt. No. 45 at 13.) Defendant alleges that labeling changes are solely within the purview of the FDA and that the FCA is not an avenue to dispute inaccurate labeling. Plaintiffs counter that their Complaint alleged more than a false labeling issue. Rather, Relators argue that it alleged that Defendant violated multiple duties to the government across multiple instances of reports and claims that failed to disclose the veracity of testing results and that deliberately obfuscated information about the vaccine's lessening efficacy.

a. FCA in General

Count One of the Complaint alleges a violation of § 3729(a)(1)(A) of the FCA, and Count Two alleges violations of § 3729(a)(1)(B).[3] (Compl. ¶¶ 152-55.) These sections of the statute impose 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). Moreover, the FCA defines "knowingly" as when a defendant

> (1) has actual knowledge of the information;
> (2) acts in deliberate ignorance of the truth or falsity of the information; or
> (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

31 U.S.C. § 3729(b).

[3] The Amended Complaint refers to these sections under their pre-2009 codification as 3729(a)(1)-(2).

To establish a claim under § 3729(a)(1)(A) of the FCA, a relator "must prove 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 v. United Health Group, Inc.*, 659 F.3d 295, 304-05 (3d Cir. 2011) (quoting *United States ex rel. Schmidt v. Zimmer, Inc.* ("*Zimmer I*"), 386 F.3d 235, 242 (3d Cir. 2004)) (referring to previous codification of the statute as § 3729(a)(1)).

Section 3729(a)(2)(B) differs in that "liability is premised on the presentation of a 'false record or statement to get a false or fraudulent claim paid or approved.'" *Id.* at 306-07 (quoting *Shaw v. AAA Eng'g & Drafting, Inc.*, 213 F.3d 519, 531 (10th Cir. 2000)) (referring to statute as 3729(a)(2), its previous codification). In contrast, "section 3729(a)(1)[(A)] requires only that a claimant present a 'false or fraudulent claim for payment or approval' without the additional element of a 'false record or statement.'" *Id.* Thus § 3729(a)(1)(A) allows a relator to bring a claim based on a defendant submitting a claim for government funds without explicitly making a false statement. *See id.*

Based on this interpretation, the Third Circuit decided in *Wilkins* that "there are two categories of false claims under the FCA: a factually false claim and a legally false claim." *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 305 (3d Cir. 2011) (quoting *U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008)). "A claim is factually false when the claimant misrepresents what goods or services that it provided to the government and a claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation which is a condition for government payment. A legally false FCA claim is based on a 'false certification' theory of liability." *Id.*

(citing *Rodriguez v. Our Lady of Lourdes Med. Ctr.*, 552 F.3d 297, 303 (3d Cir. 2008), overruled in part on other grounds by *U.S. ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 129 S. Ct. 2230, 173 L. Ed. 2d 1255 (2009)).

Within the theory of false certification, there are two further categories: express and implied false certification. *See id.* A defendant violates the FCA under express false certification when, in conjunction with a request for Federal funds, it certifies that it is in compliance with regulations that are requirements for payment. *See id.* An FCA violation occurs under implied false certification when a defendant submits or causes to be submitted a request for payment without disclosing that it is in violation of a regulation that affect its eligibility for payment. *See id.* For a relator to succeed under this theory, the Third Circuit has required relators to show "that if the Government had been aware of the defendant's violations of the Medicare laws and regulations that are the bases of a plaintiff's FCA claims, it would not have paid the defendant's claims." *Id.* at 307.

b. FCA Liability

The Court finds that the fraud-on-the-FDA theory under the FCA withstands the motion to dismiss. The *qui tam* provision states that "[a] person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government." *Id*. § 3730(b).

In memoranda in support of Defendant's motion to dismiss, Defendant argued that "with the government having declined to intervene, if Relators' case is to enforce, or restrain violations of the FDCA, it is foreclosed by 21 U.S.C. § 337(a)." (Dkt. No. 45-1 at 18.) Specifically, Defendant points the Court to Section 337(a) of the Federal Food, Drug, and Cosmetic Act ("the

FDCA") which states that "proceedings for the enforcement, or to restrain violation, of [the FDCA] *shall be by* and in the name of the United States." § 337(a).

First, Defendant argues that Relators' claims fall under the purview of the FDCA. Defendant argues Relators' claims rest on a finding that the vaccine label is misbranded, a determination which should fall squarely under the "scientific expertise" and "regulatory discretion" of the FDA under the FDCA. (Dkt. No. 45-1 at 16.) Defendant further claims that because Relators argued their version of facts to the FDA during the FDA investigation, the FDA was apprised of all the facts they allege. (Dkt. No. 45 at 4.) The theory follows: the FDA could have started an enforcement action to change the label, or to reprimand Defendant for its behavior, but it chose not to – a decision which should not be reviewed through a FCA claim. 21 U.S.C. § 331 *et seq.* As such – the argument goes - the subsequent failure of the government to intervene means that this *qui tam* action fails to be "by and in the name of the United States" under the FDCA.

Defendant relies on *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). In *Buckman*, Plaintiffs, who claimed injuries resulting from the use of orthopedic bone screws in the pedicles of their spines, alleged that the Defendant, a consulting company working for the bone screw manufacturer, made fraudulent representations to the FDA to secure FDA approval. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 343 (2001). The Court held that "plaintiffs' state-law fraud-on-the-FDA claims" were pre-empted by the Medical Device Amendment to the Federal Food, Drug, and Cosmetic Act and the FDA's regulatory scheme, and discretion, to enforce the Act. *Buckman*, 531 U.S. at 348. The Court held that "state-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently

with the Administration's judgment and objectives." *Buckman*, 531 U.S. at 350. This case is easily distinguishable. The Plaintiffs in *Buckman* sought relief under state tort law, not the FCA. *Buckman*, 531 U.S. at 343.

The United States Government filed a Statement of Interest, clarifying that, from their perspective, "Holding that only the Government, and not a relator, can litigate a False Claims Act suit arising from allegations of fraud on the FDA or conduct in violation of FDA regulations would be inconsistent with the purposes of the False Claims Act." (Dkt. No. 54 at 5.) "The fact that a False Claims Act case may involve omissions to regulatory agencies, discretion in agency action, or violations of regulations does not preclude the action from proceeding." (Dkt. No. 54 at 7.) The Court agrees. Relators allege that Defendant consistently and deliberately withheld pertinent information as to the safety and efficacy of a medication from the government. It is this alleged omission that is the grounds for FCA liability.

c. Relators' § 3729(a)(1)(A) Claim Withstands 12(b)(6) and 9(b)

Under § 3729(a)(1)(A), Relators must allege with sufficient particularity 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 304-05 (internal citations omitted).

i. **Defendants Submitted Claims to the Government**

For an FCA complaint to survive a 12(b)(6) motion under an implied false certification theory, a relator does not need to produce a specific instance of a false claim. *Id.* at 308 ("We never have held that a plaintiff must identify a specific claim for payment at the pleading stage of

the case to state a claim for relief."). In *Wilkins*, the Third Circuit noted that such a requirement may exist under 9(b), but chose not to rule on that question in this opinion. *Id.* As such, under the Third Circuit's current jurisprudence, the Court finds that Relators' Complaint survives the heightened pleading requirement of 9(b). [4] Relators plainly allege that Defendant submitted claims for payment to the government for the government's purchase of the vaccine on many occasions between 1999 and the present, following the allegedly fraudulent testing. ¶¶ 4, 144-45, 147-49, 152-55.

ii. **Claims Were False**

[4] Defendant pointed the Court to two out-of-circuit cases of which the Court took particular note. (*See* Def. Mot. to Dismiss, Dkt. No. 45-1 at 32-33, 36.) The Court found these cases instructive, but not persuasive.

In *United States ex rel. Tessitore*, the Court held that the Complaint (1) failed to include a date that any application was submitted to the FDA; (2) failed to identify who at Defendant's company made the allegedly false statements to the FDA and who was involved in the concealment scheme; (3) failed to allege any of the actual content of these submissions. *United States ex rel. Tessitore v. Infomedics, Inc.*, 847 F. Supp. 2d 256, 265 (D. Mass 2012). In *United States ex rel. Tessitore,* the specific dates of the claims was of particular relevance because the alleged adverse event reports arguably occurred after the claims were submitted, rendering Relator's fraud claims moot. In contrast, in this case, it is undisputed that claims were absolutely made after the allegedly fraudulent testing. The timing is of less relevance to the validity of Relators' claims.

Second, in *United States ex rel. Provuncher v. Angioscore*, Plaintiff/relator, a former employee of Defendant, a biotechnology firm that manufactures and distributes angioplasty catheters, brought this "whistle blower" action based on allegations that Defendant "deliberately suppressed adverse event reporting of injuries and incidents" and sold the product knowing that it was "defective" in violation of the federal False Claims Act (the "FCA"), 31 U.S.C. §§ 3729(a)(1)(A)-(B). No. 09-12176, 2012 WL 3144885, at *1 (D. Mass. 2012). Plaintiff filed a Second Amended Complaint that provided additional details, but maintained the same - and what the Court considered, the flawed – theory that there had been a violation of the FCA because there was evidence of a small error rate for the device that was not allegedly shared with the FDA. *Id.* at *1. The Court held that this theory failed to plead a violation of the FCA because, even accepting all of Plaintiff's facts as true, Plaintiff had only alleged a failure rate for the medical device for which there was already an expectation of a similar error rate. *Id.* The Court held that this was "not the evil that Congress sought to root out by passage of the False Claims Act." *Id.* The Court notes that the facts alleged in this case are distinct. In this case, Relators do not allege solely that there was a failure to report an error rate similar to one already anticipated for the vaccine. Rather, Relators allege that Defendant withheld from the government, in violation of statutory and contractual duties, information about their testing methodology and results of lessened efficacy below what was already anticipated or expected by the government.

In conclusion, the Court takes note of these cases but does not find that such specificity is required at this stage. The Court notes Defendants' argument that the current allegations fail to specify dates of submissions, how the reports were submitted, to whom specifically these reports were directed, etc. (Def. Mot. to Dismiss, Dkt. No. 45-1 at 31.) At this stage, the Court finds that these unknowns are not fatal to Relators' claims. Discovery will help to elucidate these specificities further.

Relators have sufficiently pled that there was information about the alleged lessened efficacy of the vaccine that was not shared with the government and that the omission of this information was material to the government continuing to purchase the vaccines. Relators also pled a theory of liability that the claims were "legally false." (Rel. Opp. to MTD, Dkt. No. 47 at 23-24.) Relators and Plaintiffs' allege that Defendants have a general duty to federal officials, 18 U.S.C. § 1001, a contractual and statutory duty to provide the CDC with accurate information regarding safety and efficacy of the vaccine, (Dkt. No. 12 ¶¶ 105-11), duties to the FDA under the Public Health Service Act, the Food Drug and Cosmetics Act, and FDA regulations, 21 U.S.C. § 301 *et seq.*; 42 U.S.C § 262 *et seq.*; 21 C.F.R. § 600.12(b); 21 C.F.R. § 210 *et seq.*, and duties to the National Vaccine Program and the Vaccine Injury Compensation Program. (Dkt. No. 12 ¶¶118-19.) Relators argue that Defendant's duties to report the diminished efficacy were triggered when Defendant learned of the results of its testing no later than 1999. (Dkt. No. 12 ¶ 122.) Relators allege that Defendant's "duty to disclose accurate and current information of the efficacy were not merely a condition of payment for" Defendant but also a "condition for [Defendant]'s ability to sell the vaccine at all." (Dkt. No. 47 at 23.)

In the Complaint, Relators further allege that:

- Defendant has a duty to disclose diminished efficacy to the FDA. 21 C.F.R. § 600.12(b). (Dkt. No. 12 ¶ ¶ 114-16.)
- Defendant has a duty to manufacture vaccines in conformance with cGMP. 21 C.F.R. § 210.2. Manufacturers are required to test for safety, purity, and potency of every lot of the vaccine to be sold. 21 C.F.R. § 610. If a manufacturer learns of a deviation from the specifications, it has a duty to disclose that information to the FDA, fully investigate it, and correct it. 21 C.F.R. § 600.14; 21 U.S.C. § 331(c); 21 C.F.R.§ 211.192. (Dkt. No. 12 ¶ 115.)
- Defendant has a duty to report to the FDA adverse experience events. (Dkt. No. 12 ¶ 116) (citing 21 C.F.R. § 600.80.) As a manufacturer of vaccines for pediatric population, Defendant must provide an annual report to inform the FDA of whether new studies in the pediatric population have been initiated, an analysis of

available safety and efficacy data, and an assessment of data needed to ensure appropriate labeling for the pediatric population. 21 C.F.R. § 601.28.

- Defendant has a duty to self-monitor and update labeling when new information becomes available that causes the labeling to become inaccurate, false, or misleading. (Dkt. No. 12 ¶ 117.)

Taken all together, Relators argue that there were both express and implied legal duties that the claims submitted to the government not omit the alleged poor testing results. Taking these facts alleged as true, this theory survives the Motion to Dismiss.[5]

iii. Defendant Knew Claims Were False

Realtors sufficiently allege their first-hand experience in Defendants' laboratories, where they witnessed supervisors and managers instructing staff persons to withhold information from the government regarding the diminished efficacy. For the purposes of this stage of litigation, these allegations provide Defendant with sufficient notice of the claims at issue. Relators' claim alleging a violation of § 3729(a)(1)(A) is well pled.

[5] Relators also allege that the claims were "factually false" because they contain "affirmative misrepresentations to the CDC about the vaccine's efficacy" and because Defendant fraudulently omitted "all of the information it kn[e]w[] -- but [] schemed to conceal -- on the vaccine's significantly diminished efficacy." (Dkt. No. 47 at 38.) Under this theory, the claims are factually false because they contain affirmative misrepresentations due to the deliberate omission about the efficacy of the vaccine. These deliberate omissions could rise to the level of a factually false claim. The Court notes that at this point, Relators have not been able to allege any specifics as to what information was or was not included in these claims. The Court awaits the fruits of discovery for further guidance as to the strength of the "factually false" theory.

d. Relators' § 3729(a)(1)(B) Claim Withstands 12(b)(6) and 9(b)

Relators must demonstrate that Defendant (1) knowingly made, used, or caused to be made or used a false record or statement (2) material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1)(B).[6] For this claim, Relators allege that Defendant:

> failed to disclose that its mumps vaccine was not as effective as Merck represented, (ii) used improper testing techniques, (iii) manipulated testing methodology, (iv) abandoned undesirable test results, (v) falsified test data, (vi) failed to adequately investigate and report the diminished efficacy of its mumps vaccine, (vii) falsely verified that each manufacturing lot of mumps vaccine would be as effective as identified in the labeling, (viii) falsely certified the accuracy of applications filed with the FDA, (ix) falsely certified compliance with the terms of the CDC purchase contract, (x) engaged in the fraud and concealment describe herein for the purpose of illegally monopolizing the U.S. market for mumps vaccine, (xi) mislabeled, misbranded, and falsely certified its mumps vaccine, and (xii) engaged in the other acts described herein to conceal the diminished efficacy of the vaccine the government was purchasing." (Dkt. No. 12 ¶ 155.)

i. Relators sufficiently allege that Defendant knowingly used a false statement

Relators alleged in multiple instances throughout their Complaint that false statements were given to the government, including:

- False representations through package inserts. (Dkt. No. 12 ¶¶ 71-73.) Relators allege that the Mumps Vaccine's insert states a 95 percent efficacy rate which is a clear misrepresentation of the efficacy rate Defendant found in its testing starting in 1999. (Dkt. No. 12 ¶ 72-3.)
- False representations through expanded distribution of the vaccine. (Dkt. No. 12 ¶¶ 74-78.) Relators allege that Defendant falsely represented an efficacy rate of 95 percent or higher to the FDA and the EMA in order to receive approvals to sell new products incorporating the Mumps Vaccine. (*Id.*)
- False representations through Defendant's application for a labeling change on potency of MMRII. (Dkt. No. 12 ¶¶ 79-81.) Relators allege that during the labeling change process in 2007 for MMRII, Defendant did not disclose to the FDA that their internal testing revealed a diminished efficacy rate of the Mumps Vaccine. (*Id.*) Rather, Defendant continued to maintain that the Mumps Vaccine had a 95 percent efficacy rate. (Dkt. No. 12 ¶ 81.)

[6] The Amended Complaint refers to these sections under their pre-2009 codification as 3729(a)(1)-(2).

- False representations through recent Mumps Outbreaks. (Dkt. No. 12 ¶¶ 82-96.) Relators allege that during the 2006 Mumps outbreak, Defendant failed to disclose to the CDC or the FDA its knowledge of the weaker efficacy of its Mumps Vaccine and continued to misrepresent the efficacy as 95 percent. (Dkt. No. 12 ¶¶ 83-91.) Similarly, during a 2009 outbreak, Defendant again continued to make false representations to the CDC and the FDA. (Dkt. No. 12 ¶¶ 92-96.)
- False representations through the Immunization Action Coalition. (Dkt. No. 12 ¶¶ 97-101.) Relators allege that Defendant made false representations to the IAC, reflected in the IAC's materials, which are sanctioned and supported by the CDC. (*Id.*)

At this stage, the Court holds that Relators have sufficiently pled facts that could demonstrate that Defendant provided a false statement to the government. Relators can support a claim under the FCA alleging that Defendant deliberately obfuscating or provided incomplete information to the FDA.

B. Plaintiffs' Claims (Case No. 12-3555)

Defendant moved to dismiss under 12(b)(6) and 9(b). (Dkt. No. 40.) Plaintiff adopts as true all of Relators' factual allegations in the Amended Complaint and alleges the following counts:

1. **Count I**: Monopolization in violation of the Sherman Act. 15 U.S.C. § 2. (Dkt. No. 26 ¶¶ 151-55.) In this Count, Plaintiffs allege that Defendant falsified the seroconversion rate of its Mumps Vaccine in its products and to the FDA. (Dkt. No. 26 ¶ 152.) Plaintiffs argue that because of this falsification, Defendant was effectively excluding competition from the relevant market. (Dkt. No. 26 ¶ 154.)
2. **Count II**: Violation of state consumer protection laws in twenty-four states. (Dkt. No. 26 ¶ 156-69.) Plaintiffs state that Defendant engaged in false or deceptive conduct in making statements about the efficacy of the Mumps Vaccine with the intention of misleading consumers. (Dkt. No. 26 ¶¶ 163-66.)
3. **Count III**: Breach of contract. (Dkt. No. 26 ¶¶ 170-75.) Plaintiffs allege that Defendant entered a contract to provide Mump Vaccine to Plaintiffs and the Class and that part of this standardized contract included the falsified representation of the inflated efficacy rate. (Dkt. No. ¶¶ 171-74.) Plaintiffs allege suffering for the purchase price they paid for the Mumps Vaccine because of this alleged breach of contract. (Dkt. No. ¶ 174.)
4. **Count IV**: Violation of Pennsylvania's Express Warranty Law. Pa. Stat. Ann. Tit. 13 § 2313. (Dkt. No. 26 ¶¶ 176-87.) Plaintiffs allege that Defendant acted as a

Merchant under the Pennsylvania Uniform Commercial Code, made a contract with Plaintiffs and class members to sell the Mumps Vaccine. (Dkt. No. 26 ¶¶ 177-80.) Plaintiffs allege that because the vaccine did not have an efficacy rate of 95, as represented by Defendant, Defendant breached an express warranty. (Dkt. No. 26 ¶¶ 181-87.)

5. **Count V**: Violation of Pennsylvania's Implied Warranty Law. Pa. Stat. Ann. Tit. 13 § 2315. (Dkt. No. 26 ¶¶ 188-97.) Plaintiffs allege that Defendant violated the warrant of merchantability at the time of the Mumps Vaccine's sale to Plaintiffs because the Vaccine was not 95 percent efficacious as represented by Defendant. (Dkt. No. 26 ¶¶ 188-97.)
6. **Count VI**: Unjust enrichment. (Dkt. No. 26 ¶¶ 198-205.) Plaintiffs allege that Defendant has benefitted financially because of its "deceptive and wrongful conduct" in misrepresenting the efficacy of the Mumps Vaccine at the expense of Plaintiffs. (Dkt. No. 26 ¶¶ 199-203.) Plaintiffs request compensatory and punitive damage. (Dkt. No. 26 ¶ 204.)

a. Sherman Act Allegations

In this Count, Plaintiffs allege that Defendant falsified the seroconversion rate of its Mumps Vaccine in its products and to the FDA. (Dkt. No. 26 ¶ 152.) Plaintiffs argue that because of this falsification, Defendant was effectively excluding competition from the relevant market in violation of § 2 of the Sherman Act. (Dkt. No. 26 ¶ 154.)

The Sherman Act, with its "sweeping language," makes it unlawful to "monopolize, attempt to monopolize, or conspire to monopolize, interstate or international commerce." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 306 (3d Cir. 2007) (citing 15 U.S.C. § 2.). To prove a violation of § 2 of the Sherman Act, Plaintiffs must show: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966). The acquisition or possession of monopoly power must be accompanied by some anticompetitive conduct on the part of the possessor. *Verizon Commcn's Inc. v. Law Offices of*

Curtis V. Trinko, LLP, 540 U.S. 398, 407 (2004); *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 308 (3d Cir. 2007). Conduct that merely harms competitors, however, while not harming the competitive process itself, is not anticompetitive. *See Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 224 (1993) ("It is axiomatic that the antitrust laws were passed for 'the protection of *competition*, not *competitors.*'" (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962))); *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993) ("The law directs itself not against conduct which is competitive, even severely so, but against conduct which unfairly tends to destroy competition itself.").

First, Plaintiffs have demonstrated that Defendant had monopoly power in the relevant market. Plaintiffs allege that Defendant was the sole manufacturer licensed by the FDA to sell the vaccine in the U.S. (Dkt. No. 26 ¶ 16.) This fact is not contradicted by Defendant. (Dkt. No. 40.)

Second, Plaintiffs allege that Defendant willfully maintained such monopoly power through falsifying data presented to the government, as described in greater detail in Relators' claims. (Dkt. No. 26 ¶¶ 152-55.) Plaintiffs argue that by deliberately concealing information known to Defendant about the efficacy of the vaccine, other potential entrants into the mumps vaccine market were precluded because of their presumption that the U.S. government would not create additional contracts for new vaccine products while the Defendant's vaccine had a 95% efficacy rate. The basic theory is that Defendant presented fraudulent information to the government that secured Defendant a monopoly over the market.

While a slightly novel theory of liability, at this stage, the Court finds that Plaintiff has sufficiently pled a claim of violation of the Sherman Act. The Third Circuit has held that

"'[a]nticompetitive conduct' can come in too many different forms, and is too dependent upon context, for any court or commentator ever to have enumerated all the varieties.'" *LePage's Inc. v. 3M*, 324 F.3d 141, 152 (3d Cir. 2003) (quoting *Caribbean Broad. Sys., Ltd. v. Cable & Wireless PLC*, 148 F.3d 1080, 1087 (D.C. Cir. 1998)).

For example, in *LePage's Inc. Wireless*, the Court held that finding enough facts to support the jury's holding that 3M violated Section 2 of the Sherman Act, the Court relied on the finding that 3M engaged in "exclusionary conduct that consisted of rebate programs and exclusive dealing arrangements designed to drive LePage's and any other viable competitor" from the relevant market. *LePage's Inc. v. 3M*, 324 F.3d 141, 154 (3d Cir. 2003). In *Broadcomm Corp. v. Qualcomm Inc.*, Plaintiff alleged that Defendant monopolized a market by "by falsely promising to license its patents according to the fair, reasonable, and non-discriminatory ("FRAND") terms set by the European Telecommunications Standards Institute ("ETSI") and its standards-defining organizations ("SDO") counterparts in the United States, but then reneging on those promises after it succeeded in having its technology included in the standard." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 306 (3d Cir. 2007). The Court held that " (1) in a consensus-oriented private standard-setting environment, (2) a patent holder's intentionally false promise to license essential proprietary technology on FRAND terms, (3) coupled with an SDO's reliance on that promise when including the technology in a standard, and (4) the patent holder's subsequent breach of that promise, is actionable anticompetitive conduct." *Broadcom Corp.*, 501 F.3d at 314.

Similarly, in this case, Plaintiffs have successfully pled a claim for a § 2 violation. Taking the facts in the light most favorable to Plaintiffs, Defendant's fraudulent misrepresentations

about Defendant's own product, coupled with the unique facts of this case (e.g., the 100% monopoly of the market and the arguable statutory and contractual duties to disclose information) create the basis for an antitrust claim that Defendant willfully maintained monopoly power through exclusionary tactics.[7] Plaintiffs have argued sufficient facts to sustain a claim for proximate causation, detailing the significant barriers that other companies would face to enter the Mumps vaccine market. (Dkt. No. 26 ¶ 30.)

b. State law claims

Plaintiffs have only stated claims under N.Y. Gen. Bus. Law § 349(a) (McKinney 2014) and N.J. Stat. Ann. § 56:8-2 (West 2014). In reaching this decision, the Court first considers the threshold issues of Article III standing and preemption, before considering whether Plaintiffs' surviving claims have been adequately stated under Fed. R. Civ. P. 12(b)(6) and 9(b).

i. Standing

Initially, the Court must decide whether Defendant's challenge to Plaintiffs' Article III standing is timely. This Court finds that the challenge is appropriate with respect to the *named Plaintiffs*, consistent with Supreme Court and Third Circuit precedent, and decisions reached by courts in the Eastern District of Pennsylvania,

[7] Defendant points the Court to *Oce North America, Inc. v. MCS Services, Inc.*, 795 F. Supp. 2d 337 (D. Md. 2011). The Court finds that case distinguishable as it surrounded a claim that a company had made false and misleading statements about a competitor's company; which is not at issue in this case. *Id.* at 341. Similarly, the Court distinguishes Third Circuit precedent *Santana Products, Inc. v. Bobrick Washroom Equip., Inc.*, as that case was about Section One of the Sherman Act and concerned Defendants' alleged fraudulent statements about a competitor's product. 401 F.3d 123, 134-35 (3d Cir. 2005). Moreover, in *Santana*, the allegedly fraudulent statements were made to denigrate a competitor's product so that the government would choose Defendants' product instead for the building of a specific project. *Id.* at 133. The Court stressed that despite the fraudulent statements, there was no exclusion in the overall market in a "real sense" because Plaintiff, competitor company to Defendant, "was still free to sell its products and consumers were free to buy them." *Id.* Defendant's further comparison to *Schachar v. Am. Acad. of Ophthalmology, Inc.*, is also not a great comparator as it was solely about a § 1 claim and about comments about competitors. 870 F.2d 397, 399 (7th Cir. 1989).

Plaintiffs cite *Ortiz v. Fibreboard Corp*., 527 U.S. 815 (1999), and a series of lower court cases interpreting *Ortiz*, to support their assertion that this Court should defer ruling on Article III standing until after class certification. (Dkt. No. 43 at 27) (citing *In re Chocolate Antitrust Litig.*, 602 F. Supp. 2d 538 (M.D. Pa. 2009); *Clark v. McDonald's Corp*., 213 F.R.D. 198 (D.N.J. 2003); *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002).

However, *Ortiz* is unavailing. In that case, the Supreme Court considered the timeliness of petitioners' argument that members of the putative class lacked Article III standing. *Ortiz*, 525 U.S. at 830. The Court resolved this issue by holding that certification may precede standing analysis where the former is "logically antecedent" to the latter. *Id.* Because no class had been certified, petitioners' challenge would have forced the Court to rule on the standing of persons not yet before the Court. Thus, determining the existence of a class at all logically preceded evaluating whether potential class members had proper standing.

This Court is not persuaded that the exception in *Ortiz* controls in the instant case. The Defendant does not challenge the definition of the class, or the standing of the members of the putative class. Rather, the Defendant challenges the *named Plaintiff's* standing. (Mot. Dismiss 22.) Thus, the Defendant has not asked the Court to consider the standing of persons not part of the suit, but persons, by definition, already before the Court. Because the *Ortiz* exception is inapplicable, Supreme Court precedent affirming standing as a threshold jurisdictional matter remains controlling. *See Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 94-95 (1998) (citing *Ex parte McCardle,* 7 Wall. 506, 514 (1868) ("Without jurisdiction the court cannot proceed at all in any cause."); *Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 490 (1982) ("A plaintiff's standing is a

jurisdictional matter for Art. III courts, and thus a 'threshold question' to be resolved before turning attention to more 'substantive' issues.") (Brennan, J., dissenting).

This narrow interpretation of *Ortiz* is not novel. In *In re Wellbutrin XL Antitrust Litig.*, the court faced the same legal question. 260 F.R.D. 143, 167 (E.D. Pa. 2009). Like Plaintiffs here, plaintiffs in *Wellbutrin* argued that the holding in *Ortiz* permitted the District Court to delay standing analysis until after class certification. *Id.* Rejecting that argument, the court concluded that *Ortiz* did nothing to disturb settled precedent that, with respect to named plaintiffs, standing remained a threshold issue. *Id.* at 155 (asserting that the "unique posture" of *Ortiz* and its silence concerning standing requirements of named plaintiffs "demonstrate that a standing analysis should not be deferred."). "A ruling as to the *named plaintiffs'* standing depends in no way upon the standing of *proposed class members*. Thus, the named plaintiffs' standing is not 'logically antecedent' to the issue of class certification." *Id.* (emphasis added). Thus, the court found that it was free to rule on the defendant's standing challenge before certifying a class.

This Court's narrow reading of *Ortiz* is also consistent with Third Circuit precedent, which holds that a named plaintiff must establish proper standing to bring each claim before class certification. *See In re Schering Plough Corp. Intron/Temodar Consumer Class Action,* 678 F.3d 235, 245 (3d Cir. 2012) ("A plaintiff who raises multiple causes of action must demonstrate standing for each claim he seeks to press.") (internal citation omitted); *Winer Family Trust v. Queen*, 503 F.3d 319, 325 (3d Cir. 2007) ("The initial inquiry [in a class action] … is whether the lead plaintiff individually has standing, not whether or not other class members have standing."); *In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions,* 148 F.3d 283, 306-207 (3d Cir. 1998) (" [W]hether an action presents a 'case or controversy' under Article III is

determined vis-à-vis the named parties."); *Zimmerman v. HBO Affiliates*, 834 F.2d 1163, 1169 (3d Cir. 1987) ("It is well settled that to be a class representative on a particular claim, the plaintiff must himself have a cause of action on that claim.").

Plaintiffs argue that their position is supported by a "nearly unbroken line of precedent" supporting its position from the Second Circuit, the District of New Jersey, and the Middle District of Pennsylvania. (Opp'n 30-31.) However, Plaintiffs' assertion ignores Eastern District cases that have rejected arguments nearly identical to the one made here. *See In re Processed Egg Prods. Antitrust Litig.*, 851 F.Supp.2d 867, 882 (E.D. Pa. 2012) ("…[T]here is an apparent consensus that the Court may consider the standing of the *named plaintiff's"* before deciding to certify a class) (emphasis in original); *Sheet Metal Workers 441 Health & Welfare Plan v. GlaxoSmithKline*, 263 F.R.D. 205, 210 (E.D. Pa. 2009) ("…[W]hen the *named plaintiff* lacks a cause of action, the Court should dismiss the action before proceeding to class certification.") (emphasis added); *In re Flonase Antitrust Litig.*, 610 F.Supp.2d 409, 414 (E.D. Pa. 2009) ("It would not be premature…to first determine if Plaintiffs have stated a claim…because at least one named Plaintiff must have a cause of action on a claim for that claim to survive a motion to dismiss."). Moreover, Plaintiffs ignore cases from the Fifth and Ninth Circuits that construe *Ortiz* narrowly. *See Easter v. Am. West Fin.*, 381 F.3d 948, 962 (9th Cir. 2004) (*Ortiz "*does not require courts to consider class certification before standing."); *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 319 (5th Cir. 2002) (holding that the District Court erred by not demanding plaintiffs show standing before certifying a class).

In light of the forgoing, the Court deems the Defendant's challenge ripe for decision, and will therefore conduct a standing analysis.

a) Standing: Standard of Review

The Court considers a motion to dismiss for lack of standing under Federal Rule of Civil Procedure under 12(b)(1). *Ballentine v. United States*, 486 F.3d 806, 820 (3d Cir. 2007). "When considering a motion to dismiss for lack of standing, the trial court must accept as true all material allegations in the plaintiff's complaint." *Blunt v. Lower Merion Sch. Dist.*, 559 F. Supp. 2d 548, 565 (E.D. Pa. 2008) (citing *Warth v. Seldin*, 422 U.S. 490, 501 (1975)). On a motion to dismiss for standing, the plaintiff "'bears the burden of establishing' the elements of standing." *Ballentine*, 486 F.3d at 806 (citing *FOCUS v. Allegheny Cnty. Ct. of Com. Pleas*, 75 F.3d 834, 838 (3d Cir. 1996)). However, "general factual allegations of injury resulting from the defendant's conduct may suffice." Id. (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992)).

Article III standing requires a plaintiff to prove: 1) that they have suffered an injury in fact; 2) that there is a causal connection between the injury and the alleged conduct of the opposing party; and 3) that a favorable decision will likely redress the plaintiff's injury. *Edmonson v. Lincoln Nat. Life Ins. Co.*, 725 F.3d 406, 415 (3d Cir. 2013) (citing *Lujan* 405 U.S. at 560). The Court will first consider whether the Plaintiffs have met these conditions with respect to the claims based on the laws of their home states, and then with respect to the claims based on the laws of the states where they do not reside.

b) Standing: States Where Named Plaintiffs Reside

First, Plaintiffs have adequately alleged injuries-in-fact in their home states of New York, New Jersey, and Alabama. "[M]onetary harm is a classic form of injury-in-fact. Indeed it is often assumed without discussion." *Danvers Motor Co., Inc. v. Ford Motor Co.*, 432 F.3d 286,

291 (3d Cir. 2005) (internal citations omitted). Plaintiffs assert that, as a result of Defendant's misrepresentations, they were fraudulently and deceptively induced to purchase Defendant's product and have therefore suffered an economic injury. (Dkt. No. 26 ¶ 167.) Thus, the Complaint sufficiently states a cognizable injury for Article III purposes.

Second, Plaintiffs have demonstrated a causal link between the injury and the Defendant's conduct. The injury-in-fact must be "fairly traceable" to the alleged conduct of the defendant. *Edmonson*, 725 F.3d at 415 (3d Cir. 2013) (citing *Lujan*, 504 U.S. at 560). It cannot be the result of "independent action of some third party not before the court." *Id.* Here, Plaintiffs allege that, but for the fraud and misrepresentations made by the Defendant, Plaintiffs' would not have purchased the vaccine. As a result, the plaintiffs have met their burden with respect to causation.

Third, favorable judgment by the court must be likely to provide redress to the particular injuries the plaintiffs. *Edmonson*, 725 F.3d at 415. Plaintiffs must establish a "substantial likelihood that the requested relief will remedy the alleged injury in fact." *Toll Bros., Inc. v. Twp. of Readington*, 555 F.3d 131, 143 (3d Cir. 2009) (quoting Vt. Agency of Natural Res. v. United States ex rel. Stevens, 529 U.S. 565, 571 (1999)). Here, Plaintiffs seek compensatory damages for the vaccine, as well as any other damages permitted by the statutes they invoke. (Dkt. 26 ¶ 169.) Both, should they be awarded, are likely to provide redress for the Plaintiffs economic injuries. Because Plaintiffs have met all three elements necessary to establish Article III standing with respect to these claims, the Court will not dismiss them for lack of standing.

c) Standing: States Where No Named Plaintiff Resides

Named Plaintiffs do not have standing to bring claims based on the laws of states in which they do not reside because they have not sufficiently pled injuries-in-fact in those states. "[N]amed plaintiffs who represent a class must allege and show that they personally have been injured, not that injury has been suffered by other, unidentified members of the class…." *Lewis v. Casey*, 518 U.S. 343, 357 (1996) (quoting *Simon v. Eastern Ky. Welfare Rights Organization*, 426 U.S. 26, 40 n. 20 (1976)). Plaintiffs "must allege an injury to himself that is 'distinct and palpable' as distinguished from merely 'abstract,' and the alleged harm must be actual or imminent, not 'conjectural' or 'hypothetical.'" *Reilly v. Ceridian Corp.*, 664 F.3d 38, 42 (3d Cir. 2011) (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990)).

While the Complaint provides sufficient basis to conclude Plaintiffs were injured in their home states, the same is not true for the remaining jurisdictions. The Complaint does not specify what, if any, injuries the named Plaintiffs suffered in any of the twenty-two jurisdictions whose laws they invoke. Instead, their claims rest on abstract injuries suffered by other, unidentified members of the putative class. Therefore, they have not met their burden of proof and all claims based upon those laws must be dismissed.

As a result, Count II is dismissed with respect to all claims but those based on the laws of New York and New Jersey; Count III—which does not specify the state law on which it is based—is dismissed to the extent that it relies on the laws of states where named Plaintiffs do not reside; Count IV and Count V are dismissed in their entireties for lack of standing, as no Plaintiff resides in Pennsylvania; and, Count VI—which does not specify the state law on which it is based—is dismissed to the extent it relies on the laws of states where no named Plaintiff resides.

ii. Preemption

Defendant claims that Plaintiffs' suit is a private fraud-on-the-Food & Drug Administration ("FDA") claim barred by the Supreme Court's ruling in *Buckman v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001). Defendant argues that the "gravamen of the [Plaintiffs'] allegations is that Merck has been able to falsely represent the efficacy of the mumps component of its MMR vaccine by virtue of fraudulent submission of data during an FDA licensure process." (Dkt. No. 40 at 19.) Defendant contends that, because Supreme Court's decision in Buckman bars state fraud on the FDA claims, the Plaintiffs' state law claims must be dismissed. 531 at 348 (holding fraud on the FDA claims brought under state laws must be dismissed because such claims are preempted by the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C.A. § 301 et seq.). Alternatively, the Defendant claims that Plaintiffs' suit should be preempted because it would be impossible for Defendant to comply with both state laws and FDA labeling requirements. (Dkt. No. 40 at 20.)

In *Buckman*, the plaintiff sought to recover for injuries sustained from a medical device which gained FDA approval only after the defendant misrepresented its intended uses. 531 U.S. at 344. Plaintiff argued that, but for a fraud on the FDA, the medical device would not have been approved and Plaintiff's injuries would not have occurred. *Id.* The Court held that such a suit was preempted because state tort claims would upset the FDA's "delicate balance of statutory objectives." *Id.* at 348.

Buckman is unavailing. In its wake, courts considering arguments analogous to the one made here have found that, where a plaintiff's claim incorporates, but does not rely upon a fraud on the FDA, a state tort claim is not preempted. *See In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Practice*, 701 F. Supp.2d 356, 370 (E.D. N.Y. 2010) ("In order to avoid

preemption . . . a plaintiff's claim must thread the needle . . . showing that defendant has violated the FDCA, but that plaintiff's claims are not entirely premised on that violation . . . ."). Here, Plaintiffs allege that the deception was one part of a larger scheme to maintain an anticompetitive business regime. Therefore, while their claim alleges a violation of the FDCA, the claims are not entirely premised on that violation. (Dkt. 26 ¶ 27.) Additionally, in Buckman, the Court found that judgment in favor of the plaintiff "would exert extraneous pull" on the FDA's authority by limiting its ability to "police fraud consistently with the Administration's judgment and objectives." 531 U.S. at 350, 353. The case currently at bar does not implicate this concern. A ruling in favor of the Plaintiffs on these state claims would not have any effect on the method by which the FDA regulates the Defendant, or infringe on any FDA remedy to police fraud.

Moreover, decisions subsequent to *Buckman* have raised doubts about its precedential value outside the medical device context. In *Wyeth v. Levine*, the Supreme Court again considered whether the FDCA preempted a state tort suit. 555 U.S. 555, 563 (2009). The Court reasoned that, because no amendment to the FDCA ever permitted a federal remedy for consumers harmed by unsafe or ineffective drugs, Congress "determined that widely available state rights of action provided appropriate relief for injured consumers." *Id.* at 574. Had Congress intended to preempt state lawsuits for medications, "it surely would have enacted an express preemption provision during the FDCA's 70-year history." *Id.*

Furthermore, *Wyeth* is instructive as it relates to the impossibility argument advanced by Defendant. Analogous to the instant case, defendant in Wyeth argued that it would be impossible to comply with the FDA regulatory scheme and avoid liability in tort. In response, the Court held

that "the very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning…is difficult to accept." 555 U.S. at 570. This Court finds it difficult to accept that Defendant would be penalized for providing additional information on its warning label. Defendant has cited no instances of such an event. As a result, this Court rejects Defendant's argument that it would be impossible to comply both with state law and the FDCA at this stage.

In light of the foregoing, this Court finds that preemption does not bar Plaintiffs' state law claims.

iii. New York Deceptive Acts and Practices Claim

Plaintiff has adequately stated a claim under the New York Deceptive Acts and Practices Act ("NYDAPA"), N.Y. Gen. Bus. Law § 349(a) (McKinney 2014).

The NYDAPA prohibits "deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state." N.Y. Gen. Bus. Law § 349(a). The scope of this consumer protection statute "is intentionally broad, applying 'to virtually all economic activity.'" *Blue Cross and Blue Shield of N.J., Inc. v. Philip Morris USA Inc.*, 818 N.E.2d 1140, 1143 (N.Y. 2004) (quoting *Goshen v. Mut. Life Ins. Co. of N.Y.*, 774 N.E.2d 1190, 1195 (N.Y. 2002)). Courts have consistently found that anticompetitive behavior, when predicated on defendant's deceptive conduct, is actionable under NYDAPA. *See In re Automotive Refinishing Paint Antitrust Litig.*, 515 F. Supp.2d 544, 555 (E.D. Pa. 2007); *Leider v. Ralfe*, 387 F. Supp.2d 283, 295 (S.D.N.Y. 2005) ("[A]nticompetitive conduct that is not premised on consumer deception is not within the ambit of the statute."); *Cox v. Microsoft Corp.*,

778 N.Y.S.2d 147, 148 (App. Div. 2004) (plaintiffs state a claim where they allege defendant "engaged in purposeful, deceptive monopolistic business practices.").

To plead a claim under the NYDAPA, a plaintiff must demonstrate that: the defendant has (1) engaged in consumer oriented conduct that is (2) materially misleading and (3) the plaintiff has suffered injury as a result of the allegedly deceptive act or practice. *City of New York v. Smokes-Spirits.com, Inc.*, 911 N.E.2d 834, 838 (N.Y. 2009); *See also, Goshen*, 774 N.E.2d at 1195 (N.Y. 2002); *Stutman v. Chem. Bank*, 731 N.E.2d 608, 611 (N.Y. 2000).

To be "consumer oriented" within the meaning of the statute, a defendant's acts must have an impact broader than the particular plaintiffs, as opposed to a private contract dispute. *See New York v. Feldman*, 210 F. Supp.2d 294, 301 (S.D.N.Y. 2002) ("…[C]ourts have found sufficient allegations of injury to the public interest where plaintiffs plead repeated acts of deception directed at a broad group of individuals."); *Gaidon v. Guardian Life Ins. Co. of Am.*, 725 N.E.2d 598, 603 (N.Y. 1999) (finding sufficiently "consumer oriented" conduct where defendant engaged in an "extensive marketing scheme" that induced consumers at large to purchase a product); *Oswego Laborers Local 214 Pension Fund v. Marine Midland Bank, N.A.*, 647 N.E.2d 741, 744 (N.Y. 1995) (deceptive practices "must have a broader impact on consumers at large."); *U.W. Marx, Inc. v. Bonded Concrete, Inc.*,776 N.Y.S.2d 617, 620 (App. Div. 2004) (dismissing a NYDAPA claim because it was a "complex private business transaction, not one based on a standard-form contract addressed to consumers generally."). "The critical question…is whether the matter affects the public interest in New York, not whether the suit is brought by a consumer or competitor." *Securitron Magnalock Corp. v. Schnabolk*, 65 F.3d 256, 264 (2d Cir. 1995).

Plaintiffs have alleged conduct that affects the public interest in New York. According to the Complaint, the Defendant falsely represented to consumers and the FDA that its product was substantially more effective than Defendant knew it to be. (Dkt. No. 26 ¶¶ 27, 83.) Defendant is alleged to have disseminated false advertising that helped maintain its monopoly and induced Plaintiff Klein in New York to purchase it at artificially high prices. (Dkt. 26 ¶¶ 11,13.) Such deception clearly impacts New York's interest in creating "an honest marketplace where trust, and not deception, prevails." *Goshen,* 774 N.E.2d at 1194-95 (internal citation omitted). The fact that the deception concerns a matter of public health—the state's ability to protect against Mumps outbreaks—further magnifies New York's interest. (Dkt. 26 ¶ 95.) As a result, the Complaint sufficiently states consumer oriented conduct.

Plaintiffs have sufficiently alleged a material deception within the meaning of the statute. "Whether a representation or an omission, the deceptive practice must be 'likely to mislead a reasonable consumer acting reasonably under the circumstances.'" *Stutman,* 731 N.E.2d at 611-612 (quoting in part *Oswego*, 647 N.E.2d at 745).

According to the Amended Complaint, the FDA-approved insert accompanying the vaccine states that "a single injection of the vaccine induced . . . mumps neutralizing antibodies in 96% . . . of susceptible persons," (Dkt. No. 26 ¶ 85) even though Defendant knew that this was not true. (Dkt. No. 26 ¶ 62, 66, 83, 86.) Reasonable consumers—even reasonable physicians and reasonable pharmaceutical manufacturers—would be misled into believing that the vaccine was as effective as Defendant claimed.

Having previously considered whether Plaintiffs have suffered sufficient injury to support their claim, the Court need not expound much further on this point. Plaintiffs' allege economic

damage as a result of purchasing a questionable vaccine. (Dkt. No. 26 ¶¶ 167, 168.) Moreover, their Complaint alleges injury to the public interests in creating a fair market place (Dkt. No. 26 ¶¶ 111) and maintaining public health (Dkt. No. 26 ¶ 95.)

Defendant challenges Plaintiffs' Complaint on additional grounds. First, it argues that Plaintiffs have not alleged a deception within the state of New York. (Dkt. No. 43 at 23-24.) According to the Complaint, Plaintiff Klein is a medical doctor and resident of New York who purchased the mumps vaccine directly from the Defendant. (Dkt. No. 26 ¶ 13.) Drawing all reasonable inferences in favor of the Plaintiffs, the Court infers that Klein practices medicine in the state of New York and would therefore have been subject to Defendant's deception within that state.

Second, Defendant asserts that Plaintiffs failed to allege a fiduciary duty that would have obligated Defendant to disclose the existence of the efficacy information. (Dkt. No. 43 at 26.) There is simply no requirement in the NYDAPA that Plaintiffs plead a fiduciary duty. *See Smokes-Spirits.Com, Inc.*, 911 N.E.2d at 838; *Goshen*, 774 N.E.2d at 1195; *Stutman*, 731 N.E.2d at 611.

iv. The New Jersey Consumer Fraud Act Claim

The New Jersey Consumer Fraud Act ("CFA"), N.J. Stat. Ann. § 56:8-2 (West 2014), prohibits vendors of "merchandise" from engaging in "deception, fraud…or misrepresentation," or withholding any "material fact with intent that others rely upon such…omission" when purchasing the vendor's product.

At the outset, the Court notes that it must take care to balance its obligation to apply binding Third Circuit precedent, as well as the law of New Jersey as enunciated by its legislature

and Supreme Court. Accordingly, the Court must evaluate Plaintiffs' claim in accordance with the heightened pleading standard contained in Fed. R. Civ. P. 9(b). *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007) (a claim brought under the CFA "must state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the precise misconduct with which it is charged.") (internal citation omitted). However, the Court also recognizes that New Jersey courts approach motions to dismiss in the CFA context "with hesitation." *N.J. Citizen Action v. Schering-Plough Corp.*, 842 A.2d 174, 177 (N.J. Super. Ct. App. Div. 2003), *certif. denied* 837 A.2d 1092 (N.J. 2003). Furthermore, consistent with long-held New Jersey Supreme Court precedent, this Court must construe this "remedial" statute "liberally" in its evaluation of the claim. *Real v. Radir Wheels, Inc.*, 969 A.2d 1069, 1075 (N.J. 2009) (quoting *Int'l Union of Operating Eng'rs Local No. 68 Welfare Fund v. Merck & Co., Inc.*, 929 A.2d 1076, 1079 n. 1 (N.J. 2007); *see also, Gennari v. Weichert Co. Realtors*, 691 A.2d 350, 364 (N.J. 1997) ("The history of the Act is one of constant expansion of consumer protection.").

As a threshold matter, this Court must decide whether the transaction between Plaintiff Suter and the Defendant falls within the realm of commercial activity governed by the CFA. *J&R Ice Cream Corp. v. Cal. Smoothie Licensing Corp.*, 31 F.3d 1259, 1273 (3d Cir. 1994) ("…[I]t is the character of the transaction rather than the identity of the purchaser which determines if the Consumer Fraud Act is applicable.").

Plaintiff Suter is a consumer of the Defendant's vaccine entitled to the CFA's protection. A consumer is "one who uses economic goods and so diminishes or destroys their utilities." *City Check Cashing, Inc. v. National State Bank*, 582 A.2d 809, 811 (N.J. Super. Ct. App. Div. 1990)

(citing *Hundred East Credit Corp. v. Eric Shuster*, 515 A.2d 246, 248 (N.J. Super. Ct. App. Div. 1986)), *certif. denied* 585 A.2d 391 (N.J. 1990). Where a commercial entity uses merchandise purchased for the conduct of its business, the commercial entity acts in a sufficiently consumer oriented manner for CFA purposes. *Coastal Grp., Inc. v. Dryvit Sys., Inc.*, 643 A.2d 649, 653 (N.J. Sup. Ct. App. Div. 1994) (citing *Hundred East Credit Corp.*, 515 A.2d at 248).

In light of the above, Plaintiff Suter is a consumer of the Defendant's vaccine. Plaintiff Suter uses the vaccine—an economic good—in the course of his medical practice and thereby destroys the vaccine's further utility. (Dkt. No. 26 ¶ 13.) Thus, he can accurately and fairly be considered to be a consumer of the vaccine. By contrast, he is not a reseller, or wholesaler who sells, but does not consume a particular product. Plaintiff Suter purchases the vaccine for his own private use which results in its total loss of utility. Thus, the Court finds that he is a consumer within the meaning of the statute.

Defendant argues that Plaintiff Suter acts as an intermediary between the Defendant and his patients and thus his transactions with Defendant are beyond the ambit of the statute. (Dkt. No. 40 at 27.) In making their argument, Defendant relies on *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, No. 06-5774, 2009 U.S. Dist. LEXIS 58900, at * 114-145 and *Cent. Reg'l Employees Benefit Fund v. Cephalon, Inc.*, No. 09-3418, 2009 U.S. Dist. LEXIS 93636. The Court is not persuaded. The factual scenario presented by the case at bar is simply not analogous to those in the cases cited by the Defendant. In both *Schering-Plough* and *Cent. Reg'l*, the court found that third-party-payors are not consumers because they do not purchase the medicine for their own consumption. Here, Plaintiff Suter purchases the vaccine to be consumed by his medical practice for the benefit of his medical practice. Thus, he is not a

middle-man or reseller in the sense described in *Schering-Plough* and *Cent. Reg'l*, and is therefore entitled to invoke the protection of the CFA.

Turning to the merits, a plaintiff properly before a court must demonstrate (1) unlawful conduct (i.e., deception, fraud or misrepresentation); (2) ascertainable loss; and, (3) a causal relationship between the unlawful conduct and the ascertainable loss. *Int'l Union of Operating Engineers.*, 929 A.2d at 1086.

Plaintiffs have adequately alleged Defendant's unlawful conduct. For purposes of the CFA, there exist three general categories of unlawful practices, two of which are relevant here, with similar, but distinct pleading requirements: affirmative acts and knowing omissions. Plaintiff alleges both. (Dkt. 26 ¶ 163.) Defendant does not object to Plaintiffs' characterizations of its conduct both as affirmative acts and knowing omissions in either its Motion to Dismiss (Dkt. No. 40) or its Reply Brief (Dkt. No. 52). Therefore, the Court considers the issue waived for purposes of its decision here.

The parties dispute the ascertainable injury and causation elements. Defendant argues that Plaintiffs have failed to sufficiently allege an injury and, even if they have, Plaintiffs cannot demonstrate that their injury was caused by Defendant's misrepresentations. (Dkt. No. 27-28.) The Court disagrees with both assertions.

Plaintiffs have sufficiently stated an ascertainable loss. To prove this element, "a private plaintiff must produce evidence from which a factfinder could find or infer that the plaintiff suffered an actual loss." *Thiedemann v. Mercedes-Benz USA, LLC*, 872 A.2d 783, 792 (N.J. 2005). A plaintiff need not allege loss with scientific precision; rather, "an estimate of damages, calculated within a reasonable degree of certainty will suffice." *Id*. at 793. Here, Plaintiffs meet

that burden. They seek compensatory damages for the vaccine, and thus claim to have suffered a loss in the amount of the purchase price. (Dkt. No. 26 ¶ 169.) While they do not provide an exact dollar amount, the Plaintiffs have sufficiently provided the Court with a reasonable estimate of damages as required by *Thiedemann*. Moreover, the injury is pleaded with the particularity required by Fed. R. Civ. P. 9(b)—the purchase price being a sufficiently specific measurement of economic injury.

Plaintiffs have also adequately alleged causation. Defendant contends that Plaintiffs proffer a fraud-on-the-market theory of causation (Dkt. No. 27-28) which is expressly prohibited in the context of a CFA claim. *N.J. Citizen Action*, 842 A.2d at 178-179 (extending the prohibition on fraud-on-the-market theories in state securities litigation to CFA claims). Claims predicated on this type of theory allege that a price charged was higher than it should have been as a result of defendant's fraudulent marketing campaign. *Int'l Union of Operating Engr's* , 929 A.2d at 1088.

The Court is unmoved by Defendant's argument. Here, Plaintiffs allege that "as a direct and proximate result" of Defendant's "misrepresentations and omissions" they were deceived into purchasing Defendant's product. (Dkt. No. 26 ¶ 168.) They allege that they "would not have purchased or used Mumps Vaccine had they known the truth" about its efficacy. (Dkt. No. 26 ¶ 167.) Courts have found that this direct causation argument is sufficient to survive a motion to dismiss. *See e.g., In re Bayer Corp. Combination Aspirin Prods. Mktg. and Sales Practices Litig.*, 701 F.Supp.2d 356, 383 (E.D. N.Y. 2010) (denying a motion to dismiss for a fraud-on-the-market theory where plaintiff alleged that defendant's false promises themselves induced plaintiffs to purchase the product); *In re Ford Motor Co. E-350 Van Prods. Liability Litig.*, No.

03-4558, 2008 U.S. Dist. LEXIS 108085 (D.N.J. Nov. 18, 2009) (denying a motion to dismiss for fraud-on-the-market theory where plaintiff alleged defendant's deceptive representations themselves induced the plaintiffs to purchase defendant's product). Plaintiffs' theory parallels those found to be sufficient in those cases. Thus, the court finds that—at this stage in the litigation—the Plaintiffs have properly pleaded causation.

Given that this Court must construe the Complaint in the light most favorable to the plaintiff, construe the CFA liberally, and approach motions to dismiss "with hesitation," this Court finds that Plaintiffs have adequately pleaded a claim under the CFA.

v. Breach of Contract Claim

In Count III, Plaintiffs allege that Defendant breached contracts with the Plaintiffs by delivering vaccine with a lower-than-promised efficacy rate. As a result, Plaintiffs claim they were injured in the amount of the purchase price. This claim does not meet the pleading standards set forth in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

A plaintiff's obligation to plead his case extends beyond a formulaic recitation of the elements of a cause of action. *Twombly*, 550 U.S. 544 at 555 (internal citation omitted). Rather, "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Id.* "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the alleged misconduct." *Iqbal*, 556 U.S. at 678.

Here, Plaintiffs have not pled with sufficient detail. Aside from failing to invoke the contract law of any particular jurisdiction, the Complaint only alleges Defendant "entered into a

contract to provide Mumps Vaccine" and that Defendant's representation as to the efficacy of the vaccine "form[ed] the basis of the bargain." (Dkt. No. 26 ¶170, 172.) This is legally insufficient to survive 12(b)(6) scrutiny. Plaintiffs' proffer no information about contract formation, prices paid for the vaccine, dates of execution of the alleged contracts, quantities of vaccine purchased, actual efficacy rate of the vaccine purchased, or details of any other major term of the alleged contract. Given the scarcity of detail, the Court finds that there is insufficient factual content to advance the claims beyond the level of speculation, and as such, dismisses Count III without prejudice.

vi. Unjust Enrichment

In Count VI, Plaintiffs allege that Defendant was unjustly enriched. However, the Complaint fails to invoke the law of any particular jurisdiction. Accordingly, the Court finds that Plaintiffs have failed to meet the applicable pleading standards.

The degree of specificity required in a class action alleging unjust enrichment is not a legal question of first impression within this district. In two prior cases, courts in this district have dismissed Complaints where the plaintiffs failed to invoke the law of any particular jurisdiction. *See In re Flonase Antitrust Litig.*, 610 F.Supp.2d 409, 419 (E.D. Pa. 2009) (granting leave to amend the complaint where plaintiff failed to specify the state laws they invoke); *In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 167 (E.D. Pa. 2009) (dismissing an unjust enrichment claim for failing to "reference any basis in law on which a claim…might proceed.").

Consistent with those holdings, this Court dismisses Plaintiffs' Count VI without prejudice.

vii. Conclusion

For the reasons above, the Court will grant Defendant's Motion to Dismiss for lack of standing all state claims arising under the laws of jurisdictions in which the named Plaintiffs do not reside. The court rejects Defendant's argument that Plaintiffs' surviving state claims are preempted by Federal law, and finds that Plaintiffs have adequately stated claims under the consumer protection statutes of New York and New Jersey. However, the Court finds that Plaintiffs have failed to state claims for breach of contract and unjust enrichment. Thus, the Court dismisses Count II, except for claims brought under the NYDAPA and the NJCFA; and, dismisses Count III, Count IV, Count V, and Count VI in their entireties.

An appropriate order follows.