UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PLUMBERS' LOCAL UNION NO. 690 HEALTH PLAN, **Plaintiff,** **v.** **SANOFI, S.A., SANOFI US SERVICES INC., SANOFI-AVENTIS U.S., LLC, GENZYME CORPORATION, FIDIA FARMACEUTICI S.P.A., FIDIA PHARMA USA INC., ACCENTURE PLC (ACN), DELOITTE LLP, CHRISTOPHER A. VIEHBACHER, DENNIS URBANIAK, RAYMOND GODLESKI, THOMAS C. VALENTINE, DOE DEFENDANTS A-Z, ABC CORPORATIONS AA-ZZ, AND XYZ PARTNERSHIPS AND ASSOCIATIONS AAA-ZZZ,** **Defendants.**	No. 15–cv–956 (KM)(MAH) **OPINION**

KEVIN MCNULTY, U.S.D.J.:

Plumbers' Local Union No. 690 Health Plan ("Local 690") brings a class action suit against Sanofi US Services Inc., Sanofi-Aventis U.S., LLC (together "Sanofi US"), Sanofi, S.A. (together with Sanofi US, "Sanofi"), Genzyme Corporation, [1] Fidia Farmaceutici S.p.A. ("Fidia Italy"), Fidia Pharma USA Inc. ("Fidia USA"; together with Fidia Italy, "Fidia"), Accenture PLC (ACN), Deloitte LLP, Christopher A. Viehbacher, Dennis Urbaniak, Raymond Godleski, and

[1] The 1AC defines "Sanofi" as including "Sanofi, Sanofi US and Genzyme." Many of the relevant allegations date from before Sanofi acquired Genzyme in 2011. (*See* 1AC ¶¶ 16, 19, § IV). I have attempted to parse the various uses of "Sanofi" in the 1AC to give the allegations their intended meaning.

Thomas C. Valentine. The suit complains of two separate schemes, both allegedly harming Local 690 in New Jersey and Pennsylvania: (a) all Sanofi defendants, both Fidia defendants, Genzyme, and the individual defendants allegedly provided free samples of the drugs Hyalgan and Synvisc to doctors and providers to convince them to buy and administer these drugs, resulting in higher reimbursement costs for Local 690 and the rest of the class; and 2) all Sanofi defendants, Viehbacher, Urbaniak, and Godleski, allegedly entered into contracts with Deloitte and Accenture that appeared proper, but were in fact kickbacks to induce them to cause retail pharmacies to switch to Sanofi diabetes drugs.

This matter comes before the Court on seven motions to dismiss:

1. A motion to dismiss the original complaint (ECF No. 1) by Sanofi US, Viehbacher, Urbaniak, and Godleski (ECF No. 7).
2. A motion to dismiss the first amended complaint ("1AC" (ECF No. 9)) by Sanofi US, Genzyme, Viehbacher, Urbaniak, and Godleski
3. A motion to dismiss the 1AC by Deloitte (ECF No. 36).
4. A motion to dismiss the 1AC by Accenture (ECF No. 37).
5. A motion to dismiss, joining the previous motions to dismiss the 1AC, by Valentine (ECF No. 49).
6. A motion to dismiss the 1AC by Fidia USA (ECF No. 50).
7. A motion to dismiss the 1AC by Sanofi, S.A., for lack of personal jurisdiction under Fed R. Civ. P. 12(b)(2) (ECF No. 63).[2]

I **DENY** the motion to dismiss the original complaint because it was mooted by the filing of the 1AC. I also **DENY** the motion of Sanofi, S.A., to dismiss on grounds of lack of personal jurisdiction, because it cannot be determined from the pleadings and I currently lack the necessary additional information. I **GRANT** the remaining motions to dismiss because Local 690

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[2] Fidia Italy is the only named defendant not to file a motion to dismiss or otherwise respond to the 1AC.

fails to state a claim pursuant to Fed. R. Civ. P. 12(b)(6). Reviewing the complaint, I find that it does not set forth facts sufficient to make out a plausible claim for relief against the defendants. I do not reach the other proffered bases for dismissing the 1AC.

The defects I have identified are not necessarily fatal. These dismissals are therefore without prejudice to the filing of a Second Amended Complaint within 60 days. If this misconduct occurred, and if it affected Local 690 and its beneficiaries in New Jersey and Pennsylvania, it should be possible through reasonable investigation to uncover specific facts and examples of it.

I. BACKGROUND[3]

A. Parties

1. Plaintiff

Local 690, which is located in Pennsylvania, is a third party payor ("TPP") that reimburses its members for the cost of drugs. (1AC ¶¶ 3, 5). The relevant Local 690 members who purchase the drugs are confined to New Jersey and Pennsylvania. (1AC ¶ 5)

2. Defendants

1. Sanofi S.A. is a French corporation headquartered in Paris. (1AC ¶ 7) It is a pharmaceutical company that manufactures, markets, and sells prescription pharmaceuticals. (1AC ¶ 8)
2. Sanofi US Services Inc., is a wholly owned subsidiary of Sanofi, S.A., incorporated in Delaware and headquartered in New Jersey. (1AC ¶ 10) It conducts business throughout the United States for Sanofi, S.A. (1AC ¶¶ 9, 15)

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[3] The facts that follow are taken from the complaint. They are assumed to be true solely for the purposes of the motion to dismiss.

3. Sanofi-Aventis U.S., LLC, is a wholly owned subsidiary of Sanofi, S.A., headquartered in New Jersey (1AC ¶ 11) It conducts business in the United States for Sanofi, S.A. (1AC ¶¶ 9, 15)
4. Fidia Farmaceutici S.p.A., is an Italian corporation headquartered in Italy. (1AC ¶ 20) It owned the rights to the drug Hyalgan, and until 2011 it licensed to Sanofi, S.A. the right to market Hyalgan in the U.S. (1AC ¶¶ 21–22)
5. Fidia Pharma USA Inc. is a wholly owned subsidiary of Fidia Italy, incorporated in Delaware and headquartered in New Jersey. (1AC ¶ 23)
6. Genzyme Corporation is a biotech company, headquartered in Massachusetts, that was acquired by Sanofi, S.A. in 2011. (1AC ¶ 16) Genzyme manufactures, markets, and sells Synvisc, a competitor drug of Hyalgan. (1AC ¶¶ 18, 57)
7. Accenture PLC (ACN) is an Irish corporation headquartered in Ireland that provides consulting services globally. (1AC ¶¶ 25–26) Accenture maintains two New Jersey offices. (1AC ¶ 29)
8. Deloitte LLP is headquartered in New York and provides various services through its wholly own subsidiaries. (1AC ¶ 31)
9. Christopher Viehbacher was CEO of Sanofi, S.A., from 2008 until 2014. (1AC ¶ 32) He resided during the relevant period in France and Massachusetts. (1AC ¶ 34)
10. Dennis Urbaniak "was employed by Defendants as the Vice President of the U.S. diabetes business unit" and resided in New Jersey during the relevant period. (1AC ¶¶ 35, 37)
11. Raymond Godleski "was employed by Defendants as the Assistant Vice President of Special Projects and worked as a supervisor in the U.S. diabetes marketing unit" and resided in New Jersey during the relevant period. (1AC ¶¶ 38, 40)
12. Thomas C. Valentine is a former Sanofi sales representative and manager who resides in California. (1AC ¶ 41)

B. Facts

Local 690 alleges two separate fraudulent practices: (1) an illegal scheme regarding samples of Hyalgan and Synvisc; and (2) illegal contracts with Accenture and Deloitte to persuade pharmacies to switch to Sanofi diabetes drugs.

1. Samples of Hyalgan and Synvisc

Hyalgan and Synvisc are injectable drugs used to relieve osteoarthritis pain. (1AC ¶¶ 61, 63, 67) Osteoarthritis particularly affects persons such as members of Local 690, who perform physical work. (1AC ¶ 64) The Sanofi defendants marketed and sold Hyalgan, under a license from Fidia Italy, beginning in 1997. (1AC ¶¶ 68–70) Fidia had an advisory role in marketing Hyalgan, including sampling strategy and procedure, but it assumed the role of direct marketer and distributor in 2011. (1AC ¶¶ 70–71) Synvisc was owned, marketed and sold by Genzyme from 2005 until Sanofi acquired Genzyme in 2011. (1AC ¶¶ 16–18, 72) Hyalgan and Synvisc are sold directly to doctors who administer them and then bill for the drug and their service. (1AC ¶¶ 77–78)

From 2005 to 2009 Medicare and Medicaid calculated reimbursement rates based in part on average sales prices ("ASP") reported by the drug companies. (1AC ¶¶ 74, 79) For TPPs like Local 690, Sanofi tied the price of Hyalgan to the Medicare reimbursement rates. (1AC ¶ 123) Local 690 was also responsible for a 20% co-insurance payment when Medicare reimbursed the doctor for Hyalgan and Synvisc. (1AC ¶ 124) Companies were required to factor discounts and free goods into their ASP calculations. (1AC ¶¶ 75–76)[4] If reported ASPs were not taking into account the provision of free goods, the

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[4] Local 690 provides a simplified example: If 10 units of a drug were sold for $1000 but one extra unit were thrown in for free, this would be treated as the equivalent of a sale of 11, not 10, units. Thus the company would have to report an ASP of $90.91, not $100. (*See* 1AC ¶ 76.)

result would be that Medicare and its co-payers paid an inflated price for the drug. (1AC ¶ 83)

From 2005 to 2009 Sanofi sales representatives distributed 168,000 samples of Hyalgan, but the company did not track the distribution of samples. (1AC ¶¶ 91–92) For much of that time, Medicare assigned Hyalgan the same reimbursement code as a lower-cost competitor, Supartz; as a result, Supartz offered doctors higher profits. (1AC ¶¶ 84–85) To redress that competitive disadvantage, a Sanofi sales manager directed sales representatives to "use [Hyalgan] samples as a negotiating tool," and Sanofi sales representatives promoted the "value add" of Hyalgan samples to their physician customers. (1AC ¶¶ 90, 93–94)

The 1AC alleges that "[i]t is believed and therefore averred that Genzyme acted similarly with respect to Synvisc." (1AC ¶ 96)

The 1AC alleges upon information and belief that, between 2005 and 2009, Sanofi's sales force used free samples to promote purchases in California, New York, Texas, Rhode Island, North Carolina, Indiana, Florida, and Georgia. (1AC ¶ 97) In one example from California, the amount of free samples was explicitly reduced in connection with Sanofi's reduction of the price of Hyalgan. (1AC ¶ 97(a)) Each sample, if not properly reflected in the ASP, was worth between $70 and $100 under federal health care programs, and possibly more under private reimbursement. (1AC ¶ 99)

In August 2005, Sanofi sales representatives received training that included a description of the prosecution of TAP Pharmaceuticals for its misuse of samples. (1AC ¶ 103) The sales persons were instructed to be careful regarding samples. They were told that they would be protected if they told physicians not to bill for the samples, and that samples were to be used for trials and indigent patients. (*Id.*) Sanofi sales representatives allegedly ignored the lessons of TAP and provided free samples to physicians as a means of gaining and maintaining business for Hyalgan. (1AC ¶ 110) Sanofi required its sales representatives to inform physicians about securing reimbursement for

Hyalgan. (1AC ¶ 126) Sanofi also provided a hotline and a website for doctors needing further resources. (1AC ¶ 129)

The 1AC alleges throughout that Sanofi representatives knew about or even prompted doctors to bill Medicare, private insurers, and consumers for free samples. The 1AC alleges that Fidia, Sanofi, and Genzyme knowingly through their free samples practice caused doctors to falsely certify to federal health care programs that their drug purchases were not influenced by illegal financial inducements. (1AC ¶¶ 198–200) The 1AC also alleges that Fidia, Sanofi, and Genzyme provided doctors with large amounts of free samples of Hyalgan and Synvisc to effectively lower the cost of the drugs and thus give providers an incentive to choose these drugs. (1AC ¶ 201) The 1AC alleges generally that Local 690 paid for injections of Hyalgan and Synvisc. The only specific example given is that of an unnamed beneficiary who "appears to have been switched" from Synvisc to Hyalgan. (1AC ¶ 175)

In December 2012, Sanofi settled a False Claims Act suit with the United States based on the alleged practice of giving free samples of Hyalgan. (1AC ¶ 202) In June 2013, Valentine entered into an agreement with the United States Department of Health and Human Services ("HHS") Office of the Inspector General ("OIG") debarring him from participation in federal health care programs for five years because of his involvement as a district sales manager in the alleged free samples practice. (1AC ¶¶ 42, 205)

2. Diabetes Drugs

Sanofi competes with other pharmaceutical companies in the diabetes drug market. (1AC ¶¶ 131–34) During the relevant time period, Sanofi was required to comply with the federal health care laws, including the Anti-kickback law, codified in 42 U.S.C. § 1320, *et seq.* (1AC ¶ 135) From 2012 through 2013, Sanofi, through Viehbacher, Urbaniak, and Godleski, allegedly contracted with Accenture and Deloitte to cause retail pharmacies, like Walgreens and Rite Aid, to switch from competitors' diabetes drugs to those of Sanofi. (1AC ¶ 140) Sanofi, through Viehbacher, Urbaniak, and Godleski,

miscoded these contracts in their internal systems to get them past legal review. (1AC ¶ 144)

For example, in 2012, nearly $3 million of contracts between Sanofi and either Accenture or Deloitte were allegedly miscoded as "printed materials" upon orders by Godleski. Local 690 alleges that each of those contracts actually was an "illegal kickback" intended to induce the other party "to have pharmacy prescriptions switched from other manufacturers' drugs to Sanofi drugs." (1AC ¶ 145(b–c)) Further, in January 2013, Urbaniak allegedly instructed Sanofi employees to miscode $2 million of contracts as "communication agency technical costs." Local 690 alleges that these contracts were actually between Sanofi and Walgreens, and were intended to induce Walgreens "to improperly switch prescriptions for other manufacturer's drugs to Sanofi drugs." (1AC ¶ 145(a))

In March 2013, a paralegal named Diane Ponte allegedly discovered some nine contracts, totaling $34 million, with either Accenture or Deloitte, allegedly for the purpose of having them induce pharmacies to switch prescriptions. (1AC ¶¶ 147–48) Godleski directed Ponte to approve the contracts, informed her that Viehbacher and Urbaniak knew that she was delaying their approval, and told her that Viehbacher was extremely unhappy about the delay. (1AC ¶ 156) In December 2014, Ponte filed a whistleblower suit against Sanofi in Superior Court, Essex County, describing the contract scheme and alleging that she was fired for bringing it to light. (1AC ¶ 204)

Local 690 alleges on information and belief that in October 2009 one beneficiary's diabetes medication was switched to a Sanofi drug at an increased cost to Local 690. (1AC ¶ 177) Similarly, Local 690 believes that in June 2011 one beneficiary's diabetes medication was switched to a Sanofi drug at an increased cost to Local 690 of $223.64. (1AC ¶ 176)

A Sanofi internal investigation allegedly revealed that the contracts were improperly signed and executed prior to receiving approval, and that the "contracts failed to comply with Sanofi's internal policies, and provided improper incentives and kickbacks from Sanofi to Accenture and Deloitte, to

cause pharmacy prescription switches." (1AC ¶ 161) During the investigation Urbaniak and Godleski retired from Sanofi, and Urbaniak joined Accenture. (1AC ¶ 164) Sanofi terminated Viehbacher as CEO in October 2014. (1AC ¶ 168)

C. Claims

Local 690 asserts five claims for relief against the defendants:

1. violations of New Jersey's Consumer Fraud Act, N.J.S.A. § 56:8–1, et seq (1AC ¶¶ 228–43);
2. violations of Pennsylvania's Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201–1, et seq (1AC ¶¶ 244–57), specifically:
    a. 73 P.S. § 201-2(4)(ii) (causing confusion about the source of a good or service),
    b. 73 P.S. §201-2(4)(v) (making misrepresentations about a good or service),
    c. 73 P.S. § 201-3(4)(ix) (advertising a good or service with intent to sell them not as advertised),
    d. 73 P.S. § 201-2(4)(xi) (misrepresenting the reasons for price reductions),
    e. 73 P.S. § 201-2(4)(xii) (offering to pay a buyer for a contract for goods or services when such compensation is contingent on the occurrence of a subsequent event),
    f. 73 P.S. § 201-2(4)(xxi) (any other deceptive conduct ("catchall provision"));
3. unjust enrichment (1AC ¶¶ 258–66);
4. disgorgement (1AC ¶¶ 267–75); and
5. conspiracy, concert of action, or aiding and abetting (1AC ¶¶ 276–86).

II. APPLICABLE STANDARDS

A. The New Jersey and Pennsylvania Consumer Statutes

Local 690 alleges that the two schemes—*i.e.*, the free samples scheme and the diabetes drug scheme—affected its beneficiary members in the states of New Jersey and Pennsylvania. It brings its claims primarily under the New Jersey Consumer Fraud Act ("NJCFA") and the Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPCPL").

The NJCFA affords a private right of action to consumers who have suffered unconscionable or fraudulent practices in the marketplace. It is to be liberally construed in favor of the consumer, *see Cox v. Sears Roebuck & Co.*, 647 A.2d 454, 460–61 (N.J. 1994), and "applied broadly in order to accomplish its remedial purpose," *Gonzalez v. Wilshire Credit Corp.*, 25 A.3d 1103, 1114–15 (N.J. 2011). *See also Gennari v. Weichert Co. Realtors*, 691 A.2d 350, 364 (N.J. 1997).

To state a prima facie case under the NJCFA a plaintiff must allege three elements: "(1) unlawful conduct by the defendant; (2) an ascertainable loss by the plaintiff; and (3) a causal connection between the defendant's unlawful conduct and the plaintiff's ascertainable loss." *Bosland v. Warnock Dodge, Inc.*, 964 A.2d 741, 749 (N.J. 2009) (citations omitted).

Local 690 also alleges that the defendants have violated the Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPCPL").

> The Consumer Protection Law defines "unfair methods of competition" and "unfair or deceptive acts or practices" in the conduct of trade or commerce, and declares them to be unlawful. 73 P.S. § 201–3. The statute creates a private right of action in persons upon whom unfair methods of competition and unfair or deceptive acts or practices are employed and who as a result, sustain an ascertainable loss. 73 P.S. § 201–9.2. The Consumer Protection Law lists specific unfair methods of competition and unfair or deceptive acts or practices, and includes a catchall provision. 73 P.S. § 201–2(4)(i)–(xvii).

Toy v. Metro. Life Ins. Co., 928 A.2d 186, 191 n.4 (Pa. 2007); *accord Hunt v. U.S. Tobacco Co.*, 538 F.3d 217, 221 (3d Cir. 2008).

"To bring a private cause of action under the UTPCPL, a plaintiff must show that he justifiably relied on the defendant's wrongful conduct or representation and that he suffered harm as a result of that reliance." *Yocca v. Pittsburgh Steelers Sports, Inc.*, 578 Pa. 479, 501, 854 A.2d 425, 438 (2004); *accord Milliken v. Jacono*, 628 Pa. 62, 72, 103 A.3d 806, 812 (2014), *as modified on reconsideration* (Nov. 12, 2014); *see also Hunt*, 538 F.3d at 221.

B. 12(b)(6) Motions to Dismiss

Defendants move to dismiss the complaint for failure to state a claim under Fed. R. Civ. P. 12(b)(6). To state a valid claim for relief under Rule 12(b)(6), the complaint must contain: (1) a short and plain statement of the grounds for the court's jurisdiction; (2) a short and plain statement of the claim showing that the pleader is entitled to relief; and (3) a demand for the relief sought. Fed R. Civ. P. 8(a).

For the purposes of a motion to dismiss, the facts alleged in the complaint are accepted as true and all reasonable inferences are drawn in favor of the plaintiff. *N.J. Carpenters & the Trs. Thereof v. Tishman Const. Corp. of N.J.*, 760 F.3d 297, 302 (3d Cir. 2014). Fed. R. Civ. P. 8(a) does not require that a complaint contain detailed factual allegations. Nevertheless, "a plaintiff's obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 1964–65 (2007). Thus, the complaint's factual allegations must be sufficient to raise a plaintiff's right to relief above a speculative level, so that a claim is "plausible on its face." *Id.* at 555, 570; *see also W. Run Student Hous. Assocs., LLC v. Huntington Nat. Bank*, 712 F.3d 165, 169 (3d Cir. 2013).

From the seminal modern cases of *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), the Third Circuit has extracted a three-step process for reviewing a complaint:

> To determine whether a complaint meets the pleading standard, our analysis unfolds in three steps. First, we outline the elements a plaintiff must plead to a state a claim for relief. *See* [*Iqbal*, 556

> U.S.] at 675; *Argueta* [*v. U.S. Immigration & Customs Enf't*, 643 F.3d 60, 73 (3d Cir. 2011)]. Next, we peel away those allegations that are no more than conclusions and thus not entitled to the assumption of truth. *See Iqbal*, 556 U.S. at 679; *Argueta*, 643 F.3d at 73. Finally, we look for well-pled factual allegations, assume their veracity, and then "determine whether they plausibly give rise to an entitlement to relief." *Iqbal*, 556 U.S. at 679; *Argueta*, 643 F.3d at 73. This last step is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679.

Bistrian v. Levi, 696 F.3d 352, 365 (3d Cir. 2012).

C. Rule 9(b) Heightened Pleading Standard for Fraud

For claims of fraud, Federal Rule of Civil Procedure 9(b) imposes a heightened pleading requirement, over and above that of Rule 8(a). Specifically, it requires that "in all averments of fraud or mistake, the circumstances constituting the fraud or mistake shall be stated with particularity." Fed. R. Civ. P. 9(b). "Malice, intent, knowledge, and other conditions of a person's mind," however, "may be alleged generally." *Id.* That heightened pleading standard requires the plaintiff to "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." *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007) (internal quotation marks and citations omitted).

In general, "[t]o satisfy this [heightened] standard, the plaintiff must plead or allege the date, time, and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation." *Id.* "Plaintiff must also allege who made the misrepresentation to whom and the general content of the misrepresentation." *Lum v. Bank of Am.*, 361 F.3d 217, 224 (3d Cir. 2004) (internal citation omitted); *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 276–77 (3d Cir. 2006) ("Rule 9(b) requires, at a minimum, that plaintiffs support their allegations of fraud 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." (internal quotation marks and citations omitted)).

> The purpose of Rule 9(b) is to provide notice of the precise misconduct with which defendants are charged and to prevent false or unsubstantiated charges. Courts should, however, apply the rule with some flexibility and should not require plaintiffs to plead issues that may have been concealed by the defendants.

Rolo v. City Investing Co. Liquidating Trust, 155 F.3d 644, 658 (3d Cir. 1998) (internal quotation marks and citations omitted).

In cases of corporate fraud, the particularity requirement can be relaxed for information peculiarly in the corporation's control, but a plaintiff still must allege that facts pleaded based on information and belief are in the exclusive control of a defendant and "must accompany such an allegation with a statement of facts upon which their allegation is based." *Shapiro v. UJB Fin. Corp.*, 964 F.2d 272, 285 (3d Cir. 1992); *see also Zavala v. Wal-Mart Stores, Inc.*, 393 F. Supp. 2d 295, 314 (D.N.J. 2005), *aff'd sub nom. Zavala v. Wal Mart Stores Inc.*, 691 F.3d 527 (3d Cir. 2012).

> "[A] complaint must delineate at least the nature and scope of plaintiffs' effort to obtain, before filing the complaint, the information needed to plead with particularity. This requirement is intended to ensure that plaintiffs thoroughly investigate all possible sources of information, including but not limited to all publicly available relevant information, before filing a complaint.

Shapiro, 964 F.2d at 285.

NJCFA and UTPCPL both encompass fraud in the traditional sense, but also a range of other deceptive or unconscionable practices. Rule 9(b)'s heightened standard for pleading applies to a NJCFA claim, s*ee Frederico*, 507 F.3d at 200, 202–03, but only to the extent that the claim sounds in fraud. "Some claims under the CFA may not require pleadings complying with Rule 9(b). Not every such claim involves an affirmative misrepresentation or material omission." *Smajlaj v. Campbell Soup Co.*, 782 F. Supp. 2d 84, 98 n.9 (D.N.J. 2011). Similarly, when a claim under the UTPCPL is based on fraudulent representations, Rule 9(b)'s heightened standard for pleading applies, but if it is based upon other conduct, Rule (9)(b) does not apply. *See Belmont v. MB Inv. Partners, Inc.*, 708 F.3d 470, 498 n.33 (3d Cir. 2013).

D. Application

The defendants characterize Local 690's NJCFA and UTPCPL claims as fraud claims, and ask the Court to apply the heightened pleading standard of Rule 9(b) to the 1AC. (*See e.g.*, Deloitte Br. 6–7 (ECF No. 36–1)) Local 690 agrees in part, but states that at least some parts of their claims do not sound in fraud, and therefore should not be judged by Rule 9(b) standards. (*See e.g.*, Local 690 Opp. to Deloitte and Accenture MTD 21 (ECF No. 51 at 25)) The complaint leaves its options open; it does not come down clearly on one side or the other.

The gravamen of the Hyalgan and Synvisc claim is that providers, with the participation of some of the defendants, are misrepresenting the true cost of Hyalgan and Synvisc in order to receive higher payments from Local 690. To some degree, and perhaps primarily, this is a scheme involving misrepresentation, false statements, and deception. Counts 1 and 2 also allege, however, that the same conduct constituted unlawful conduct or an unconscionable business practice. The diabetes medication claim is more difficult to characterize, perhaps because its nature is less clearly defined. It appears, however, that false statements were made about the contracts to conceal their true nature (*i.e.*, that they allegedly functioned as kickbacks).

To the extent the schemes rest on falsehoods or misrepresentations—*e.g.*, about the true price of the drugs, about the nature of the contracts, or the *bona fides* of the pharmacies' prescription practices—I believe they sound in fraud. To that extent I will apply Rule 9(b). *See Smajlaj*, 782 F. Supp. 2d at 98 n.9; *Belmont*, 708 F.3d at 498 n.33. To the extent the claims may be viewed in the alternative as alleging, *e.g.*, regulatory violations or unconscionable business practices, they would fall under the ordinary Rule 8(a) standard. I will therefore, in the course of the analysis, advert to both standards.

III. ANALYSIS

The 1AC alleges two broad schemes: the first involves free samples of Hyalgan and Synvisc, and the second involves inducements to switch to Sanofi's diabetes drugs. The 1AC fails to allege certain crucial specifics of those schemes. Even more critically, it fails to allege facts sufficient to link those schemes to any adverse effect on Local 690 or its members in Pennsylvania and New Jersey. Thus I dismiss the 1AC without prejudice, for failure to state a claim.

1. Free Samples of Hyalgan and Synvisc

i. The Sanofi defendants

Setting aside merely conclusory allegations, *see Bistrian, supra,* I find that Local 690's factual allegations against the Sanofi defendants regarding the free-samples scheme are meager. Here is a summary:

- From 2005 to 2009 Sanofi sales representatives distributed 168,000 samples of Hyalgan in the U.S., but did not track the sales force's use of those samples. (1AC ¶¶ 91–92)
- Companies were required to factor discounts and free goods into their ASP calculations. (1AC ¶¶ 75–76)
- In an effort to remedy a competitive disadvantage in price, a Sanofi sales manager directed sales representatives to "use samples as a negotiating tool," and Sanofi sales representatives did promote the "value add" of samples. (1AC ¶¶ 90, 93–94)
- Upon information and belief, between 2005 and 2009 Sanofi's sales force promised free samples with purchases in California, New York, Texas, Rhode Island, North Carolina, Indiana, Florida, and Georgia. (1AC ¶ 97)
- Sanofi required its sales representatives to inform physicians about reimbursement for Hyalgan and related administrative procedures. (1AC ¶ 126) Sanofi also provided a hotline and a website for doctors needing further assistance. (1AC ¶ 129)

- The price charged TPPs for Hyalgan was tied by a formula to the Medicare reimbursement rates. (1AC ¶ 123) Local 690 was also responsible for a 20% co-insurance payment when Medicare reimbursed the doctor for Hyalgan and Synvisc. (1AC ¶ 124)
- Local 690 paid for injections of Hyalgan and Synvisc. One of its beneficiaries was switched from Synvisc to Hyalgan. (1AC ¶ 175)
- In December 2012, Sanofi settled a False Claims Act suit with the United States based on the alleged practice of giving free samples of Hyalgan. (1AC ¶ 202) In 2013, Valentine settled a case brought by HHS's OIG regarding his role as a district sales manager in the alleged free sample practice. (1AC ¶ 205)

Before setting the parties on a course of class action discovery and litigation, I must be satisfied that a claim is adequately set forth. These allegations lack the required specificity.

Local 690, in conclusory fashion, alleges that Sanofi helped physicians illicitly bill Medicare for the free samples that Sanofi provided to those physicians. (1AC ¶ 101) Yet, the 1AC fails to explain the who, what, when, where, and how of this scheme. *See In re Suprema Specialties*, 438 F.3d at 276–77. Did doctors switch to a more expensive medicine and then bill Local 690? Did doctors receive samples for free and then bill Local 690 for them? Did the doctors accept free samples for permissible purposes (*e.g.*, patient trials or indigent patients) but then divert them? Or is Local 690 saying only that the free samples had an indirect effect on the ASP, and hence the price?[5] The complaint alleges generally that certain activities were going on, but because the 1AC contains no pertinent concrete facts, it is impossible to tell what is being alleged factually.

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[5] Local 690 fails to actually allege that Sanofi overstated Hyalgan's ASP to Medicare, although the 1AC implies it.

Local 690 sues on behalf of its beneficiaries in New Jersey and Pennsylvania. Fatally, however, the 1AC says nothing about this scheme as it relates to New Jersey or Pennsylvania. It makes sweeping statements about the general nature of Sanofi's practices nationwide, but specifics are lacking. Local 690 alleges on "information and belief" examples of individual Sanofi sales representatives' misuse of samples to promote Hyalgan to doctors in several states. Yet these "information and belief" allegations, even taken as true, do not include the states of New Jersey or Pennsylvania. (1AC ¶ 97)

The 1AC fails to provide the necessary minimal support for its information-and-belief allegations. *See Shapiro*, 964 F.2d at 285 (Rule 9(b) requires plaintiffs to state, *inter alia,* the nature and scope of plaintiffs' effort to obtain, before filing the complaint, the information needed to plead with particularity); *see also* Fed. R. Civ. P. 11, Notes of Advisory Committee on 1993 Amendments (pleading on information and belief "does not relieve litigants from the obligation to conduct an appropriate investigation into the facts that is reasonable under the circumstances; it is not a license to...make claims...without any factual basis or justification").

The 1AC does not provide any pertinent example—*i.e.,* with dates, dollars, or circumstances—of a New Jersey or Pennsylvania doctor's billing or mis-billing anyone (let alone billing Local 690) for a Hyalgan sample (let alone one the doctor received for free).[6] Nor does Local 690 allege factually the existence or amount of any payment that Local 690 would not have made but for the alleged free sample scheme.

Local 690 cites Sanofi's training of its sales representatives:

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[6] The sole allegation that Local 690 ever paid for a Hyalgan injection does not advance its case. That beneficiary was allegedly switched from Synvisc to Hyalgan. (1AC ¶ 175) Local 690 alleges, however, that Synvisc was subject to the same free-sample practices as Hyalgan. (1AC ¶ 96) Switching between those two drugs, then, does not support Local 690's allegation that the switch was prompted by the practice of giving free samples, or its allegation that it suffered a financial loss as a result of paying for Hyalgan in this instance.

> For example, on or about August 15-26, 2005, a Hyalgan sales representative conducted a Phase II training and gave a PowerPoint presentation advising the ISG sales representatives of the government's prosecution of TAP Pharmaceuticals for its misuse of Lupron samples. The instructor training Sanofi's ISG sales representatives warned the ISG sales representatives to be "careful" regarding the use of samples, and instructed them that they would be "protected" as long as they told the physicians, including the Doctor Defendants that (a) the samples were to be used for patient trials and indigent patients, and (b) the physicians, including the Doctor Defendants, were not supposed to bill for the samples.

(1AC ¶ 103) That training, says Local 690, demonstrates that Sanofi knew of the illegality of the free sample practice, knew of the TAP prosecution, and yet still employed free samples to promote sales of Hyalgan. (*See* 1AC ¶ 110.) That is a step too far. The training may support the minimal inference that Sanofi was aware of the standards for proper use of free samples. It is illogical to infer, however, that New Jersey and Pennsylvania sales representatives, because they were trained in the *proper* use of samples, must therefore have engaged in the *improper* use of samples. Rule 8(a) requires allegations "plausibly suggesting (not merely consistent with)" wrongdoing, *Twombly*, 550 U.S. at 557, and Rule 9(b) requires even more specificity.

Also alleged "upon information and belief" is the sales representatives' encouragement of billing for free samples. And upon that shaky foundation, Local 690 builds a still shakier edifice of "implicit" representations, a "notion" that physicians would bill for free samples, and the doctors' "frequent[]" commingling of free and purchased Hyalgan. (AC ¶ 111)[7] It is then alleged with

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[7] 1AC Paragraph 111, in full, reads:

> Indeed, upon information and belief, implicit within the ISG sale representatives' training and instruction to explain to physicians, including the Doctor Defendants, that the free samples given would reduce the cost of Hyalgan, was the notion that physicians, including the Doctor Defendants, would bill for the free samples. Physicians' offices, including offices of the Doctor Defendants, frequently commingles the

certainty (*i.e.*, not on information and belief) that this conduct (alleged on information and belief) was "condoned by Sanofi." (AC ¶ 112) More is required to bridge the gap between conceivability and plausibility.

From the 1AC, I cannot discern that Sanofi engaged in any allegedly unlawful conduct that had any effect on Local 690 and its New Jersey or Pennsylvania beneficiaries. Such allegations are essential to a valid claim under NJCFA or UTPCPL. *See* § II.A, *supra*. The motion to dismiss is granted as to Sanofi.

ii. Fidia

The 1AC is devoid of specifics regarding Fidia. The only substantive mentions of Fidia in the complaint are that:

- Fidia owned Hyalgan. (1AC ¶ 72)
- Fidia licensed Hyalgan to Sanofi (1AC ¶¶ 21, 68)
- Fidia had an advisory role in marketing Hyalgan, including sampling strategy and procedure, until it assumed the role of direct marketer and distributor in 2011. (1AC ¶¶ 70–71)
- Fidia knowingly through its free samples practice caused doctors to falsely certify to federal health care programs that their drug purchases were not influenced by illegal financial inducements. (1AC ¶¶ 198–200)
- Fidia provided doctors with free samples of Hyalgan and Synvisc to effectively lower the cost of the drugs and thus induce providers to choose these drugs. (1AC ¶ 201)

These are conclusory allegations which lack any specific factual allegations of fraudulent or deceptive action by Fidia. Fidia licensed Hyalgan to Sanofi and allegedly knew about Sanofi's acts or advised Sanofi, in some

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free samples of Hyalgan provided by the ISG sales representatives with the Hyalgan syringes that the offices had purchased.

unspecified way, regarding "strategy" relating to samples. There are no further allegations as to Fidia's role in any illicit action as it relates to Local 690. No specific factual examples are given. There are no allegations showing that any Local 690 beneficiary in Pennsylvania or New Jersey was affected. That Fidia regained control of Hyalgan distribution in 2011 is irrelevant: the alleged time period for the sampling infractions is 2005 to 2009. (*See, e.g.*, 1AC ¶¶ 91–92) These allegations do not state a valid claim for relief.

iii. Genzyme

As to Genzyme, the 1AC's "information and belief" allegations are all belief, and no information. The 1AC essentially alleges that Sanofi acted wrongfully with respect to Hyalgan, and that "it is believed and therefore averred" that Genzyme must therefore have done the same with respect to Synvisc. (1AC ¶ 96) There are no individualized allegations against Genzyme, and the 1AC contains no facts as to Genzyme's practices. Genzyme was not acquired by Sanofi until 2011, well after the 2005–09 time period for the free samples allegations. (1AC ¶ 16) Local 690's allegations against Genzyme do not satisfy Rule 8(a), let alone Rule 9(b), and they fail to state a claim for relief.

iv. Individual defendants

There are no pertinent factual allegations regarding Viehbacher, Urbaniak, or Godleski as to the free samples scheme. Thus the complaint fails to state a claim against them as to that scheme.

Local 690 alleges that Valentine, as a sales representative or sales manager, delivered or supervised the delivery of samples of Hyalgan to doctors. (1AC ¶¶ 42–43) These activities are alleged to have taken place only in California, not New Jersey or Pennsylvania. (1AC ¶¶ 41, 97(a)) There is no allegation establishing Valentine's connection to Local 690 or his relationship, if any, with Pennsylvania or New Jersey.

In sum, the 1AC, insofar it alleges a scheme involving free samples of Hyalgan and Synvisc, fails to state a claim under the NJCFA or UTPCPL against any of the defendants.

2. Diabetes Drugs

The second scheme alleged is a kickback arrangement with Accenture and Deloitte to induce pharmacies to switch from competitors' diabetes drugs to those of Sanofi. The factual allegations are skimpy. The allegations about diabetes drugs mention the Sanofi defendants, Accenture, Deloitte, Viehbacher, Urbaniak, and Godleski; I therefore confine my analysis to them.

Local 690 alleges that from 2012 through 2013, Sanofi (through Viehbacher, Urbaniak, and Godleski) entered into contracts with Accenture and Deloitte. The FAC specifically identifies twelve of these contracts. Three of these, according to Local 690, were assigned misleading "spend categories" for, *e.g.*, "communication agency technical costs," or "printed materials," to help elude detection. (AC ¶¶ 144, 145) The other nine were discovered during the approval process by Diane Ponte, a former paralegal for Sanofi. (1AC ¶¶ 147–157, 204) The true purpose of these contracts, however, was allegedly to cause Accenture and Deloitte to induce retail pharmacies like Walgreens and Rite Aid to switch from other manufacturer's diabetes drugs to Sanofi's diabetes drugs. (1AC ¶ 140) The upshot is that these contracts are alleged to be disguised kickbacks.

Local 690's allegations rest primarily on other allegations pleaded by Ponte in a whistleblower suit in Superior Court, Essex County, New Jersey. (*See* 1AC ¶¶ 147–157, 204; Local 690 Opp. to Sanofi US MTD 3, 9 (ECF No. 24)) Ponte allegedly discovered nine contracts with Accenture and Deloitte, totaling $34 million, that were executed without approval by the normal channels. (1AC ¶¶ 149–50) Godleski allegedly directed Ponte to approve the contracts, informed her that Viehbacher and Urbaniak knew that she was delaying review, and told her that Viehbacher was extremely unhappy about it. (1AC ¶ 156) Ponte "determined" that the contracts were kickbacks. (1AC ¶ 151)

A Sanofi internal investigation allegedly confirmed that certain contracts were improperly signed and executed prior to receiving approval, and that the "contracts failed to comply with Sanofi's internal policies, and provided

improper incentives and kickbacks from Sanofi to Accenture and Deloitte, to cause pharmacy prescription switches." (1AC ¶ 161)[8]

Emblematic of the grounds for dismissal is Local 690's request for "disgorgement" of amounts that Sanofi paid to Accenture and Deloitte. This is not a derivative suit brought by a Sanofi shareholder; surely Local 690 must be required to allege some loss to itself or its members. That it fails to do.

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[8] There are problems with these allegations. Local 690 readily acknowledges that it is incorporating the allegations of Ponte. (Local 690 Opp. to Sanofi US MTD 3, 9) But Ponte herself pleads several of them "on information and belief"—a caveat that somehow gets lost in translation to Local 690's complaint. If Local 690 has a better basis than Ponte for believing Ponte's allegations to be based in fact, that basis does not appear.

Local 690's descriptions of the three contracts not discovered by Ponte, for example, are identical to allegations in Ponte's complaint. (1AC ¶ 145) Local 690's complaint, however, omits the fact that Ponte alleged that the contracts were kickbacks based on her "information and belief" that *other* employees "including but not limited to [Jan] Smith and [Jean] Kazmir" knew or believed they were kickbacks. (Haviland Cert. Ex. D ("Ponte Complaint") ¶ 77 (ECF No. 24–2)).

Ponte's allegations regarding Sanofi's internal investigation are likewise made upon information and belief. (Ponte Complaint ¶¶ 97–106) Once again, Local 690 seemingly copies Ponte's allegations, but drops her "information and belief" caveat. (1AC ¶¶ 160–62) Both Local 690 and Ponte, by the way, place the word "investigation" in scare quotes, presumably to cast doubt upon it. They then allege, however, that the investigation confirms their allegations. (Ponte Complaint ¶¶ 97–106; 1AC ¶¶ 160–62)

A related securities fraud complaint, substantially based on the whistleblower allegations of Ponte, was itself dismissed for failure to state a claim. *See In re Sanofi Sec. Litig.*, —F. Supp. —, No. 14–CV–9624, 2016 WL 93866, at *7-8 (S.D.N.Y. Jan. 6, 2016) (securities fraud claim based on allegations mirroring those of Ponte failed to meet the particularity standards of *Iqbal*, Rule 9(b), and the PSLRA).The court in *In re Sanofi* gave three examples of pleading deficiencies in allegations based on Ponte's complaint that are relevant here: 1) Ponte's complaint alleges upon information and belief that the miscoded contracts were illegal kickbacks between Sanofi and both Deloitte and Accenture, which did not suffice under the PSLRA; 2) Ponte's nine contracts are not identified and no information is given as to why Ponte believed these contracts to be for illegal kickbacks; 3) Ponte alleges that an internal investigation confirmed her suspicion but alleges no other facts about that investigation. 2016 WL 93866, at *7-8. District Judge Castel, granting a motion to dismiss, held that "[w]hile plaintiffs have plausibly alleged the existence of certain contracts, they have failed to allege beyond a speculative level that those contracts amounted to illegal, fraudulent, or otherwise improper conduct." *Id.* at *7 (internal quotation marks omitted).

Local 690 does not plead any facts suggesting that this scheme, however nefarious, had any effect upon itself or its members. The 1AC cites just two examples of beneficiaries whose diabetes medications were switched: In October 2009, one unnamed Local 690 beneficiary's diabetes medication was allegedly switched to a Sanofi drug at an increased cost to Local 690. (1AC ¶ 177) Similarly, in June 2011, one unnamed Local 690 beneficiary's diabetes medication was switched to a Sanofi drug at an increased cost to Local 690 of $223.64. (1AC ¶ 176) These allegations, however, date from 2009 and 2011, well before the 2012–13 time period of the alleged kickback contracts. (1AC ¶ 140, 176–77)

These 2009 and 2011 examples also lack essential details that would tie them to the alleged kickback scheme. No pharmacy is specified. Nor is it alleged factually that any such pharmacy dealt with Accenture or Deloitte. Nor is it alleged that any such pharmacy served Local 690's New Jersey and Pennsylvania members. Indeed, the 1AC does not allege that either drug switch was made by a pharmacy at all. The allegation is merely that the medication "was switched"; a doctor, or the patient, could just as easily have been the decision maker. Finally, these allegations are pleaded upon information and belief, even though they relate to Local 690's own beneficiaries. (1AC ¶¶ 176–77)

What remains is a portmanteau allegation that some twelve contracts, contents unknown, broke a number of rules and laws and constituted improper kickbacks to induce Accenture and Deloitte to perform acts that may or may not have occurred, and may or may not have affected Local 690 and its members. As to the diabetes drug scheme, the 1AC fails to state a valid claim for relief against any of the defendants under the NJCFA and UTPCPL.

D. Unjust Enrichment, Disgorgement and Conspiracy

Local 690's remaining claims for unjust enrichment, disgorgement and conspiracy must be dismissed. Unjust enrichment and disgorgement require a properly pleaded claim that the defendants unjustly received a benefit from

Local 690 that in equity should be returned to Local 690. *See, e.g., VRG Corp. v. GKN Realty Corp.*, 641 A.2d 519, 526 (N.J. 1994) ("To establish unjust enrichment, a plaintiff must show both that defendant received a benefit and that retention of that benefit without payment would be unjust."); *S.E.C. v. Hughes Capital Corp.*, 124 F.3d 449, 455 (3d Cir. 1997) ("Disgorgement is an equitable remedy designed to deprive a wrongdoer of his unjust enrichment and to deter others from violating securities laws" (internal quotation marks and citations omitted)). And a civil conspiracy claim requires a properly pleaded unlawful act. *See G.D. v. Kenny*, 15 A.3d 300, 321 (N.J. 2011) (dismissing a civil conspiracy claim where the plaintiff could not "establish that defendants committed an unlawful act or a wrong against him that constitutes a tort entitling him to a recovery.").

For the reasons stated above, Local 690 has failed to plead an underlying unjust or unlawful action resulting in a payment of money by Local 690 that it is entitled to recover. It follows that Local 690 has failed to state a claim for unjust enrichment, disgorgement, or conspiracy.

E. Defendants' Other Arguments

Defendants' motions assert a number of other arguments. I do not reach them, but because I have granted leave to amend, I advert to them briefly for the guidance of the parties, should any amended pleading be filed.

- Fidia US argues that it was only incorporated in 2011, after the alleged wrongful conduct. (Fidia US Br. § I.A (ECF No. 50–11)) The current complaint does not actually specify the nature or dates of Fidia US's allegedly wrongful conduct.
- Defendants argue that Local 690 is not a "consumer" under the NJCFA. (*See, e.g.*, Sanofi US Br. § II.A (ECF No. 19–1))
- Defendants argue that Pennsylvania's economic loss rule bars any claim under the UTPCPL. (*See, e.g.*, Deloitte Br. § I.C.2);

- Defendants argue that the Hyalgan claim is barred by a prior release or res judicata. (*See, e.g.*, Sanofi US Br. § I)[9]
- Accenture disputes basic matters relating to the existence and terms of the contracts. (*See* Accenture Br. § I (ECF No. 37–1).) Resolution, whether on a motion to dismiss or later, may require inspection of the contracts themselves.
- Sanofi, S.A., asserts that this court lacks personal jurisdiction over it. (*See, e.g.*, Sanofi, S.A. Br. (ECF No. 63–1).) Such issues are likely to require jurisdictional discovery.
- Defendants make a number of standing arguments as well.

I will put off deciding these issues until Local 690, if it chooses to do so, submits a Second Amended Complaint, and its claims are more defined. Some contentions may become moot, while others may require discovery or further proceedings. For now, I dismiss the 1AC for failure to sufficiently plead a claim.

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[9] Releases and res judicata are matters for defense, and they rely on evidence extrinsic to the current complaint. It is within my discretion under Rule 12(d) to convert this motion to one for summary judgment under Rule 56. *Campanello v. Port Auth. of N.Y. & N.J.*, 590 F. Supp. 2d 694, 703 (D.N.J. 2008) (citing *Kulwicki v. Dawson*, 969 F.2d 1454, 1463 n.11 (3rd Cir.1991). I instead opt to await a second amended complaint, if any.

IV. CONCLUSION

The motion to dismiss the original complaint is **DENIED** because it was mooted by the filing of the 1AC. The motion of Sanofi, S.A., to dismiss the complaint for lack of personal jurisdiction is **DENIED** with leave to refile if a Second Amended Complaint is filed and Sanofi, S.A., is still named as a defendant. The remaining motions to dismiss are **GRANTED** because the First Amended Complaint fails to state a claim, pursuant to Fed. R. Civ. P. 12(b)(6). This dismissal is without prejudice to the filing of a Second Amended Complaint within 60 days.

Dated: May 11, 2016

Hon. Kevin McNulty
United States District Judge