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

UNITED STATES OF AMERICA ex rel. RONALD J. STRECK, et al.,	:	CIVIL ACTION NO. 08-5135
Plaintiffs,	:	
v.	:	
ALLERGEN, INC., et al.,	:	
Defendants.	:	

M E M O R A N D U M

EDUARDO C. ROBRENO, J. JULY 3, 2012

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I. INTRODUCTION

Relator Ronald J. Streck ("Plaintiff") brings this health care fraud qui tam suit in accordance with the False Claims Act ("FCA"), 31 U.S.C. § 3729 (2006 & Supp. IV 2011). Plaintiff alleges that Defendants Allergan, Inc., Amgen, Inc., AstraZeneca Pharmaceuticals, L.P., Biogen Idec, Inc., Bradley Pharmaceuticals, Inc., Cephalon, Inc., Eisai, Inc., Genzyme Corp., Mallinckrodt, Inc., Novo Nordisk, Inc., Reliant Pharmaceuticals, Inc., Sepracor, Inc., and Upsher-Smith Laboratories, Inc. (collectively, "Defendants") fraudulently reported their Average Manufacturer Price ("AMP") to the Government in an effort to pay a smaller Medicaid rebate. In his Fourth Amended Complaint, Plaintiff pleads twenty-eight counts. Counts I through III allege violations of the FCA. Counts IV through XXVIII allege violations of the false claims statutes of the District of Columbia and the following states: Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and Wisconsin. Defendants collectively filed a Motion to Dismiss Plaintiff's Fourth Amended Complaint.

For the reasons that follow, the Court will grant Defendants' Motion in part and deny it in part.

II. BACKGROUND[1]

Plaintiff is a pharmacist and lawyer with over forty years of experience in the pharmaceutical industry. Plaintiff spent eleven years as the president and chief executive officer of the Healthcare Distribution Management Association. In 2008, when Plaintiff filed this lawsuit, he was the chief executive officer of Rx Distribution Network, a network of regional pharmaceutical wholesalers. While in this role, Plaintiff avers he became familiar with the practices of pharmaceutical manufacturers, including Defendants, and the agreements Defendants entered into with various wholesalers and retailers.

Defendants are pharmaceutical manufactures and all participate in the Medicaid Drug Rebate Program. This program endeavors to "establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser." H.R. Rep. No. 101-881, at 96 (1990), reprinted in 1990

[1] In accordance with the appropriate standard of review, see infra Part III, the Court takes the facts in this section from Plaintiff's Fourth Amended Complaint and assumes their truth.

U.S.C.C.A.N. 2017, 2108. In compliance with this program, Defendants pay rebates to state Medicaid programs. This rebate is calculated based, at least in part, on each manufacturer's AMP.[2] AMP, generally speaking, is the price that a wholesaler or retailer pays directly to the manufacturer for a product, on a per unit basis. To determine the amount of the rebate, each manufacturer must submit its calculated AMP to the Center for Medicaid and Medicare Services ("CMS"), a federal agency. According to Plaintiff, a lower reported AMP will result in Defendants paying a smaller rebate.

Plaintiff avers that Defendants engaged in two practices that fraudulently lowered the AMPs they reported. Plaintiff avers that from 2004 to the present Defendants and the pharmaceutical industry's wholesalers began executing and implementing distribution service agreements. Wholesalers generally purchase drugs from the manufacturer and then act as the distributor to retailers for the manufacturer's drugs. These agreements generally discussed a service arrangement

[2] The rebate Defendants pay to Medicaid is calculated for brand-name drugs as follows: the greater of (1) the difference between the manufacturer's "best price" and AMP; or (2) a percentage of AMP (presently, 23.1 percent). See 42 U.S.C. § 1396r-8(c)(1)(A)-(B) (2006 & Supp. IV 2011). The rebate owed by a manufacturer on generic drugs is a percentage of AMP (presently, 13 percent). Id. § 1396r-8(c)(3)(A)-(B).

between Defendants and wholesalers where wholesalers would perform services for Defendants such as warehousing goods, distributing goods, various accounting, and other services. In exchange for these services, Defendants generally paid wholesalers a certain percentage of the net sales each wholesaler purchased from Defendants.

These agreements are at the heart of Plaintiff's claims and are broken down into two types. One, there are agreements that facilitated certain Defendants ("Discount Defendants")[3] to report a lower AMP by illegally deducting the service fees under these agreements from the calculated AMP. Two, there are agreements that facilitate certain other Defendants ("Service Fee Defendants")[4] to report a lower AMP by concealing price increases and preventing such price increases from being considered in the AMP calculation. Plaintiff's FCA claims rest on these two types of alleged fraudulent dealings.

Briefly, the allegations are summarized as follows: (1) Discount Defendants characterize service fees for the following types of services as "discounts": distribution

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[3] Discount Defendants in this case are AstraZeneca, Biogen Idec, Cephalon, and Genzyme.

[4] Service Fee Defendants in this case are Allergan, Amgen, Bradley, Eisai, Mallinckrodt, Novo Nordisk, Reliant, Sepracor, and Upsher-Smith.

services, data reporting services, inventory management services, chargeback and returns processing services, customer service support, new product launch services, consolidated deliveries to providers, consolidated accounts receivable management, and sophisticated ordering technology. Fourth Am. Compl. ¶¶ 66-67. Certain discounts may be deducted from an AMP calculation, but "bona fide service fees" are expressly excluded from the calculation of AMP. The services listed above that Discount Defendants contracted for, according to Plaintiff, are statutorily and regulatorily defined as bona fide service fees and should not be characterized as discounts. Therefore, by characterizing the service fees as discounts instead of bona fide service fees, Discount Defendants incorrectly reported lower AMPs because they deducted the amount of the fee from the price wholesalers paid. (2) Service Fee Defendants allegedly do not dispute that the same rendered services are bona fide services. Service Fee Defendants, however, require that wholesalers credit the service fees they charge Service Fee Defendants with any price increases in the market that wholesalers were able to take advantage of by selling already purchased stock at the new higher price. By doing this, Plaintiff avers that Service Fee Defendants effectively hide the

true price paid by wholesalers to Defendants and, thus, effectively lower their AMP reported to the Government.

Plaintiff, as a relator under the qui tam provision of the FCA, brought this suit on October 28, 2008, against thirty pharmaceutical manufacturers under the FCA and various states' laws. ECF No. 1. In accordance with the FCA, Plaintiff's Complaint was under seal while the United States and the various states conducted an investigation to determine if they would intervene in this lawsuit. 31 U.S.C. § 3730(b)(2) (2006 & Supp. IV 2011). The Court extended this seal on several occasions to facilitate this investigation. See ECF Nos. 4, 11, 17, 24, 34, 39. During that time, Plaintiff amended his complaint three times. See ECF Nos. 5, 20, 45. On April 25, 2011, the Court ordered the unsealing of Plaintiff's Third Amended Complaint. See ECF No. 42. On May 9, 2011, all of the states declined to intervene in this case, and the Government declined to intervene except as to one Defendant. ECF No. 57. Thereafter, on September 29, 2011, Plaintiff filed, with leave of Court and no opposition, his Fourth Amended Complaint against only thirteen of the original defendants. ECF No. 76. On April 30, 2012, the Government provided notice that it declined to intervene in this case. ECF No. 164.

Defendants moved to dismiss this Fourth Amended Complaint. ECF No. 140. Plaintiff responded in opposition, and Defendants moved for leave to file a reply. ECF Nos. 147, 156. On May 18, 2012, the Court held oral argument. See ECF No. 168. The motion is now ripe for disposition.

III. STANDARDS OF REVIEW

A party may move to dismiss a complaint for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). When considering such a motion, the Court must "accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom, and view them in the light most favorable to the non-moving party." DeBenedictis v. Merrill Lynch & Co., Inc., 492 F.3d 209, 215 (3d Cir. 2007) (internal quotation marks omitted). Defendants move to dismiss Plaintiff's Fourth Amended Complaint under the pleading standards of Federal Rule of Civil Procedure 8(a) and Federal Rule of Civil Procedure 9(b).

A. Pleading Under Rule 8(a)

Under Rule 8(a), to withstand a motion to dismiss, the complaint's "[f]actual allegations must be enough to raise a right to relief above the speculative level." Bell Atl. Corp.

v. Twombly, 550 U.S. 544, 555 (2007). This "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Id. Although a plaintiff is entitled to all reasonable inferences from the facts alleged, a plaintiff's legal conclusions are not entitled to deference and the Court is "not bound to accept as true a legal conclusion couched as a factual allegation." Papasan v. Allain, 478 U.S. 265, 286 (1986).

The pleadings must contain sufficient factual allegations so as to state a facially plausible claim for relief. See, e.g., Gelman v. State Farm Mut. Auto. Ins. Co., 583 F.3d 187, 190 (3d Cir. 2009). "'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. (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)). In deciding a Rule 12(b)(6) motion, the Court is to limit its inquiry to the facts alleged in the complaint and its attachments, matters of public record, and undisputedly authentic documents if the complainant's claims are based upon these documents. See Jordan v. Fox, Rothschild, O'Brien & Frankel, 20 F.3d 1250, 1261 (3d Cir. 1994); Pension Benefit Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993).

B. Pleading Under Rule 9(b)

Rule 9(b) provides, "In 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). This heightened pleading standard requires "plaintiffs to plead with particularity the 'circumstances' of the alleged fraud in order 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). Stated differently, "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." In re Rockefeller Ctr. Props., Inc. Sec. Litig., 311 F.3d 198, 217 (3d Cir. 2002) (internal quotation marks omitted). FCA claims must be pleaded with particularity in accordance with Rule 9(b). See United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 234 (3d Cir. 1998); United States ex rel.

Schmidt v. Zimmer, Inc., No. 00-1044, 2005 WL 1806502, *1 (E.D. Pa. July 29, 2005).

IV. DISCUSSION

The FCA's purpose "is to indemnify the government — through its restitutionary penalty provision — against losses caused by a defendant's fraud." United States ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 304 (3d Cir. 2011) (internal quotation marks omitted). The FCA permits an individual, known as a relator, to bring an action on behalf of the Government. 31 U.S.C. § 3730(b)(1) (2006 & Supp. IV 2011). The Government may intervene and litigate the relator's claims. Id. § 3730(b)(2). Similarly, various state laws permit a state to intervene if it chooses to enforce violations of its state laws. In this case, the Government and the states chose not to intervene.

As relevant here, the FCA imposes liability on any person who:[5]

[5] On May 20, 2009, Congress enacted the Fraud Enforcement and Recovery Act of 2009 ("FERA"), Pub. L. No. 111-21, 123 Stat. 1617 (2009), which amended the FCA and re-codified its provisions. As Plaintiff's claims span from 2004 to the present, Plaintiff brings his FCA claims under both the pre-2009 statute and the currently effective statute. In particular, Plaintiff brings his FCA claims under the following statutory provisions: 31 U.S.C. § 3729(a)(1) (2006), 31 U.S.C. §

> (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;
>
> . . . . or
>
> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government . . . .

31 U.S.C. § 3729(a)(A), (B), (G) (Supp. IV 2011).

A relator may establish a prima facie claim under the FCA by showing "(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." Wilkins, 659 F.3d at 305.[6] Defendants argue that Plaintiff's claims fail under Rule

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3729(a)(1)(A) (Supp. IV 2011), 31 U.S.C. § 3729(a)(1)(B) (Supp. IV 2011), 31 U.S.C. § 3729(a)(7) (2006), and 31 U.S.C. § 3729(a)(1)(G) (Supp. IV 2011). The parties do not contend that the 2009 amendments affect the disposition of the instant motion.

[6] The FCA defines "knowing" and "knowingly" to "(A) mean that a person, with respect to information — (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require[s] no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1)(A)-(B).

8(a). In the alternative, Defendants argue that Plaintiff fails to plead with the required particularity under 9(b).

A. Whether Plaintiff's Fourth Amended Complaint Meets the Pleading Requirements of Rule 8(a)

Defendants argue that Plaintiff failed to meet Rule 8(a)'s pleading standards with respect to the required scienter for a FCA claim. Specifically, Defendants argue that Rule 8(a) requires, even in a claim for fraud, that Plaintiff provides some facts for the Court to conclude it is plausible that Defendants acted with the required scienter — in this case, that Defendants were at least reckless vis-à-vis the falsity of their AMP calculations. In this regard, Defendants contend that during the relevant time, from 2004 to the present, they relied on a good faith interpretation of the FCA's definition of AMP when calculating and reporting AMP to the Government. Therefore, as Plaintiff fails to plead any facts that show Defendants specifically knew, as defined by the FCA, of some falsity, Plaintiff's claims must fail because Defendants cannot act with knowledge of falsity if they relied on a good faith interpretation of the law. Defendants also argue that Plaintiff's Fourth Amended Complaint fails to plausibly show

that Defendants engaged in any conduct that violated any regulatory requirement or statute.

It cannot be reasonably disputed that the Fourth Amended Complaint does not point to direct evidence that Defendants knew their conduct was fraudulent. For example, there is no smoking gun evidence showing that Defendants engaged in fraudulent activity. See U.S. ex rel. Hendow v. Univ. of Phoenix, 461 F.3d 1166, 1168 (9th Cir. 2006) (finding inference of scienter where evidence showed defendant bragged about fraudulent activity). Therefore, Plaintiff's claims rest on the indirect evidence that the statutory and regulatory provisions involved were so clear that Defendants' calculation of AMP was at least reckless.

The Supreme Court recently was faced with a similar argument. See Safeco Ins. Co. of Am. v. Burr, 551 U.S. 47 (2007). Safeco was a class action alleging a violation of the Fair Credit Reporting Act ("FCRA"). Id. at 52. The FCRA imposes liability on anyone who "willfully fails" to provide notice of an adverse action based upon information contained in a consumer credit report. Id. (citing 15 U.S.C. §§ 1681m(a), 1681n(a) (2000)). The defendants in Safeco were insurance companies accused of failing to provide a required notice to a consumer after the company reviewed a credit report and provided

less favorable rates to the consumer based upon that report. Id. at 55. The defendants argued that they did not willfully fail to comply with the FCRA, but were just wrong in their interpretation of the relevant statue that they did not need to provide notice to the consumer. Id. at 56-57. After holding that the term "willfully" encompasses recklessness, the Supreme Court considered whether it could infer from Safeco's reading of the statute that Safeco acted recklessly. Id. at 69. The Supreme Court held, "[A] company subject to FCRA does not act in reckless disregard of it unless the action is not only a violation under a reasonable reading of the statute's terms, but shows that the company ran a risk of violating the law substantially greater than the risk associated with a reading that was merely careless." Id. The Court explained that Safeco did not have any statutory or regulatory guidance "that might have warned it away from the view it took." Id. at 70. Moreover, there were no court decisions interpreting the regulations at issue to provide guidance to the defendants. In the end, the Supreme Court concluded, "Given this dearth of guidance and the less-than-pellucid statutory text, Safeco's reading was not objectively unreasonable, and so falls well short of raising the 'unjustifiably high risk' of violating the statute necessary for reckless liability." Id.

Accordingly, under Safeco, for Plaintiff's Fourth Amended Complaint to survive, the Court must conclude that it plausibly shows that Defendants' interpretation of how to calculate AMP "ran a risk of violating the law substantially greater than the risk associated with a reading that was merely careless." Id.; see also United States ex rel. K & R L.P. v. Mass. Hous. Fin. Agency, 530 F.3d 980, 983 (D.C. Cir. 2008) (applying Safeco to FCA case). With this standard in mind, a careful examination of the statutes and regulations at issue here is warranted.

1. Statutory and Regulatory Scheme for AMP Calculations

The statute defining AMP has been in place from 1991 through the present. From 1991 through 2007 Congress defined AMP as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts." 42 U.S.C. § 1396r-8(k)(1) (2000). The Deficit Reduction Act of 2005 changed, in a significant way, AMP's definition. In particular, effective January 1, 2007, Congress decided to exclude from the AMP calculation any prompt pay discounts. See id. (2006) (defining AMP as "the average price

paid to the manufacturer for the drug in the United States by . . . wholesalers for drugs distributed to the retail pharmacy class of trade," but specifically stating, "[t]he average manufacturer price for a covered outpatient drug shall be determined without regard to customary prompt pay discounts extended to wholesalers").

In October 2007, CMS provided the following regulatory guidance for the first time on AMP calculation:

> AMP shall be determined without regard to customary prompt pay discounts extended to wholesalers. AMP shall be calculated to include all sales and associated discounts and other price concessions provided by the manufacturer for drugs distributed to the retail pharmacy class of trade unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation.
>
> . . . .
>
> Sales, rebates, discounts, or other price concessions excluded from AMP. AMP excludes —
>
> . . . .
>
> (19) Bona fide service fees;
>
> . . . .
>
> AMP includes cash discounts except customary prompt pay discounts extended to wholesalers, free goods that are contingent on any purchase requirement, volume discounts, chargebacks, incentives, administrative fees, service fees, distribution fees, (except bona fide service fees), and any other rebates, discounts or other price concessions, other than rebates under section 1927 of the Act, which reduce the price

> received by the manufacturer for drugs distributed to the retail pharmacy class of trade.

42 C.F.R. § 447.504(a), (h)(19), (i)(1) (2007). Therefore, not only were prompt pay discounts excluded from AMP, but bona fide services fees were also excluded. Relevant here, CMS also specifically defined bona fide service fees as follows:

> [F]ees paid by a manufacturer to an entity; that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement; and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Id. § 447.502 (2007). In 2010, Congress passed the Patient Protection and Affordable Care Act ("ACA"). See Pub. L. 111-148, 124 Stat. 310 (to be codified in scattered sections of U.S.C.). The ACA changed the statutory definition of AMP and defines AMP as follows:

> (1) Average manufacturer price
>
> (A) In general
>
> Subject to subparagraph (B), the term "average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by —
>
> (i) wholesalers for drugs distributed to retail community pharmacies; and

> (ii) retail community pharmacies that purchase drugs directly from the manufacturer.
>
> (B) Exclusion of customary prompt pay discounts and other payments
>
> (i) In general
>
> The average manufacturer price for a covered outpatient drug shall exclude —
>
> (I) customary prompt pay discounts extended to wholesalers;
>
> (II) bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs);
>
> . . .
>
> Notwithstanding clause (i), any other discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies shall be included in the average manufacturer price for a covered outpatient drug.

42 U.S.C. § 1396r-8(k)(1) (Supp. IV 2011). In response to this legislation, CMS repealed its regulations.

On February 2, 2012, however, CMS proposed a new rule to clarify the calculation of AMP. That new rule is substantially similar to the previous regulation and specifically excludes from AMP calculations bona fide service

fees. Under the new regulation, bona fide services would include, but are not limited to, "distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative service agreements and patient care programs (such as medication compliance programs and patient education programs)." Medicaid Program; Covered Outpatient Drugs, 77 Fed. Reg. 5318-01, 5359 (proposed Feb. 2, 2012) (to be codified at 42 C.F.R. pt. 447). Finally, CMS stated in the preamble to the proposed rule its view that retroactive price increase credits are not bona fide service fees and should not be included in such fees. See id. at 5335.

2. Discount Defendants

What is apparent from this discussion of the statutory and regulatory history of AMP calculation is that there was a definitive change in January 2007 to the guidance in AMP calculations. Therefore, the Court will analyze Plaintiff's allegations from 2004 until January 2007, and then from January 2007 to the present.

a. Whether Discount Defendants' AMP interpretation was reckless before 2007

Relevant to this case, from 2004 through January 2007 there appears little guidance on what discounts Discount Defendants could include in their AMP calculations.[7] The statute itself is silent regarding any type of permitted service fee discounts. The only guidance available before January 2007 was a CMS release issued in 1994, referred to as Release 14. This release stated that CMS "consider[ed] administrative fees,

[7] It is true that CMS provided regulatory guidance on the calculation of Average Sales Price ("ASP") in 2004. CMS specifically defined ASP to exclude costs paid by the manufacturer to the wholesaler for bona fide services. Medicare Program: Revisions to Payment Policies and Other Changes to Payment Under Part B, 71 Fed. Reg. 69,624, 69,666-67 (Dec. 1, 2006) (codified at 42 C.F.R. pts. 405, 410). Plaintiff argues that this regulatory guidance shows that Discount Defendants knew their discounts were really bona fide services and that Discount Defendants should not have deducted such discounts during their AMP calculations. The Court is not persuaded. First, ASP relates to Medicare, not Medicaid as in this case. Second, CMS did not, though it presumably could have, issue any regulation regarding AMP until 2007. Third, there were several types of discounts that a manufacturer could still deduct from ASP even after the regulations in 2004. Indeed, even the current ASP regulations still allow customary prompt pay discounts to be deducted when determining ASP. See 42 C.F.R. § 414.804(a)(2)(i)(B) (2011). Congress expressly excluded such discounts from AMP in 2007. See 42 U.S.C. § 1396r-8(k)(1) (2006). Therefore, it cannot be inferred that the policies undergirding ASP and AMP calculations are the same. Accordingly, the Court finds that a comparison of ASP and AMP is not sufficiently similar to demonstrate that the AMP regulations were sufficiently clear in 2004 to allow the Court to infer scienter from the facts pleaded.

incentives, promotional fees, chargebacks and all discounts or rebates, other than rebates under the Medicaid drug program, to be included in the calculation of AMP, if the those sales are to an entity included in the calculation of AMP, and best price." Medicaid Drug Rebate Program Release No. 14 (Dec. 21, 1994) (emphasis added). The language in this release suggests that Discount Defendants reasonably concluded that service fees were discounts until the statutory and regulatory changes in 2007.

Plaintiff does not direct the Court to any persuasive evidence of why Discount Defendants' interpretation of AMP — defined as the price paid to manufacturers by wholesalers and retailers — could not have included deductions for service fees. These fees, after all, were paid directly to wholesalers and effectively lowered the price wholesalers paid to manufacturers.[8] Therefore, the price paid to the manufacturer changed as a result of these discounts. Indeed, on May 30, 2006, the Inspector General pointed to the opaqueness of the regulatory guidance and explained that manufacturers inconsistently calculated AMP. See Office of the Inspector Gen., HHS,

[8] Briefly, the service fees and relation to AMP are described as follows: If the wholesale price of a drug is $100, and the service fee is $2, then the total price paid by the wholesaler for the drug to the manufacturer is $98. This $98 is then the amount used by the manufacturer when calculating its AMP.

Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005, at 4 (May 30, 2006), http://oig.hhs.gov/oas/reports/region6/60600063.pdf ("Existing requirements for determining certain aspects of AMPs are not clear and comprehensive, and manufacturers' methods of calculating AMPs are inconsistent."). Accordingly, from 2004 to at least January 2007, Plaintiff fails to plead sufficient facts that Discount Defendants' interpretation of the statutory and regulatory scheme was unreasonable, let alone that Discount Defendants' interpretation raised "the 'unjustifiably high risk' of violating the statute necessary for reckless liability." Safeco, 551 U.S. at 70. There was simply no guidance — within the statute itself, regulations, or from the courts — of what types of services could be discounted and what types of services should be excluded from AMP calculations. In short, there was nothing that "warned [Discount Defendants] away from the view [they] took." Id.; see United States ex rel. Pritzker v. Sodexho, Inc., No. 03-6003, 2009 WL 579380, at *16-17 (E.D. Pa. Mar. 6, 2009), aff'd, 365 F. App'x 787 (3d Cir. 2010) ("[L]ack of clarity regarding the proper interpretation of the regulations indicates that no basis exists for imposing FCA liability on [d]efendants, who merely adopted a reasonable interpretation of

regulatory requirements which favored their interests."); cf. United States ex rel. Oliver v. Parsons Co., 195 F.3d 457, 464 (9th Cir. 1999) ("[R]elying on a good faith interpretation of a regulation is not subject to [FCA] liability . . . because the good faith nature of his or her actions forecloses the possibility that the scienter requirement is met."). The lack of statutory or regulatory guidance ended in 2007, however. The Court will now analyze, with respect to Discount Defendants, whether from 2007 onward there are sufficient facts that plausibly show that Discount Defendants acted in reckless disregard of the law in their calculations of AMP.

b. Whether Discount Defendants' AMP interpretation was reckless after 2007

The statutory change to the definition of AMP implemented by the Deficit Reduction Act of 2005 changed, in a significant way, the calculation of AMP. For the first time, manufacturers could no longer include prompt pay discounts within their calculations of AMP. This discount had been explicitly allowed since AMP's inception and its exclusion by the Deficit Reduction Act represented a significant change in how AMP was calculated. Congress signaled the pharmaceutical industry that the types of discounts allowed within the AMP

calculation had narrowed significantly. Indeed, as explained above, the CMS regulations promulgated in October 2007 confirmed this significant change by delineating the specific types of discounts allowed under AMP calculations and also confirming that a fee known as a bona fide service fee could not be included within Discount Defendants' AMP calculations.

In light of this change, Plaintiff argues that Discount Defendants knew that the service fees and agreements with wholesalers fit within the definition of bona fide service fees and should not have been included within Discount Defendants' AMP calculations. Plaintiff pleads with respect to each Discount Defendants that it had contracts with wholesalers that required wholesalers to perform, inter alia, distribution services, customer service reports, data reporting services, and inventory management. See Fourth Am. Compl. ¶¶ 66-67, 196, 198, 211, 220, 222, 229. The details of these contracts show that Discount Defendants specifically claim that the service fees paid for such services were "discounts." See id. ¶¶ 200, 213, 221, 231. Plaintiff argues the services provided by wholesalers within these agreements were actually bona fide services as defined by statute and regulation, and the statutory text and regulations defining bona fide services were so clear that Discount Defendants knew the services they contracted for with

wholesalers were really bona fide. Therefore, Discount Defendants calling such service fees "discounts" shows that they knew such services were bona fide services but desired to reclassify these services as discounts to deduct the fees in their AMP calculations.

With the 2007 change in the law, some statutory guidance put Discount Defendants on notice that fees that were at one time allowed to be included within AMP were no longer allowed. Nonetheless, Safeco explains that even when there is statutory and regulatory guidance, unless Discount Defendants' interpretation is reckless, Plaintiff's claims must fail. Under this theory, the question therefore is whether Plaintiff's Fourth Amended Complaint plausibly shows that Discount Defendants were at least reckless in concluding that their service agreements were not for bona fide services. Under the circumstances of this case, the Court answers this question in the affirmative.

In October 2007, CMS promulgated a rule that defined excludable bona fide service fees as those fees that met the following four-prong test:

> (1) The fee paid must be for a bona fide, itemized service that is actually performed on behalf of the manufacturer;

> (2) The manufacturer would otherwise perform or contract for the services in the absence of the service arrangement;
> (3) The fee represents fair market value; and
> (4) That are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Medicare Program: Revisions to Payment Policies and Other Changes to Payment Under Part B, 71 Fed. Reg. 69,624, 69,668 (Dec. 1, 2006) (codified at 42 C.F.R. pts. 405, 410); see Medicaid Program: Prescription Drugs, 72 Fed. Reg. 39,142, 39,182-83 (July 17, 2007) (codified at 42 C.F.R. pt. 447) (adopting four-prong bona fide service fee test from ASP); see also 42 C.F.R. § 447.502 (2007). The regulations for ASP also provide the same definition of bona fide service fees and provide the guidance that "the manufacturer may presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on." Medicare Program: Revisions to Payment Policies and Other Changes to Payment Under Part B, 71 Fed. Reg. at 69,669.

Plaintiff's Fourth Amended Complaint is devoid of facts that state the service fees paid under the contracts are a fair market value for the services rendered by wholesalers to Discount Defendants. That conclusion, however, is not fatal to Plaintiff's claims at this early pleading stage. Plaintiff pleads other facts for the Court to conclude Plaintiff plausibly

shows that Discount Defendants' service agreements were for bona fide services.

First, several of the agreements themselves indicate that wholesalers believed the service fees to be bona fide service fees, despite Discount Defendants' conclusion that they were discounts. See Fourth Am. Compl. ¶ 213 (providing that wholesaler warrants that "the fees are bona fide fees for service"); id. ¶ 221 (providing that wholesaler's "position is that the payments are a bona fide fee for service provided under this agreement"); id. ¶ 231 ("Fees paid . . . are bona fide inventory management services.").

Second, Service Fee Defendants had very similar contracts with wholesalers as Discount Defendants. These contracts were for the same or similar services as the contracts Discount Defendants entered. Service Fee Defendants admit that such services were bona fide services. Therefore, given that wholesalers, and indeed other manufactures, believed these services that Discount Defendants contracted for were bona fide, it is plausible that Discount Defendants were at least reckless in concluding that their service fees were in fact not discounts, but bona fide service fees. Put another way, because Discount Defendants showed a sense of awareness to call the service fees discounts in the face of other manufacturers and

wholesalers stating otherwise, as well as in the face of the change in the statutory and regulatory landscape in 2007, the Court can infer the required knowledge of falsity.[9] Therefore, as the law from 2007 onward provided guidance that such bona fide service fees were to be excluded in AMP calculations, Plaintiff pleads sufficient facts to plausibly show that Discount Defendants were at least reckless in their AMP calculations.[10]

Discount Defendants rely heavily upon United States ex rel. Pilecki-Simko v. Chubb Inst., 443 F. App'x 754 (3d Cir. 2011). That case involved FCA claims for misrepresentations to the Department of Education. Id. at 755. The plaintiffs there

[9] Although some of these contracts appear to have been entered into before 2007, this does not change the Court's previous conclusion regarding Discount Defendants' interpretation of AMP before this time. There may be many reasons, most unknown to the Court, why Discount Defendants called such services "discounts," one of which may have been for purposes of ASP. The guidance before 2007 would not have given Discount Defendants pause to change this contractual language vis-à-vis AMP calculations. After 2007, however, and drawing all reasonable inference in favor of Plaintiff, the Court finds it is plausible Discount Defendants acted at least recklessly given the change in the statutory and regulatory landscape.

[10] Although the regulations providing that bona fide service fees were to be excluded were not in effect until October 2007, the Deficit Reduction Act indicated Congress's intent to limit the types of fees included within AMP. Given this intent, there are enough facts to plausibly infer that from January 2007 onward Discount Defendants acted with the required scienter.

made the conclusory allegations that "Chubb knows that this claim . . . is false because Chubb knows its students are not eligible under the Title IV program due to Chubb's violations of the HEA incentive compensation ban and is ineligible for those funds because of its intentional violations of the HEA funding statute." Id. at 761 (internal quotation marks omitted). The Third Circuit affirmed dismissal of the plaintiffs' claims because they failed to state a plausible claim for relief.

The conclusory allegations in Chubb are far afield from this case. Here, Plaintiff pleads specific statutory and regulatory guidance that Discount Defendants failed to follow. Such guidance allows the Court to infer that it is plausible Discount Defendants knew — as defined by the FCA — that their service agreements were for bona fide services. Indeed, unlike in Safeco, from 2007 onward, with respect to Discount Defendants, there was some statutory, regulatory, and industry guidance that plausibly "warned [Discount Defendants] away from the view [they] took." Safeco, 551 U.S. at 70. Therefore, there are sufficient facts to support a conclusion that Discount Defendants acted at least recklessly in concluding that their reported AMPs were correct. Cf. Nevada ex rel. Steinke v. Merck, 432 F. Supp. 2d 1082, 1087-88 (D. Nev. 2006).

3. Service Fee Defendants

Plaintiff avers that Service Fee Defendants conceal price increases — described by Plaintiff as retroactive price increases — within bona fide service fees and, therefore, effectively lower their AMP reported to the Government. The use of these retroactive price increases results from a change in the relationship between manufacturers and wholesalers. Before 2004, wholesalers made their profits by "forward buying." Forward buying is buying inventory from manufacturers at one price and then hoping for a price increase while they still have some inventory left to gain an additional profit. In 2004, manufacturers began demanding that wholesalers provide the manufacturer with this extra profit. In response, manufacturers and wholesalers entered into service agreements where wholesalers began charging fees for services they normally performed for free, such as distribution services, warehousing, and other services. These agreements generally define the fees as some percentage of sales by the manufacturer to the wholesaler. See, e.g., Fourth Am. Compl. ¶ 85. In addition, the manufacturer by way of a price credit on the service fee recoups any price-increase profit when the wholesaler has inventory at the time of a price increase. Service Fee Defendants contend that these price credits are properly part of

bona fide service fees; therefore, the price credits are excluded from AMP calculations.

The issue with respect to Service Fee Defendants is not whether those Defendants had service agreements for bona fide services — there is no dispute that they had such agreements and that they implemented these price adjustments — it is whether those service agreements could properly contain what Plaintiff avers were retroactive price adjustments. Such adjustments, according to Plaintiff, should have actually been included within Service Fee Defendants' calculation of AMP because the adjustments affected the price paid by wholesalers to manufacturers.

Service Fee Defendants argue that a retroactive price adjustment — or as Service Fee Defendants call it, a price credit — is a mechanism by which a service fee is paid and, therefore, is properly considered a service fee and not a price increase. Service Fee Defendants provide the following example:

> [A]ssume that one of the Service Fee Defendants had an agreement with a wholesaler that provided for an agreed-upon fair market value service fee of 5% of the net purchases by the wholesaler of the manufacturer's products during the quarter and also contained a price appreciation credit clause. If the wholesaler had $1,000,000 in net purchases from the Service Fee Defendant in a quarter and the manufacturer took no prices increases on its products during that quarter, the wholesaler would receive as its service fee for the quarter $50,000, or 5% of its net purchases of the

> manufacturer's products. If, on the other hand, the Service Fee Defendant took a price increase on one of its products during the quarter and the wholesaler had inventory on hand of that product at the time of the price increase, the wholesaler would still receive as its service fee $50,000, or 5% of its net purchases from the manufacturer. The only difference is that, in the latter instance, the payment to the wholesaler involves two components, the price appreciation credit and the balance of the service fee owed, but in both instances the wholesaler would receive the same fair market value service fee agreed-upon between the parties, i.e., $50,000.

Defs.' Reply Br. 14-15, ECF No. 156. According to Service Fee Defendants, these credits only apply when, after a wholesaler purchases a set quantity of drugs at some price certain, the price increases before the wholesaler's next purchase.

A review of the agreements between Service Fee Defendants and wholesalers reveals that Service Fee Defendants' description is not entirely accurate. The agreements explain that for any price increase on the drugs wholesalers already have in inventory, wholesalers must remit to Service Fee Defendants the value of those drugs — that is, the difference between the post-price-increase profit wholesalers would make on the drugs and the pre-price-increase profit wholesalers would make on the drugs. In some instances, the price increase may be great enough to consume the service fee itself, resulting in wholesalers actually owing Service Fee Defendants money and not

receiving the $50,000 service fee described in Service Fee Defendants' example.

Nonetheless, Plaintiff fails to plead how such a price credit methodology changes in any way the price paid to the manufacturer for the drug by the wholesaler. Given the dearth of guidance on price appreciation credits, it is not unreasonable, let alone reckless, for Service Fee Defendants to have concluded that the "price paid to the manufacturer" under AMP is just that, the price initially paid to the manufacturer by the wholesaler. This does not include any additional profits manufacturers' claw back after a price increase because the price actually paid for the drugs does not change. The price credit certainly cuts into the wholesaler's additional profits from a price increase. But the price credit does not appear to alter the wholesaler's initial profits and, therefore, does not alter the price wholesaler paid for the drug.

Even assuming that these price credits or retroactive price adjustments were not permissible as a payment method for service fees, there was simply no statutory or regulatory guidance to that effect for Service Fee Defendants to consider. The only guidance to the contrary has come recently in the preamble to a proposed rule. That preamble states, "We note however that retroactive price adjustments, sometimes also known

as price appreciation credits, do not meet the definition of a bona fide service fee as they do not reflect any service or offset of a bona fide service performed on behalf of the manufacturer." Medicaid Program; Covered Outpatient Drugs, 77 Fed. Reg. at 5332. The lack of regulatory guidance is fatal to Plaintiff's claims until at least February 2, 2012, which is after the filing of Plaintiff's Fourth Amended Complaint. Unlike Discount Defendants, and similar to Safeco, there was no regulatory, statutory, or judicial guidance that would have "warned [Service Fee Defendants] away from the view [they] took. Safeco, 551 U.S. at 70. There are simply no facts for the Court to plausibly infer that Service Fee Defendants' price credit methods were not a reasonable interpretation of AMP, let alone to plausibly infer that Service Free Defendants engaged in "the 'unjustifiably high risk' of violating the statute necessary for reckless liability." Id. Accordingly, Plaintiff's claims against Service Fee Defendants will be dismissed because Plaintiff fails to plead facts that Service Fee Defendants acted at least recklessly in concluding that such credits could not be included in the bona fide service fees until at the earliest February 2, 2012.[11]

[11] The Government, after it declined to intervene, submitted to the Court a Statement of Interest in Response to

B. Whether Plaintiff's Fourth Amended Complaint Meets the Pleading Requirements Under Rule 9(b)

In the alternative, Defendants argue that Plaintiff's Fourth Amended Complaint fails the particularity requirement of

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Defendants' Motion to Dismiss. See ECF No. 171. Therein, the Government argues that Safeco is inapplicable because the FCA imposes liability not only for reckless conduct, but also for deliberate ignorance. Id. at 2. The Government then proceeds to explain the difference between the scienter requirement under the FCA and the falsity requirement. It concedes that the "existence of regulatory ambiguity may be relevant to a defendant's scienter." Id. at 4. The Government appears to argue that any regulatory ambiguity is irrelevant to a determination that the claims submitted by Defendants in this case were false. Therefore, the Court should not rely upon Safeco as dispositive in this case.

The Government misapprehends Safeco's application. The Court is not considering the regulatory ambiguity for whether Defendants' AMP calculations were false, but instead considers the regulatory framework in deciding whether there are sufficient facts to plausibly show Defendants had the required state of mind. The Government attempts to distinguish Safeco on the grounds that recklessness and deliberate ignorance are not the same states of mind. This distinction is without a difference, as recklessness is the floor for the required mental state for a FCA claim. See K & R Ltd., 530 F.3d at 983 ("To successfully oppose summary judgment, K & R must show that a reasonable factfinder, drawing all justifiable inferences from the evidence in K & R's favor, could find MassHousing at least recklessly disregarded the falsity of its claims." (citation omitted) (internal quotation marks omitted)). Even if the Court assumes there is some difference, it is irrelevant in this case because Defendants' interpretation of AMP, for the time periods discussed above, was reasonable in light of the statutory and regulatory guidance available.

Rule 9(b).[12] Defendants argue that Plaintiff's Fourth Amended Complaint only includes conclusory allegations that Defendants actually incorrectly calculated and inaccurately reported AMPs to the Government. Defendants argue that Plaintiff's allegations fail the requirement under Rule 9(b) to show the "who, what, where, when, and how" of the fraud. Defendants argue that nowhere in Plaintiff's Fourth Amended Complaint does Plaintiff set forth facts explaining what calculations any of Defendants used when preparing their AMP reports, what false AMP calculations resulted, and whether the AMP calculations were falsely reported. Moreover, Defendants argue that Plaintiff fails to plead the required mental state under Rule 9(b). Specifically, Defendants argue that although Rule 9(b) allows a plaintiff to aver a fraudulent mental state generally, Plaintiff must still meet the requirements of Rule 8(a) and plead sufficient facts to plausibly show Defendants had the required mental state — that is, that Defendants knew, as defined by the FCA, that they calculated the AMP incorrectly.

Plaintiff argues that it cannot plead such facts because only the Government and Defendants are allowed such

[12] The Court does not address Defendants' arguments that Plaintiff's Fourth Amended Complaint fails to plead sufficient facts of a FCA violation to survive under Rule 8(a) because Rule 9(b)'s standard is more exacting than Rule 8(a).

information. And, Plaintiff's facts providing specific contractual provisions, along with the statutory and regulations in force, are sufficiently particular to put Defendants on notice of Plaintiff's claims.

In this case, while Plaintiff has not provided the exact claims filed by Defendants that are allegedly fraudulent, Plaintiff did provide specific contracts between Defendants and wholesalers. Plaintiff detailed how the alleged fraud occurred, Plaintiff specified the statutory and regulatory provisions violated, and also indicated that Defendants had to file their AMP reports with the Government "not later than 30 days after the last day of each rebate period under the agreement." 42 U.S.C. § 1396r-8(b)(3)(A)(i). This detail is sufficient to meet the particularity requirement of Rule 9(b) in this case.[13]

To be sure, this Court has in the context of a FCA claim adopted the view that a plaintiff cannot "merely [] describe a private scheme in detail but then . . . allege simply

[13] Defendants compare the need to plead the "who, what, where, when, and how" required under Rule 9(b), which Plaintiff has satisfied, with the details of the specific allegedly false information submitted by Defendants to the Government. Once discovery in this case proceeds, and the veil of confidentiality covering the information Defendants submitted to the Government is lifted, see 42 U.S.C. § 1396r-8(b)(3)(D) (providing confidentiality of information submitted to Government under statute), Plaintiff may fill in the missing false figures upon which Plaintiff claims Defendants based their AMP calculations.

and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government." United States ex rel. Schmidt v. Zimmer, Inc., No. 00-1044, 2005 WL 1806502, at *3 (E.D. Pa. July 29, 2005) (Robreno, J.). Schmidt involved an alleged kickback scheme where the defendant paid unlawful remuneration to healthcare providers in exchange for those providers buying the defendant's orthopedic products. Id. at *1-2 The plaintiff's complaint in that case failed to identify a single false claim submitted to the Government and also failed to provide any factual detail of the alleged kickback scheme and why it was unlawful. Id. at *2-3. Therefore, the Court concluded that the complaint failed to satisfy Rule 9(b)'s particularity requirement. Id. at *3.

Schmidt is distinguishable here for several reasons. First, in this case there is a statutory scheme that dictates that Defendants must submit AMP calculations every thirty days after the close of each rebate period and Defendants do not contend they have not complied with this requirement. Second, Plaintiff in this case provided rich detail of the contracts involved and how those contracts facilitate AMP calculations that allegedly violate the statute and regulations.

Third, although the Third Circuit has not spoken directly on the issue, it specifically noted under Rule 12(b)(6) that a plaintiff need not provide evidence of one submitted false claim at the motion to dismiss stage. See Wilkins, 659 F.3d at 308 (explaining under Rule 12(b)(6) standard that "to our knowledge 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," but declining to decide if that is necessary under Rule 9(b)). In addition, since Schmidt, circuit courts and other district courts within this circuit have come to the opposite conclusion of Schmidt and hold that a plaintiff need not, in certain circumstances, provide details of one false claim to survive a motion to dismiss. See United States ex rel. Underwood v. Genetech, Inc., 720 F. Supp. 2d 671, 676-77 (E.D. Pa. 2010) (collecting cases and finding that plaintiff can provide other indicia of particularity in lieu of specifics of a false claim to survive motion to dismiss under Rule 9(b)).

Under the facts of this case, the Court finds that Plaintiff's detailed complaint, despite its absence of a specific false claim submitted by Defendants, satisfies Rule 9(b)'s particularity requirement. Given the ample facts describing the alleged scheme and details of contracts Defendants had with wholesalers, Defendants cannot argue that

they are unaware of the precise "misconduct with which they are charged." Seville, 742 F.2d at 791.

With respect to the required averments of intent under Rule 9(b), Defendants' arguments parallel their arguments under Rule 8(a). That is, although Rule 9(b) allows the pleading of intent to be averred "generally," Rule 8(a) still requires Plaintiff to plead sufficient facts that Defendants plausibly knew of the fraudulent AMP calculations. See Iqbal, 556 U.S. at 686-87 (explaining in context of alleging intent "generally," "Rule 9 merely excuses a party from pleading discriminatory intent under an elevated pleading standard. It does not give him license to evade the less rigid — though still operative — strictures of Rule 8"). For the reasons stated above, Plaintiff failed to plead sufficient facts that any Defendants acted in reckless disregard of the law in their AMP calculations before 2007. Yet, from 2007 to the present, Plaintiff pleaded sufficient facts to show a plausible claim that Discount Defendants were reckless in concluding that the service fee agreements with wholesalers were not bona fide service fee agreements. Finally, Plaintiff failed to plead sufficient facts to show plausibly that Service Fee Defendants acted with reckless disregard of the law when they included price increase credits within their calculation of bona fide service fees.

C. Whether Plaintiff's State Law Claims Should be Dismissed

Defendants also move to dismiss Plaintiff's state law claims. Defendants argue that if the Court dismisses Plaintiff's claims under the FCA, the Court must also dismiss Plaintiff's state law claims.[14] Defendants also argue that Plaintiff's claims under Delaware and New Mexico's FCAs fail because those states require either that the state intervene or the state provide a written determination that there is substantial evidence that a violation occurred for Plaintiff to continue his qui tam action alone. Defendants argue that those states have not provided this written determination in this case. Defendants also argue that Plaintiff is not an "affected person" under Delaware and New Mexico law and, therefore, in accordance with the substantive FCA law of those states, Plaintiff cannot bring a qui tam action.

Moreover, Defendants argue that Plaintiff's claims under New Hampshire and Texas's FCAs fail because New Hampshire

[14] In addition to the specific states discussed below, Defendants have moved to dismiss the following state law claims to the extent the federal claims are dismissed: California, Florida, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Nevada, North Carolina, Tennessee, Virginia, Wisconsin, and the District of Columbia.

and Texas require the state to intervene for Plaintiff to proceed and those states have not intervened in this case. Finally, Defendants argue that the remaining claims under Connecticut, Georgia, Indiana, Montana, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, and Rhode Island's FCAs fail because the FCA statutes in those states were enacted after Plaintiff's Complaint, and the FCA statutes were not made retroactive. Defendants admit, however, that any AMP calculations submitted after the effective dates of those statutes could survive.

1. Delaware and New Mexico Claims

Plaintiff's claims under the Delaware and New Mexico FCA statutes cannot proceed as pleaded. Under both state's statutes, for a qui tam action to continue without state intervention, the Attorney General (in Delaware) or the Department of Human Services (in New Mexico) must issue a written determination, that there is substantial evidence that a violation occurred. See Del. Code Ann. tit. 6, § 1203(b)(4)(b) (2005); N.M. Stat. § 27-14-7(E)(2) (2007). There is no dispute that neither state provided this written determination.

Nonetheless, Delaware amended its FCA in 2009 to eliminate this requirement. See Claims — Reports — Delaware

False Claims & Reporting Act, 2009, 2009 Del. Legis. Serv. 166 (West). Therefore it seems that for any conduct after this amendment, Plaintiff's claims could proceed to the same extent as Plaintiff's federal claims. New Mexico did not make a similar amendment.

Defendants also argue that Plaintiff is not an "affected person" within the meaning of the Delaware statute in effect when Plaintiff filed his Complaint. Plaintiff admits that the FCA in effect when he filed his Complaint defined "affected person" as an "employee or former employee of [the defendant] or a labor organization," Del. Code Ann. tit. 6, § 1202(4) (2005), and that Plaintiff does not meet this definition. In 2009, Delaware changed this definition and allowed "any person" to bring a qui tam FCA suit. Del. Code Ann. tit. 6, § 1203(b)(1) (Supp. 2010). Defendants argue that there is no legislative intent to make this change retroactive. While that may be true, Delaware's FCA law has a ten-year statute of limitations. Id. § 1209(a). Therefore, even though there was no intent to make the new definition of "affected person" retroactive, Plaintiff could still bring suit in this case for Defendants' conduct that allegedly began at least after that statute's effective date. Dismissing Plaintiff's claims under Delaware law because he filed before the new Delaware

definition of "affected person" would be futile; Plaintiff could simply re-file the same claim under the new statutory definition.

Plaintiff argues that in the State's Notice of Election to Decline Intervention filed in this Court, the states provide:

> "Although the above States decline to intervene, the States request under their respective statutes, which permit Relator to maintain the action in the name of the above States, that Relator be permitted to dismiss the case on behalf of each State only if the Court and each such State give written consent to the dismissal and their reasons for consenting.

States' Notice of Election to Decline Intervention 2, ECF No. 57. Therefore, Plaintiff argues that each state, including Delaware and New Mexico, consented to Plaintiff proceeding in this case. The Court cannot take this one statement as overruling the clear statutory language in the Delaware and New Mexico statutes. Moreover, the Notice language specifically refers to each state's respective statutes and, in Delaware and New Mexico, the respective statutes do not permit Plaintiff to bring a claim in this case. Accordingly, Plaintiff's claims under Delaware and New Mexico law must be dismissed, except that Plaintiff's claims under Delaware law may proceed for AMP calculations filed from July 16, 2009, onward.

2. New Hampshire and Texas Claims

Similar to Plaintiff's claims under Delaware and New Mexico law, at the time of the filing of Plaintiff's Complaint in 2008, the law of New Hampshire did not permit Plaintiff to bring an action where it decline to intervene. See N.H. Rev. Stat. Ann. § 167:61-c(II)(e) (Supp. 2008); New Hampshire amended its statute, effective June 29, 2009, to permit relators to pursue claims without state intervention. See N.H. Rev. Stat. Ann. § 167:61-c(II)(e) (Supp. 2011). Accordingly, Plaintiff's claims that post-date June 29, 2009, will survive consistent with his federal claims. Texas had a similar law, but Texas amended its statute, effective May 4, 2007, to also allow a relator to proceed with a claim absent intervention. See Tex. Hum. Res. Code Ann. § 36.104 (West Supp. 2008). This was before Plaintiff's initial Complaint, but after some of Defendants' AMP submission Plaintiff alleges violated the FCA. The Texas statute also provides, "This Act applies only to conduct that occurs on or after the effective date of this Act." Civil Remedies & Qui Tam Provisions Under the Medicaid Fraud Prevention Act, ch. 29, § 6, 2007 Tex. Sess. Law. Serv. 29 (West). Therefore, Plaintiff's claims must be dismissed for any AMP calculations submitted before each statute's effective date.

Plaintiff argues that the Court should permit fraudulent acts that occurred before the passage of these new statutes to proceed because the states declined to intervene after the amendment of their respective FCA statutes. See Pl.'s Br. 43, ECF No. 147 (citing United States ex rel. King v. Solvay S.A., 823 F. Supp. 472, 521-22 (S.D. Tex. 2011), vacated in part on other grounds on reconsideration by No. 06-2662, 2012 WL 1067228 (S.D. Tex. Mar. 28, 2012)). This argument is against the weight of other persuasive authority holding to the contrary. See, e.g., United States ex rel. Wall v. Vista Hospice Care, 778 F. Supp. 2d 709, 723-24 (N.D. Tex. 2011); United States ex rel. Lisitza v. Johnson & Johnson, 765 F. Supp. 2d 112, 130 (D. Mass. 2011). Therefore, the Court finds that both New Hampshire and Texas do not allow a relator to bring a claim without state intervention for claims filed before the statutes' effective dates.

3. Remaining State Law Claims

Several other states did not have FCAs in force when Plaintiff brought his Complaint in 2008. Since that time, many states have enacted FCA statues. Plaintiff admits that none of the newly enacted statutes apply retroactively. Plaintiff does not dispute that the following states did not permit Plaintiff

to bring an action for claims preceding those statutes' effective dates: Connecticut (effective October 5, 2009); Georgia (effective May 24, 2007); Indiana (effective May 11, 2005); Montana (effective October 1, 2005); New York (effective April 1, 2007); Oklahoma (effective November 1, 2007); and Rhode Island (effective February 15, 2008). Accordingly, AMP calculations allegedly submitted by Defendants before those dates must be dismissed. AMP calculations submitted after those dates, however, shall proceed consistent with the Court's disposition of Plaintiff's federal claims.

V. CONCLUSION

For the reasons set forth above, the Court will dismiss all claims for alleged fraudulent AMP calculations submitted to the Government before January 1, 2007, against Discount Defendants, dismiss all claims against Service Fee Defendants, and dismiss the state law claims consistent with the analysis above with prejudice as to Plaintiff only.[15] The case will proceed against Discount Defendants for AMP calculations submitted after January 1, 2007, and any state law claims after

[15] In its statement of interest, the Government asks the Court to dismiss Plaintiff's claims without prejudice as to the Government. Defendants' response to the Government's statement of interest does not oppose this request.

that time that are not otherwise barred, as discussed above. An appropriate order will follow.