995 F.Supp.2d 357
United States District Court,
E.D. Pennsylvania.

UNITED STATES of America,
ex rel. Amy BERGMAN, Relator,
v.
ABBOT LABORATORIES, Defendant.

Civil Action No. 09–4264. | Jan. 30, 2014.

Synopsis
Background: Relator brought action under False Claims Act (FCA) and corresponding state statutes alleging that pharmaceutical manufacturer falsely and misleadingly marketed its prescription drug for off-label and medically unnecessary uses, and knowingly paid illegal kickbacks to physicians, thereby causing submission of false claims to government healthcare systems. Manufacturer moved to dismiss.

Holdings: The District Court, Jones, II, J., held that:

[1] relator stated plausible claim under FCA;

[2] relator pled FCA claim with sufficient particularity;

[3] dismissal on First Amendment free speech grounds was not warranted;

[4] Wartime Suspension of Limitations Act (WSLA) did not toll FCA's statute of limitations;

[5] state's failure to intervene barred relator's claims under Texas Medicaid Fraud Prevention Act (TMFPA) to extent that they were based on pre-amendment conduct;

[6] state's failure to intervene or to certify that there was substantial evidence for relator's claims barred relator's claims under Delaware False Claims and Reporting Act (DCFRA) to extent that they were based on pre-amendment conduct; and

[7] retroactive application of Tennessee and Wisconsin false claims statutes did not violate Ex Post Facto Clause.

Motion granted in part and denied in part.

West Headnotes (14)

[1] United States
Making or Presentation of False Claims and Other Offenses Relating to Claims

To establish claim under False Claims Act (FCA), relator must prove that: (1) defendant presented or caused to be presented to agent of United States claim for payment; (2) claim was false or fraudulent; and (3) defendant knew that claim was false or fraudulent. 31 U.S.C.A. § 3729(a)(1)(A).

Cases that cite this headnote

[2] United States
Making or Presentation of False Claims and Other Offenses Relating to Claims

Claim is factually false under False Claims Act (FCA) when claimant misrepresents what goods or services that it provided to government, and claim is legally false when claimant knowingly falsely certifies that it has complied with statute or regulation that is condition for government payment. 31 U.S.C.A. § 3729(a)(1).

Cases that cite this headnote

[3] United States
Making or Presentation of False Claims and Other Offenses Relating to Claims

Defendant violates False Claims Act (FCA) under express false certification when, in conjunction with request for federal funds, it certifies that it is in compliance with regulations that are requirements for payment. 31 U.S.C.A. § 3729(a)(1).

Cases that cite this headnote

[4] United States
Making or Presentation of False Claims and Other Offenses Relating to Claims

False Claims Act (FCA) violation occurs under implied false certification when defendant

submits or causes to be submitted request for payment without disclosing that it is in violation of regulation that affects its eligibility for payment, and government would not have paid claims had it been aware of defendant's violations. 31 U.S.C.A. § 3729(a)(1).

1 Cases that cite this headnote

[5] United States

Making or Presentation of False Claims and Other Offenses Relating to Claims

Relator's allegations that pharmaceutical manufacturer falsely and misleadingly marketed and misbranded its prescription drug for off-label and medically unnecessary uses, thereby causing submission of false claims to government healthcare systems, and that United States and states would not have paid claims but for manufacturer's illegal and fraudulent conduct were sufficient to state plausible claim under False Claims Act (FCA). 31 U.S.C.A. § 3729(a)(1); Health Insurance for the Aged Act, § 102(a), 42 U.S.C.A. § 1395y(a)(1)(A).

Cases that cite this headnote

[6] United States

Making or Presentation of False Claims and Other Offenses Relating to Claims

Relator's allegations that pharmaceutical manufacturer falsely and misleadingly marketed and misbranded its prescription drug for off-label and medically unnecessary uses, thereby causing submission of false claims to TRICARE and Federal Employee Health Benefits Program (FEHBP), and that TRICARE and FEHBP would not have paid claims but for manufacturer's illegal and fraudulent conduct were sufficient to state plausible claim under False Claims Act (FCA). 31 U.S.C.A. § 3729(a)(1); 32 C.F.R. § 199.4(g)(15)(i)(A).

Cases that cite this headnote

[7] Federal Civil Procedure

Fraud, mistake and condition of mind

Relator asserting claims under False Claims Act (FCA) does not need to show specific submitted false claim in order to comply with particularity requirements for pleading fraud claims if false claims are submitted by third party and not defendant. Fed.Rules Civ.Proc.Rule 9(b), 28 U.S.C.A.; 31 U.S.C.A. § 3729(a)(1).

1 Cases that cite this headnote

[8] Federal Civil Procedure

Fraud, mistake and condition of mind

Relator pled with sufficient particularity claim that pharmaceutical manufacturer violated False Claims Act (FCA) by falsely and misleadingly marketing its prescription drug for off-label and medically unnecessary uses, thereby causing submission of false claims to government healthcare systems, even though relator did not identify specific submitted false claim, where alleged false claims were submitted by third party physicians, and relator provided myriad details of manufacturer's marketing statements that contradicted its Food and Drug Administration (FDA)-approved label, including specific misrepresentations that manufacturer directed its representatives to make to physicians. Fed.Rules Civ.Proc.Rule 9(b), 28 U.S.C.A.; 31 U.S.C.A. § 3729(a)(1).

2 Cases that cite this headnote

[9] Federal Civil Procedure

Fraud, mistake and condition of mind

Relator pled with sufficient particularity claim that pharmaceutical manufacturer violated False Claims Act by providing illegal financial incentives to physicians to prescribe its prescription drug for off-label and medically unnecessary uses, in violation of Anti–Kickback Statute, even though relator did not identify any specific false claim, where relator detailed how manufacturer allegedly provided its representatives with funds for honoraria and meals as rewards for physicians who prescribed or encouraged other physicians to prescribe drug, and asserted how lack of kickbacks was condition of payment and that kickbacks

thus caused submission of false claims for reimbursement. Fed.Rules Civ.Proc.Rule 9(b), 28 U.S.C.A.; 31 U.S.C.A. § 3729(a)(1); Social Security Act, § 1128B(b)(2), 42 U.S.C.A. § 1320a–7b(b)(2).

Cases that cite this headnote

[10] Federal Civil Procedure

Fact issues

Issue of whether pharmaceutical manufacturer's representations to physicians regarding off-label uses of its prescription drug were truthful involved fact issues that could not be resolved on motion to dismiss relator's action against manufacturer under False Claims Act (FCA) on ground that manufacturer's speech was protected by First Amendment. U.S.C.A.Const.Amend. 1; 31 U.S.C.A. § 3729(a)(1).

1 Cases that cite this headnote

[11] Limitation of Actions

War

Wartime Suspension of Limitations Act (WSLA) did not toll False Claims Act's (FCA) statute of limitations for relator in case that did not involve military or war-related contracts and in which government declined to intervene. 18 U.S.C.A. § 3287; 31 U.S.C.A. § 3731(b)(1).

3 Cases that cite this headnote

[12] States

Making or presentation of false claims

Under Texas law, state's failure to intervene barred relator's qui tam claims under Texas Medicaid Fraud Prevention Act (TMFPA) to extent that they were based on conduct that occurred before effective date of statutory amendment eliminating intervention requirement. V.T.C.A., Human Resources Code § 36.001.

1 Cases that cite this headnote

[13] States

Making or presentation of false claims

Under Delaware law, state's failure to intervene or to certify that there was substantial evidence for relator's claims barred relator's qui tam claims under Delaware False Claims and Reporting Act (DCFRA) to extent that they were based on conduct that occurred before effective date of statutory amendment eliminating intervention or certification requirement. 6 West's Del.C. § 1203(b)(2).

1 Cases that cite this headnote

[14] Constitutional Law

Civil Actions and Proceedings

States

Making or presentation of false claims

Tennessee and Wisconsin statutes permitting qui tam false claims actions were not punitive in nature, and thus their retroactive application did not violate Ex Post Facto Clause, even though statutes permitted recovery of treble damages and penalties, where statutes did not permit affirmative disability or restraint, did not require guilty knowledge, applied to somewhat wider range of behavior than just criminal fraud, and had alternative purposes of compensation and incentivizing relators to come forward. U.S.C.A. Const. Art. 1, § 10, cl. 1; West's T.C.A. § 4–18–106(b); W.S.A. 20.931(15).

2 Cases that cite this headnote

Attorneys and Law Firms

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MEMORANDUM

JONES, II, District Judge.

I. *BACKGROUND*

Qui tam Relator Amy Bergman ("Relator") brings this action against Abbott Laboratories ("Defendant") under the False Claims Act (FCA), 31 U.S.C. § 3729 et seq., and similar state statutes. First Amended Complaint ("AC") (Dkt. No. 18) ¶¶ 1–2. Specifically, Relator alleges that Defendant falsely and misleadingly marketed its prescription drug TriCor for off-label and medically unnecessary uses, and knowingly paid illegal kickbacks to physicians, thereby causing the submission of false claims to government healthcare systems, including Medicare, Medicaid, TRICARE, and the Federal Employee Health Benefits Program (FEHBP). *See generally* AC ¶¶ 130–60. Abbott moves to dismiss the Complaint pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b), arguing that the uses for which Abbott marketed ***360** TriCor were reimbursable—regardless of whether those uses were off-label—and therefore Abbott did not cause the submission of false claims for reimbursement. Def's. Mot. to Dismiss (Dkt. No. 47) at 18–19. Abbott also argues that the Relator fails to plead with sufficient particularity the allegations of illegal kickbacks, that Relator tries to impose FCA liability on speech protected by the First Amendment, that the federal claims are barred by the applicable statute of limitations, and that the state law claims should be dismissed for similar reasons. Def's. Mot. to Dismiss, 19–20.

A. *The Parties*

Abbott Laboratories is a corporation organized under the laws of the state of Illinois and is a citizen of Illinois, but it regularly transacts business in the Eastern District of Pennsylvania. AC ¶ 30. Abbott manufactures and sells pharmaceuticals both internationally and domestically. AC ¶ 31. Abbott also maintains a national sales force which it directs from its national office in Abbott Park, Illinois. AC ¶ 31. Abbott began marketing TriCor in 1998. AC ¶ 34.

Relator was an employee of Abbott Laboratories from July 1, 1999 through January 2008. AC ¶ 35. During Relator's time at Abbott, Relator worked as a sales representative and was assigned to promote TriCor starting in January 2000 and ending in January 2008. AC ¶ 35. Relator claims she was trained and directed, along with other representatives, to promote TriCor for "off-label and medically unnecessary uses." AC ¶ 21. At the time of the Complaint's filing Relator "resid[ed] and [was] domiciled in Boca Raton, Florida, and [was] a citizen of the State of Florida. AC ¶ 29.

B. *Relator's Allegations*

In the Complaint, Relator, alleges that Abbott illegally marketed its drug TriCor from January 2000 to January 2008, and possibly into the present. AC ¶ 12. These marketing activities violated the FDA's restrictions on "off-label" marketing, 21 U.S.C. § 331(a)-(b), and the Medicare and Medicaid Anti–Kickback statutes ("AKS"), 42 U.S.C. § 1320a–7b. *See* AC ¶ 3. As a result of Abbott's illegal marketing activities, claims for reimbursement were submitted to the Federal and various state governments, which violated the Federal False Claims Act, 31 U.S.C. § 3729, et seq., and similar state statutes.[1] It is under the Federal and State False Claims Act statutes that the Relator brings twenty-eight causes of action.

TriCor is a lipid-regulating agent approved by the FDA for the treatment of hypercholesterolemia, mixed dyslipidemia, and hypertriglyceridemia. *Id.* ¶ 4. According to TriCor's label, the FDA approved TriCor as "an adjunctive therapy to diet" for reducing lipid and cholesterol levels in adult patients with hypercholesterolemia and mixed dyslipidemia, and for treating adult hypertriglyceridemia. AC Ex. 1 at 3. Relator details Abbott's marketing of TriCor as follows:

> ... Abbott improperly promoted TriCor as a first-line treatment for treating or preventing cardiac health risks in diabetic patients even though TriCor was not approved for such use by the FDA and even though TriCor had ***no demonstrated effect*** on cardiovascular morbidity and mortality in the diabetic population. Abbott also improperly promoted TriCor for use in combination with highly popular statin drugs even though TriCor ***361** was not approved for use in combination with statins by the FDA, and despite ***specific warnings*** regarding combined use with statins contained in the FDA-mandated product labelling. Abbott

> also made regular representations concerning the efficacy of TriCor which were contrary to the FDA required labeling, were false and misleading, and which did not represent the FDA required fair balance of information regarding uses and risks.

AC ¶ 7. Essentially, Relator claims that Abbott marketed TriCor starting in 2002 and lasting until at least 2008 for two particular off-label uses: (1) as a first-line treatment for cardiac health in diabetics, and (2) as a combination drug to be used with statins. AC ¶¶ 62, 87. Relator notes that TriCor's label includes a warning about using it in combination with statin drugs. AC ¶¶ 7, 60–62, 87. Relator also alleges that Abbott provided "unlawful payments" and "other illicit financial incentives to physicians, including for off-label and medically unnecessary uses, in a knowing violation of the Medicare and Medicaid Anti–Kickback statute." AC ¶ 8.

Relator describes Abbott's marketing activities as consisting of encouraging sales representatives:

b. to misrepresent and withhold clinical information regarding the known risks associated with the use of TriCor, particularly in combination with statins;

c. to misrepresent and withhold clinical information regarding questions concerning the efficacy of TriCor;

d. to misrepresent that TriCor was superior to other drugs when clinical studies either established otherwise, or where there was no clinical study comparing the two drugs; and

e. to improperly use study results of other drugs to suggest that TriCor would have the same or better results.

AC ¶ 13.

Relator claims that clinical studies did not support Abbott's marketing claims about TriCor's efficacy or safety for such off-label or medically unnecessary uses. AC ¶ 14. Abbott nevertheless instructed its representatives to deemphasize risks of TriCor and emphasize its efficacy and support these claims with studies that sometimes involved drugs that were similar but not identical to TriCor. AC ¶ 15a-i. Abbott also allegedly provided its representatives with funds for honoraria and meals as rewards for physicians who prescribed or encouraged other physicians to prescribe TriCor. AC ¶ 15j. Abbott also knew that the targeted patient population of this marketing included many patients who were poor, elderly, or disabled and likely to be on government programs. AC ¶ 17. Furthermore, Abbott explained to its representatives that the diabetes market was expanding and that they should target that market. AC ¶ 67. Relator asserts that Relator has personal knowledge of these marketing practices because Relator was assigned to promote TriCor, among other drugs, and was trained to promote TriCor "for off-label and medically unnecessary uses, and to target and provide illegal financial incentives." AC ¶ 21. In Relator's territory of Palm Beach County, Florida, Abbott instructed representatives to market TriCor as a joint therapy with statins to pharmacists, targeting those pharmacists who sought physician verification or simply refused to fill TriCor prescriptions for patients who were also taking statins. AC ¶ 115. Abbott also targeted physicians "who wrote a large number of prescriptions for statins." AC ¶ 122. Relator includes in the Complaint lists of physicians to whom Abbott marketed TriCor for off-label and medically unnecessary uses, AC ¶ 134, physicians who prescribed TriCor ***362** for such uses, AC ¶ 135, and physicians who informed Abbott that they had prescribed TriCor to diabetics as a first-line treatment, AC ¶ 136.

Defendant allegedly concealed its off-label and/or misleading marketing practices by instructing sales representatives to not record their discussions of off-label uses in their otherwise required post-discussion "call notes." AC ¶ 118. Defendant also instructed representatives in 2009 to return all allegedly off-label or medically unnecessary marketing materials. AC ¶ 119.

Another component of the Defendant's alleged illegal marketing scheme was the paying of illegal kickbacks to providers to induce them to prescribe TriCor. *See* AC ¶¶ 120–29. Defendant allegedly "made or caused others to make illegal kickbacks and prohibited remuneration to physicians in order to induce them to prescribe TriCor for Medicare, Medicaid, and other Government health insurance programs covered patients including for off-label and medically unnecessary use." AC ¶ 120. Relator also notes that the Anti–Kickback Statute ("AKS") also applies to the inducement of prescriptions for "on-label and medically necessary uses." AC ¶ 121. The Defendant allegedly carried this plan out by giving its sales representatives "quarterly allowances" to arrange dinners, meetings, and other events for physicians, and to provide them with honoraria or speaker fees. *See* AC ¶¶ 124–27. The Defendant would allegedly target physicians who wrote high numbers of prescriptions for TriCor, or those

physicians that the Defendant thought could be persuaded to write more prescriptions for TriCor. AC ¶¶ 127–29. These practices occurred in Relator's marketing region, Relator was personally aware of these practices, and Relator also arranged some of the events or gifts which would constitute the alleged kickbacks. AC ¶¶ 123–29.

As a result of this illicit marketing scheme, Abbott caused physicians to submit reimbursements to federal and state programs for uses of TriCor for which those programs would not have made payments had they known of Abbott's "illegal and fraudulent conduct." AC ¶ 11, 17, *see also* AC ¶ 130. (claims "would not have been written or submitted but for Abbott's unlawful conduct"). Relator alleges that the submission of these ineligible reimbursements was the "natural, intended, and foreseeable result" of Abbott's illegal marketing. AC ¶ 55; *see also* AC ¶ 133 ("... Abbott knew —and in fact it was Abbott's goal—that its illegal marketing scheme would cause the submission of many thousands of false claims to be submitted to Medicare, Medicaid, and to other Government-funded and State-funded health insurance programs.").

Relator concedes that Defendant "did not directly submit the false claim for TriCor to the federal and state health insurance programs; however, Abbott knew—and in fact it was Abbott's goal—that its illegal marketing scheme would cause the submission of many thousands of false claims to be submitted to Medicare, Medicaid, and to other Government-funded and State-funded health insurance programs." But, Relator alleges that through Defendant's marketing, Defendant knew that a higher number of written prescriptions for TriCor would result in more claims being submitted to these programs, as well as more profits for Defendant. *Id.*

Relator sums up the allegations by claiming that "each off-label, medically unnecessary, or kickback-tainted claim for a TriCor prescription that Abbott knowingly caused to be submitted to [Medicare, Medicaid, TRICARE, or the FEHBP] for reimbursement constitutes a false claim for which Abbott is accountable under the Federal False Claims Act." AC ¶ 143; *see also* AC ¶¶ 148, 153, 160.

*363 C. *Procedural Posture*

Relator filed the original Complaint in this matter on September 18, 2009. Relator's Response to the Motion to Dismiss ("RMTD"), 2. On January 6, 2012, prior to the unsealing of the case, Relator filed the first Amended Complaint. AC, 1. The Amended Complaint asserts twenty-eight causes of action against Abbott: violations of the federal False Claims Act, 31 U.S.C. § 3729(a)(1)-(2) (now re-codified as 31 U.S.C. § 3729(a)(1)(A)-(B)); and violations of similar statutes in twenty-two states and the District of Columbia. AC ¶ 161–435.

On March 22, 2012, the United States filed its notice of election to decline intervention. RMTD, 2. On November 9, 2012, Abbott filed its Motion to Dismiss. *Id.* On January 7, 2013, Relator filed the response, followed by the Defendant's Reply on February 6, 2013. RMTD, 82; Defendant's Reply to Relator's Response to the Defendant's Motion to Dismiss ("RRMTD"), 10. On March 29, 2013, Relator filed a Supplemental Response to the Motion to Dismiss, to which the Defendant filed a reply on May 23, 2013. Relator's Supplemental Response to the Motion to Dismiss ("SRMTD"), 5; Defendant's Response to Relator's Supplemental Response to the Motion to Dismiss ("RSRMTD"), 12.

II. *MOTION TO DISMISS*

Abbott Laboratories moves to dismiss Relator's Amended Complaint for its failure to state a claim for which relief can be granted under Fed.R.Civ.P. 12(b)(6) and for its failure to plead fraud with sufficient particularity under Rule 9(b). MTD, 16, 20. Defendant argues that the Complaint does not sufficiently allege the three elements of a prima facie violation of the False Claims Act: "(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." MTD, 18. (citing *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 304–05 (3d Cir.2011)). Defendant argues that Relator's off-label marketing-based liability theories are conclusory and do not provide sufficiently particular factual allegations to meet the requirements of Rule 12(b)(6) or 9(b); and that the AKS-based liability theories fail under Rule 9(b) due to a lack of detail. MTD, 16, 20, 46. Additionally, the Defendant argues that the marketing statements implicated in the Complaint are protected by the First Amendment, and run afoul of various statutes of limitations. [2]

For purposes of deciding the Motions to Dismiss, this memorandum takes as true the facts as alleged in the Second Amended Complaint. *See Phillips v. County of Allegheny,*

515 F.3d 224, 233 (3d Cir.2008). For the reasons that follow, Defendant's Motion to Dismiss is DENIED IN PART and GRANTED IN PART.

A. *12(b)(6)*

In deciding a motion to dismiss pursuant to Rule 12(b)(6), courts must accept all factual allegations as true, construe the ***364** complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief. *Id.* (internal quotation and citation omitted). Complaints that contain only "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009) (citing *Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955 (2007)). The facts must demonstrate that the Plaintiff is entitled to relief, not just show a "mere possibility of misconduct." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir.2009) (quoting *Iqbal* at 679, 129 S.Ct. 1937). This standard asks that the complaint " 'state a claim to relief that is plausible on its face.' " *Ashcroft v. Iqbal*, 556 U.S. 662, 663, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.' " *Iqbal*, 556 U.S. at 679, 129 S.Ct. 1937 (quoting *Twombly*, 550 U.S. at 557, 127 S.Ct. 1955). in *Ashcroft v. Iqbal*, the Supreme Court clarified that this standard applies to all civil cases. *Iqbal*, 129 S.Ct. at 1949.

When deciding a motion to dismiss under 12(b)(6), the "court must consider only the complaint, exhibits attached to the complaint, matters of public record, as well as undisputedly authentic documents if the complainant's claims are based upon these documents." *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir.2010). Assessing the sufficiency of a complaint is "a context-dependent exercise" because "[s]ome claims require more factual explication than others to state a plausible claim for relief." *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 98 (3d Cir.2010) (cited in *United States ex rel. Galmines v. Novartis Pharms. Corp.*, 2013 WL 4511626, 2013 U.S. Dist. LEXIS 120672 (E.D.Pa. Aug. 23, 2013)) (citations omitted).

B. *9(b)*

Fed.R.Civ.P. 9(b) states "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed.R.Civ.P. 9(b). The aim of this heightened pleading standard is "to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral and fraudulent behavior." *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir.1984). This standard "requires, at a minimum, that plaintiffs support their allegations of ... fraud with all of the essential factual background ... that is, the who, what, when, where and how of the events at issue." *United States of America ex rel. Ronald J. Streck v. Allergan, Inc.*, 894 F.Supp.2d 584, 601 (E.D.Pa.2012) (citing *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir.2002)). [3]

***365** III. *FCA IN GENERAL*

Count One of the Amended Complaint alleges a violation of § 3729(a)(1)(A) of the FCA, and Count Two alleges violations of § 3729(a)(1)(B). [4] AC ¶¶ 161–73. These sections of the statute impose liability on:

> [A]ny person who—
>
> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim[.]

31 U.S.C. § 3729(a)(1). Moreover, the FCA defines "knowingly" as when a defendant

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

31 U.S.C. § 3729(b).

[1] To establish a claim under § 3729(a)(1)(A) of the FCA, a relator "must prove that '(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent.' " *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 304–05 (3d Cir.2011) (quoting *United States ex rel. Schmidt v. Zimmer, Inc. ("Zimmer I")*, 386 F.3d 235, 242 (3d Cir.2004)) (referring to previous codification of the statute as § 3729(a)(1)). Section 3729(a)(2)(B) differs in that "liability is premised on the presentation of a 'false record or statement to get a false or fraudulent claim paid or approved.' " *Id.* at 306–07 (quoting *Shaw v. AAA Eng'g & Drafting, Inc.*, 213 F.3d 519, 531 (10th Cir.2000)) (referring to statute as ***366** 3729(a)(2), its previous codification). In contrast, "section 3729(a)(1)[(A)] requires only that a claimant present a 'false or fraudulent claim for payment or approval' without the additional element of a 'false record or statement.' " *Id.* Thus § 3729(a)(1)(A) allows a relator to bring a claim based on a defendant submitting a claim for government funds without explicitly making a false statement. *See id.*

[2] Based on this interpretation, the Third Circuit decided in *Wilkins* that "there are two categories of false claims under the FCA: a factually false claim and a legally false claim." *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 305 (3d Cir.2011) (quoting *U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir.2008)). "A claim is factually false when the claimant misrepresents what goods or services that it provided to the government and a claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation which is a condition for government payment. A legally false FCA claim is based on a 'false certification' theory of liability." *Id.* (citing *Rodriguez v. Our Lady of Lourdes Med. Ctr.*, 552 F.3d 297, 303 (3d Cir.2008), overruled in part on other grounds by *U.S. ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 129 S.Ct. 2230, 173 L.Ed.2d 1255 (2009)).

[3] **[4]** Within the theory of false certification, there are two further categories: express and implied false certification. *See id.* A defendant violates the FCA under express false certification when, in conjunction with a request for Federal funds, it certifies that it is in compliance with regulations that are requirements for payment. *See id.* An FCA violation occurs under implied false certification when a defendant submits or causes to be submitted a request for payment without disclosing that it is in violation of a regulation that affect its eligibility for payment. *See id.* For a relator to succeed under this theory, the Third Circuit has required relators to show "that if the Government had been aware of the defendant's violations of the Medicare laws and regulations that are the bases of a plaintiff's FCA claims, it would not have paid the defendant's claims." *Id.* at 307.

IV. *OFF–LABEL PROMOTION AS A BASIS FOR FCA LIABILITY*

Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301–97, the Food and Drug Administration (FDA) has authority to approve drugs for sale in interstate commerce if the manufacturer can demonstrate that the drug is safe and effective for specific intended uses. *See United States ex rel. Franklin v. Parke–Davis*, 147 F.Supp.2d 39, 44 (D.Mass.2001). The uses for which a drug has not been proven safe and effective are known as "off-label" uses. *See id.* The FDA also has the authority to prohibit drug manufacturers from marketing a drug for off-label uses, but the FDA does not interfere with the medical judgment of physicians who retain the discretion to prescribe a drug for off-label purposes. *See id.* (citing *Buckman Co. v. Plaintifs' Legal Comm.*, 531 U.S. 341, 121 S.Ct. 1012, 1018, 148 L.Ed.2d 854 (2001)); *see also In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 240 (3d Cir.2012).

Defendant argues generally that all of the uses for which Relator alleges the Defendant marketed TriCor fell within the ambit of TriCor's FDA approved indications. *See generally* MTD, 20–25. Even if the uses were off-label, Defendant adds, the FDA's off-label marketing regulations are not conditions of payment under Medicare, Medicaid (under state or federal regulations), FEHBP, or TRICARE; instead ***367** "medical necessity" is the proper condition of payment. *See generally* MTD, 25–36.

Relator alleges in the Amended Complaint:

> Abbott's deceptive and off-label marketing of TriCor resulted in TriCor becoming 'misbranded' under the Food, Drug and Cosmetic Act. It was and is a violation of federal law to introduce a misbranded drug into interstate commerce, or to cause a drug in interstate commerce to become misbranded. 21 U.S.C. § 331(a) and (b).

AC ¶ 9. Relator does not allege that this violation in itself gives rise to false claims for reimbursement under government programs, but instead alleges under the false certification theory that the off-label uses for which Abbott marketed TriCor were "not reasonable and necessary for treatment," which makes those uses ineligible for reimbursement under Medicare and Medicaid regulations. *Id.* at ¶¶ 10–11. Because Abbott, through its false and misleading marketing, knowingly caused physicians to submit claims for reimbursement for off-label uses that did not meet the requirement for payment of medical necessity, it is liable for causing the submission of false claims under the FCA. *Id.*

For an FCA complaint to survive a 12(b)(6) motion under an implied false certification theory, a relator does not need to produce a specific instance of a false claim. *Id.* at 308 ("[we] never have held that a plaintiff must identify a specific claim for payment at the pleading stage of the case to state a claim for relief."). However, the Third Circuit has noted that a specific false claim is a requirement for a complaint to survive 9(b) for certain regulatory violations that may underlie an FCA claim. *See id.* (where underlying regulatory violation related to marketing under Medicare Advantage program) (citing *Ebeid ex rel. U.S. v. Lungwitz*, 616 F.3d 993, 998–99 (9th Cir.2010)). The District Courts within the Third Circuit are split as to this 9(b) requirement of a specific claim for other kinds of regulatory violations, but the Eastern District of Pennsylvania and the District of New Jersey have held that claims of off-label marketing violations do not require the production of a specific false claim in the relator's complaint. *See Underwood*, 720 F.Supp.2d 671, 679 (E.D.Pa.2010), *U.S. ex rel. Simpson v. Bayer Corp.*, No. 05–3895, 2013 WL 4710587 at *13, 2013 U.S. Dist. LEXIS 124928 at *43 (D.N.J. Aug. 30, 2013), *but see United States ex rel. Wilkins v. United Health Group, Inc. (Wilkins II)*, 2011 WL 6719139, 2–3, 2011 U.S. Dist. LEXIS 146448, 6–8 (D.N.J. Dec. 20, 2011) (dismissing under 9(b) an Anti–Kickback–based FCA claim for lacking specificity).

A. Off–Label Marketing Under 12(b)(6)

When arguing an implied (or express) false certification theory, the relator "must show that compliance with the regulation which the defendant allegedly violated was a condition of payment from the Government" in order to survive a 12(b)(6) motion. *Id.* at 309. A "condition of payment" is distinct from a "condition of participation" in a program such as Medicare or Medicaid. *Id.* A condition of participation, when violated by a defendant, does not sustain an FCA claim under an implied certification theory. [5]

In the Amended Complaint, the Relator claims:

> ***368** Generally, no payments may be made under the Medicare and Medicaid programs for expenses incurred for items and services, including drugs that are not 'reasonably necessary' for the diagnosis and treatment of an illness or injury. See, 42 U.S.C. § 1395y(a)(1)(A). Medicare, Medicaid and other government funded health insurance payors, such as TRICARE and the Federal Employee Health Benefits Program do not cover and pay for off-label uses of prescription drugs, except for in very limited circumstances not applicable here. The off-label uses that were the object of Abbott's illegal marketing scheme were not 'reasonable and necessary.'

AC ¶ 10.

Relator also alleges that there was a chain of causation from Abbott's off-label marketing to the reimbursement of TriCor prescriptions for medically unnecessary uses:

> As a direct result of Abbott's illegal off-label marketing and misbranding of TriCor, physicians prescribed TriCor for off-label uses and/or for uses which were not reasonable and necessary for treatment and claims for reimbursement for off-label uses and medically unnecessary uses of TriCor were submitted to the federal government and the States in connection with such prescriptions, giving rise to liability under their respective False Claims Acts. The United States and the States would not have paid these claims for TriCor but for Abbott's illegal and fraudulent conduct.

AC ¶ 11.

The Third Circuit has held that in order to properly allege causation, the illegal marketing scheme must be a "substantial factor" in influencing third parties, such as physicians to file false claims. [6]

[5] The Defendant asserts that the Amended Complaint does not allege that compliance with the regulatory prohibition on off-label marketing is a precondition of payment. MTD, 22. However, based on the excerpt above from ¶ 10, the Complaint clearly states that drugs must be "reasonably necessary" to be reimbursed under Medicare and Medicaid, that drugs cannot be prescribed for off-label uses in order to be reimbursed under TRICARE or the FEHBP, and that the off-label uses for which Abbott marketed TriCor were not "reasonable and necessary." AC ¶ 10. [7] This fulfills the requirement articulated in *Wilkins* that Relator must demonstrate that the alleged regulatory violation be of a requirement for payment under federal programs. *See Wilkins*, 659 F.3d at 309.

Defendant also argues, correctly, that the absence of off-label marketing is not a ***369** precondition of payment *per se;* instead it is a precondition that the drugs be prescribed for purposes that are in the "much broader category of 'medically accepted' indications [for which] reimbursement extends to prescriptions that are 'reasonable and necessary.' " MTD, 26. The Defendant goes on to note that a drug indication is "medically accepted" for Medicare and Medicaid reimbursement purposes, 42 U.S.C. § 1395y(a)(1)(A), if it is an FDA-approved indication, *or* a use "supported by one or more citations in a medical compendium, 42 U.S.C. § 1396r–8(k)(6)." In turn, § 1396r–8(k)(6) cites to § 1396r–8(g)(1)(B)(i), which lists three approved compendia. [8] Defendant argues that one of these compendia supports the lipid-lowering and good-cholesterol-raising health benefits of fenofibrates such as TriCor. MTD, 28–29.

Generally, Relator alleges that "clinical studies of TriCor did not support its efficacy and/or safety for the off-label and medically unnecessary uses Abbott instructed its sales representatives promote." AC ¶ 14. Relator then goes on to allege more specifically that TriCor is described on its label as a "lipid regulating agent," and that it is an "adjunctive therapy to diet for treatment of adult patients with certain types of hyperchol esterolemia, mixed dyslipidemia, or hypertriglyceridemia." *Id.* at ¶ 56–57. Additionally, "TriCor is not approved or indicated as a first-line drug for treatment for diabetic patients," or as a "combination therapy with statin drugs." *Id.* at ¶ 59–60. The Eastern District of Pennsylvania, in *Galmines*, found that it is sufficient for a relator to allege that an off-label use of a drug is medically *risky* in order to assume that the relator means the off-label use was medically unnecessary. *See Galmines*, 2013 WL 2649704 at *7, 2013 U.S. Dist. LEXIS 83100 at *19. The Eastern District also allowed an AKS and off-label-marketing-based FCA claim to survive a motion to dismiss without any discussion of medical necessity due to the marketing being intertwined with illegal kickbacks. *See Underwood*, 720 F.Supp.2d 671, 680. The District of New Jersey's ruling in *Simpson*, however, diverges from the Eastern District, finding that off-label uses of drugs may be "reasonable and necessary," and therefore covered, if those uses are "supported by a listing in a major drug compendium." *Simpson*, 2013 WL 4710587, at *10–*11, 2013 U.S. Dist. LEXIS 124928, at *35–*36. *Galmines*, however, repeatedly cites to *United States ex rel. Franklin v. Parke–Davis*, 147 F.Supp.2d 39 (D.Mass.2001), in which the court distinguished truthful off-label marketing, which it did not address, from off-label marketing comprised of "knowingly making false statements to doctors." *Franklin*, 147 F.Supp.2d 39, at 52. The latter form of off-label marketing makes it foreseeable that claims could be submitted for uncovered off-label uses induced by the fraudulent statements of the drug manufacturer. *Id.* And, indeed, Relator ***370** alleges in the Amended Complaint that Abbott marketed TriCor for off-label uses which were risky and made false and misleading representations to physicians, to wit:

> Abbott also improperly promoted TriCor for use in combination with highly popular statin drugs even though TriCor was not approved for use in combination with statins by the FDA, and despite ***specific warnings*** regarding combined use with statins contained in the FDA-mandated product labelling. Abbott also made regular representations concerning the efficacy of TriCor which were contrary to the FDA required labeling, **were false and misleading,** and which did not represent the FDA required fair

> balance of information regarding uses and **risks.**

AC ¶ 7 (bold emphasis added). Relator further details such false and misleading claims in Section V.E. of the Amended Complaint. *See* AC ¶ 96–108.

Therefore, based on numerous allegations made in Relator's Amended Complaint about the off-label marketing of TriCor being based on false or misleading studies and the risks associated with those off-label uses, the Amended Complaint fulfills the pleading requirements under 12(b)(6). *See* AC ¶ ¶ 61–108; *see also Galmines,* 2013 WL 2649704 at *3, 2013 U.S. Dist. LEXIS 83100 at *8.

B. TRICARE and FEHBP

Defendant also maintains that the uses for which Relator alleges Defendant marketed TriCor are eligible for reimbursement under TRICARE and FEHBP because they fall within the category of "medically accepted indications." MTD, 27. [9]

[6] Defendant, however, misconstrues Relator's citation of regulations for TRICARE, 32 C.F.R. § 199.4(g)(15)(i)(A), which generally does not cover off-label prescriptions unless "review[ed] for medical necessity, [which] requires demonstrations from medical literature, national organizations, or technology assessment bodies that the unlabeled or off-label use of the drug is safe, effective and in accordance with nationally accepted standards of practice in the medical community." *See* MTD, 27 (citing AC ¶ 150–51) (citing 32 C.F.R. § 199.4(g)(15)(i)(A)); *see also* § 199.4(g)(15)(i)(B)-(D). Relator also cites a similar regulation for FEHBP denying coverage for off-label uses unless proven medically necessary. AC ¶ 158. Given these even stricter regulations for TRICARE and FEHBP, the chain of causation is even stronger between off-label marketing and the submission of claims for reimbursement for uses that violate a condition of payment. Thus, the Complaint survives the motion to dismiss with regard to the alleged false claims made to TRICARE and FEHBP.

C. Off–Label Marketing Under 9(b)

The Defendant argues that Relator must "identify a representative example of a specific claim or claims that are allegedly fraudulent" for the claim to satisfy 9(b), or at least provide " 'particular details of a scheme to submit false claims,' in combination with 'reliable indicia that lead to a strong inference that claims were actually submitted,' " MTD, 46–47. (quoting *Singh,* 2006 WL 2642518, at *2–*3, 2006 U.S. Dist. LEXIS 65268, at *7; and ***371** *United States ex rel. Piacentile v. Sanofi Synthelabo, Inc.*, No. 05–2927(KSH), 2010 WL 5466043, *8, 2010 U.S. Dist. LEXIS 137895, at *21 (D.N.J. Dec. 30, 2010) (quoting *United States ex rel. Grubbs v. Kanneganti,* 565 F.3d 180, 190 (5th Cir.2009))).

[7] In order for FCA claims to survive 9(b), however, this District has found that a relator **does not** need to show a specific submitted false claim if the false claims are submitted by a third party and not the defendant. *See Underwood,* 720 F.Supp.2d at 679; *Streck,* 894 F.Supp.2d at 602; *Wilkins,* 659 F.3d at 308. These third parties are usually doctors, as they are in the instant case. *Id.* [10]

Defendant cites a number of District-level cases in the Third Circuit that draw from a line of reasoning articulated in the Eleventh Circuit case, *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.,* 290 F.3d 1301, 1311 (11th Cir.2002), where the court required a relator to produce a specific false claim for payment in order for the complaint to survive 9(b). MTD, 36–37. The Third Circuit cited the rationale from *Clausen* in *United States ex rel. Quinn v. Omnicare, Inc.*, 382 F.3d 432, 434, 439–40 (3d Cir.2004), and some District Courts applied it in subsequent cases. *See United States ex rel. Bartlett v. Tyrone Hosp., Inc.*, 234 F.R.D. 113, 120 (W.D.Pa.2006); *United States ex rel. Schmidt v. Zimmer, Inc.* ("*Zimmer II*"), No. 00–1044, 2005 WL 1806502, at *1, *2–*3, 2005 U.S. Dist. LEXIS 15648, at *1, *7–*8 (E.D.Pa. July 29, 2005). However, as Defendant notes, other District-level decisions have allowed complaints to proceed without specific claims as long as they provide "alternative means of injecting precision and some measure of substantiation into their allegations of fraud." MTD, 38 (citing *Singh,* 2006 WL 2642518, at *2–*3, 2006 U.S. Dist. LEXIS 65268, at *7) (internal citations omitted); *see also* MTD, 38 (citing *United States ex rel. Piacentile v. Sanofi Synthelabo, Inc.*, No. 05–2927(KSH), 2010 WL 5466043, at *6, 2010 U.S. Dist. LEXIS 137895, at *17 (D.N.J. Dec. 30, 2010)). Defendant nevertheless maintains that even under these less stringent 9(b) standards, Relator's Complaint fails. MTD, 38. Defendant asserts that Relator's Complaint lacks sufficient detail to support the claim that Abbott's off-label marketing of TriCor directly caused physicians to submit

requests for payment for TriCor to federal programs. MTD, 47.

The Third Circuit, however, has been more open to relaxing 9(b) requirements than Defendant claims. *See Rolo v. City Investing Co. Liquidating Trust,* 155 F.3d 644, 658 (3d Cir.1998). The Eastern District notes in *Underwood* that the Third Circuit has "cautioned against overemphasizing the specificity requirement," and quotes *Rolo:*

> [Plaintiffs] need not, however, plead the date, place or time of the fraud, so long as they use an alternative means of injecting precision and some measure of substantiation into their allegations of fraud.

Underwood, 720 F.Supp.2d at 675 (quoting *Rolo,* 155 F.3d at 658 (3d Cir.1998) (internal citations omitted)). [11]

***372** The Eastern District subsequently provided greater substantive details regarding the specificity required under 9(b) in *United States ex rel. Galmines v. Novartis Pharmaceuticals Corp.,* No. 06–3213, 2013 WL 2649704, at *1, 2013 U.S. Dist. LEXIS 83100, at *2 (E.D.Pa. June 13, 2013). There, the relator alleged that the defendant marketed the drug Elidel to physicians to prescribe for children under the age of two even though the FDA did not approve Elidel for children of that age. *Galmines,* No. 06–3213, 2013 WL 2649704, at *1, 2013 U.S. Dist. LEXIS 83100, at *2. The relator alleged that the off-label marketing scheme included a study funded by the defendant which demonstrated that the drug was safe for children under the age of two, that the defendant trained marketing personnel to publicize the study and even reprimanded marketing personnel who did not present the study to physicians. *Id.* The complaint also recounted the FDA's finding that 14% of the prescriptions for Elidel were off-label and that this came to about 1.2 million off-label prescriptions. *Id.* at *1, 8, 2013 U.S. Dist. LEXIS 83100 at *3, 21. Additionally, after the FDA issued an explicit warning that Elidel posed a risk to children under two for whom Elidel was not approved, sales of the drug "dropped substantially." *Id.* at 1, 2013 U.S. Dist. LEXIS 83100 at 3. These alleged facts led the *Galmines* Court to further develop the reasoning in *Underwood* by noting that the relator "injected precision" by "pleading a myriad of details," which "are sufficiently specific both to inform [Novartis] of the 'precise misconduct' charged, and to make it unlikely that [Mr. Galmines] has commenced this action in bad faith." *Galmines,* (quoting *Underwood,* 720 F.Supp.2d 671 at 680).

[8] Here, although the off-label marketing was not as blatant as the under-age marketing and FDA-warning-flouting in *Galmines,* Relator nevertheless provides myriad details of Abbott's marketing statements that contradict its FDA-approved label. Specifically, Relator alleges that there were no clinical data supporting the use of TriCor as a first-line therapy for diabetics to treat cardiovascular morbidity and mortality, which was an off-label use. *See* AC ¶ 65. Nevertheless, Abbott directed its representatives to respond strategically to these kinds of objections from physicians and to provide studies of a different, albeit similar, drug to support the off-label claims Abbott was making about TriCor. *See* AC ¶¶ 69–73. Abbott also promoted to physicians the results of a limited study of TriCor that was not reviewed by the FDA, which supported TriCor's use in diabetics. *See* AC ¶¶ 81–83. These marketing activities, if they in fact occurred as Relator alleges, flout the provision on the FDA-approved package insert for TriCor which notes that the drug's effects on cardiovascular morbidity and mortality have not been established. *See* AC ¶ 73. Regarding the alleged off-label promotion of TriCor for use as a joint therapy with statins, the FDA warns on the TriCor label that "TriCor should be ***373** used in combination with statins only in patients where the physician has determined that the benefits of adding TriCor outweigh the risks of doing so." *See* AC ¶ 88. Relator goes on to allege "[n]ot only did Abbott's actions fail to present a balanced presentation regarding the benefits and risks of TriCor to physicians, it also endangered the very patients Abbott was purportedly trying to help." *Id.* Relator also alleges that Abbott targeted pharmacists who asked for physician confirmation or refused to fill prescriptions for TriCor when alerted that the patient was also taking a statin. *See* AC ¶ 115. Additionally, Relator's allegations of off-label marketing, much like the off-label marketing allegations in *Underwood,* were linked to the illegal kickbacks made to physicians as a means for inducing the physicians to prescribe TriCor for off-label uses. *See* AC ¶ 21.

These claims are specific and particular enough to inform Abbott of the "precise misconduct charged" and make it unlikely that Relator is proceeding in bad faith. Moreover, the Complaint details the substance of Abbott's false and misleading statements which, given that substance, plausibly could have caused the submission of reimbursements for medically unnecessary uses of TriCor, especially if Abbott were coupling those statements to illegal kickbacks. Finally, although the government has chosen not to intervene in this case, any further details about the allegedly fraudulent

conduct remain solely in the hands of the Defendant and Relator should be afforded the opportunity for discovery. *See Underwood*, 720 F.Supp.2d at 677; *see also* discussion at end of Part II, *supra*.

For the foregoing reasons, this court DENIES the Defendant's Motion to Dismiss insofar as Counts One and Two are based on federal false claims which are in turn based on off-label marketing.

V. *ANTI–KICKBACK STATUTE VIOLATIONS AS A BASIS FOR FCA LIABILITY*

In the Amended Complaint, Relator advances a theory of FCA *United States ex rel. Streck v. Allergan, Inc.*, 894 F.Supp.2d 584, 601 (E.D.Pa.2012); liability based on the Defendant's underlying violations of the AKS, and Defendant moved to dismiss this part of the Complaint based on Relator's failure to comply with the pleading requirements of F.R.C.P. 9(b), but not 12(b)(6).

The Federal AKS states in relevant part:

> (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a–7b(b)(2).

Following other Circuits, the Third Circuit has determined "[c]ompliance with the AKS is clearly a condition of payment under Parts C and D of Medicare." *Wilkins*, 659 F.3d at 314. Thus, "[f]alsely certifying compliance with the ... Anti–Kickback Act[ ] in connection with a claim submitted to a federally funded insurance program is actionable under the FCA," and can stand upon a theory of implied false certification. *See* ***374** *Wilkins*, 659 F.3d at 313 (citing *U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 94 (3d Cir.2009)).

However, on a Motion to Dismiss, the Third Circuit has only ruled on AKS-based FCA claims under 12(b)(6), and not 9(b). *Wilkins*, 659 F.3d at 313 n. 20. Nevertheless, the Third Circuit notes that under 12(b)(6), a relator who puts forward an implied false certification theory of FCA liability must allege that the defendant "received payment from the federal health insurance programs despite their knowing violation of the AKS." *Wilkins*, 659 F.3d at 313. The Third Circuit has also found that a complaint alleging an AKS-based FCA violation can meet 12(b)(6)'s causation threshold if the complaint alleges a kickback scheme large enough for the defendant to know that at least some of the claims submitted by a third-party would be kickbacktainted. *U.S. ex rel. Schmidt v. Zimmer*, 386 F.3d 235, 243–244.

Beyond that, District Courts remain split on the further pleading requirements for an AKS-based FCA claim under 9(b). For example, in *Wilkins II*, even though the relator alleged the dollar amount of the kickback given to a care provider, the District of New Jersey determined that the complaint did not satisfy 9(b) because the relator did not specify the "date, place or time of fraud," nor did the complaint contain enough "precision or substantiation" beyond the amount of the kickback. *United States ex rel. Wilkins v. United Health Group, Inc.*, 2011 WL 6719139, 2–3, 2011 U.S. Dist. LEXIS 146448, 6–8 (D.N.J. Dec. 20, 2011). Abbott Labs echoes the *Wilkins II* ruling and aligns it with its argument in the instant case that the Defendant's "[c]omplaint does not allege the 'who, what, when, where and how' of both the alleged AKS violations and the resulting false claims, as required by Rule 9(b)." However, other Courts in the Third Circuit have relaxed the pleading standard under 9(b) for such cases. In *Underwood*, the Eastern District of Pennsylvania considered whether a relator needs to produce a specific false claim when accusing a defendant company of bribing physicians with kickbacks to prescribe a drug off-label. *Underwood*, 720 F.Supp.2d at 678. The *Underwood* court determined that the relator does not need to produce a specific false claim because the relator alleged a "wide-ranging 'marketing scheme' " where the submission of false claims by third parties (i.e., the bribed physicians) can be

presumed. *Id.* at 679. The Court reasoned that it would be too onerous for a relator to obtain actual false claims submitted by third parties such as physicians or pharmacists. *See id.* at 679. The Court noted that because the FCA creates liability for "anyone who 'presents, or *causes to be presented,* a false or fraudulent claim for payment' " it would negate the second clause if, at the pleading stage, a relator had to obtain actual false claims from those who the defendant caused to present false claims. *Id.* Additionally, the court determined that when a relator alleges a kickback scheme large enough such that the submission of false claims is inevitable, then the relator has sufficiently alleged causation under 9(b). [12]

***375** **[9]** In the instant case, Relator alleges in the Complaint that Abbott provided illegal financial incentives to physicians to prescribe TriCor for off-label and medically unnecessary uses. AC ¶ 21. Relator also details how Abbott allegedly provided its representatives with funds for honoraria and meals as rewards for physicians who prescribed or encouraged other physicians to prescribe TriCor. AC ¶ 15j. Finally, Relator asserts how a lack of kickbacks is a condition of payment and that the kickbacks thus caused the submission of false claims for reimbursement. "[t]he Medicare and Medicaid programs [ ] do not cover or pay for claims for reimbursement that were the result of violations of the Medicare and Medicaid Anti-kickback statute." AC ¶ 10; *see also* AC ¶ 130. (claims "would not have been written or submitted but for Abbott's unlawful conduct").

For the foregoing reasons, this court denies the Defendant's Motion to Dismiss insofar as Counts One and Two are based on federal false claims that are in turn based on illegal kickbacks.

VI. *FIRST AMENDMENT DEFENSE*

Defendant argues that the marketing activities referred to in the Amended Complaint—whether off-label or not—are protected by the First Amendment and therefore cannot be subject to civil liability under the FCA. MTD, 44–46. The Defendant cites Supreme Court precedent holding that the government has no interest in protecting the public from —and thus restricting—truthful commercial speech. MTD, 44. Based on the Supreme Court's ruling in *Sorrell v. IMS Health Inc.*, —— U.S. ——, 131 S.Ct. 2653, 180 L.Ed.2d 544 (2011), Defendant argues that First Amendment protection necessarily extends to off-label marketing. MTD, 45. Moreover, Defendant cites cases from the Third, Ninth, and DC Circuits to argue that even the imposition of civil liability can cause just as much of a chilling effect as regulatory or criminal sanctions. MTD, 45. (citing *In re Orthopedic Bone Screw Prods. Liability Litig.*, 193 F.3d 781, 792 (3d Cir.1999); *Boehner v. McDermott*, 484 F.3d 573, 579–80 (D.C.Cir.2007); and *Monteiro v. Tempe Union High School Dist.*, 158 F.3d 1022, 1029 (9th Cir.1998)).

[10] Relator responds to this argument by reiterating the allegations from Relator's Complaint that Abbott marketed TriCor by making "false and misleading statements." *See* RMTD, 72 (citing AC ¶¶ 6–7). Relator also notes that the Supreme Court has ruled that "[u]ntruthful speech, commercial or otherwise, has never been protected for its own sake." (citing *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 771, 96 S.Ct. 1817, 48 L.Ed.2d 346 (1976)) (citing *Gertz v. Robert Welch, Inc.*, 418 U.S. 323, 340, 94 S.Ct. 2997, 41 L.Ed.2d 789 (1974)) (quotation marks omitted). This principle was more fully articulated in *Central Hudson Gas & Elec. Corp. v. Public Service Commission of New York*, 447 U.S. 557, 100 S.Ct. 2343, 65 L.Ed.2d 341 (1980), where the Court wrote: "[f]or commercial speech to come within [the First Amendment], it at least must concern lawful activity and *not be misleading.*" (emphasis added). This holding has been cited favorably by the Third Circuit at least twice, and has recognized more generally a governmental interest in regulating advertisements to ensure their truthfulness. *See American Future Systems, Inc. v. Pennsylvania State University*, 688 F.2d 907, 913 (3d Cir.1982); *Ad World, Inc. v. Doylestown Tp.*, 672 F.2d 1136, 1139 n. 6 (3d Cir.1982) ("Advertisements may be regulated to insure their truthfulness and to prevent harm to the public."); *U.S. Healthcare, Inc. v. Blue Cross of Greater Philadelphia*, ***376** 898 F.2d 914, 928 (3d Cir.1990) ("In the context of government restriction of speech, false and misleading commercial speech have no First Amendment value."). Because Relator has alleged that Defendant's marketing of TriCor included false and misleading statements, and, under a 12(b)(6) analysis, these allegations must be accepted as true, this Court finds that Abbott's commercial speech does not warrant First Amendment protection at this stage.

VII. *STATUTE OF LIMITATIONS*

Defendant claims that:

> Actions under the FCA are subject to a statute of limitations of six years. 31 U.S.C. § 3731(b)(1). The limitations period begins to run on the date that the

> first request for payment is allegedly made. United States ex rel. *Bauchwitz v. Holloman*, 671 F.Supp.2d 674, 686 (E.D.Pa.2009).... In any event, because Relator filed her complaint on September 18, 2009, the applicable six-year statutory limitations period requires that Counts I and II be dismissed to the extent they relate to alleged false claims submitted prior to September 18, 2003.

MTD, 50–51. Defendant also notes that "[t]his Court has held that 'the three-year tolling period in [31 U.S.C.] § 3731(b)(2) does not apply in cases where the government does not intervene.' *Bauchwitz*, 671 F.Supp.2d at 694–95." MTD, 50 n. 20. Relator acknowledged this argument and agrees Counts I and II be dismissed insofar as they alleged false claims made before September 18, 2003, which is six years prior to the date Relator filed the original Complaint. Reply to the MTD, 78.

Relator then retracted this acquiescence in a Supplemental Reply to Defendant's Motion to Dismiss filed on March 29, 2013. Relator cited a Fourth Circuit case which decided that the statute of limitations for non-intervened FCA claims is tolled under the Wartime Suspension of Limitations Act (WSLA), 18 U.S.C. § 3287. SRMTD, 3. (citing *United States ex rel. Benjamin Carter v. Halliburton et al.*, 710 F.3d 171 (4th Cir.2013)). The WLSA applies to Relator's claims and suspends the statute of limitations because of the United States' war in Iraq. SRMTD, 4. The Fourth Circuit determined that the war began on October 11, 2002, when Congress formally authorized the President to use military force. *Id.* Relator argues that the war continued until at least 2010 although it acknowledges that courts disagree as to whether Congress and the President have formally ended the war. *Id.*

In response, Defendant notes that *Carter* is a Fourth Circuit case, and, as such, is not binding on this court. Substantively, Defendant argues that *Carter* is an anomalous case for the Fourth Circuit anyway because it deviates from the Fourth Circuit's previous holding on statutes of limitations for the FCA in *United States ex rel. Sanders v. North American Bus Indus., Inc.*, 546 F.3d 288, 293 (4th Cir.2008) (*cert. denied*, 557 U.S. 904, 129 S.Ct. 2793, 174 L.Ed.2d 291 (2009)). *Sanders* does not deal with the WSLA specifically, but it does hold that the FCA's own statutory tolling provision does not apply to non-intervened cases, a point which the dissent to *Carter* emphasizes. The *Carter* dissent also notes that the Fourth Circuit has never held "(other than in dicta) that the WSLA applies to civil cases where the United States is not a plaintiff or intervenor in the *qui tam* action." RSRMTD, 3 n. 3 (citing *Carter*, 710 F.3d at 189 (Agee, J., dissenting)). Defendant also points to the legislative history of the WSLA and the early case law following its passage in 1942 which indicate that Congress's intent for the WSLA was to relieve the Government's burden during wartime of having to bring cases against parties alleged to have defrauded the government in connection ***377** with the war effort. This interpretation of the law is supported by the dissent *Carter*, which in turn argues that the Supreme Court in *Bridges v. U.S.*, 346 U.S. 209, 216, 73 S.Ct. 1055, 97 L.Ed. 1557 (1953), and the legislative history of the 2008 amendments to the WSLA reinforce this interpretation.

The Third Circuit has only cited the WSLA in *U.S. v. Levine*, 658 F.2d 113, 120 n. 7 (3rd Cir.1981), and did so in a footnote to make a point unrelated to the issues here. Moreover, very few civil cases from the Eastern District of Pennsylvania involve the WSLA and none of those involve private relators proceeding in civil cases without the government's intervention. *See U.S. v. Salvatore*, 140 F.Supp. 470 (E.D.Pa.1956); *U.S. v. Covollo*, 136 F.Supp. 107 (E.D.Pa.1955); *U.S. v. Kolsky*, 137 F.Supp. 359, 361 (E.D.Pa.1955) (holding that the WSLA applies to civil cases brought by the government, not just criminal cases); *U.S. v. Murphy–Cook & Co.*, 123 F.Supp. 806 (E.D.Pa.1954).

[11] The Eastern District has, however, held that the FCA's own tolling provision does not apply to cases where the government has chosen not to intervene. *U.S. ex rel. Bauchwitz v. Holloman*, 671 F.Supp.2d 674, 694–95 (E.D.Pa.2009). The Eastern District decided this based on the Supreme Court's reversal of a Third Circuit decision to the contrary in resolution of a circuit split. *See United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 129 S.Ct. 2230, 173 L.Ed.2d 1255 (2009); *Rodriguez*, 552 F.3d 297 (3d Cir.2008). The most penetrating analysis of *Carter* from within the Third Circuit comes from a memorandum opinion of the Western District of Pennsylvania, which has found that the tolling provisions of the WSLA do not apply in non-intervened FCA cases. *U.S. ex rel. Emanuele v. Medicor Associates*, Slip Copy, 2013 WL 3893323, 2013 U.S. Dist. LEXIS 104650 (W.D.Pa. Jul. 26 2013). The court based this decision on the dissent from *Carter* and that dissent's analysis of the legislative history of the WSLA and its policy arguments. *See id.* at *2, 2013 U.S. Dist. LEXIS 104650, at *5–*7. The court also cited the early case law on the WSLA (quoting *United States v. Smith*, 342 U.S. 225, 228–29, 72

S.Ct. 260, 96 L.Ed. 252 (1952)), and the court's previous decision (like the Eastern District *supra*) not to extend the FCA's tolling provision to non-intervened cases. *See id.* at *2, 2013 U.S. Dist. LEXIS 104650, at *5–*7 (stating that FCA's tolling provision "parallels" WSLA). The Western District held that the WSLA does not toll the FCA's statute of limitations for relators without the government's intervention, especially when those cases do not involve military or war-related contracts, and this court follows suit. *Id.* at *2–*3, 2013 U.S. Dist. LEXIS 104650, at *7.

For the foregoing reasons, this court grants the Defendant's Motion to Dismiss with regard to all of Relator's allegations based on federal false claims made before September 18, 2003.

VIII. *STATE LAW CLAIMS*

The above analysis of Relator's federal FCA claims under Rules 12(b)(6) and 9(b) also applies to Relator's state law claims. However, Defendant contends that some state law claims should be dismissed for other reasons, and Relator has provided a response to each of those reasons. The arguments for and against dismissal are as follows:

(1) Certain states have decided to not intervene in the litigation. MTD, 53.

- Relator has agreed to voluntarily dismiss the New Hampshire (Count Nineteen) and New Mexico (Count Twenty) claims based on the states' nonintervention, but maintains that ***378** the claims in Delaware (Count Five) and Texas (Count Fifteen) must stand. RMTD, 64.

(2) Some state laws were not in effect at the time of the alleged misconduct and do not apply retroactively. MTD, 58–62.

- "Recognizing this presumption against retroactivity, Relator concedes that with respect to those states where the state FCA statute was enacted during the time period covered by the Amended Complaint, and where the state FCA did not specifically provide for retroactive application, the following limitations on Relator's recovery of the state portion of any Medicaid recovery apply based upon the enactment dates of the state statutes at issue ..." However, Relator maintains that the Massachusetts (Count Eleven), Tennessee (Count Fourteen), and Wisconsin (Count Twenty–Six) statutes explicitly allow for retroactive application. RMTD, 78–84.

(3) Some claims are barred by the states' statutes of limitations. MTD, 62–63.

- Relator concedes that the federal six year statute of limitations applies to these state statutes. Texas's four-year statute of limitations does not apply. RMTD, 91–92.

- The Texas statute of limitations is moot due to the lack of intervention which bars claims from before May 4, 2007 as discussed in (1).

(4) Relator is prohibited from bringing suit under the Tennessee statute. MTD, 63.

- The Tennessee False Claims Act, although it limits recovery for conduct that also violates the Medicaid False Claims Act, does not act as a bar to bringing claims under both. RMTD, 93–94.

In addition to the claims under the laws of New Hampshire (Count Nineteen) and New Mexico (Count Twenty), Relator has also agreed to "Dismiss Count Twenty–Three Alleging Violations of Michigan Law, As Duplicative of Relator's Allegations in Count Twenty–Two." RMTD, 94.

The Court now looks at the above four arguments in turn.

1. Non–Intervention

Defendant argues that Delaware False Claims and Reporting Act ("DCFRA"), Del.Code tit. 6, § 1203(b)(2), was amended in July 2009 and that because the false claims that Relator alleges occurred before July 2009, the prior version of the statute applies. MTD, 57 n. 26. The prior version of the statute requires that the Delaware Attorney General conduct an investigation and proceed with the litigation or certify that there is "substantial evidence" of a violation for the relator to proceed alone. *Id.* Because the Attorney General neither proceeded with the litigation nor certified that there was "substantial evidence" for Relator's claims, Defendant claims that Count Five must be dismissed. *Id.*

With regard to the claims brought under Texas law, Defendant argues essentially the same point for Texas Medicaid Fraud Prevention Act ("TMFPA"), Tex. Hum. Res.Code § 36.001 et seq., which, until May 4, 2007, required the dismissal of qui tam lawsuits in which the state does not

intervene within 60 days after being served with the suit. Thus, Count Fifteen must be dismissed insofar as it includes violations alleged by Relator which occurred before the May 4, 2007 amendment.

Relator counters by noting that the case law to which the Defendant refers involves suits that were filed before the dates of the ***379** statutes' respective amendments. *See United States ex rel. Streck v. Allergan, Inc.*, 894 F.Supp.2d 584 (E.D.Pa.2012); *United States ex rel. Conrad v. GRIFOLS Biologicals Inc.*, No. RDB 07–3176, 2010 WL 2733321, at *6–*7, 2010 U.S. D. Dist. LEXIS 68775, at *21 (D.Md. July 9, 2010); *United States ex rel. King v. Solvay S.A.*, 823 F.Supp.2d 472, 521–522 (S.D.Tex.2011), [*Solvay I*], *vacated in part on other grounds on reconsideration by* 2012 WL 1067228, 2012 U.S. Dist. LEXIS 42482 (S.D.Tex. Mar. 28, 2012) [Solvay II] (all three cases dismiss the Delaware claims because the suits were filed before the amendment which would allow the relator to proceed, *Streck* also finds that because the suit was filed after the amendment of the Texas statute, it survives but only as it applies to fraudulent transactions occurring after the amendment). [13] Relator stresses that the undisputed date of the suit's filing is September 18, 2009 and that the suit should be allowed to proceed under the Texas statute which was amended on May 4, 2007, and the Delaware statute, which was amended on July 16, 2009.

Because Relator filed the suit after the amendment of both the Texas and the Delaware statute, the suits are not barred for the states' failure to intervene; or, in the case of Delaware for the state's failure to certify that there is "substantial evidence" of a violation. However, these amendments do prevent certain fraudulent transactions underlying the suit from being included. Because *Streck* is the most recent case law on point from this District, this court relies on its holding that "for any conduct after this [Delaware] amendment, Plaintiff's claims could proceed to the same extent as Plaintiff's federal claims ... Plaintiff's claims under Delaware law may proceed for [administrative claims] filed from July 16, 2009, onward." For the Texas claims, this district has stated "Plaintiff's claims must be dismissed for any [administrative claims] submitted before [the] statute's effective date."

[12] Here, Relator alleges that the fraudulent conduct took place "[s]tarting no later than 2000, and continuing until at least 2008, and upon information and belief continuing to the present." AC ¶ 12. Relator cites a Statement of Interest filed by the State of Texas which explains that relators may bring suits based on conduct dating from September 1, 1995, when the original Texas Medicaid Fraud Prevention Act was enacted, because possible defendants are on notice of the proscribed conduct from that date. RMTD, 80–81. The Statement reasons that even though Relator's rights were more limited before the 2007 amendment to the Texas law, the State could bring a suit from the original passage in 1995. *Id.* at 81. Relator also cites Delaware case law which interprets the statute with an emphasis on legislative intent in order to argue that the main purpose of the Delaware statute, like that of the Texas statute is to enhance the power of the state to recover fraudulently obtained funds. *Id.* (citing *See Cordero v. Gulfstream Dev. Corp.*, 56 A.3d 1030, 1032 (Del.2012)). Moreover, the State of Texas, in its statement, claims that the "conduct" that the amendment refers to is the decision of the State to intervene or not, as opposed to the underlying fraudulent transactions. *Id.* at 82. Relator cites the case, *Solvay I*, 823 F.Supp.2d at 521–22, ***380** which arrives at this same conclusion. *Id.* Within the Eastern District, however, the court in *Streck*, specifically rejects the reasoning in *Solvay I* and instead relies on contrary case law to arrive at the conclusion that with regard to the Texas statute, the "Plaintiff's claims must be dismissed for any [administrative claims] submitted before [the] statute's effective date." [14] *Streck*, 894 F.Supp.2d at 604. Relator attempts to distinguish the contrary case law that the *Streck* court relies on since both of the cases that *Streck* cites involved complaints filed before the amendment to the Texas statute RMTD, 82–83 (citing *U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, 778 F.Supp.2d 709, 713, 724 (N.D.Tex.2011); and *U.S. ex rel. Lisitza v. Johnson & Johnson*, 765 F.Supp.2d 112, 130–31 (D.Mass.2011), *reconsideration denied*, CIV.A. 07–10288–RGS, 2011 WL 1827357, 2011 U.S. Dist. LEXIS 50796 (D.Mass. May 12, 2011)). [15] However, *Solvay I* also involved a complaint filed before the amendment; although Texas's decision not to intervene occurred after the amendment, leading the court to interpret the non-intervention as the relevant "conduct" to which the amended, intervention-requirement-free, law applied. *Solvay I*, 823 F.Supp.2d at 521–22. Nevertheless, the *Streck* court resolved the matter definitively for the Eastern District by allowing claims under the Texas statute to proceed without intervention if filed after the date of the amendment, but only as they pertain to fraudulent conduct occurring after the date of amendment. *See Streck*, 894 F.Supp.2d at 604. Thus, this court dismisses Count Fifteen as it applies to allegedly fraudulent conduct that occurred before May 4, 2007.

In the case of Delaware, since the pre-amendment statute also allowed non-intervened claims to proceed with a determination by the state that there was "substantial evidence" of a violation, further analysis is required. Defendant notes that Relator has not alleged in the complaint that the State of Delaware has filed a determination of "substantial evidence." MTD, 57 n. 26; *see also* ***381** RRMTD, 9. Relator responds by pointing to *Solvay I* which observes:

> There is no contention that the Delaware Attorney General determined that there was substantial evidence that a violation of Delaware's FCA occurred. However, [Defendant] has failed to explain how dismissal under Rule 12(b)(6) is appropriate. The Substantial Evidence Section does not state that the Delaware Attorney General must notify the *court* of its determination regarding substantial evidence, and Relators are not required on a Rule 12(b)(6) motion to come forward with evidence. Relators could not have alleged in their complaint that the Delaware government had issued such a notice since the statute does not require such a notification until after the complaint is filed. [Defendant's] motion to dismiss the Delaware False Claims and Reporting Act claim (Count 10) because the Delaware Attorney General has failed to provide notice that the Relators may proceed is DENIED.

RMTD, 83 (quoting *Solvay I*, 823 F.Supp.2d at 520).

Admittedly, the court in *Solvay I* raised an interesting argument about the apparent Catch–22 of factoring in Delaware's "substantial evidence" determination at the summary judgment stage where evidence is not yet required in the pleading. *See id.* However, once again, the Eastern District has made a more focused and definitive ruling. In *Streck*, the relator filed the initial complaint on October 28, 2008, followed by four amended complaints with the fourth filed on September 29, 2011. Delaware amended its statute to no longer require a finding of "substantial evidence" on July 16, 2009. Consequently, the *Streck* court ruled to dismiss the Delaware claims, except for claims based on fraudulent conduct that occurred from the day of the amendment onward.

[13] Here, the Complaint was filed after the Delaware amendment, on September 18, 2009; and, just as in *Streck*, Delaware neither intervened nor found "substantial evidence" for any claims arising from the pre-amendment fraudulent conduct which Relator alleges. Granted, in this case, Delaware did not need to intervene or find "substantial evidence" because the Complaint was filed after the amendment; whereas, in *Streck*, where the complaint was filed before the amendment, the state of Delaware did have a chance to intervene or find "substantial evidence" and did neither. Moreover, the Eastern District decided in a more recent FCA case to dismiss the Delaware claims for lack of a "substantial evidence" determination because the original complaint was filed in 2006 when the old statute applied. *See Dale v. Abeshaus*, 2013 WL 5379384, *14–*15, 2013 U.S. Dist. LEXIS 138634, *55–*56 (E.D.Pa. Sept. 26, 2013). The Eastern District has not decided on a complaint filed post-amendment based on pre-amendment conduct. Thus, the court turns to Delaware state law on retroactivity, which presumes that laws are not meant to operate retrospectively. When applied to the Delaware False Claims and Reporting Act, the State has ruled—albeit for a complaint filed before the amendment—the old version of the statute applies. *See United States ex rel. Conrad v. GRIFOLS Biologicals Inc.*, No. RDB 07–3176, 2010 WL 2733321, at *6, 2010 U.S. Dist. LEXIS 68775, at *20–*21 (D.Md. July 9, 2010) (citing *Wilson v. Triangle Oil Co.*, 566 A.2d 1016, 1018 (Del.Super.Ct.1989)) ("Delaware courts will not infer an intention to make an act retroactive."); *id.* (citing *Whaley v. Allstate Ins. Co.*, 595 F.Supp. 1023, 1027 (D.Del.1984)) ("[I]f there is any doubt whether an amendment was intended to operate retrospectively, the doubt must be resolved against such operation.") (emphasis ***382** in original). Given Delaware's strong presumption against retroactivity as articulated in *Whaley* and *Wilson*, and the lack of any case law allowing a non-intervened claim without a finding of "substantial evidence" to proceed insofar as it is based on pre-amendment fraudulent conduct, this court dismisses Count Five insofar as it is based on conduct from before July 16, 2009.

2. Retroactivity

Defendant argues that certain counts from Relator's Amended Complaint should be dismissed insofar as they apply to

conduct that occurred before the date that relevant state statutes were enacted or adopted qui tam provisions. [16]

Relator concedes eleven (11) counts, [17] and notes that the conceded dismissals only apply to the state portions of any Medicaid recoveries before those dates. *Id.* at 84, 84 n. 23.

[14] Relator does not concede the following (3) counts, contending that:

> [w]ith respect to the state statutes for Massachusetts (Count Eleven), Tennessee (Count Fourteen), and Wisconsin (Count Twenty–Six), however, the statutes' effective dates do not end the analysis, as all three of those states' statutes explicitly allow for retroactive application so long as the conduct is otherwise actionable under the statutes of limitations provided therein.

Id. at 86. Relator explains that the Massachusetts statute, which was enacted July 1, 2000, has a six-year statute of limitations. *Id.* (citing Mass. Gen. Laws Ann. ch. 12, § 5K (West)). Therefore, even if this court were to find that the statute applies retroactively to conduct occurring before that date, the statute of limitations only allows allegations to proceed if they are based on conduct occurring after September 18, 2003, which is six years before Relator's filing date. *See id.* Tennessee and Wisconsin, however, have ten-year statutes of limitations and their enactment dates are July 1, 2001, and October 27, 2007, respectively. *See id.* (citing Tenn.Code Ann. § 4–18–106 (West); and Wis. Stat. Ann. § 20.931 (West)). Given that Relator filed the Complaint on September 18, 2009, these statutes could allow Relator's claims to proceed based on conduct going back to September 18, 1999 if the statutes are also found to be retroactive. RMTD, 86–87. And indeed, both of these statutes do contain express provisions allowing ***383** actions to be brought for conduct occurring before the statute's passage. [18] *See* Wis. Stat. Ann. § 20.931(15) (2013); Tenn.Code Ann. § 4–18–106(b) (2013). Defendant argues that, for Tennessee and Wisconsin in particular, retroactive application would violate the Ex Post Facto clause of the Constitution. *Id.* at 59; U.S. Const. Art. I, § 10. [19]

The Supreme Court articulated in *Smith v. Doe* that in order for a law's retroactivity provision to pass Constitutional muster, the Court must determine whether the intention of the legislature was to impose punishment for certain conduct or simply to enact a civil regulatory scheme. *See Smith v. Doe*, 538 U.S. 84, 92, 123 S.Ct. 1140, 155 L.Ed.2d 164 (2003) (internal citations omitted) (cited *in Bulles v. Hershman*, 2009 WL 435337, *4–*5, 2009 U.S. Dist. LEXIS 12815, *13–*14 (E.D.Pa. Feb. 19, 2009)). If that scheme, however, is so punitive as to contradict its "civil" label, then the Court will examine the scheme further. *Id.* Since the Court defers to the intent of the legislature, it only accepts the clearest proof that the scheme constitutes a criminal penalty despite its "civil" label. *Id.* (citing *United States v. Ward*, 448 U.S. 242, 249, 100 S.Ct. 2636, 65 L.Ed.2d 742 (1980)); *see also Myrie v. Commissioner, N.J. Dept. of Corrections*, 267 F.3d 251, 256 (3d Cir.2001) (citing *Ward*, 448 U.S. at 249, 100 S.Ct. 2636). Moreover, "formal attributes of a legislative enactment, such as the manner of its codification or the enforcement procedures it establishes, are probative of the legislature's intent." *Id.* at 94, 123 S.Ct. 1140. The Third Circuit cites *Smith* favorably in this regard. *See U.S. v. Harley*, 315 Fed.Appx. 437, 441 (3d Cir.2009).

Here, both state statutes allow relators to bring "a civil action" based on conduct occurring before the dates of enactment. *See* note 8, *supra.* The Tennessee statute is located in Title 4 of the state code which contains all provisions for the structure and administration of state government, and the Wisconsin statute is located in Chapter 20 which is entitled "Appropriations and Budget Management" in Subchapter X entitled "General Administrative Provisions." *See* Wis. Stat. Ann. § 20.931(15) (2013); Tenn.Code Ann. § 4–18–106(b) (2013).

Once the facially civil character of a statute has been established, the court must then decide whether the statute is nevertheless punitive in effect. *See id.* at 92, 123 S.Ct. 1140; *see also* ***384** *Harley*, 315 Fed.Appx. at 441. To determine this, the Third Circuit has adopted the Supreme Court's seven analytical factors:

> [(1) w]hether the sanction involves an affirmative disability or restraint, [(2)] whether it has historically been regarded as punishment, [(3)] whether it comes into play only on a finding of scienter, [(4)] whether its operation will promote the traditional aims of punishment-retribution and deterrence, [(5)] whether the behavior to which it applies is already a crime, [(6)] whether an alternative

> purpose to which it may rationally be connected is assignable for it, and [(7)] whether it appears excessive in relation to the alternative purpose assigned....

Harley, 315 Fed.Appx. at 441 (citing *Kennedy v. Mendoza–Martinez*, 372 U.S. 144, 168–69, 83 S.Ct. 554, 9 L.Ed.2d 644 (1963)) (internal quotations omitted); *see also Smith*, 538 U.S. at 97, 123 S.Ct. 1140 (also citing *Mendoza–Martinez* but only employing five factors, excluding 3 and 5, and noting that the seven factors are "neither exhaustive nor dispositive," a determination which the Third Circuit has also recognized in *Artway v. Attorney General of State of N.J.*, 81 F.3d 1235, 1263 (3d Cir.1996)).

The Third Circuit has not applied this seven factor test to any False Claims Act either at the federal or state level, but other circuits have. *See* RMTD, 87–88. (citing *U.S. ex rel. Drake v. NSI, Inc.*, 736 F.Supp.2d 489, 502 (D.Conn.2010); *Solvay I*, 823 F.Supp.2d at 533–34; *United States ex rel. Miller v. Bill Harbert Int'l Constr., Inc.*, 608 F.3d 871, 878–79 (D.C.Cir.2010) ("The Ex Post Facto Clause of the Constitution applies only to penal legislation.... The FCA is not penal."); *Massachusetts v. Schering–Plough Corp.*, 779 F.Supp.2d 224, 238 n. 8 (D.Mass.2011); *United States ex rel. Baker v. Community Health Sys., Inc.*, 709 F.Supp.2d 1084, 1108–12 (D.N.M.2010), *United States ex rel. Sanders v. Allison Engine Co.*, 667 F.Supp.2d 747, 758 (S.D.Ohio 2009), *vacated*, 703 F.3d 930 (6th Cir.2012); *New Mexico ex rel. Foy v. Vanderbilt Capital Advisors, LLC*, No. D–101–CV–2008–1895, 2010 WL 3216465, 2009 U.S. Dist. LEXIS 105528 (N.M.Dist.Ct. Apr. 28, 2010)). The Third Circuit has, however, applied these seven factors to other civil penalties. *See National Taxpayers Union v. U.S. Social Sec. Admin.*, 302 Fed.Appx. 115, 120 (3d Cir.2008). Drawing from the Third Circuit and others, this court assesses each factor in turn.

a. Affirmative Disability or Restraint

The Third Circuit has acknowledged that the first factor requires that the penalty in question be assessed for how closely it approaches the "infamous punishment of imprisonment." *Myrie v. Commissioner, N.J. Dept. of Corrections*, 267 F.3d 251, 260 (3d Cir.2001) (citing *Flemming v. Nestor*, 363 U.S. 603, 617, 80 S.Ct. 1367, 4 L.Ed.2d 1435 (1960)) (internal quotations omitted). The Supreme Court has also declared that "the payment of fixed or variable sums of money [is a] sanction which ha[s] been recognized as enforceable by civil proceedings since the original revenue law of 1789." *Hudson v. U.S.*, 522 U.S. 93, 104, 118 S.Ct. 488, 139 L.Ed.2d 450 (1997) (citing *Helvering v. Mitchell*, 303 U.S. 391, 400, 58 S.Ct. 630, 82 L.Ed. 917 (1938)). Here, the monetary penalties authorized by each state, although substantial, do not approach the punitive nature of imprisonment. [20]

***385 b. Historically Regarded As Punishment**

Regarding the second factor: "the Supreme Court has stated that monetary penalties have not 'historically been viewed as punishment.' " *National Taxpayers Union*, 302 Fed.Appx. at 120 (quoting *Hudson*, 522 U.S. at 104, 118 S.Ct. 488); *see also Allison Engine*, 703 F.3d at 946; *but see United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 956 n. 24 (10th Cir.2008); *Austin Capital*, 297 P.3d at 368 (citing *United States ex rel. Sikkenga v. Regence Bluecross Blueshield*, 472 F.3d 702, 734 (10th Cir.2006) (Hartz, J., concurring in part, dissenting in part) ("The [False Claims] Act is punitive in two respects. The availability of treble damages, even though it has a compensatory side, also has a punitive character[.] In addition, [Section] 3729(a)(7) of the Act provides for a penalty of $5,000 to $10,000 regardless of actual damages.") (internal quotation marks and citations omitted)); *see also Austin Capital*, 297 P.3d at 367 (citing *Louis Vuitton S.A. v. Spencer Handbags Corp.*, 765 F.2d 966, 970–72 (2d Cir.1985) ("stating that the punitive nature of the treble damages provision in the Trademark Counterfeiting Act of 1984 could raise ex post facto concerns)"). Here, in line with the Third and Sixth Circuits, this court does not consider the monetary penalties quoted above to be historically regarded as punishment.

c. Element of Scienter

Both statutes have an intent requirement of knowledge and define "knowingly" as having "actual knowledge," acting in "deliberate ignorance," or acting in "reckless disregard," just like the federal FCA. *See* Wis. Stat. Ann. § 20.931(1)(d); Tenn.Code Ann. § 71–5–182(1); 31 U.S.C. § 3729(b)(1). The Sixth Circuit finds that "Because the current [federal False Claims] act can be violated by a lower *mens rea* than knowingly ... this factor does not weigh in favor of finding that the effect of the act is to punish." *Allison Engine*, 703 F.3d at 946. The Third Circuit characterizes

"scienter" as including both knowledge and wilful blindness, but distinct from recklessness. *See U.S. v. Stadtmauer*, 620 F.3d 238, 255–56 (3d Cir.2010). Here, these statutes, by virtue of their inclusion of recklessness in their *mens rea* requirements, monetarily penalize acts carried out without guilty knowledge. Therefore, these statutes do not intend to punish behavior that they consider criminal because they do not require guilty knowledge.

d. Promotion of the traditional aims of punishment: retribution and deterrence, and whether the behavior to which the statutes apply is already a crime

The FCA does have deterrent effects, but those effects are not dispositive in determining whether a statute's penalties serve both civil and criminal goals. *Allison* ***386** *Engine*, 703 F.3d at 946 (citing *United States v. Bornstein*, 423 U.S. 303, 309, 96 S.Ct. 523, 46 L.Ed.2d 514 (1976); and *Hudson*, 522 U.S. at 105, 118 S.Ct. 488). Also, fraud committed against insurance and employee benefit programs are crimes codified in other statutes (*See* Wis. Stat. Ann. § 943.395; Tenn.Code Ann. § 39–14–133), but the False Claims statutes apply to a somewhat wider range of behavior than just criminal fraud. *Id.* at 946, n. 15. Nevertheless, because they do still include criminally fraudulent behavior within that range, the statutes may have some punitive character. *See id.*

e. Whether an alternative purpose to which the statutes may rationally be connected is assignable for them

The Sixth Circuit has determined that:

> Supreme Court has found 'compensatory traits' in the FCA damages multiplier such that the treble damages available under the FCA 'have a compensatory side, serving remedial purposes in addition to punitive objectives.' *Cook Cnty. v. United States ex rel. Chandler*, 538 U.S. 119, 130, 123 S.Ct. 1239, 155 L.Ed.2d 247 (2003). The Court reached this conclusion based on several 'facts about the FCA,' including the facts that 'some liability beyond the amount of the fraud is usually necessary to compensate the Government completely for the costs, delays, and inconveniences occasioned by fraudulent claims,' the FCA contains a qui tam feature which means that 'as much as 30 percent of the Government's recovery' may be diverted to the relator and thus the 'remaining double damages ... provide elements of make-whole recovery beyond mere recoupment of the fraud,' and the FCA does not provide for pre-judgment interest or consequential damages that often accompany recovery for fraud. *Id.* at 130–31, 123 S.Ct. 1239 (internal quotation marks omitted). Given the Supreme Court's analysis of the FCA's treble damages provision, an alternative purpose may be assigned—that of compensating, or making whole, the government for its losses suffered due to fraud—and this factor weighs in favor of finding a civil purpose or effect.

Allison Engine, 703 F.3d at 947.

The Eastern District has echoed this analysis as it has also approvingly cited *Chandler'* s acknowledgement that treble damages can be both compensatory and punitive in nature. *Alexander v. Wash. Mut., Inc.*, 2011 WL 2559641, 2011 U.S. Dist. LEXIS 69906 (E.D.Pa. June 28, 2011) (ultimately distinguishing section 2607(d)(2) of the Real Estate Settlement Procedures Act as having more of a deterrent and punitive purpose due to the text of legislative reports); *see also Pascocciello v. Interboro Sch. Dist.*, 2006 WL 1284964, 2006 U.S. Dist. LEXIS 27390 (E.D.Pa. May 8, 2006); *Dambrosio v. Comcast Corp.*, 2005 WL 3543794, 2005 U.S. Dist. LEXIS 35871 (E.D.Pa. Dec. 27, 2005). This court agrees with the Sixth Circuit's analysis and considers the compensatory character of the statutes to weigh in favor of their having a civil effect.

f. Whether the statutes appear excessive in relation to the alternative purpose assigned

The Supreme Court has, at various times, found treble damages in general and the treble damage provisions in the FCA in particular to be so great as to be punitive. *See Tex. Indus., Inc. v. Radcliff Materials, Inc.*, 451 U.S. 630, 639, 101 S.Ct. 2061, 68 L.Ed.2d 500 (1981); *Vt. Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784, 120 S.Ct. 1858, 146 L.Ed.2d 836 (2000). More recently, however, the Court seems to have relaxed this view. *See Chandler*, 538 U.S. at 130–32, 123 S.Ct. 1239; *see also* ***387** *PacifiCare Health Systems, Inc. v. Book*, 538 U.S. 401, 405–06, 123 S.Ct. 1531, 155 L.Ed.2d 578 (2003) (remarking that the Court has "placed different statutory treble-damages provisions on different points along the spectrum between purely compensatory and strictly punitive," and describing both *Stevens* and *Chandler*). In *Chandler*, the Court noted that there are other purposes to the FCA such as giving the relator a large enough incentive and to compensate the

government not just for the value of the false claims but also for the delay in compensation and administrative costs. *Chandler*, 538 U.S. at 130–32, 123 S.Ct. 1239.

Here, the treble damages provided for in each statute, although hefty enough to strongly suggest a punitive character, are not excessive enough to completely obliterate their compensatory purpose. Regardless, that punitive character is not so weighty as to tip the scale in favor of finding the entire statute punitive.

Overall, of the seven *Mendoza–Martinez* factors, the three weighing the heaviest in favor of finding the statutes criminally punitive in effect are discussed in section d. and e.: (1) the statutes apply to behavior that is already a crime, (2) they have a somewhat deterrent purpose, and (3) their treble damages are arguably excessive. The other four factors weight against finding a criminal effect: (1) no affirmative disability or restraint, (2) not historically regarded as punishment, (3) no finding of scienter is required, and (4) they have the alternative purposes of compensation and incentivizing relators to come forward. In conclusion, this Court finds that the Tennessee and Wisconsin retroactivity provisions do not violate the Ex Post Facto Clause of the Constitution and therefore Relator may proceed with the claims under those statutes (Counts Fourteen and Twenty–Six) based on fraudulent conduct from before their enactment but within their ten-year statutes of limitations, i.e. from September 18, 1999 forward.

3. Statutes of Limitations

Defendant asserts that "eighteen of the twenty-five state counts are barred to the extent they are based on conduct occurring before September 18, 2003 (six years from the date Relator first filed the suit)." [21] MTD, 62. Relator concedes that these claims are, in fact, limited by this six-year statute of limitations. RMTD, 88. Relator also concedes that the "claims pursuant to the laws of Georgia (Count Eight), Indiana (Count Seventeen), Oklahoma (Count Twenty–Five), Rhode Island (Count Twenty–Seven), and New Jersey (Count Twenty–Eight) are further limited by their effective dates of May 24, 2007, July 1, 2005, November 1, 2007, July 1, 2007, and March 13, 2008, respectively, because their statutes are not retroactive. *Id.* at 89.

***388** Defendant has also moved to dismiss the claims under the New Mexico and Texas statutes based on their four-year statutes of limitations, which would bar the claims insofar as they are based on conduct occurring before September 18, 2005. MTD, 62–63. As discussed above, Relator has agreed to voluntarily dismiss the New Mexico claim and this Court has granted a dismissal of the Texas claim (Count Fifteen) insofar as it is based on conduct occurring before May 4, 2007, thus requiring no further analysis of the Texas statute of limitations.

4. Bringing an Action under the Tennessee Statute

Relator argues:

> Count Fourteen asserts that Abbott's alleged conduct violated the Tennessee False Claims Act, Tenn.Code § 4–18–101 et seq. (*See generally* Am. Compl. ¶¶ 272–280.) However, to the extent Relator also maintains that Abbott's alleged conduct violated the Tennessee Medicaid False Claims Act, Tenn.Code. § 71–5–181 et seq.—as she does, *see id.* ¶¶ 265–271 (asserting violation of the Tennessee Medicaid False Claims Act)—Count Fourteen must be dismissed because Tennessee law does not permit a private litigant to pursue such a claim. *See* Tenn.Code § 4–18–108 (Tennessee False Claims Act: Applicability) ("This chapter shall not apply to any conduct, activity or claims covered by the Medicaid False Claims Act[ ].").

MTD, 63.

Relator responds by arguing that the Tennessee False Claims Act (TFCA) and the Tennessee Medicaid False Claims Act (TMFCA) make the same provisions for relators to bring claims on behalf of themselves and the state; the main difference being that the TFCA applies more broadly to state funds, property, and obligations to pay the state; whereas the TM FCA just applies to the state Medicaid program. The TFCA also includes a provision, which Defendant cites, that excludes false claims arising from the state Medicaid program from the FCA. Relator concedes that this section limits recovery for fraudulent Medicaid claims under the TFCA, but maintains that it does not act as an absolute bar to bringing claims under both statutes.

The case law on the co-interpretation of these statutes is virtually non-existent, although a few cases have addressed the issue in passing. *See U.S. ex rel. Dennis v. Health Management Associates, Inc.*, 2013 WL 146048, 2013 U.S. Dist. LEXIS 5212 (M.D.Tenn. Jan. 14, 2013); *U.S. v. Chattanooga–Hamilton County Hosp. Authority*, 958 F.Supp.2d 846 (E.D.Tenn.2013). One court has observed that "seeking recovery under the Tennessee False Claims Act,

Tenn.Code Ann. § 4–18–103, is *clearly redundant* of the claims for relief asserted under the TM FCA, Tenn.Code Ann. §§ 71–5–182(a)(1)." *Dennis,* 2013 WL 146048, *6, 2013 U.S. Dist. LEXIS 5212, *18–*19 (dismissing both claims for not being pled with particularity under 9(b)) (emphasis added). Another court refers to both the TMFCA and TFCA as "collectively, the 'TFCA.' " *Chattanooga–Hamilton,* 958 F.Supp.2d at 850 (dismissed on other grounds).

Here, the Amended Complaint alleges, in Count Fourteen "The State of Tennessee by and through *Tennessee-funded health plans,* and unaware of Defendant's illegal practices paid the claims submitted by health care providers and third party payors in connection therewith." AC ¶ 277 (emphasis added). Relator does not specify Tennessee's Medicaid program as the sole alleged victim of Defendant's false claims; it simply refers to "Tennessee-funded health plans." *Id.* Relator concedes that the TFCA's Medicaid exclusion could limit recovery. RMTD, 93. Indeed, ***389** recovery would be determined after discovery and further litigation traces false claims to Tennessee Medicaid and/or other Tennessee health plans. The state of Tennessee does, in fact, also administer a health plan to its state employees which would be covered by the TFCA. *See* Tenn.Code Ann. § 8–27–202, et seq. Because other courts have not taken issue with claims under both statutes proceeding in tandem and because Relator alleges false claims which may have been submitted to non-Medicaid health plans, the Motion to Dismiss Count Fourteen is denied.

IX. *CONCLUSION*

For the foregoing reasons, Defendant's Motion to Dismiss is Granted in Part and Denied in Part. An appropriate Order follows.

ORDER

AND NOW, this 30th day of January, 2014, upon consideration of Relator Amy Bergman's Second Amended Complaint (Dkt. No. 18), Defendant Abbott Labs' Motion to Dismiss the Second Amended Complaint (Dkt. No. No. 47–2), and the parties' subsequent responses it is hereby ORDERED as follows:

• With respect to Counts One and Two, the Relator VOLUNTARILY DISMISSES said counts for all claims submitted before September 18, 2003, and Defendant's Motion to Dismiss is DENIED for all claims submitted after September 18, 2003.

• With respect to Counts Three, Six, Seven, Nine, Ten, Eleven, Thirteen, Sixteen, Eighteen, and Twenty–Two, Relator VOLUNTARILY DISMISSES said counts for all claims submitted before September 18, 2003, and Defendant's Motion to Dismiss is DENIED for all claims submitted after September 18, 2003.

• With respect to Court Four, the Defendant's Motion to Dismiss is DENIED in its entirety.

• With respect to Count Five, Defendant's Motion to Dismiss is GRANTED for all claims submitted before July 16, 2009 and DENIED for all claims submitted after July 16, 2009.

• With respect to Count Eight, the Relator VOLUNTARILY DISMISSES said count for all claims submitted before May 24, 2007, and Defendant's Motion to Dismiss is DENIED for all claims submitted after May 24, 2007.

• With respect to Count Twelve, Defendant's Motion to Dismiss is GRANTED for all claims submitted before October 1, 2005 and DENIED for all claims submitted after October 1, 2005.

• With respect to Counts Fourteen and Twenty–Six, Defendant's Motion to Dismiss is granted for all claims submitted before September 18, 1999, and DENIED for all claims submitted after September 18, 1999.

• With respect to Count Fifteen, Defendant's Motion to Dismiss is GRANTED for all claims submitted before May 4, 2007 and DENIED for all claims submitted after May 4, 2007.

• With respect to Count Seventeen, the Relator VOLUNTARILY DISMISSES said count for all claims submitted before July 1, 2005, and Defendant's Motion to Dismiss is DENIED for all claims submitted after July 1, 2005.

• With respect to Counts Nineteen, Twenty, and Twenty–Three, the Relator VOLUNTARILY DISMISSES said counts in their entirety.

• With respect to Count Twenty–One, the Relator VOLUNTARILY DISMISSES said count for all claims submitted before July 1, 2007, and Defendant's Motion ***390**

to Dismiss is DENIED for all claims submitted after July 1, 2007.

• With respect to Count Twenty–Four, the Relator VOLUNTARILY DISMISSES said count for all claims submitted before April 1, 2007, and Defendant's Motion to Dismiss is DENIED for all claims submitted after April 1, 2007.

• With respect to Count Twenty–Five, the Relator VOLUNTARILY DISMISSES said count for all claims submitted before November 1, 2007, and Defendant's Motion to Dismiss is DENIED for all claims submitted after November 1, 2007.

• With respect to Count Twenty–Seven, the Relator VOLUNTARILY DISMISSES said count for all claims submitted before July 1, 2007, and Defendant's Motion to Dismiss is DENIED for all claims submitted after July 1, 2007.

• With respect to Count Twenty–Eight, the Relator VOLUNTARILY DISMISSES said count for all claims submitted before March 13, 2008, and Defendant's Motion to Dismiss is DENIED for all claims submitted after March 13, 2008.

Footnotes

1 Relator alleges that Abbott violated state statutes in Illinois, California, Delaware, District of Columbia, Florida, Georgia, Hawaii, Louisiana, Massachusetts, Montana, Tennessee, Texas, Virginia, Indiana, Nevada, New Hampshire, New Mexico, Michigan, New York, Oklahoma, Wisconsin, Rhode Island, and New Jersey.

2 Defendant argues that:

> [The] Relator's claims are also subject to a six-year statute of limitations, which requires that Counts I and II be dismissed to the extent they relate to alleged false claims submitted prior to September 18, 2003. Finally, the claims alleged by Relator under the false claims acts of twenty-two states and the District of Columbia should be dismissed because they are barred for various reasons including her failure to properly plead the claims with particularity, the failure of certain states to intervene as required by statute, improper retroactive application of state law, the applicable statutes of limitations, and other reasons....

MTD, 20.

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

In other FCA cases, however, the Third Circuit has cited approvingly—but has not formally adopted—the heightened standard used by the Eleventh Circuit whereby a Relator cannot "describe a private scheme in detail" and then allege fraud simply by assuming that "requesting illegal payments must have submitted, were likely submitted or should have been submitted to the Government." *United States ex rel. Quinn v. Omnicare, Inc.*, 382 F.3d 432, 439–40 (3d Cir.2004) (citing *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir.2002)). The District Courts within the Third Circuit have been split on this issue with some courts dismissing complaints that do not refer to a specific false claim for payment and others allowing more general complaints to proceed. *See Underwood*, 720 F.Supp.2d at 677 (citing *United States ex rel. Bartlett v. Tyrone Hosp., Inc.*, 234 F.R.D. 113, 120 (W.D.Pa.2006); and *United States ex rel. Schmidt v. Zimmer, Inc.*, No. 00–1044, 2005 WL 1806502, at *1, *2–*3, 2005 U.S. Dist. LEXIS 15648, at *1, *7–*8 (E.D.Pa. July 29, 2005) for granting dismissals; and *United States ex rel. Singh v. Bradford Reg'l Med. Ctr.*, No. 04–186, 2006 WL 2642518, 2006 U.S. Dist. LEXIS 65268 (W.D.Pa. Sept. 13, 2006); *United States ex rel. Landsberg v. Levinson*, No. 03–1429, 2006 WL 6936820, 2006 U.S. Dist. LEXIS 66689 (W.D.Pa. Feb. 13, 2006); *Gibbons ex rel. United States v. Kvaerner Phila. Shipyard, Inc.*, No. 05–685, 2006 WL 328362, 2006 U.S. Dist. LEXIS 5172 (E.D.Pa. Feb. 10, 2006) for denying dismissals.). Looking at other circuits, however, the Eastern District of Pennsylvania has noted that the availability of evidence of fraud from the Government, as opposed to evidence being solely in the hands of the Defendant is a crucial factor in determining whether an FCA complaint should contain evidence of an actual claim in order to survive Rule 9(b). *See Underwood*, 720 F.Supp.2d at 677; *United States ex rel. Streck v. Allergan, Inc.*, 894 F.Supp.2d 584, 601 (E.D.Pa.2012).

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

5 *Id.* (citing *U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1220 (10th Cir.2008) (" 'Conditions of participation ... are enforced through administrative mechanisms, and the ultimate sanction for violation of such conditions is removal from the

government program,' while '[c]onditions of payment are those which, if the government knew they were not being followed, might cause it to actually refuse payment.' "))

6 *See Zimmer,* 386 F.3d 235, 244–45 ("In *United States ex rel. Cantekin v. Univ. of Pittsburgh,* 192 F.3d 402, 416 (3d Cir.1999), this Court applied ordinary causation principles from negligence law in determining responsibility under the FCA. Under those principles, the "intervention of a force which is a normal consequence of a situation created by the actor's ... conduct is not a superseding cause of harm which such conduct has been a *substantial factor* in bringing about." Restatement (Second) of Torts § 443. Thus, assuming that a jury were to conclude that [the Defendant] Zimmer's marketing scheme was a *substantial factor* in bringing about [third-party hospital] Mercy's filing and that Mercy's filing was a normal consequence of the situation created by that scheme, Zimmer could be found to have caused, and thus be held responsible for, that filing.") (emphasis added); *see also Galmines,* 2013 WL 2649704 at *7, 2013 U.S. Dist. LEXIS 83100 at *19 (citing *United States ex rel. Franklin v. Parke–Davis,* 147 F.Supp.2d 39, 52–53 (D.Mass.2001)).

7 Relator does allege in AC ¶ 9 that Abbott's off-label marketing violated the FDCA, 21 U.S.C. § 331(a) and (b), and is thus misbranded, but it does not allege that this violation is what underlies the falsity of the claims for payment.

8 "(I) American Hospital Formulary Service Drug Information; (II) United States PharmacopeiaDrug Information (or its successor publications); and (III) the DRUGDEX Information System." The Defendant also characterizes the FDA label and compendia as " 'exhibits attached to the complaint and facts of which the court will take judicial notice' [which] may be considered without converting a motion to dismiss into a motion for summary judgment. *Pryor v. Nat'l Coll. Athletic Ass'n,* 288 F.3d 548, 560 (3d Cir.2002); 5B Wright & Miller, Federal Practice & Procedure § 1357 (3d ed. 2004)." Mot. to Dismiss, 17–18. Although this court has reviewed and considered these documents, it does not find that they resolve as a matter of law (or fact) whether TriCor was marketed for medically unnecessary uses, particularly when considering Relator's allegations that Defendant made "representations" to physicians that were "false and misleading." AC ¶ 7; *see also* discussion in this section.

9 "TRICARE, formerly known as CHAMPUS is a managed care program established by the United States Department of Defense, 10 U.S.C. § 1071–1110." AC ¶ 149. "The Federal Employees Health Benefits Program (FEHBP) is a federally funded health care program established by Congress in 1959, pursuant to the Federal Employees Health Benefits Act, 5 U.S.C. § 8901 et seq." AC ¶ 154.

10 *See also* AC ¶ 11 ("As a direct result of Abbott's illegal off-label marketing and misbranding of TriCor, *physicians prescribed TriCor* for off-label uses and/or for uses which were not reasonable and necessary for treatment, and claims for reimbursement for off-label uses and medically unnecessary uses of TriCor were submitted to the federal government and the States in connection with such prescriptions, giving rise to liability under their respective False Claims Acts.") (emphasis added).

11 In addition to *Underwood,* the Eastern District came to similar conclusions about not requiring specific claims in *Streck,* as did the District of New Jersey in its holding in *Simpson. See Underwood,* 720 F.Supp.2d at 680; *Streck,* 894 F.Supp.2d at 601; *Simpson,* 2013 WL 4710587 at *14, 2013 U.S. Dist. LEXIS 124928 at *47–*48. However, the districts remain split as to what other details are required. *See Simpson,* 2013 WL 4710587 at 14, 2013 U.S. Dist. LEXIS 124928 at 47–48 (the allegation of a kickback scheme is enough to survive 9(b) since kickbacks "would inevitably cause false claims to be submitted to the government by healthcare providers." However, the off-label-based FCA claim did not survive 12(b)(6) for reasons discussed above.); *Underwood,* 720 F.Supp.2d at 680 (allowing both the off-label and anti-kickback bases of the complaint to survive 9(b) because the kickbacks were provided in order to induce off-label prescriptions. Also, the "Relator's allegations [were] sufficiently specific both to inform Genentech of the 'precise misconduct' charged, and to make it unlikely that Relator has commenced this action in bad faith.").

12 This reasoning has been followed in two other District cases: *Simpson v. Bayer* and *Galmines v. Novartis.* in *Simpson,* the District of New Jersey found that since the kickback-tainted claims for payment were submitted by a third party, the relator did not need to identify any particular false claims. *U.S. ex rel. Simpson v. Bayer Corp.,* No. 05–3895, 2013 WL 4710587, 2013 U.S. Dist. LEXIS 124928 (D.N.J. Aug. 30, 2013). In *Galmines,* although the court lacked jurisdiction over the AKS-based false claims, it applied a relaxed 9(b) analysis as described in Part IV. *supra* with regard to off-label marketing-based false claims. *Galmines,* 2013 WL 2649704 at *8, 2013 U.S. Dist. LEXIS 83100 at *21–*22.

13 In the text of the session law the Texas legislature explains that the amendment applies "only to conduct that occurs on or after the effective date [May 4, 2007] of this Act. Conduct that occurs before the effective date of the Act is governed by the law in effect at the time the conduct occurred, and that law is continued in effect for that purpose." Texas Acts 2007, 80th Leg., Ch. 29, § 6, eff. May 4, 2007 (bracketed language in original).

14 The Court's full argument in *Streck* is as follows: "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. This argument is against the weight of other persuasive authority holding to the contrary. 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." *Streck,* 894 F.Supp.2d at 604 (citations omitted).

15 Although the relator in *Wall* filed the complaint before the Texas Amendment and the State did not intervene, the court was clear that the amendment applies based not on the date of the complaint, but on the date of the allegedly fraudulent conduct, which was dispositive in dismissing Wall's complaint:

> "The TMFPA was later amended to allow actions to proceed when the state declines to intervene, but this 'applies only to conduct that occurs on or after' May 4, 2007. *Because all of the conduct that Wall complains of occurred before this date, Count Ten is DISMISSED without prejudice.*"

U.S. ex rel. Wall v. Vista Hospice Care, Inc., 778 F.Supp.2d 709, 724 (N.D.Tex.2011).

> *"In Fitzgerald, Judge Godbey interpreted "conduct" to be the actions of the defendant that are the subject of the relator's complaint, not the decision of the state not to intervene, as Wall urges. This Court agrees with Judge Godbey's analysis."*

Id. at 724 n. 84 (citing *United States ex rel. Fitzgerald v. Novation, L.L.C.*, No. 3:03–CV–1589–N, 2008 WL 9334966 (N.D.Tex. Sept. 17, 2008) (Godbey, J.)) (emphasis added); contra *Solvay I*, 823 F.Supp.2d at 522 (simply asserting without precedent that "conduct" means the state's decision not to intervene as opposed to the underlying fraudulent conduct).

16 These state statutes, effective dates, and their corresponding counts are as follows:

> Delaware (Count Five) (effective date June 30, 2000); Georgia (Count Eight) (effective date May 24, 2007); Hawaii (Count Nine); (effective date May 26, 2000); Indiana (Count Seventeen) (effective date July 1, 2005); Massachusetts (Count Eleven) (effective date July 1, 2000); Montana (Count Twelve) (effective date May 1, 2005); ... New Jersey (Count Twenty–Eight) (effective date March 13, 2008); ... New Mexico II (Count Twenty–One) (effective date July 1, 2007); New York (Count Twenty–Four) (effective date April 1, 2007); Oklahoma (Count Twenty–Five) (effective date November 1, 2007); Rhode Island (Count Twenty–Seven) (effective date July 1, 2007); Tennessee II (Count Fourteen) (effective date July 1, 2001); Virginia (Count Sixteen) (effective date January 1, 2003); Wisconsin (Count Twenty–Six) (effective date October 27, 2007).

MTD, 59–62.

17 "Delaware (Count Five), effective June 30, 2000; Georgia (Count Eight), effective May 24, 2007; Hawaii (Count Nine), effective May 26, 2000; Montana (Count Twelve) effective [May] 1, 2005; Virginia (Count Sixteen), effective January 1, 2003; Indiana (Count Seventeen), effective July 1, 2005; New Mexico II (Count Twenty–One), effective July 1, 2007; New York (Count Twenty Four), effective April 1, 2007; Oklahoma (Count Twenty–Five), effective November 1, 2007; Rhode Island (Count Twenty–Seven), effective July 1, 2007; New Jersey (Count Twenty–Eight), effective March 13, 2008." RMTD, 85

18 "A civil action may be brought based upon acts occurring prior to October 27, 2007, if the action is brought within the period specified in s. 893.981." Wis. Stat. Ann. § 20.931(15) (2013); "A civil action under § 4–18–104 may be brought for activity prior to July 1, 2001, if the limitations period set in subsection (a) has not lapsed." Tenn.Code Ann. § 4–18–106(b) (2013)

19 in support of its argument, the Defendant cites a New Mexico case, *New Mexico ex rel. Foy v. Vanderbilt Capital Advisors, LLC*, No. D–101 CV200801895, 2010 WL 3216465 (N.M. 1st Jud.Dist.Ct. Apr. 28, 2010). This is perhaps the only case on point involving an Ex Post Facto Clause challenge to a state FCA with an explicit retroactivity provision for the entire statute. However, it relies heavily on a case that has recently been vacated by the Sixth Circuit, *Sanders v. Allison Engine Co., Inc.*, 703 F.3d 930 (6th Cir.2012) (involving retroactive application of an amendment to the federal FCA with an explicit, albeit temporally limited, retroactivity provision for civil actions already commenced, not the false claims themselves). *Vanderbilt* was eventually appealed under the name of its companion suit, and the trial court's reasoning was upheld despite the reversal of *Allison Engine* because New Mexico appeals court decided to "take a broader view of federal case law and place more emphasis on New Mexico case law." *State ex rel. Foy v. Austin Capital Management, Ltd.*, —— N.M. ——, 297 P.3d 357, 367 (N.M.App.2012). This court, however, will rely on Third Circuit precedent and other federal case law.

20 *See* Wis. Stat. Ann. § 20.931(2)-(3) (2013) ("Except as provided in sub. (3), any person who does any of the following is liable to this state for 3 times the amount of the damages sustained by this state because of the actions of the person, and shall forfeit not less than $5,000 nor more than $10,000 for each violation ... The court may assess against a person who violates sub. (2) not less than 2 nor more than 3 times the amount of the damages sustained by the state because of the acts of the person, and shall not assess any forfeiture, if the court finds all of the following"); Tenn.Code Ann. § 4–18–103(a)–(b) (2013) ("Any person who commits any of the following acts shall be liable to the state or to the political subdivision for three (3) times the amount of damages that the state or the political subdivision sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state or to the political subdivision for the costs of a civil action brought to recover any of those penalties or damages, and shall be liable to the state or political subdivision for a civil penalty of not less than two thousand five hundred dollars ($2,500) and not more than ten thousand dollars ($10,000) for each false claim ... Notwithstanding subsection (a), the court may assess not less than two (2) times nor more than three (3) times the amount of damages that the state or the political subdivision sustains because of the act of the person described in that subsection, and no civil penalty, if the court finds all of the following").

21 Delaware False Claims and Reporting Act, Del.Code. tit. 6, § 1209(a)(1); District of Columbia Procurement Reform Amendment Act, D.C.Code § 2–381.05(a); Florida False Claims Act, Fla. Stat. § 68.089(1); Georgia False Medicaid Claims Act, Ga.Code §

49–4–168.5; Hawaii False Claims Act, Haw.Rev.Stat. § 661–24; Illinois False Claims Act, 740 Ill. Comp. Stat. Ann. 175/5(b)(1); Indiana False Claims and Whistleblower Protection Act, Ind.Code. § 5–11–5.5–9(b)(1); Louisiana Medical Assistance Programs Integrity Law, La.Rev.Stat. § 46:439.1(B); Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5K(1); Michigan Medicaid False Claim Act, Mich. Comp. Laws § 400.614(1)(a); New Hampshire Medicaid Fraud & False Claims Act, N.H.Rev.Stat. § 167:61–b, VII(a); New Jersey False Claims Act, N.J. Stat. § 2A:32C–11(a); Nevada False Claims Act, Nev.Rev.Stat. Ann. § 357.170(1); Oklahoma Medicaid False Claims Act, Okla. Stat. Ann. tit. 63, § 5053.6(B)(1); Rhode Island False Claims Act, R.I. Gen. Laws § 9–1.1–5(b)(1); Tennessee Medicaid False Claims Act, Tenn.Code Ann. § 71–5–184(b)(1); Virginia Fraud Against Taxpayers Act, Va.Code § 8.01–216.9.

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