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

UNITED STATES OF AMERICA; THE STATES OF CALIFORNIA, DELAWARE, FLORIDA, ILLINOIS, INDIANA, LOUISIANA, MASSACHUSETTS, MICHIGAN, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, OKLAHOMA, RHODE ISLAND, TEXAS, VIRGINIA, WISCONSIN, AND THE DISTRICT OF COLUMBIA, ex rel. HERBERT J. NEVYAS AND ANITA NEVYAS-WALLACE, Plaintiffs, v. ALLERGAN, INC., Defendant.	CIVIL ACTION NO. 2:09-cv-00432 **Hon. Thomas N. O'Neill, Jr.**

AMENDED MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF ALLERGAN, INC.'S AMENDED MOTION TO DISMISS RELATORS' SECOND AMENDED COMPLAINT

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I. INTRODUCTION

Relators Herbert Nevyas and Anita Nevyas-Wallace ("Relators") have brought this action on behalf of the federal government, nineteen state governments, and the District of Columbia under the *qui tam* provisions of the False Claims Act ("FCA") and similar state false claims laws. For several years, Relators have searched in vain for a viable *qui tam* theory to level against Allergan, Inc. ("Allergan"), a manufacturer of prescription eye care drugs, among other things. They have amended their complaint twice, in the process abandoning their original theory. In their latest pleading, Relators seek their bounty by mischaracterizing as kickbacks legitimate business activities that ***Allergan*** itself has openly advertised and discussed with industry professionals for more than a decade. This very fact indicates that there is no surreptitious fraud to expose and that Allergan's good faith negates any *scienter* that would support liability. Relators have pled insufficient facts to suggest otherwise, and their latest theory is no more tenable than their prior theories.

Implausibly, Relators contend that Allergan should be punished under the FCA and similar state laws for allegedly inducing physicians to write prescriptions for Allergan products, which patients then took to be filled by pharmacists, who then may have sought reimbursement for some of those products from federal and state health care programs, particularly Medicare Part D and the Medicaid programs of nineteen states and the District of Columbia. In addition to failing to provide any particulars regarding those physicians, prescriptions, patients, or claims for payment, Relators base their theory of liability on another critical element that remains completely unidentified: certifications the pharmacists may have made in connection with ***their*** submission of claims to government programs, verifying ***their own compliance*** with unidentified conditions of payment, potentially including the federal Anti-Kickback Statute ("AKS") or similar state laws. It is those certifications that, according to Relators, render claims at issue in this case "false," a key element of Relators' cause of action.

Setting aside the tenuous causal chain between Allergan's alleged conduct and the allegedly "false" certifications by pharmacists, the "implied false certification" theory on which

Relators rely would result in an extension of the FCA not recognized or permitted by Third Circuit precedent. And even if Allergan could be held liable for unidentified certifications made by unidentified pharmacists who submitted unidentified claims for reimbursement to government health care programs, Relators' theory impermissibly expands the bounds of the AKS and similar state anti-kickback laws—underlying statutory violations Relators must adequately plead to survive a motion to dismiss—and attempts to punish legitimate business activities and protected speech.

The business activities at issue here comprise *Allergan Access*, a website that Allergan itself has openly advertised and discussed with eye care professionals and others since 2002 that offers practice management templates and educational materials for eye care practices, and limited advice and training provided by a small group of Allergan eye care business advisors ("ECBAs"). Relators view these practice management consultation activities as kickbacks, even though they amount either to (1) educational advice and training, the content of which may or may not have any value and which the government may not regulate, or (2) website content for which Allergan charged a subscription fee. The only money that changed hands here ***was paid by physicians to Allergan*** for access to these basic website materials. This is an unusual kickback case indeed.

As Relators' Second Amended Complaint, ECF No. 15 (Sept. 27, 2010) ("SAC"), concedes, Allergan's activities support the eye care community and ophthalmology practices' use of Allergan's eye care products. The SAC alleges that such product-support services violate the AKS and therefore the FCA. But the services at issue, such as reimbursement guidance or advice on improving a "dry eye" practice, are similar to those described in the U.S. Department of Health and Human Services' Office of Inspector General ("OIG") Compliance Program Guidance for Pharmaceutical Manufacturers (2003) ("OIG Guidance") as permissible under the AKS. 68 Fed. Reg. 23731, 23735 (May 5, 2003) (attached hereto as Exhibit 1). The law does not prohibit the kind of activity at issue here. If it did, it would also proscribe and criminalize a broad swath of commonplace business conduct, including protected commercial speech. Here,

Relators would have the difference between criminal conduct and legitimate business activity turn on the ***value of the content*** of the business advice provided. Under Relators' theory, a government prosecutor would have to evaluate the content of the practice management advice that Allergan allegedly provided to eye care practices and determine whether that advice is more or less valuable to a practice than the product-support communications and services permitted by the OIG Guidance. This inquiry would be required even though the services acknowledged by the government as unobjectionable, such as product reimbursement support, have a direct impact on a physician's bottom line, whereas practice management advice may or may not be practicable or profitable. The law does not require—or even permit—the inquiry that Relators' theory demands.

Even if the First Amendment allowed the type of content-based determinations that Relators propose—and it does not—Allergan's belief that its *Allergan Access* and ECBA program did not violate the AKS or the FCA was reasonable and, on the face of the SAC, negates liability. The allegations in the SAC do not contradict Allergan's view and do not support any liability whatever—much less the punitive FCA liability that Relators envision.

In sum, Relators' theory is fundamentally flawed, and this Court should dismiss the SAC for several separate and independent reasons:

First, Relators have not alleged a plausible violation of the FCA or the AKS. They have not adequately pled that Allergan had the requisite intent to violate either statute. Further, they have failed to plead any falsity in any statement or claim submitted to the government, as required by the FCA. As Relators acknowledge, retail pharmacists without any knowledge of the alleged kickbacks would have submitted to the government any claims at issue in this case. Any certifications of compliance (express or implied) that the pharmacists may have made with respect to their claims for payment were accurate and cannot support FCA liability against Allergan. Therefore, Relators have failed to state a claim upon which relief may be granted, and the SAC should be dismissed under Federal Rule of Civil Procedure 12(b)(6).

Second, Relators also have not pled fraud with the particularity required by Federal Rule of Civil Procedure 9(b). The only "particulars" that the Relators allege relate to their own efforts to entrap Allergan after abandoning their original theory. Even the "particulars" of Relators' involvement are not specific at all. In a perverse use of the FCA, Relators have identified only themselves as recipients of the purported kickbacks, yet they have not specified a single false claim, a single false statement, a single false certification, a single improper prescription they (or anyone else) wrote as a result of an alleged kickback, a single government program beneficiary who improperly used the Allergan products Relators prescribed as a result of the alleged kickback, or a single pharmacy that filled such a prescription and submitted a claim to a government program. In short, Relators have not alleged the who, what, when, where, or how required by Rule 9(b), even for the fraud purportedly perpetrated on and by their own practice, much less the particulars needed to support their allegations regarding a nationwide fraudulent scheme.

Third, Relators' state-law claims are deficient for a slew of reasons, including Relators' failure to allege any particular conduct in any of the relevant states, their failure to meet applicable statutes of limitations, their lack of standing, and the fact that many of the claims would impermissibly require the retroactive application of state law.

For all of these reasons—and for the reason that Relators already have had three opportunities to file a viable complaint—the Court should dismiss the SAC with prejudice.

II. BACKGROUND

More than five years ago, Relators filed this action against Allergan on behalf of the United States, twenty-two states, and the District of Columbia under the *qui tam* provisions of the FCA and various state laws. Compl., ECF No. 1 (Jan. 30, 2009). The original Complaint alleged that Allergan "systematically and illegally promoted [two eye care pharmaceutical products] for off-label indications," *id.* ¶¶ 2–3, a claim no longer found in the operative SAC.

Relators' First Amended Complaint renewed their allegations regarding off-label promotion. ECF No. 8 (Nov. 12, 2009) ("FAC"). As amended, it also advanced—for the first

time—a FCA liability theory premised on purported violations of the AKS. *Id.* ¶¶ 2–5. Just ten months later, Relators abandoned their initial off-label theory and filed the SAC on behalf of the United States, nineteen states, and the District of Columbia.[1] This time, Relators relied solely on allegations that Allergan should be subject to FCA liability on the basis of alleged AKS violations. The SAC contains twenty-one counts: one for the federal FCA and an additional count for each of the *qui tam* statutes of the various states and the District of Columbia. SAC ¶¶ 320–494.

Relators' latest effort hinges on allegations that Allergan sold subscriptions to the *Allergan Access* program, at an annual fee of $895, which provided eye care practices with access to a website containing practice management consultation materials and educational features, as well as access to various forms of advice and education provided by Allergan's ECBA group. *Id.* ¶ 221.[2] As Relators themselves concede, the *Allergan Access* program was widely advertised and discussed, including with large numbers of eye care practitioners and other individuals. *See id.* ¶¶ 107, 112, 159, 173, 184, 218.[3] Relators generally allege that the fair market value of Allergan's practice management consultation materials and activities exceeded the annual subscription fee and, therefore, amounted to a kickback under the AKS and similar state laws. *Id.* ¶¶ 221–31. Moreover, Relators allege that Allergan's ECBAs provided impermissible advice and educational training in an effort to increase sales in violation of federal and state anti-kickback laws. *Id.* ¶¶ 197–205. The SAC also briefly describes additional kickbacks allegedly provided by Allergan in the form of participation in a "speakers' bureau," *id.*

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[1] For reasons unknown to Allergan, Relators dropped Georgia, Hawaii, and Tennessee from the SAC.

[2] Although this Court must accept plaintiffs' pleadings as true in evaluating this Motion, Allergan notes that the price of *Allergan Access* actually changed over time.

[3] Although much of the detail regarding the *Allergan Access* program was publicly disclosed, further fact development is needed to determine whether such disclosures trigger the FCA's jurisdictional bar on claims based upon public information. 31 U.S.C. § 3730(e)(4). Accordingly, Allergan reserves the right to assert this jurisdictional argument, which cannot be waived, at a later date.

¶¶ 286–91, "sponsored meetings and dinners," *id.* ¶¶ 292–302, and funding for "independent research," *id.* ¶¶ 303–04.

Relators claim that physicians who received the alleged kickbacks subsequently prescribed Allergan products to patients who participated in federal health care programs, including Medicare and Medicaid. *Id.* ¶¶ 3–4, 309. Relators further assert that, because unnamed third-party retail pharmacies, which were both unaffiliated with Allergan and unaware of any alleged kickbacks, allegedly certified (expressly or impliedly) their compliance with the AKS when submitting unspecified claims for payment to government health care programs, the claims are legally "false" and Allergan should be held liable under the federal FCA and similar state statutes. *Id.* ¶ 312. Relators do not allege that Allergan ever submitted claims to the government or certified its own compliance with the AKS in connection with claims relating to the eye care pharmaceuticals at issue. *See generally id.*

Relators themselves are the only "[p]rescribing Ophthalmologists and Optometrists who received Allergan's illegal inducements" identified in the SAC, and assuming they wrote prescriptions for Allergan products for patients who participated in government health care programs, they improperly "directed referrals of patients in federally-funded health care programs to Allergan's products in violation of the federal [AKS] and similar state anti-kickback laws." *Id.* ¶¶ 15, 23, 94–304 (identifying Relators as ophthalmologists and describing the purported kickbacks they received), 309 (stating that ophthalmologists who received the kickbacks violated the law by "direct[ing] referrals of patients in federally-funded health care programs to Allergan's products"). But despite being uniquely situated to provide details regarding any allegedly false claims, Relators do not identify even a single prescription they (or any other physician) wrote for a government program beneficiary as the result of a kickback, much less a claim or certification of compliance with any statutes relating to such a prescription that a retail pharmacy actually submitted to a government health care program for payment. *See generally id.*

Despite the fact that Relators allege damages in the "hundreds of millions of dollars," *id.* ¶ 332, the United States, the District of Columbia, and each of the nineteen states identified in the SAC declined to intervene in this action more than three years ago. *See* Mot. to Unseal, ECF No. 41 at 4.[4]

III. LEGAL FRAMEWORK

The FCA imposes treble damages and per-claim penalties on any person who "knowingly presents, or causes to be presented, to an officer or employee of the United States Government … a false or fraudulent claim for payment or approval," as well as any person who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." 31 U.S.C. § 3729(a)(1)–(2) (pre-2009 amendments).[5] The FCA's primary purpose is to "indemnify the government—through its

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[4] "On December 21, 2010, the United States, on behalf of itself and the named states, with the exception of the Commonwealth of Massachusetts, filed its Notice of Election to Decline Intervention in this *Qui Tam* action." Mot. to Unseal, ECF No. 41 at 4. Massachusetts also has since declined to intervene.

[5] On May 20, 2009, Congress enacted the Fraud Enforcement and Recovery Act of 2009 ("FERA"), Pub. L. No. 111-21, 123 Stat. 1617 (2009), which amended the FCA to create liability for:

> [A]ny person who—
>
> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
>
> (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)(A)–(B). FERA contains a retroactivity provision, which applies only to 31 U.S.C. § 3729(a)(1)(B) and is limited to "claims" pending "on or after" June 7, 2008. Pub. L. No. 111–21 § 4(f). To the extent Relators purport to rely upon 31 U.S.C. § 3729(a)(1)(B) (formerly 31 U.S.C. § 3729(a)(2)), their failure to identify the particular false claims at issue makes it impossible to know if the pre- or post-FERA provision, or both provisions, applies. The bulk of the time period alleged in the SAC is prior to June 7, 2008, *see* SAC ¶ 199 ("since at least 2002, Allergan has provided valuable practice management and business advisory services"), but the only specific conduct alleged occurred after that date, *see* SAC ¶¶ 111–96 (describing interactions between Relators and Allergan personnel in 2009 and 2010). Since the actual factual allegations of the SAC appear to rely on 31 U.S.C. § 3729(a)(1)(A) (formerly § 3729(a)(1)), rather than on the "false statements" theory of

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restitutionary penalty provisions—against losses caused by a defendant's fraud." *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 304 (3d Cir. 2011) (quotations omitted).

To establish a *prima facie* FCA violation under section 3729(a)(1), 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.'" *Wilkins*, 659 F.3d at 304–05. Under section 3729(a)(2)—"known as the false statements prong of the FCA—a plaintiff also must show that the defendant made or used (or caused someone else to make or use) a false record in order to cause the false claim to be actually paid or approved." *United States ex rel. Schmidt v. Zimmer, Inc.*, No. 00-cv-1044, 2005 U.S. Dist. LEXIS 15648, at *4 (E.D. Pa. July 29, 2005) (quotations and citations omitted); *see also Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 665 (2008) (interpreting section 3729(a)(2) before the FERA amendments and holding that "a plaintiff … must prove that the defendant ***intended*** that the false record or statement be material to the Government's decision to pay or approve the false claim" (emphasis added)).

The Third Circuit has explained that "[t]here are two categories of false claims under the FCA: a factually false claim and a legally false claim." *Wilkins*, 659 F.3d at 305 (citing *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008)). Factually false claims involve misrepresented goods or services, whereas "a claim is legally false ***when the claimant knowingly falsely certifies*** that it has complied with a statute or regulation the compliance with which is a condition for Government payment." *Id*. (emphasis added). There are two types of legally false claims: those based on express false certifications and those based on implied false certifications. *Id.* The "express false certification" theory applies when an entity expressly "falsely certif[ies] … compliance with regulations which are prerequisites to

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§ 3729(a)(1)(B) (formerly § 3729(a)(2)), under which they clearly do not state a claim, it probably is a distinction without a difference in this case.

Government payment in connection with the claim for payment of federal funds." *Id.* In contrast, the "implied false certification" theory applies "when a claimant seeks and makes a claim for payment from the Government ***without disclosing*** that it violated regulations that affected its eligibility for payment." *Id.* (emphasis added). Because the existence and scope of implied certifications can be difficult to discern in advance and are subject to varying reasonable interpretations, to avoid turning "the FCA … into a blunt instrument," the courts limit liability under the implied certification theory to situations where it is clear that the underlying "regulations … are a precondition to payment." *Id.* at 307 (citations and quotations omitted).

Relators' theory of civil FCA liability here depends in part on their ability to demonstrate that Allergan violated the criminal AKS. *See* SAC ¶¶ 63–86. Under this theory, an AKS violation by itself is insufficient to give rise to FCA liability. Instead, it is a ***certification of compliance*** with the AKS that provides the nexus to the FCA. *See Wilkins*, 659 F.3d at 305 ("A legally false FCA claim is based on a 'false certification' theory of liability."); *see also United States ex rel. Rost v. Pfizer, Inc.*, 736 F. Supp. 2d 367, 376 (D. Mass. 2010) (quoting *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996)) ("A claim cannot be false merely because the activity underlying the claim was illegal, '[i]t is the false certification of compliance which creates liability.'").[6]

The federal AKS makes it a crime to "knowingly and willfully offer[] or pay[] 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

[6] The Patient Protection and Affordable Care Act ("PPACA"), enacted in 2010, amended the AKS to provide that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." Pub. L. No. 111-148 § 6402(f). However, the PPACA does not apply retroactively, and therefore the amendment is inapplicable in this case. *Wilkins*, 659 F.3d at 311 n.19 (citing *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 283 n.1 (2010)).

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." 42 U.S.C. § 1320a-7b(b)(2). The "willfully" requirement in particular requires proof of a high level of *mens rea*: Relators must plead facts that will prove Allergan had "an evil-meaning mind," knew that its conduct was unlawful, and continued to act in disregard of the law. *Bryan v. United States*, 524 U.S. 184, 193 (1998).

IV. LEGAL STANDARDS

A. Federal Rules Of Civil Procedure 8 And 12(b)(6).

A complaint that fails to allege "enough facts to state a claim to relief that is plausible on its face" must be dismissed under Federal Rules of Civil Procedure 8 and 12(b)(6). *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). The *Twombly* "plausibility standard" demands "more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Accordingly, Relators cannot survive a Rule 12(b)(6) motion by pleading facts that "permit the court … to infer the ***mere possibility*** of misconduct." *Id.* at 679 (emphasis added). Nor may Relators rely on "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Id.* at 678. Even at the pleading stage, the Court is not "bound to accept as true a legal conclusion couched as a factual allegation." *Papasan v. Allain*, 478 U.S. 265, 286 (1986) (quoted in *Twombly*, 550 U.S. at 555).

The Court may "consider only the complaint, exhibits attached [thereto], matters of public record, as well as undisputedly authentic documents if the complainant's claims are based upon these documents" in deciding a Rule 12(b)(6) motion. *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010). Because Relators relied on the OIG Guidance, *see* Exhibit 1, the Court may consider that document without converting this motion into a request for summary judgment under Rule 56.

B. Federal Rule Of Civil Procedure 9(b).

"In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Under Third Circuit law, "plaintiffs must plead FCA claims with particularity in accordance with Rule 9(b)." *Wilkins*, 659 F.3d at 301 n.9 (citing *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 234 (3d Cir. 1998)). "[A]t a minimum … plaintiffs [must] support their allegations of … fraud with all of the essential factual background that would accompany 'the first paragraph of any newspaper story' – that is, the 'who, what, when, where and how' of the events at issue." *In re Rockefeller Ctr. Props., Inc.*, 311 F.3d 198, 217 (3d Cir. 2002); *see also Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007) ("To satisfy this standard, the plaintiff must plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation."); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997).

The AKS allegations underlying a FCA claim must pass muster under Rule 12(b)(6), *see Wilkins*, 659 F.3d at 301 n.9, and be pled with particularity in accordance with Rule 9(b)'s requirements, *United States ex rel. Wilkins v. United Health Grp., Inc.*, No. 08-cv-3425, 2011 U.S. Dist. LEXIS 146448, at *5 (D.N.J. Dec. 20, 2011). Although "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally" under Rule 9(b), this "does not give [plaintiffs] license to evade the less rigid—though still operative—strictures of Rule 8." *Iqbal*, 556 U.S. at 686–87 ("Rule 8 does not empower [plaintiff] to plead the bare elements of his cause of action, affix the label 'general allegation,' and expect his complaint to survive a motion to dismiss.").

V. ARGUMENT

A. Relators Fail To Articulate A Cognizable Claim Under Any False Claims Act Legal Framework.

Relators' SAC fails to articulate a viable legal theory under the FCA or to plead facts that would support liability. Their theory is premised on the notion that Allergan should be held liable for unspecified, yet allegedly "false," certifications made by retail pharmacists—in the

course of seeking reimbursement for prescriptions they filled for patients of eye care physicians—regarding the pharmacists' own compliance with the AKS or similar state anti-kickback laws. Relators' claims seek to extend FCA liability beyond the scope that Third Circuit precedent recognizes or permits. Thus the SAC fails to plead the facts necessary to state a claim upon which relief may be granted and should be dismissed. Fed. R. Civ. P. 12(b)(6).

1. Relators Fail To Articulate A Viable Claim Under A "Factually False" Theory.

Ignoring Third Circuit FCA jurisprudence, Relators assert that AKS violations render a claim "factually false" even without a false certification. *See* SAC ¶ 78. But a claim is factually false only "when the claimant misrepresents what goods or services that it provided to the Government." *Wilkins*, 659 F.3d at 305; *see also Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001) (explaining that factually false claims are claims involving "an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided").

Relators do not make any such allegations here. They do not, for example, allege that Allergan submitted claims to government health programs for products that were never delivered or that Allergan otherwise misrepresented the actual products provided to program participants. *See Wilkins*, 659 F.3d at 305 (explaining that there was no factually false claim where "appellants do not contend the appellees did not deliver the services for which they sought payment"). Holding that a claim is "factually false" solely because of an underlying AKS violation would render the Third Circuit's false certification jurisprudence irrelevant. Thus, Relators' factual falsity claims fail.

2. Relators Fail To Articulate A Viable Claim Under The False Certification Theory.

Under the false certification theory, an AKS violation alone is insufficient to give rise to FCA liability. As discussed above, it is a ***certification of compliance*** with the AKS in connection with the submission of a claim for payment to the government that provides the nexus to the FCA. *Wilkins*, 659 F.3d at 305 ("A legally false FCA claim is based on a 'false

certification' theory of liability."); *see also Rost*, 736 F. Supp. 2d at 376 (quoting *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996)) ("A claim cannot be false merely because the activity underlying the claim was illegal, '[i]t is the false ***certification of compliance*** which creates liability.'" (emphasis added)). Relators do not allege that Allergan itself submitted a claim for payment or ever certified compliance with the AKS or similar state laws. *See generally* SAC. And the SAC does not identify any other certifications that would give rise to FCA liability for Allergan under a recognized express or implied certification theory.

a. Relators Fail To Identify Any Relevant "Certifications Of Compliance" With The Anti-Kickback Statute Or Similar State Laws To Support The Express False Certification Theory.

Absent any specific certifications of compliance with the AKS or similar state laws, Relators cannot state a claim premised on the "express" false certification theory. *See Wilkins*, 659 F.3d at 305. Here, Relators do not identify any relevant "express certifications" (e.g., on claim submission forms) through which Allergan (or any other party) certified its compliance with the AKS or any other law. Although the SAC references various documents that purport to comprise "express false certifications," those documents are completely unrelated to the claims at issue here. Specifically, Relators cite to Medicare provider agreements related to hospitals, physicians, and "Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers," even though those documents have nothing to do with claims submitted to the government ***by retail pharmacies*** for dispensing the type of eye care drugs prescribed by ophthalmology and optometrist practices and at issue in this case. *See* SAC ¶ 82.

Relators also fail to specify the text of any claim submission form (or other document that could contain an express certification) applicable to any federal health care program other than Medicare (the deficiency of which is described above), such as CHAMPUS/TRICARE, CHAMPVA, or any of the state Medicaid plans. To the extent Relators rely on the express false certification theory, this failure alone requires dismissal of the claims. *See United States ex rel. Rostholder v. Omnicare, Inc.*, No. 07-cv-1283, 2012 U.S. Dist. LEXIS 114278, at *49–50 (D. Md. Aug. 14, 2012) (dismissing claim where the relator did "not sufficiently explain[] the nature

of th[e] [reimbursement] process or direct[] the court to the specific regulations, guidance manuals, or specific forms that are used in the payment process ….").

b. Relators Fail To Plead Facts That Establish That Each and Every State's—or Any State's—Regulatory Regime Conditions Medicaid Payments On Compliance With The Anti-Kickback Statute Or Similar State Laws.

"[T]o plead a claim … under a false certification theory, either express or implied," the relator must establish that the government conditioned payment on "compliance with the regulation which the defendant allegedly violated." *Wilkins*, 659 F.3d at 309. In an implied certification case, "the underlying statute or regulation upon which the plaintiff relie[s] [must] ***expressly state[]*** the provider must comply ***in order to be paid***." *Mikes*, 274 F.3d at 700 (first emphasis in original); *see also Conner*, 543 F.3d at 1219 (a defendant's "general sweeping language" promising to comply with all "underlying laws and regulations" is insufficient to establish the false certification necessary to sustain a claim under the FCA); *Wilkins*, 659 F.3d at 310 ("[L]ike … the courts of appeals in *Conner* and *Mikes*, we question the wisdom of regarding every violation of a … regulation as a basis for a *qui tam* suit.").

Relators do not identify any state Medicaid laws or regulations that condition payment on compliance with the federal AKS or similar state laws. Although the *Wilkins* court found that compliance with the federal AKS can be a condition of payment ***for Medicare*** (for a provider submitting the claim and thus making the implied certification), it did so only after an exhaustive regulatory analysis of the specific regulations at issue. *See* 659 F.3d at 307–14. Relators' failure to identify any relevant Medicaid program forms or state regulations that expressly make compliance with the AKS or similar state laws a condition of payment precludes the type of evaluation that the *Wilkins* court undertook. State-by-state and program-by-program analysis is critical because each state has a unique regulatory framework, and the Third Circuit has cautioned that "the implied certification theory of liability should not be applied expansively." *Id.* at 307. Relators' theory would require just that. Because Relators have not stated a claim

under a false certification theory for Medicaid, their claims based on that program should be dismissed.

c. Allergan Cannot Be Held Liable Based On Unspecified Certifications Made By Pharmacists Under Any Theory Of False Claims Act Liability.

Even if Relators had identified express certifications or state laws or regulations that expressly conditioned payment on compliance with anti-kickback laws, their ***federal and state*** claims—all of their claims—must be dismissed because the underlying "false" certifications stem from reimbursement claims submitted by retail pharmacies that are complete strangers to the allegedly unlawful conduct. *See* SAC ¶ 312 ("Medicaid and Medicare claims for the payment of Allergan's eye care pharmaceutical products induced by illegal kickbacks are submitted to the United States and/or the States ***by the pharmacists*** who fill the patients' prescriptions." (emphasis added)). Relators do not allege that Allergan submitted any pertinent claims or certifications to the government. Nor do they allege that such claims or certifications were submitted by the physicians who allegedly received the kickbacks. Only the pharmacists allegedly submitted claims, although Relators identify no actual claims. But "[i]n most or all cases, … [the pharmacists] do[] not know whether the prescription has been induced by a kickback." SAC ¶ 312. And the SAC does not allege that the pharmacists violated the AKS. Thus, any certification by the pharmacists that ***they*** complied with the AKS would have been accurate, and there would be nothing false about the claims they submitted.

The SAC does not even attempt to describe how the pharmacists' reimbursement claims could have certified—expressly or impliedly—***Allergan's*** compliance with the AKS. Stretching pharmacists' certifications to cover the conduct of third parties like Allergan would conflict with Third Circuit precedent and inappropriately expand the false certification theory. *Wilkins* explicitly held that "a claim is legally false when ***the claimant*** knowingly falsely certifies that ***it has complied*** with a statute or regulation the compliance with which is a condition for Government payment." 659 F.3d at 305 (emphases added). And, as noted above, the Third Circuit cautioned that "the implied certification theory of liability should not be applied

expansively, particularly when advanced on the basis of FCA allegations arising from the Government's payment of claims under federally funded health care programs." *Id.* at 307.[7]

In *Rost*, the District of Massachusetts rejected the theory of FCA liability that Relators must rely upon here. 736 F. Supp. 2d at 377. Following other federal district courts, the *Rost* court concluded that "the pharmacies that submitted the claims implicitly certified compliance with applicable statutes and regulations ***only with respect to themselves and those persons they control*** (e.g., employees)." *Id.* (emphasis added); *see also United States ex rel. Thomas v. Bailey*, No. 06-cv-00465, 2008 U.S. Dist. LEXIS 91221, at *26 (E.D. Ark. Nov. 6, 2008) ("[A] hospital's act of submitting a claim for payment to the government impliedly certifies that the hospital has complied with the [AKS] … but, it is another matter to say that a hospital's act of submitting a claim for payment is an implied certification that a person who is not employed by the hospital, is not an agent or subcontractor of the hospital, and who does not act under the hospital's control, complied with the [AKS].").[8] This Court too should hold that pharmacists' certifications regarding their own conduct, where such pharmacists were unaware of any alleged

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[7] Although *Wilkins* recognized the implied certification theory of FCA liability, the defendants there were private insurance carriers that provided coverage under Medicare Parts C and D and, therefore, directly "submit[ted] claims to the Government." 659 F.3d at 299. The court in *Wilkins* did not apply the false certification theory to defendants who do not submit claims (e.g., pharmaceutical companies) based on alleged certifications made by unaffiliated third parties (e.g., retail pharmacies) who were unaware of any kickbacks, as Relators' theory requires.

[8] In *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, the First Circuit found that Medicare claim forms could support FCA liability as applied to "violations caused by third parties." 647 F.3d 377, 393 (1st Cir. 2011) Here, however, Relators have not identified any underlying Medicare and Medicaid certifications, and thus it is not clear whether they are similar to the forms at issue in *Hutcheson*. Moreover, the First Circuit adopted this expansive, unprecedented interpretation of the FCA only after ***explicitly rejecting*** the interpretative approach applied by most other Circuits, including the Third Circuit. *Id.* at 385 ("We decline to employ the district court's [factually false and legally false] categories here."). Notably, when the district court in *Hutcheson* applied the "factually false" and "legally false" framework adopted by the Third Circuit, it concluded that the "certification is specific to the party seeking reimbursement" and that the certification was "not in itself a certification that the entire transaction complied with the [AKS]." *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 694 F. Supp. 2d 48, 65–66 (D. Mass. 2010).

kickbacks, fraud, or falsity, cannot constitute false certifications for purposes of holding unaffiliated third parties liable under the FCA. For that reason, Relators' claims should be dismissed.

3. Relators Fail To Adequately Plead *Scienter*.

To plead a FCA claim, Relators must plausibly allege that Allergan "knowingly" caused false claims to be presented to the government. The FCA requires that the defendant have "actual knowledge of the information" that is allegedly false, "act[] in deliberate ignorance of the truth or falsity of the information," or "act[] in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). Given the potential for "abuse by the government and *qui tam* relators" of the implied false certification theory—and the draconian treble damages and per-claim penalties under the FCA—the *scienter* element is especially important. *See United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1270 (D.C. Cir. 2010) ("[T]his very real concern [regarding abuse of the FCA] can be effectively addressed through strict enforcement" of the *scienter* element.). Relators fail to adequately plead that Allergan acted "knowingly."

First, Relators do not allege that Allergan "w[as] aware or informed of the violations" in such a way "that would support a plausible claim that they knowingly submitted false claims." *United States ex rel. Pilecki-Simko v. Chubb Inst.*, 443 F. App'x 754, 761 (3d Cir. 2011). As explained above, some courts have explicitly held that pharmacist certifications ***do not*** cover the actions of third parties like pharmaceutical companies. *See* Section V.A.2.c. Thus, even if this Court were to hold differently, the ambiguity surrounding the scope and impact of the pharmacist certifications would undermine any allegation that Allergan ***knowingly*** caused false claims to be submitted in violation of the FCA. *See Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 70 n.20 (2007) ("Where, as here, the statutory text and relevant court and agency guidance allow for more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation as a knowing or reckless violator."); *United States ex rel. Pritsker v. Sodexho, Inc.*, No. 03-cv-6003, 2009 U.S. Dist. LEXIS 51469, at *53–54 (E.D. Pa. Mar. 6, 2009), *aff'd United States ex rel. Pritsker v. Sodexho, Inc.*, 2010 U.S. App.

LEXIS 2645 (3d Cir. Feb. 9, 2010) (holding that defendants were not liable under FCA where they operated under a reasonable interpretation of regulations).

Moreover, courts have consistently rejected FCA claims predicated on the "collective knowledge" theory, under which "a plaintiff [could] prove *scienter* by piecing together scraps of 'innocent' knowledge held by various corporate officials, even if those officials never had contact with each other or knew what others were doing in connection with a claim seeking government funds." *Sci. Applications Int'l Corp.*, 626 F.3d at 1275 (noting that the court "[k]nows of no circuit that has applied the 'collective knowledge' theory to the FCA") (quoting *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 918 n.9 (4th Cir. 2003)) (quotations omitted). Yet, here, Relators attempt to ***expand*** the "collective knowledge" theory to include not only "various corporate officials"—the theory rejected in *Science Applications International Corp.*—but also unaffiliated third parties. Relators ask this Court to impose FCA liability on Allergan based upon the "collective knowledge" of ***Allergan employees*** (who allegedly provided *Allergan Access* and other purported kickbacks to eye care professionals), ***physicians*** (who allegedly prescribed Allergan products to patients who participate in government health care programs after receiving kickbacks), and ***pharmacists*** (who allegedly submitted claims for payment to the government and certified compliance with the AKS). Relators have not identified a single Allergan official who possessed all of the knowledge necessary to establish the fraudulent scheme alleged in the SAC.

It is not enough for Relators to plead the word "knowingly," SAC ¶ 322; they must plead facts plausibly indicating that someone at Allergan knew that it was causing the submission of false claims. Nor may Relators "piec[e] together scraps" of knowledge possessed by unaffiliated entities. *Sci. Applications Int'l Corp.*, 626 F.3d at 1275. To do so would sweep aside the statutory *scienter* requirement. *Id.* at 1274 ("[U]nder the FCA, 'collective knowledge' provides an inappropriate basis for proof of *scienter* because it effectively imposes liability, complete with treble damages and substantial civil penalties, for a type of loose constructive knowledge that is inconsistent with the Act's language, structure, and purpose.").

Second, Allergan cannot be held to have acted ***knowingly*** where, as here, it has adopted a reasonable interpretation of the AKS and related regulatory guidance with respect to sales activity and product-support services. The alleged practice management consultation activities fall well within a reasonable interpretation of the realm of permissible activities under the AKS. Regardless, the legal requirements relating to these kinds of business activities are ambiguous, and therefore Relators cannot show that Allergan acted "knowingly" for purposes of the FCA.

In *Safeco Insurance Company of America v. Burr*, the Supreme Court concluded that "[w]here … the statutory text and relevant court and agency guidance allow for more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation as a ***knowing*** … violator." 551 U.S. at 70 n.20 (emphasis added). Under *Safeco*, the assessment of whether a defendant acted with the requisite *scienter* despite ambiguous law and guidance is an objective question that a court should resolve without recourse to allegations about the defendant's subjective intent. *See id*.[9]

The OIG Guidance cited in the SAC recognizes that product-support services like those that Allergan allegedly provided are permissible under the AKS. The Guidance recognizes that "[p]harmaceutical manufacturers sometimes offer purchasers certain support services in connection with the sale of their products. These services may include billing assistance tailored to the purchased products, reimbursement consultation, and other programs specifically tied to support of the purchased product." OIG Guidance, 68 Fed. Reg. at 23735 (Exhibit 1). Under OIG's view, services such as "limited reimbursement support in connection with [a pharmaceutical company's] own products" have "no independent value" and thus do not raise "kickback concerns." *Id.* The OIG Guidance does not define the limits of such services. Further, it sanctions such services even though (1) these activities directly result in quantifiable value to physicians' practices, (2) pharmaceutical companies recoup the costs associated with

[9] As *Safeco* details, the Fair Credit Reporting Act, like the FCA, includes a *mens rea* element requiring evidence that the defendant acted knowingly.

compensating product-support personnel by selling products, and (3) pharmaceutical companies provide these services to facilitate the writing of prescriptions by the physicians who receive the services.

Further, the OIG Guidance certainly does not attempt to preclude pharmaceutical companies from employing sales representatives, *cf.* 68 Fed. Reg. at 23738–39 (Exhibit 1), even though (1) they provide value to physicians through their educational and informational presentations and associated advice, (2) the costs associated with a sales force, including, salaries, benefits, and transportation are significant, (3) pharmaceutical companies recoup those costs by selling products, and (4) sales representatives are employed to pitch the companies' products to the very physicians they present to and advise.[10] Here, Relators allege that Allergan provided various forms of services that are either clearly authorized product-support services or are similar to such services but ***less valuable*** than those product-support services and the everyday services provided by unobjectionable sales representatives. Therefore, it was reasonable to conclude that the services alleged in the SAC did not violate the AKS.

Relators allege that Allergan provided product-support services, including "reimbursement analysis" and "billing and coding advice," to induce ophthalmologists and optometrists to sell Allergan products, including Restasis®. SAC ¶¶ 3, 98; *see also id.* ¶¶ 121 (alleging that Allergan provided "encouragement and support for physicians to build a successful 'Dry Eye' practice" related to "Allergan's product Restasis® [which] is the first and currently the only prescription therapy approved in the United States for the treatment of chronic dry eye"), 251–52 (describing the "payer" and "reimbursement" tools available on *Allergan Access*). Under an objectively reasonable interpretation of the AKS and the OIG Guidance, Allergan could conclude that these product-related support services were permissible. *See* 68 Fed. Reg. at 23735 (Exhibit 1).

[10] Under the PhRMA Code, on which Relators also rely, *see* SAC ¶ 93, sales representatives may even provide lunches and certain other items of some value to health care professionals.

Relators also allege that *Allergan Access* and the ECBAs offered "business advisory services," benchmarking tools, and educational materials. SAC ¶¶ 3, 98. The SAC alleges that these practice management resources were directed toward eye care practices that prescribe Allergan products. *See id.* ¶ 98. Thus Allergan allegedly offered these services "in connection with its own products," 68 Fed. Reg. at 23735 (Exhibit 1). Like the expenses associated with permissible product-support services, the costs related to these resources, including the ECBAs' advice and consultation, are overhead recouped in part through Allergan's product sales. However, Allergan also charged physicians a not-insignificant subscription fee for the resources, recognizing that some of the content of the practice management consultation activities was perhaps less similar to other product-support services that the OIG Guidance expressly acknowledges are legitimate. Allergan reasonably charged physician practices based on an annual subscription model because the same content was available on the website to anyone who subscribed.

The general practice management business advice that Relators allege amounted to a kickback is arguably less valuable than the direct product-support services that OIG has authorized and that directly improve a physician's bottom line (i.e., by helping the physician get reimbursed for using a product). Thus, the structure of Allergan's programs reflected an objectively reasonable interpretation of the law. Allergan, after all, succeeded in getting physicians to pay a pharmaceutical company, rather than the other way around. *See* SAC ¶ 131. Even if Allergan was mistaken about the permissibility of these services and practice management resources, its interpretation of the statute was reasonable rather than reckless, and this negates any allegation that Allergan ***knowingly*** caused the submission of false claims. *See United States ex rel. Streck v. Allergan, Inc.*, 894 F. Supp. 2d 584, 600 (E.D. Pa. 2012) (quoting *Safeco*, 551 U.S. at 70) ("There are simply no facts for the Court to plausibly infer that [defendants'] … methods were not a reasonable interpretation …."). For that reason, the SAC should be dismissed for failure to state a claim upon which relief may be granted. Fed. R. Civ. P. 12(b)(6).

4. Relators Fail To Adequately Allege That Allergan Caused The Submission Of False Claims.

The FCA "seeks to redress fraudulent activity which attempts to or actually causes economic loss to the United States government." *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 184 (3d Cir. 2001). Claims "which do not or would not cause [such] financial loss … are not within the [FCA's] purview." *Id.*

Even if Relators' SAC satisfied the other FCA elements—and it does not—the SAC must be dismissed because it does not plausibly plead how Allergan's alleged actions "caused" financial loss to the government. As an initial matter, Relators do not specifically claim that recipients of the alleged "kickbacks" prescribed Allergan products that would not have been otherwise prescribed and reimbursed by the Medicaid and Medicare programs. Relators fail to identify ***any*** increase in prescriptions traceable to the challenged activities; prescribers may well have continued the same prescribing patterns or changed them for reasons other than the alleged kickback—the point is that Relators have not pled facts plausibly demonstrating causation. In fact, Relators have not even alleged that the physicians who received the purported kickbacks were aware of them.[11] Of course, without such knowledge "there is no inducement for referrals." *United States ex rel. West v. Ctr. for Diagnostic Imaging, Inc.*, 787 F. Supp. 2d 1213, 1222 (W.D. Wash. 2011). Absent any such allegations, there is no basis to conclude that the alleged conduct caused a financial loss to the government. Relators' barebones causation allegations are inadequate, and therefore the SAC should be dismissed.

B. Relators Fail To Adequately Plead A Violation Of The Anti-Kickback Statute And Therefore Cannot Proceed With Their False Claims Act Allegations.

Relators' FCA theory hinges on their ability to plausibly allege that Allergan ***knowingly*** and ***willfully*** offered or provided ***impermissible*** remuneration in violation of the AKS. *See* Section III. Although the Third Circuit has, in very limited circumstances not present here,

[11] This point is particularly important here because eye care practices were ***paying Allergan*** for the alleged kickbacks (i.e., the *Allergan Access* program and ECBA services).

recognized FCA claims rooted in violations of the AKS, Relators must adequately plead the elements of an AKS violation to proceed on such a theory. *See Wilkins*, 659 F.3d at 312–14; *see also Klaczak v. Consol. Med. Transp.*, 458 F. Supp. 2d 622, 662 n.33 (N.D. Ill. 2006) (an AKS violation is a "necessary precondition" for relators' FCA theory). That is, Relators cannot state a FCA claim based on a ***false*** certification theory unless they plausibly allege that Allergan violated the AKS, ***thereby rendering false*** a certification of compliance with the statute according to Relators' theory.

The SAC does not plausibly allege an AKS violation. Even accepting Relators' allegations as true—which Allergan does not—the SAC does not conceivably allege that Allergan intended to break the law, and the SAC therefore fails to allege plausibly that Allergan acted ***knowingly*** and ***willfully***. Relators do not (as they must) allege with the requisite level of detail that Allergan knowingly and willfully offered impermissible remuneration or set the prices for the practice management consultative services below fair market value. Nor do Relators allege that Allergan knowingly and willfully offered compensation above fair market value for the "additional inducements" identified in the SAC. Further, Relators' theory would penalize Allergan for speech protected by the First Amendment.

1. Relators Fail To Adequately Allege That Allergan Acted "Willfully" With Regard To The Practice Management Consultative Services As Required By The Anti-Kickback Statute.

The federal AKS makes it illegal for someone to "***knowingly and willfully*** offer[] or pay[] any remuneration … to any person to induce" or reward the referral of federal health care program business." 42 U.S.C. § 1320a-7b(b)(2) (emphasis added). Accordingly, a defendant may "not be held accountable for an 'unknowing' illegal payment arrangement." *Wilkins*, 659 F.3d at 314 (explaining that, to be held liable under an AKS-based FCA theory, the alleged kickbacks must have been made "knowingly and willfully"). Even evidence "that a reasonable person would have been strongly suspicious, or … should have been aware of criminal knowledge," is insufficient to establish that a defendant acted knowingly and willfully. *United States v. Carrillo*, 435 F.3d 767, 782 (7th Cir. 2006); *see also Klaczak*, 458 F. Supp. 2d at 674.

The "willfulness" standard in particular requires proof that the defendant "acted with an evil-meaning mind, that is to say, that he acted with knowledge that his conduct was unlawful." *Bryan*, 524 U.S. at 193; *see also United States ex rel. Kosenske v. Carlisle HMA, Inc.*, No. 05-cv-2184, 2010 U.S. Dist. LEXIS 31619, at *31 (M.D. Pa. Mar. 31, 2010) (citing *United States v. Jain*, 93 F.3d 436, 441 (8th Cir. 1996)) ("[P]roof that a defendant knowingly violated the [AKS] requires satisfaction of a 'heightened *mens rea* standard.'").[12] Thus, to sustain their AKS-based FCA claims, Relators must allege sufficient facts to establish that Allergan knew it was acting unlawfully and continued to do so in disregard of the law. *See United States ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 149 (D. Mass. 2000) (dismissing an AKS-based FCA claim where relators failed to adequately allege the requisite level of *scienter*).

Here, Relators do not plead sufficient facts to plausibly allege that Allergan "acted with an evil-meaning mind" when providing practice management consultative services or any of the other alleged "inducements" described in the SAC. Relators do not allege that Allergan attempted to conceal any aspect of the ECBAs' role or the features of *Allergan Access*. Rather, as the SAC concedes, Allergan freely and openly discussed *Allergan Access* and the associated ECBA services, advertising the details of the program to various eye care professionals and others through literature and in-person presentations.[13] *See, e.g.*, SAC ¶¶ 107, 112 (ECBA

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[12] Where, as here, an alleged "AKS violation is arguably more fairly likened to a violation of a detailed regulatory framework or a highly technical area of regulated activity," some courts have held that the willfulness standard can only be met if the defendant acted with knowledge that it was violating ***the specific regulatory provision at issue***. *See Klaczak*, 458 F. Supp. 2d at 675–77 (holding that relator's claim failed under either interpretation of willfulness). The PPACA amended the AKS's *scienter* requirement to provide that "a person need not have actual knowledge of this section or specific intent to commit a violation of this section." Pub. L. No. 111-148 § 6402(f). As discussed above, however, the PPACA does not apply retroactively and thus does not apply here. *Wilkins*, 659 F.3d at 311 n.19 (citing *Graham Cnty.*, 559 U.S. at 283 n.1).

[13] *See* SAC ¶¶ 107 ("According to marketing literature issued by Allergan in 2007, 'The Allergan Eye Care Business Advisory Group designs, develops, and delivers practice management resources that bring a sustainable competitive advantage to its customers.'"), 230 (describing a case study allegedly published on *Allergan Access*), 273–75 (describing

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allegedly presented to 16 to 20 eye care professionals), 159 (ECBA allegedly presented to 35 to 40 members of Relators' staff), 173 (ECBA allegedly presented to "approximately 30 Optometrists"), 184 (alleged invitation to be sent to "Optometric network"), 218 (alleging that ECBA represented that there are approximately 1,500 members of *Allergan Access*). Far from evincing an "evil-meaning mind," Allergan's alleged conduct was consistent with the belief that its programs were lawful, and Relators allege no facts suggesting that anyone at Allergan thought otherwise. *Cf. Klaczak*, 458 F. Supp. 2d at 627, 675 (noting, in finding relators' case "fundamentally implausible," that "Relators' AKS theory … is not fairly likened to people personally pocketing bribes, transferred in remote parking lots so others could not see what was transpiring, in return for medical referrals"). The SAC's conclusory statements that Allergan acted "knowingly and willfully," *see, e.g.*, SAC ¶¶ 203, 305, 310, cannot salvage Relators' claims.[14]

Moreover, Relators acknowledge that Allergan charged physicians subscription fees for the practice management consultative services. *See* SAC ¶¶ 221–31. Relators question the price Allergan charged, but fail to plead that Allergan set the fees too low "with knowledge that [its] conduct was unlawful." *Bryan*, 524 U.S. at 193. Numerous courts have held that to satisfy the remuneration element of AKS-based FCA claims like those at issue here, a relator must establish that the defendant provided "transfers of items or services for free or for other than fair market value." *See, e.g.*, *United States ex rel. Westmoreland v. Amgen, Inc.*, 738 F. Supp. 2d 267, 274 (D. Mass. 2010) (quoting 42 U.S.C. § 1320a-7a(i)(6)) (stating in a FCA action that "[u]nder the

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Allergan's announcement that it would be limiting the scope of the *Allergan Access* program).

[14] Tellingly, only paragraph 203 of the SAC alleges that Allergan acted "willfully"—and even that paragraph is devoid of any particular factual allegation that would support a plausible inference that Allergan acted with an "evil-meaning mind." SAC ¶ 203 ("Allergan knowingly and willfully offers and provides these valuable practice management and business advisory services to [physicians] ….").

[AKS], 'remuneration' is broadly defined as 'transfers of items or services for free or for other than fair market value'"); *United States ex rel. Fair Lab. Practices Assocs. v. Quest Diagnostics, Inc.*, No. 05-cv-5393, 2011 U.S. Dist. LEXIS 37014, at *8–9 (S.D.N.Y. Mar. 24, 2011) (same). As these cases recognize, the AKS does not prohibit all forms of remuneration provided to physicians. It only prohibits those forms of remuneration that were made "knowingly and willfully" to induce referrals. 42 U.S.C. § 1320a-7b(b)(2); *Wilkins*, 659 F.3d at 314.

The SAC asserts that the services were provided at prices below fair market value, but Relators do not allege specific facts demonstrating the *scienter* that an AKS violation requires. For instance, Relators do not allege that Allergan intentionally undertook a faulty fair market value analysis or otherwise intended to price the services below fair market value in violation of the law. *Cf.* SAC ¶ 225 ("The fair market value of all of the comprehensive services offered on Allergan Access … far exceeds the $895 fee paid [by physicians]."). Instead, Relators implausibly compare *Allergan Access* to high-end, individualized consulting services in an attempt to establish that Allergan's price was too low. *See, e.g.*, SAC ¶¶ 225–27 (discussing *Allergan Access* and consultants that allegedly provided content). This comparison is entirely inapt, and Relators plead no facts to suggest otherwise. Relators fail even to allege that the services offered by stand-alone professional consultants were similar to those that Allergan offered. SAC ¶¶ 226–27. Indeed, the resources Allergan made available were demonstrably unlike the stand-alone professional consulting services to which the Relators compare them, as is clear in all of the references to "self-assessment"—work the physicians would have to do for themselves—by Relators in the SAC. *See* SAC ¶¶ 247, 253, 255, 257, 260, 262. And as the SAC concedes, unlike the stand-alone professional consulting services, Allergan priced its services using a subscription model. With this subscription model, which is akin to cable television and similar services, there are no additional costs to provide additional subscribers with access to the same content. Many of Relators' allegations regarding this issue are premised on nothing more than Relators' own "information and belief." *See, e.g.*, SAC ¶ 239. But "where allegations of fraud are based on information and belief, the complaint must set forth a factual

basis for such belief," and Relators have not done so here. *Walsh*, 98 F. Supp. 2d at 147 (citing *Thompson*, 125 F.3d at 903); *United States ex rel. Waris v. Staff Builders, Inc.*, No. 96-1969, 1999 U.S. Dist. LEXIS 2998, at *18–19 (E.D. Pa. Mar. 4, 1999) (O'Neill, J.) ("[P]laintiffs may be allowed to plead 'on information and belief' under some circumstances, but such beliefs must be accompanied by factual allegations that provide substantiation and make them plausible").

In sum, Relators offer only conclusory statements regarding Allergan's purported failure to charge fair market value for the services, and they do not properly allege that such a failure was "knowing" and "willful." The SAC therefore should be dismissed for failure to state a claim upon which relief may be granted.

2. Relators Fail To Adequately Allege The Elements Of An Anti-Kickback Statute Violation With Regard To The "Additional Inducements" Alleged In The Second Amended Complaint.

The SAC briefly describes "additional inducements" allegedly provided by Allergan in the form of participation in a "speakers' bureau," SAC ¶¶ 286–91, "sponsored meetings and dinners," *id.* ¶¶ 292–302, and funding for "independent research," *id.* ¶¶ 303–04. For the reasons described above, the SAC does not articulate a cognizable FCA cause of action for any of the alleged kickbacks, including these "additional inducements." *See* Section V.A. But Relators also fail to adequately plead the elements of an AKS violation with regard to Relators' "additional" claims.

As an initial matter, Relators do not plead that the compensation provided to members of the alleged "speakers' bureau," invitees to alleged "sponsored meetings," or recipients of alleged research funding was above fair market value for the services rendered. *See* SAC ¶¶ 286–304. Thus, Relators have not adequately alleged the remuneration element of an AKS violation. *See Amgen, Inc.*, 738 F. Supp. 2d at 274 (quoting 42 U.S.C. § 1320a-7a(i)(6)) (stating in a FCA action that "[u]nder the [AKS], 'remuneration' is broadly defined as 'transfers of items or services for free or for other than fair market value'"). Even if they had alleged that there was remuneration, Relators do not allege (much less with the requisite level of detail) that Allergan acted ***knowingly*** and ***willfully*** with an intent to disobey the law with regard to these "additional

inducements." As with the *Allergan Access* allegations discussed above, Relators do not allege that Allergan undertook a faulty fair market value analysis or otherwise intended to pay providers in violation of the law, rather than as legitimate service providers. *See* 42 C.F.R. § 1001.952(d) ("'[R]emuneration' does not include any payment made by a principal to an agent as compensation for the services of the agent ….''). These deficiencies constitute an independent basis to dismiss Relators' claims to the extent they are premised on the alleged "additional inducements."

3. Relators Seek To Impose Liability On Allergan For Speech Protected By The First Amendment.

The SAC also fails to plead an AKS violation because Relators' theory would impermissibly punish Allergan for speech protected by the First Amendment. On its face, the SAC alleges that by providing physicians various forms of advice, consultation, and guidance relating to their eye care practices, Allergan violated the AKS and, as a result, the FCA. But "the creation and dissemination of information"—like the advice and educational information regarding health care, business, and financial matters at issue here—comprise speech protected by the First Amendment. *Sorrell v. IMS Health, Inc.*, ___ U.S. ___, 131 S. Ct. 2653, 2667 (2011); *see also In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 793–94 (3d Cir. 1999) (recognizing "non-commercial medical discussion" and "continuing medical education" seminars as pure speech). Indeed, even "[s]peech in aid of pharmaceutical marketing … is a form of expression protected by the Free Speech Clause of the First Amendment." *Sorrell*, 131 S. Ct. at 2659. Because the First Amendment precludes civil judgments based even in part on protected speech, Relators' SAC fails as a matter of law. *See, e.g.*, *N.A.A.C.P. v. Claiborne Hardware Co.*, 458 U.S. 886, 915 (1982); *New York Times Co. v. Sullivan*, 376 U.S. 254, 279–80 (1964); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d at 793–94. At the very least, the Court should adopt a "limiting interpretation" of the AKS in keeping with the constitutional avoidance doctrine. *See, e.g.*, *Skilling v. United States*, ___ U.S. ___, 130 S. Ct. 2896, 2929–30 (2010); *United States v. Caronia*, 703 F.3d 149, 162 (2d Cir. 2012) (construing the Federal Food,

Drug, and Cosmetic Act in a pharmaceutical marketing context in a manner that avoided an impermissible infringement on First Amendment rights). Specifically, the Court should conclude that activities comprising speech do not constitute remuneration under the AKS.

Under *Sorrell*, content- and speaker-based restrictions on speech demand "heightened judicial scrutiny." 131 S. Ct. at 2664. As applied here, Relators' AKS and FCA theory would target a particular type of speaker (a pharmaceutical company) based on the content of its protected speech. *Caronia*, 703 F.3d at 164–65; *cf. Sorrell*, 131 S. Ct. at 2665 ("An individual's right to speak is implicated when information he or she possesses is subjected to 'restraints on the way in which the information might be used' or disseminated.") (quoting *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 32 (1984)). Under Relators' theory, the Court—or a criminal prosecutor—must assess the value of speech and determine whether it is permissible on that basis. That is, if not for Allergan's status as a pharmaceutical company and if not for the information's ***value*** to eye care professionals, it could permissibly provide the advice and educational information regarding eye care practice management at issue here. If the advice provided by Allergan was bad—and thus had no value—it would not be remuneration under the AKS. If it happened to be good advice, and helped an eye care practice run more effectively, according to Relators' theory, it would violate the AKS and the FCA. By definition, this requires an analysis of content, as well as different levels of restriction based on the speech's content. Accordingly, Relators' theory is "presumptively invalid" under the First Amendment. *Caronia*, 703 F.3d at 163 (quoting *R.A.V. v. City of St. Paul*, 505 U.S. 377, 382 (1992)).

Further, Relators' AKS and FCA theory is "more extensive than [] necessary" to serve the government's interest in deterring health care fraud and abuse. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980); *see also Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 371 (2002) ("[If] the Government could achieve its interests in a manner that does not restrict speech, ***or that restricts less speech***, the Government ***must do so***." (emphases added)). Even the government has acknowledged, at least implicitly, that the AKS is broader than necessary to deter fraud and abuse: "We, of course, recognize that many …

advertising activities and marketing activities ***do not warrant prosecution*** …." Preamble to 1991 Final Safe Harbor Rules, 56 Fed. Reg. 35952, 35974 (July 29, 1991) (emphasis added). The government's interest would be adequately served, for example, by a construction of the AKS that barred companies from providing true "expense relief" services, i.e., handling office work that physicians would otherwise need to do themselves to run a practice, such as stuffing envelopes or answering telephone calls. This would preserve companies' ability to communicate useful information to physicians, such as straightforward advice as to how they might do those things ***better*** (a topic on which pharmaceutical representatives might be qualified to comment because they visit and learn about many practices in the industry).

Where, as here, an anti-inducement statute is applied in a way that is more extensive than necessary to serve the government's interest, the courts must intervene. In *Bailey v. Morales*, for example, the Fifth Circuit held that a statute barring chiropractors from offering anything of value to induce a potential patient to try chiropractic services was unconstitutional as applied. 190 F.3d 320, 325 (5th Cir. 1999). The court reasoned that the offer constituted commercial speech and that "[c]hiropractors engage in such conduct with an intent to convey a particularized message: hire me, try my service." *Id.* Further, the statute was "neither reasonably tailored nor reasonably proportional" because it "facially applie[d] to any advertising" and "criminalize[d] commercial speech that is both unobjectionable and unquestionably protected." *Id.*

The speech that Relators seek to punish here is even more worthy of First Amendment protection than the offers at issue in *Bailey*. Accordingly, this Court should conclude that the First Amendment shields Allergan from liability for the alleged practice management advice at issue here or construe the AKS such that it does not bar such protected speech.

C. The Second Amended Complaint Is Deficient Under Rule 9(b).

1. Relators Fail To Identify Specific False Claims And Related Information.

Even if Relators could adequately allege an AKS violation and a viable theory of FCA liability, the SAC still fails because it does not plead the alleged fraud with the particularity required by Rule 9(b). Rule 9(b)'s standard "serves to provide defendants with notice of the

precise misconduct with which they are charged, and to safeguard defendants against spurious charges of … fraudulent behavior." *Waris*, 1999 U.S. Dist. LEXIS 2998, at *15–16 (O'Neill, J.) (citations and quotations omitted). To that end, Rule 9(b) "requires, at a minimum, that plaintiffs support their allegations of … fraud with all of the essential factual background that would accompany 'the first paragraph of any newspaper story' – that is, the 'who, what, when, where and how' of the events at issue." *In re Rockefeller*, 311 F.3d at 217 (citations omitted).

These pleading requirements pertain to ***both*** Relators' federal and state FCA claims. *Wilkins*, 659 F.3d at 301 n.9.[15] In cases like this one where information about the claims at issue is available, Rule 9(b) requires relators to "identify with particularity the ***precise claims*** submitted to the government that are alleged to be false or fraudulent." *Schmidt*, 2005 U.S. Dist. LEXIS 15648, at *5 (emphasis added) (collecting cases); *United States ex rel. Barlett v. Tyrone Hosp., Inc.*, 234 F.R.D. 113, 122 (W.D. Pa. 2006) ("[T]he Court also finds ***it fatal to that pleading that the Plaintiffs failed to produce even one specific claim*** by the Defendants that was submitted to the Government as an evidentiary example of the claims submitted …." (emphasis added)).

When information is uniquely in the possession of the defendant, some courts have relaxed the requirement that relators plead actual examples of false claims submitted to the government. *See United States ex rel. Underwood v. Genentech, Inc.*, 720 F. Supp. 2d 671, 677 (E.D. Pa. 2010) (quoting *United States ex rel. Doe v. Dow Chem. Co.*, 343 F.3d 325, 330 (5th Cir. 2003) ("It is possible that the pleading stage requirements of Rule 9(b) may be relaxed … when, … the facts relating to the fraud are ***peculiarly within the perpetrator's knowledge***." (emphasis added)). But "[t]his 'relaxed' application of Rule 9(b) is not, however, a license for

[15] *Petruska v. Gannon Univ.*, 462 F.3d 294, 310 (3d Cir. 2006) ("[T]he pleading requirements of Rule 9(b) 'appl[y] not only to fraud actions under federal statutes, but to fraud claims based on state law.'") (citation omitted); *United States ex rel. Bergman v. Abbott Labs.*, No. 09-cv-4264, 2014 WL 348583, at *16 (E.D. Pa. Jan. 30, 2014) ("The [] analysis of Relator's federal FCA claims under Rules 12(b)(6) and 9(b) also applies to Relator's state law claims.").

plaintiffs to base fraud claims on speculation and conclusory allegations." *Waris*, 1999 U.S. Dist. LEXIS 2998, at *17 (citations and quotations omitted). Indeed, a relaxed pleading standard is ***only*** appropriate when the information is "***exclusively*** within the defendant's control":

> Plaintiffs must allege that essential information is ***exclusively*** within the defendant's control. They must also delineate at least the nature and scope of [their] effort to obtain, before filing the complaint, the information needed to plead with particularity and demonstrate that they have thoroughly investigated ***all possible sources of information***, including but not limited to all publicly available relevant information, before filing a complaint.

Id. at *18 (emphases added) (quotations and citations omitted); *see also Genentech*, 720 F. Supp. 2d at 677 (even courts that have relaxed the pleading standard refuse to do so "when the evidence of the defendant's fraud is available from the Government").

Here, Relators do not—and cannot—"allege that essential information is ***exclusively*** within the defendant's control." *Waris*, 1999 U.S. Dist. LEXIS 2998, at *18 (emphasis added). Nor do they "delineate at least the nature and scope of [their] efforts" to obtain this information or "demonstrate that they have thoroughly investigated all possible sources of information." *Id.* In fact, Relators are much better situated than Allergan to identify specific false claims. Relators purport to be among those eye care physicians who availed themselves of *Allergan Access* and the advice and educational training allegedly provided by an Allergan ECBA—indeed, Relators are the only such physicians identified in the SAC. They also claim to have been personally offered participation in the "speakers' bureau," invitations to "sponsored meetings and dinners," and funding for "independent research." SAC ¶¶ 286–304. At a minimum, Relators should have pled particular facts regarding the prescriptions for Allergan products ***they wrote*** that were ultimately submitted for reimbursement to government health care programs as a result of the alleged Allergan kickbacks described in the SAC.[16] In other words, they should have pled ***who***

[16] For purposes of billing for their own evaluation and management services (as opposed to any Allergan pharmaceuticals they prescribed that were later dispensed at a pharmacy), Relators should know which of their patients participated in government health care programs. Regardless, information regarding prescriptions for Allergan products that were ultimately submitted for reimbursement to government health care programs—including those written by ***other recipients*** of the alleged kickbacks (i.e., physicians other than Relators)—is not

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filed false claims (e.g., the specific physicians, pharmacists, and patients involved), ***what*** the "false claims" comprised (e.g., the products, certifications, and health care programs at issue), ***when*** the violations occurred (e.g., the dates the affected prescriptions were written, the "false" certifications were made, and the "false" claims were filed), ***where*** the violations occurred (e.g., the cities and eye care practices involved), and ***how*** the "false claims" arose (e.g., the particular kickback that "caused" a physician to write a particular prescription and the forms used to make the certifications and submit the claims to the government). *See In re Rockefeller*, 311 F.3d at 217. Allergan, on the other hand, would have no way of knowing most of these details. Because Relators do not plead with particularity critical elements of the alleged fraud, their claims should be dismissed.[17]

2. Relators' Allegations Otherwise Fail To Comply With Rule 9(b).

a. Relators Do Not Plead An Underlying Fraudulent Scheme With Particularity.

Even aside from the lack of particular information about specific claims, Relators' allegations fail to comply with Rule 9(b) because they lack other specific information regarding critical elements of a FCA claim, including the claim submission mechanism (e.g., specific Medicare or Medicaid claim forms) by which false claims were allegedly submitted and the

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exclusively within Allergan's control. *See Waris*, 1999 U.S. Dist. LEXIS 2998, at *18. This information likely would be in the custody and control of the relevant physicians, patients, and pharmacies, as well as the government. Yet the SAC does not "delineate at least the nature and scope of [Relators'] efforts" to obtain this information. *Id.* Thus, Relators' FCA claims—including those premised on prescriptions written by doctors other than themselves—should be dismissed under Rule 9(b).

[17] This Court previously held that even where relators can point to "at least one false invoice," the allegations were insufficient to plead a broad scheme under Rule 9(b). *Waris*, 1999 U.S. Dist. LEXIS 2998, at *20 (dismissing complaint even though relators argued that they were able to plead "(1) the specific time period over which [the defendant] allegedly submitted false reimbursement reports to Medicare for his services; (2) the identity of one of defendant's officers involved … ; (3) at least one false invoice thus submitted to Medicare; and (4) the nature of the allegedly false claims").

extent to which the alleged kickbacks "caused" physicians to alter their prescribing decisions. This failure dooms the SAC because generalized allegations that false claims must have been submitted to the government are insufficient. *See United States ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432, 440 (3d Cir. 2004) (quoting and citing approvingly to *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002)) ("[A FCA] plaintiff cannot 'merely … describe a private scheme in detail but then … allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government.'"). In sum, Relators' allegations do not satisfy Rule 9(b) after three pleading attempts and should be dismissed with prejudice.

b. The Relators Do Not Plead A Nationwide Fraudulent Scheme With The Requisite Particularity.

To maintain a claim alleging a wide-ranging, nationwide fraudulent scheme, Relators must allege particularized facts, rather than extrapolating expansively from isolated statements and events. *See Ctr. for Diagnostic Imaging, Inc.*, 787 F. Supp. 2d at 1222 (holding that relators cannot "extrapolate a broader scheme" from the complaint's limited factual allegations); *United States ex rel. Wall v. Vista Hospice Care, Inc.*, 778 F. Supp. 2d 709, 723–24 (N.D. Tex. 2011) (dismissing state claims where the relator failed to allege facts specific to those states); *Thomas*, 2008 U.S. Dist. LEXIS 91221, at *19–20 (holding that relators must "allege, with sufficient particularity to meet the demands of Rule 9(b), a nationwide, corporate policy on the part of [the defendant] to cause false claims to be submitted by entering into agreements with physicians in violation of the [AKS]" and rejecting relator's claims concerning a nationwide scheme where they were based on "five episodes, anecdotal in nature, based on hearsay").

The bulk of the SAC's allegations recount purported interactions and communications among Relators and a small number of Allergan personnel over a short period of time. *See* SAC ¶¶ 111–304. From these limited allegations, Relators conjure a multi-state and multi-year scheme involving kickbacks and false claims. *See, e.g.*, SAC ¶ 4 (broadly alleging that Allergan

caused false claims to be submitted to numerous state and federal health care programs). But the SAC does not detail allegations related to purported recipients of kickbacks other than Relators, and it does not plead (much less with particularity) any conduct related to alleged kickbacks or false claims outside a limited geographical region (the Philadelphia metro area)—or outside one eye care practice (Relators' practice). Indeed, the SAC is devoid of any particularized allegations relating to kickbacks provided, or false claims submitted to Medicaid programs, in ***any*** of the nineteen states (or the District of Columbia) identified in the SAC.[18] As a result, ***all*** of Relators' claims related to state Medicaid programs must be dismissed. To the extent this case is permitted to go forward—and Allergan believes it should not—it should be limited to claims, if any, found to have been pled with particularity, not as a nationwide case.

D. Relators' Claims Should Be Dismissed To The Extent They Are Barred By State Inaction, Subject To Statutes Of Limitations, Or Would Require Impermissible Retroactive Application Of State Law.

In addition to the reasons discussed above, Relators' claims are barred for various other reasons, including applicable statutes of limitations, the failure of certain states to intervene, Relators' lack of standing, or the impermissible retroactive application of state law. The chart set forth below details myriad additional reasons to dismiss Relators' claims.

Basis → **State (Count) ↓**	**Statute of Limitations**	**Nonintervention or Lack of Standing**	**Impermissible Retroactive Application of State Law**
Federal FCA (Count I)	✓		
Delaware (Count III)	✓	✓	

[18] The SAC contains some allegations related to purported interactions between Relators and Allergan personnel in Pennsylvania. *See* SAC ¶¶ 111–96. But Relators neither allege any violations of Pennsylvania law nor assert that any false claims were submitted to Pennsylvania's Medicaid program.

Basis → **State (Count) ↓**	**Statute of Limitations**	**Nonintervention or Lack of Standing**	**Impermissible Retroactive Application of State Law**
District of Columbia (Count XXI)	✓		
Florida (Count IV)	✓		
Illinois (Count V)	✓		
Indiana (Count VI)	✓		✓
Louisiana (Count VII)	✓		
Massachusetts (Count VIII)	✓		
Michigan (Count IX)	✓		
Montana (Count X)	✓		✓
Nevada (Count XI)	✓		
New Hampshire (Count XII)	✓	✓	✓
New Jersey (Count XIII)	✓		✓
New Mexico (Count XIV)	✓	✓	✓
New York (Count XV)			✓
Oklahoma (Count XVI)	✓		✓
Rhode Island (Count XVII)	✓		✓
Texas (Count XVIII)	✓	✓	
Virginia (Count XIX)	✓		✓

1. Counts Three, Twelve, Fourteen And Eighteen Should Be Dismissed For Lack Of Required Intervention Or Action By The State Or Relators' Lack Of Standing.

Four of Relators' state claims—Delaware (Count Three), New Hampshire (Count Twelve), New Mexico (Count Fourteen), and Texas (Count Eighteen)—should be dismissed in whole or in part because those states chose not to intervene in this lawsuit or issue a written determination in lieu of intervention, as required by statute to permit a relator's claim to proceed.[19] Relators also lack standing to sue under the New Mexico statute because it limits standing to "affected persons," not individuals like Relators.

Where, as here, the State of New Mexico "declines to take over the action," a *qui tam* relator may only proceed upon a determination "that there is substantial evidence" of a statutory violation. N.M. Stat. § 27-14-7(E)(2). Relators do not allege that New Mexico made such a determination; therefore, this count must be dismissed. *Streck*, 894 F. Supp. 2d at 604 (holding that "Plaintiff's claims under … New Mexico law must be dismissed" for this reason). Moreover, only an "affected person" may bring a private civil action under New Mexico's false claims statute. N.M. Stat. § 27-14-7(B). Although the statute does not define "affected person," federal courts have determined that the phrase does not encompass relators with no connection to New Mexico, such as out-of-state residents. *See, e.g.*, *United States ex rel. King v. Solvay S.A.*, 823 F. Supp. 2d 472, 520–21 (S.D. Tex. 2011), *vacated in non-relevant part on reconsideration*, 2012 WL 1067228 (S.D. Tex. Mar. 28, 2012). As Pennsylvania residents, SAC ¶ 14, Relators are not "affected persons" within the meaning of the statute. Thus, the Count brought under New Mexico state law must be dismissed.

In addition, the Delaware and New Hampshire false claims provisions in effect when Relators filed their original complaint, and the Texas statutory provision in effect during a prior relevant period, precluded actions if the state declined to intervene (or to issue a written

[19] *See* Mot. to Unseal, ECF No. 41, at 4 ("On December 21, 2010, the United States, on behalf of itself and the named states [except Massachusetts] filed its Notice of Election to Decline Intervention in this *Qui Tam* action.").

determination in lieu of intervention, in the case of Delaware).[20] *Streck*, 894 F. Supp. 2d at 603–05. Delaware, New Hampshire, and Texas have declined to intervene in this case, *see* Mot. to Unseal, ECF No. 41 at 4, and Relators have not alleged that the Delaware Attorney General issued a determination of "substantial evidence of a violation" that would permit the action to proceed.

Delaware, New Hampshire, and Texas have since amended their false claims statutes to remove these requirements: Delaware on July 16, 2009, New Hampshire on June 29, 2009, and Texas on May 4, 2007. *Streck*, 894 F. Supp. 2d at 603–05. Nevertheless, as courts within the Third Circuit have consistently recognized, Relators' Delaware, New Hampshire, and Texas claims must be dismissed insofar as they are based on conduct "preceding those statutes' effective dates." *Id.* at 605 (dismissing Delaware, New Hampshire, and Texas counts to the extent based on conduct pre-dating the amendments); *Bergman*, 2014 WL 348583, at *17–19 (allowing same three state claims to proceed "only as they pertain to fraudulent conduct occurring after the date of amendment"). Accordingly, Relators' claims should be dismissed to the extent based on conduct pre-dating each statutory amendment: July 16, 2009 (Delaware), June 29, 2009 (New Hampshire), and May 4, 2007 (Texas).

2. Relators' Claims Should Be Dismissed To The Extent That They Impermissibly Rely On The Retroactive Application Of State Law.

To the extent not otherwise dismissed, nine of Relators' twenty state claims should be dismissed because they depend on an impermissible retroactive application of state law. Relators' claims are premised on conduct that allegedly took place between, at most, 2002 and 2010. *See* SAC ¶¶ 2, 96, 102, 212. However, nine state laws that Relators invoke were not

[20] *See* Del. Code tit. 6, § 1203(b)(2)-(4) (requiring state intervention or Attorney General determination "that there is substantial evidence that a violation occurred"); N.H. Rev. Stat. § 167:61-c(II)(e) (providing that the "action shall be dismissed" if the state "declines to take over the action"); Tex. Hum. Res. Code § 36.104(b) ("If the state declines to take over the action, the court shall dismiss the action").

enacted until well into that time period and are either silent as to, or expressly forbid, retroactive application. As a result, Relators should not be permitted to apply these statutes retroactively.

The Court should dismiss Relators' counts brought under the following statutes to the extent Relators seek to apply them to alleged conduct occurring before each statute's effective date: Indiana (Count Six) (effective date July 1, 2005); Montana (Count Ten) (effective date May 1, 2005); New Hampshire (Count Twelve) (effective date January 1, 2005); New Jersey (Count Thirteen) (effective date March 13, 2008); New Mexico (Count Fourteen) (effective date May 19, 2004); New York (Count Fifteen) (effective date April 1, 2007); Oklahoma (Count Sixteen) (effective date November 1, 2007); Rhode Island (Count Seventeen) (effective date July 1, 2007); Virginia (Count Nineteen) (effective date January 1, 2003).[21] *See Bergman*, 2014 WL 348583, at *24–25 (declining to retroactively apply Indiana, Montana, New Jersey, New York, Oklahoma, Rhode Island, and Virginia statutes before effective dates); *Streck*, 894 F. Supp. 2d at

[21] **Indiana** False Claims and Whistleblower Protection, Ind. Code § 5-11-5.5 *et seq.*); *see State v. Pelley*, 828 N.E.2d 915, 919 (Ind. 2005) ("Statutes are to be given prospective effect only, unless the legislature unequivocally and unambiguously intended retrospective effect as well."); **Montana** False Claims Act, Mont. Code § 17-8-401 (2005) *et seq.*; 2005 Mont. Laws Ch. 465 § 14 (rendering Montana FCA effective on May 1, 2005); *see State v. Hamilton*, 164 P.3d 884, 886 (Mont. 2007) (same); **New Hampshire** Medicaid Fraud & False Claims Act, N.H. Rev. Stat. § 167:61-a *et seq.* (*qui tam* provisions effective Jan. 1, 2005); 2004 N.H. Laws ch. 167, § 167:4 ("No provision of this act shall apply with respect to any claim … submitted prior to January 1, 2005"); **New Jersey** False Claims Act, N.J. Stat. § 2A:32C-1 *et seq.*; *see Oberhand v. Dir., Div. of Taxation*, 940 A.2d 1202, 1209 (N.J. 2008) (explaining that there is a general rule of prospective application unless the legislature expresses an intent that the statute is to be applied retroactively); **New Mexico** False Claims Act, N.M. Stat. § 27-14-1 *et seq.*; *see Howell v. Heim*, 882 P.2d 541, 547 (N.M. 1994) (explaining that a presumption against retroactive application applies "absent a clear intention to the contrary"); **New York** False Claims Act, 2010 N.Y. Sess. Laws ch. 379, § 13 (effective Apr. 1, 2007, amended Aug. 27, 2010) (codified as amended at N.Y. State Fin. § 187 *et seq.*); *see Logan v. Salvation Army*, 809 N.Y.S.2d 846, 849 (Sup. Ct. 2005) (same); **Oklahoma** Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053 *et seq.*; *see CAN Ins. Co. v. Ellis*, 148 P.3d 874, 877 (Okla. 2006) (disapproving retroactive application of statutes); **Rhode Island** False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.*; *see Pion v. Bess Eaton Donuts Flour Co.*, 637 A.2d 367, 371 (R.I. 1994) (presuming statutes operate prospectively absent clear legislative intention to the contrary); **Virginia** Fraud Against Taxpayers Act, Va. Code § 8.01-216.1 *et seq.*; *see Adams v. Alliant Techsystems, Inc.*, 544 S.E.2d 354, 356 (Va. 2001) (holding that statutes operate prospectively "'unless a contrary intent is manifest'").

603-05 (declining to retroactively apply Indiana, Montana, New York, Oklahoma, and Rhode Island statutes prior to their effective dates).

3. Relators' Claims Should Be Dismissed To The Extent Barred By Federal And State Statutes Of Limitations.

To the extent not otherwise dismissed, Relators' federal claims and seventeen of Relators' state claims are subject to statutes of limitations that operate as absolute bars. Actions under the federal FCA are subject to a six-year statute of limitations. 31 U.S.C. § 3731(b)(1).[22] Relators' present claims were first raised in the amended complaint filed on November 12, 2009. *See generally* FAC. Relators' allegations in the FAC are entirely different from and thus do not relate back to the original complaint. *Hericks v. Lincare Inc.*, No. 07-cv-387, 2014 WL 1225660, *14 (E.D. Pa. Mar. 25, 2014) (holding that relation back doctrine does not apply to new and different kickback claims added in amended complaint).[23] Accordingly, Relators' claims must be dismissed to the extent that they relate to alleged false claims submitted before November 12, 2003, which is six years prior to the FAC. *See Bergman*, 2014 WL 348583, at *15–16 (dismissing complaint to the extent based on allegedly fraudulent claims made more than six years before filing).[24] In addition, seventeen of Relators' twenty state-law claims must be dismissed to the extent barred by similarly operative statutes of limitations. Fifteen of those state Counts—Delaware, the District of Columbia, Florida, Illinois, Indiana, Louisiana,

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[22] The FCA's tolling provision does not apply to cases where the government has chosen not to intervene. *United States ex rel. Bauchwitz v. Holloman*, 671 F. Supp. 2d 674, 694–95 (E.D. Pa. 2009). The Wartime Suspension of Limitations Act (WSLA), 18 U.S.C. § 3287, is similarly inapplicable. *Bergman*, 2014 WL 348583, at *16.

[23] For an amended complaint to relate back to an original pleading, there must be "a common core of operative facts in the two pleadings," and the amendments must "restate the original claim with greater particularity or amplify the factual circumstances surrounding the pertinent conduct, transaction or occurrence in the preceding pleading." *Bensel v. Allied Pilots Ass'n,* 387 F.3d 298, 310 (3d Cir. 2004).

[24] Because Relators' original complaint was devoid of kickback allegations, *see generally* Compl., ECF No. 1, the claims Relators advance in the SAC relate back only to the FAC, filed November 12, 2009.

Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, Oklahoma, Rhode Island, and Virginia—are subject to six-year statutes of limitation,[25] and are thus barred to the extent that they are based on conduct occurring before November 12, 2003. *See id.* at *24–25 (dismissing eighteen of twenty-five state law claims "limited by this six-year statute of limitations"). Two other state Counts—New Mexico and Texas—are subject to four-year statutes of limitations,[26] and are thus barred to the extent that they are based on conduct occurring before November 12, 2005. *See id.*

VI. CONCLUSION

Relators' third attempt to state a claim against Allergan relies on a legal theory that would require this Court to depart from Third Circuit precedent and expand the FCA and AKS beyond their lawful bounds. Relators offer no viable reason to do so. Far from pleading plausible causes of action with the requisite specificity, the SAC provides no basis to permit Relators' case to continue. Relators' SAC is their third effort to plead a cognizable claim—and it, too, fails entirely to state such a claim. Accordingly, this Court should dismiss the SAC with prejudice.

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[25] Del. Code tit. 6, § 1209(a)(1); D.C. Code § 2-381.05(a); Fla. Stat. § 68.089(1); 740 Ill. Comp. Stat. 175/5(b)(1); Ind. Code § 5-11-5.5-9(b)(1); La. Rev. Stat. § 46:439.1(B)); Mass. Gen. Laws ch. 12, § 5K(1); Mich. Comp. Laws § 400.614(1)(a); Mont. Code § 17-8-404; Nev. Rev. Stat. § 357.170(1); N.H. Rev. Stat. § 167:61-b, VII(a); N.J. Stat. § 2A:32C-11(a); Okla. Stat. tit. 63, § 5053.6(B)(1); R.I. Gen. Laws § 9-1.1-5(b)(1); Va. Code § 8.01-216.9.

[26] N.M. Stat. § 27-14-13(A); N.M. Stat. § 37-1-4; Tex. Civ. Prac. & Rem. Code § 16.051.

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