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, M.D. AND ANITA NEVYAS-WALLACE, M.D.,	:	Civil Action No. 09-432
Plaintiffs,	:	Hon. Thomas N. O'Neill, Jr.
v.	:	JURY TRIAL DEMANDED
ALLERGAN, INC.,	:	
Defendant.	:	

RELATORS' RESPONSE TO ALLERGAN, INC.'S AMENDED
MOTION TO DISMISS RELATORS' SECOND AMENDED COMPLAINT

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I. INTRODUCTION

Doctors who treat Medicare and Medicaid recipients must provide the healthcare services and medications that are in their patients' best interest—not the ones that generate the greatest financial benefits for the doctors. The Anti-Kickback Statute prohibits pharmaceutical companies from offering financial benefits in order to persuade the doctors to write prescriptions for certain products. Allergan willfully violated the Anti-Kickback Statute and the False Claims Act by gifting an elaborate set of business resources, including access to sophisticated consultants, to ophthalmologists and optometrists in order to persuade them to prescribe Allergan eye care drugs. Because government health insurance programs such as Medicare and Medicaid pay for a large portion of these prescriptions, Allergan's illegal inducements to the prescribers violate the Anti-Kickback Statute and render false all reimbursement claims to Medicare and Medicaid for these tainted prescriptions. Allergan knew its conduct was wrong because it not only violated the Anti-Kickback Statute, but also the basic code of ethics created by the very pharmaceutical industry in which Allergan participates.

Prescriptions written for Allergan's blockbuster Restasis® drug demonstrate the pernicious effect of kickbacks. In deciding what medication to prescribe for the condition known as dry eye, an ophthalmologist must decide between a $5 over-the-counter eye drop, or a $190/month prescription for Restasis®, often required for life, covered by Medicare and Medicaid. Often it is a judgment call. Illegal kickbacks to the prescribing doctors improperly influence these sorts of judgments in a way that imposes on the government hundreds of millions of dollars in inflated costs.

Plaintiffs' operative Complaint is replete with detailed allegations describing Allergan's nationwide scheme to offer valuable consulting services to doctors for free in order to induce prescriptions for Allergan eye care products. The Relators describe the names of the

people involved in the inducements, the dates and locations of the meetings where the inducements took place, the particular details of the services actually provided, and the incriminating statements that reveal Allergan's illegal motivations. The law in this circuit, consistent with the law across all circuits, holds pharmaceutical companies liable under the federal and state False Claims Acts for illegally inducing claims for prescription reimbursements, even when the false claims are actually submitted by pharmacies not involved in the kickbacks.

Allergan's spin on the allegations and their legal citations are misleading. Allergan spent most of its *original* motion to dismiss arguing that the *Allergan Access* website publicly disclosed all of the services that Allergan provided to doctors. As it turns out, that public disclosure argument was baseless. The publicly available website that Allergan contended was a public disclosure of the *Allergan Access* services was not the *Allergan Access* website at all. Rather, it was a public website sponsored by an independent company; in contrast, access to Allergan's members-only *Allergan Access* website required a special username and password. Moreover, the public site did not contain any description of the sophisticated one-on-one, in-person business consulting services that comprise the focal point of this lawsuit.[1]

[1] In both its original and amended motions to dismiss, Allergan notes the $895 annual subscription price for its members-only website and points out in a footnote that the price Allergan charged for the website changed over time. (Def. Br. at p. 5, n.2.) Notably, Allergan does not describe for the Court how the prices changed and the significance of those changes to the merits of Relators' claims. *See, e.g.*, SAC ¶¶ 278-83. As Allergan is aware, during the investigation phase of this case, Allergan provided more than 130,000 pages of documents to the New York and Massachusetts Attorneys General, all of which have been reviewed by the Relators. Dkt. No. 41, ¶¶ 4, 6. These documents directly relate to the allegations in this lawsuit, including the pricing of the Allergan website. Allergan produced these documents *after* the operative Complaint was filed. *Id.* Pursuant to a confidentiality agreement, Relators are currently limited in using those documents or disclosing their contents. Thus, Allergan remains free to disparage Relators' case without fear that its statements might be contradicted in dramatic fashion by its own documents. This troubling predicament for Relators is addressed further in the last section of this response brief. Even without relying upon the information in these documents, however, Relators' operative Complaint more than sufficiently details Allergan's violations of the False Claims Acts.

Allergan has since abandoned (at least for now) its public disclosure argument. Its remaining arguments rest on gross misstatements of the law, as shown below:

Allergan's Principal Arguments	**The Most Basic Reason Why Each Argument Fails**
Allergan cannot be liable under the FCA for AKS violations based on claims made by pharmacists.	Allergan ignores the plain statutory language and long-standing Third Circuit precedent that holds defendants liable for "causing" the submission of a false claim.
Allergan did not cause the submission of any factually false claims.	Kickback-tainted claims are factually false because the government does not get what it bargained for when it pays for services tainted by a kickback.
Relators fail to identify any relevant "Certifications of Compliance" to support a false certification theory.	Relators have alleged that healthcare providers, including pharmacies, must certify that claims submitted to federal health insurance programs comply with the AKS.
State Medicaid regulatory regimes do not condition payments on compliance with the AKS.	There is no basis in principle, precedent, or state statute to treat Medicaid claims differently from Medicare claims.
Relators fail to plead causation.	Relators have alleged that Allergan's kickback scheme rendered claims for Allergan's drugs false, and that the submission of those claims was not only foreseeable but the intended result of Allergan's illegal kickbacks.
Relators fail to adequately allege scienter under the FCA.	Scienter is a question of fact, and Relators have alleged that Allergan knew what it was offering and why; Allergan itself lauded the value of its offerings and explicitly asked physicians to prescribe its products to show their appreciation for those offerings by prescribing Allergan products.
Relators fail to adequately allege willfulness under the AKS.	Scienter is a question of fact, and Allergan's feigned ignorance of the law cannot be countenanced when Allergan knew that under both the AKS and industry guidelines (to which it subscribed), it could not offer valuable services for the purpose of inducing prescriptions.
Relators fail to allege that the "additional inducements" were remuneration under the AKS.	Alleging "remuneration" requires only that Relators allege that Allergan was offering something of value with one purpose being to induce prescriptions, which the Complaint alleges repeatedly.
The First Amendment immunizes Allergan against AKS liability.	Allergan's right to free speech cannot immunize its conduct that otherwise violates the law.
Relators fail to identify specific false claims under Rule 9(b).	The overwhelming majority of courts in the Third Circuit and elsewhere have held that Rule 9(b) does not require identification of specific false claims in a relator's complaint. Identification of specific claims is irrelevant to Allergan's receipt of notice of the misconduct alleged, and requiring it would improperly force Relators to prove their

Allergan's Principal Arguments	**The Most Basic Reason Why Each Argument Fails**
	case before discovery.
Relators fail to plead an underlying fraudulent scheme with particularity.	The Complaint contains dozens of detailed allegations (including names, dates, places, statements, and other details), pleaded with particularity, setting out Allergan's scheme to provide an elaborate set of business resources and other kickbacks to eye care professionals in order to induce them to prescribe Allergan's eye care drugs.
Relators fail to plead a nationwide fraudulent scheme with particularity.	According to Allergan itself, its business advisors operated nationwide, and 1,500 physicians across the country were members of its *Allergan Access* website.

II. ALLEGATIONS IN THE OPERATIVE COMPLAINT

A. Allergan

Allergan discovers, develops, commercializes, manufactures, and markets products for the ophthalmic specialty market. Second Amended Qui Tam Complaint ("SAC") ¶¶ 30, 33. Allergan's Eye Care Pharmaceutical Line includes Restasis®, the only prescription alternative to the over-the-counter drops used for the treatment of a condition called Chronic Dry Eye. SAC ¶¶ 33, 35, 95. Restasis® is Allergan's best-selling eye care product. SAC ¶ 38.[2] Since 2005, Allergan's net sales from Restasis® have been as follows: $190.9 million in 2005; $270.2 million in 2006; $344.5 million in 2007; $444 million in 2008, and $522.9 million in 2009. SAC ¶ 38. Because Restasis® is significantly more expensive than

[2] Within its Specialty Pharmaceutical Segment, Allergan develops, manufactures, and markets a broad range of prescription and non-prescription, over-the-counter products designed to treat diseases and disorders of the eye. SAC ¶ 33. Allergan's Eye Care Pharmaceutical Product Line includes, but is not limited to, the following products:

- Chronic Dry Eye Products: Restasis®;
- Glaucoma Related Products: Lumigan®; Alphagan®; Combigan®; Ganfort®;
- Inflammation Products: Acular®; Acular PF®; Acular LS®; Acuvail®; Pred Forte®;
- Infection Products: Zymar®; Zymaxid®; and
- Allergy Products: Alocril®; Elestat®.

SAC ¶ 33.

over-the-counter alternatives (in 2006, a one-month Restasis® prescription cost approximately $190), Allergan's revenue from Restasis® depends heavily upon the decision of ophthalmologists and optometrists to prescribe Restasis® to their patients. SAC ¶ 95. Allergan maintains that most patients will need to continue using Restasis® indefinitely in order to treat their dry eyes. SAC ¶ 95.

The most significant component of Allergan's kickback program is the Eye Care Business Advisor ("ECBA") program–a team of sophisticated business consultants that Allergan provides for certain targeted eye care practices that have the potential to write large numbers of prescriptions for Allergan products. Allergan has, since at least 2002, knowingly and willfully provided valuable business practice management and consulting services to these ophthalmologists and optometrists for virtually no charge in order to induce them to prescribe its eye care products, including but not limited to Restasis®. SAC ¶¶ 2-3, 98, 106-08, 203.

ECBAs have substantial experience in the healthcare industry, some having worked in the industry for more than 30 years. SAC ¶ 106. Many of the ECBAs have advanced degrees and/or certifications, including Masters in Business Administration and Certified Ophthalmic Executives. SAC ¶ 106. Additionally, many of Allergan's ECBAs have prior experience as product sales representatives with Allergan or other pharmaceutical manufacturers. SAC ¶¶ 106, 116.

It is not the job of the ECBAs to advise physicians regarding medically relevant information about Allergan products. Instead, their job is to teach medical practices how to make more money both from selling Allergan products and from changing the business structure of their medical practices generally. SAC ¶¶ 106-08. One of the ECBAs explained that his "objective is to help practices become more profitable while making the business of managing a

practice more rewarding and fun." SAC ¶ 139. Business consultants like these would normally command hourly rates of $280 or more, SAC ¶ 226, and charge thousands, if not tens of thousands, of dollars for this type of one-on-one, in-person business consulting. Allergan ECBAs provided this consulting for free to select top prescribers of its products. SAC ¶¶ 131, 220. The restricted access website itself offered the doctors other valuable services unrelated to Allergan's products—like financial benchmark analyses, human resources and recruiting advice, and Continuing Medical Education courses—all as a way to induce participants to write Allergan prescriptions. SAC ¶ 3.

Physicians, hospitals, and pharmacies enter into Provider Agreements with the Centers for Medicare and Medicaid Services ("CMS"), an agency of the Department of Health and Human Services ("HHS"), in order to establish their eligibility to seek reimbursement from the Medicare Program. SAC ¶¶ 49, 82. As part of that agreement, without which physicians, hospitals, and pharmacies may not seek reimbursement from federal health insurance programs, the provider must sign the following certification:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws, regulations, and program instructions are available through the [Medicare] contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, *the Federal Anti-Kickback statute* and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare.

SAC ¶ 82 (emphasis added).

The Pharmaceutical Research and Manufacturers of America ("PhRMA") represents research-based pharmaceutical and biotechnology companies throughout the United States, including Allergan. SAC ¶ 87. PhRMA has issued guidance relating to interactions with healthcare professionals, which took effect on July 1, 2002 ("PhRMA Code I") and January 2009

("PhRMA Code II", attached hereto as Exhibit A). SAC ¶ 89. Allergan is a signatory to, and has agreed to abide by, the PhRMA Code II. SAC ¶ 90. The PhRMA Code II states, in relevant part, that "No grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a health care professional in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's prescribing practices." SAC ¶ 91 (citing PhRMA Code II, Section 13 (Exhibit A at p. 13)).

As a direct result of Allergan's improper practices, Allergan caused federal and state health insurance programs to pay false or fraudulent claims for reimbursement for Allergan's prescription drugs that resulted from Allergan's illegal kickbacks. SAC ¶ 4. Although Allergan did not directly submit claims for prescription drugs to federal and state health insurance programs, it knew and intended that its illegal financial inducements would cause the submission of thousands of claims to these health programs for prescriptions that were not eligible for program reimbursement. SAC ¶ 12. Notwithstanding its knowledge that prescriptions for Allergan's eye care products induced by kickbacks were not eligible for federal and state reimbursement, Allergan knowingly undertook such illegal kickback practices to increase prescriptions for its eye care products. SAC ¶ 313.

B. <u>The Relators and Their Experience with Allergan Inducements</u>

Plaintiffs/Relators Herbert J. Nevyas, M.D. and Anita Nevyas-Wallace, M.D. are board-certified Ophthalmologists, licensed to practice medicine in Pennsylvania, New Jersey, and, for Relator Nevyas, Florida. SAC ¶¶ 15, 23. Both are in private practice with Nevyas Eye Associates. SAC ¶¶ 16, 24. Relator Nevyas has been in private practice since 1964, and Relator Nevyas-Wallace has been in private practice since 1988. SAC ¶¶ 16, 24. Both Relators earned

their undergraduate and medical degrees from the University of Pennsylvania, and Relator Nevyas has served on its faculty as Chief of the Division of Ophthalmology, as well as on the faculties of other colleges. SAC ¶¶ 17, 22, 25. Relator Nevyas-Wallace is a Clinical Associate of the University of Pennsylvania Department of Ophthalmology. SAC ¶ 27. Both Relators are current and former members of many prestigious professional societies. SAC ¶¶ 20, 27. Relators' practice, Nevyas Eye Associates, specializes in medical and surgical ophthalmology through offices in Bala Cynwyd, PA, Philadelphia, PA, and Marlton, NJ. SAC ¶ 16. The Bala Cynwyd location houses the Delaware Valley Laser Surgery Institute, a fully accredited ambulatory surgery center, with two operating rooms, two minor surgery suites, and a dedicated LASIK surgery suite. SAC ¶ 16. Because of the size of Relators' ophthalmology practice, Allergan targeted their practice to receive free business consulting services in order to induce them to write more Allergan prescriptions. The Complaint details Allergan's specific efforts.

1. Allergan's "Dry Eye Dinner" on March 16, 2009

Allergan Territory Manager Matthew Schlegel invited Relators to attend a "Dry Eye Dinner" held on March 16, 2009, at the restaurant Maia in Villanova, Pennsylvania. SAC ¶ 111. Relators were among 16-20 eye care professionals (predominantly ophthalmologists) who attended the event. SAC ¶ 112. The Allergan representatives in attendance included Schlegel and Pete Pecoraro (both marketing representatives), J. Scott Youmans (an Area Manager in Dry Eye/External Disease), and Bob Teale (an Allergan ECBA). SAC ¶¶ 113, 116. Teale was the featured speaker at the dinner. SAC ¶¶ 114-15, 118.

Teale was one of 12-15 Allergan ECBAs, each of whom was responsible for a specific geographic territory, who provided a uniform set of business advisory and consulting services to select medical practices around the country. SAC ¶¶ 105-06. Teale was based out of Virginia, and his territory included parts of the East Coast. SAC ¶ 118. Teale offered similar

services and made the same presentations to eye care professionals all across the United States. SAC ¶ 118. Teale is a Certified Ophthalmic Executive, with more than 30 years' experience in the healthcare industry. SAC ¶ 117. He worked with a Fortune 100 company for 19 years in the areas of retail and hospital sales, sales management, product management, corporate sales team development, employee training, and national accounts. *Id*.

Teale explained to the eye care professionals present at the Dry Eye Dinner that becoming a "Dry Eye Center of Excellence" with Allergan's assistance could increase the revenues of their respective practices by hundreds of thousands of dollars. SAC ¶¶ 119-20, 122-23, 129-30. Teale stated that Allergan could provide strategies and tools to build a Dry Eye Center of Excellence, including, but not limited to: scripts, marketing letters, and patient quizzes. SAC ¶¶ 124-25. Teale also spent substantial time during his presentation describing the business tools the physicians could obtain through the restricted *Allergan Access* website, which could help them to target dry eye patients. SAC ¶¶ 131-32. Allergan did not require any of the eye care professionals present at the Dry Eye Dinner to pay a fee for the valuable business advisory and consulting services provided by Teale. SAC ¶ 137.

On March 17, 2009, the day after the Dry Eye Dinner, Sales Manager Schlegel emailed Relator Nevyas-Wallace thanking her for attending the Dry Eye Dinner. SAC ¶ 138. Schlegel wrote: "I hope Bob [Teale] was able to show both you and Dr. [Herbert] Nevyas the value of what Allergan brings to the table for specific accounts in the Phila. Area. Dry eye/Restasis® is only one component of the support we can provide to you and to your patients." SAC ¶ 138. That same day, Teale emailed Relators a description of the services offered by the business advisory group at Allergan. SAC ¶ 139. In that email, Teale stated "My objective is to

help practices become more profitable while making the business of managing a practice more rewarding and fun." SAC ¶ 139.

2. Relators' Meeting With Allergan Eye Care Business Advisor Teale on September 18, 2009

On September 18, 2009, at Allergan's request, Relators met with Teale at the Bala Cynwyd office of Nevyas Eye Associates to discuss the types of services that Allergan's Business Advisor Group could provide to Relators' practice. SAC ¶¶ 140-41. During this meeting, Teale discussed in detail the valuable business advisory and consulting services that Allergan could provide for free, including from outside consultants such as the BSM Consulting Group, The Corcoran Group, and John Pinto. SAC ¶¶ 142-45. Teale offered to instruct Relators' employees on the use of the online e-learning courses available through *Allergan Access*, as well as the business consulting services offered through the website. SAC ¶¶ 146-53. Teale also explained that the "Dry Eye Recall program" section of *Allergan Access* could result in increased income to Relators' practice from an initial dry eye visit, three follow-up visits, and any additional conditions which could be treated, such as cataracts. SAC ¶ 147. Teale repeatedly told Relators that Allergan's business advisory services offered through the *Allergan Access* website were very valuable and would be quite expensive to obtain without Allergan. SAC ¶ 148.

Allergan did not require Relators to pay any fee for the valuable business advisory services provided and/or described by Teale on September 18, 2009. SAC ¶ 154. Teale, however, told Relators that "none of this would be possible" without Allergan, and that Allergan paid Teale's salary. SAC ¶ 149. Teale repeatedly told Relators that he would expect them to "show their appreciation" for Allergan's business advisory services by prescribing Allergan's

products. SAC ¶ 150. Teale further added that if another company and Allergan made similar products, Relators should prescribe the Allergan product. SAC ¶ 150.

3. Relators' Meeting With Allergan Eye Care Business Advisor Teale on October 12, 2009

On October 12, 2009, Teale gave a presentation to the staff of Nevyas Eye Associates at their offices in Bala Cynwyd, Pennsylvania. SAC ¶ 155. The presentation had nothing to do with the clinical aspects of any of Allergan's products. Instead, the services he provided were aimed at helping the Relators attract new patients. Teale gave the presentation to 35 to 40 staff members about business skills the practice could use to attract and retain new patients, including suggestions on how the front desk staff should answer the telephone and greet patients. SAC ¶ 159.

Teale also spoke privately with Relators for approximately one hour in the conference room of the Nevyas Eye Associates offices, and talked at length about the financial benchmarking assistance that Allergan could provide to Relators. SAC ¶¶ 160-61, 167-68. The benchmarking included many different areas, including coding benchmarking, revenue benchmarking, overhead costs benchmarking, and even benchmarking the number of staff Relators have in their offices compared to other practices across the country. SAC ¶ 161.[3]

Teale also proposed that Allergan provide Relators with additional business advisory services, free-of-charge, to strengthen the referrals that Relators received from area optometrists. SAC ¶¶ 162-66. First, Teale told Relators to arrange a dinner for local optometrists, and said that during this meeting Teale would give a detailed lecture on business advisory and consulting issues. SAC ¶ 162. Teale told Relators that they, not Teale, should

[3] With the Office Managers of Nevyas Eye Associates, Teale discussed the continuing education portion of *Allergan Access* (offered to member practices for free), offered to help employees select appropriate courses, and encouraged the employees to take as many courses as possible. SAC ¶¶ 157-58.

invite the optometrists to the dinner meeting (which was held on January 19, 2010), so that the optometrists would understand that Relators were the ones responsible for arranging the valuable, free business advisory and consulting services. SAC ¶ 163. Second, Teale told Relators that Allergan would provide billing and coding assistance to Relators' referring optometrists, so long as the optometrists first called Relators with their questions. SAC ¶ 164. Teale explained that Relators could then pass along to the optometrists the answers provided by Allergan. SAC ¶ 165. Teale stated that proceeding in this manner would allow Allergan to further help Relators expand and strengthen the valuable referrals they received from area optometrists. SAC ¶¶ 162-66. Because optometrists frequently refer patients to ophthalmologists, Allergan's offer to help Relators expand and strengthen their optometric referral network represented a substantial financial opportunity for Relators. SAC ¶ 166.

Teale emphasized that the ECBA services he was providing and the services that were available on the *Allergan Access* website would not be possible without financial support from Allergan, and also would not be possible without Relators supporting Allergan. SAC ¶ 169. Teale repeatedly stated during the meeting that he wanted Relators to show their appreciation to Allergan for these valuable business advisory services by using Allergan products. SAC ¶ 170. Teale told Realtors that if there is a choice between comparable products, Relators should show their appreciation to Allergan for the business advisory services they were receiving by choosing the Allergan product. SAC ¶¶ 170-71.

On October 13, 2009, Relator Nevyas-Wallace received an email from Sales Manager Schlegel, asking her whether Teale's presentation was "valuable for the practice." SAC ¶ 172. In that email, Schlegel also invited Relator Nevyas-Wallace to attend a dinner two days later regarding Allergan's new product Acuvail®. SAC ¶ 172.

4. Teale Meets with Relators' Referring Optometrists on January 19, 2010.

On January 19, 2010, Allergan ECBA Teale gave a presentation to a group of approximately 30 optometrists who refer patients to Relators' practice. SAC ¶¶ 173-74. During his meeting with Relators on October 12, 2009, Teale had suggested making this presentation to allow Allergan to help Relators expand and strengthen their network of referring optometrists. SAC ¶ 174. Teale gave a one-hour presentation to the optometrists on the topic of "What You Should Know About Managing an Optometric Practice." SAC ¶ 175. During the presentation, Teale discussed numerous issues related to effectively managing an optometric practice, including, but not limited to: dealing with vendors, contracting with vendors and payors, managing an optical shop, determining appropriate staffing, and benchmarking optometric practices. SAC ¶ 175.

Allergan did not charge Relators, or any of the attending optometrists, for Teale's valuable business advisory presentation on January 19, 2010. SAC ¶ 176. Following the presentation, Teale emailed Relator Nevyas-Wallace: "I truly believe that most of the attendees felt they left the meeting with some valuable information that they can truly apply to their practices. I would be very happy to present again for you in the future, if you wish. Thanks again for your support." SAC ¶ 177. The day after Teale's presentation, Relator Nevyas-Wallace received another email from Sales Manager Schlegel. SAC ¶ 178. In that email, Schlegel stated, in relevant part: "The purpose of this email is to follow-up on last night's OD diner [sic] with Bob Teale. Bob informed me that the program was successful on many levels. I feel very strongly that Bob brings many, many resources to you and Nevyas Eye and he is someone that you can lean on to take your business to the next level of ophthalmic excellence." SAC ¶ 178. Schlegel asked Relator Nevyas-Wallace for the names of the optometrists who

attended the Teale presentation, "so that I can make sure these doctors are seen [by Allergan representatives] in the near future." SAC ¶ 179. Schlegel further stated: "I still would like to schedule a dry eye preceptorship with either yourself or Dr. Goyal [another ophthalmologist at Nevyas Eye Associates] to take a look at the true potential that Restasis® could help these important patients." SAC ¶ 179.

5. Allergan Offered Non-Product Related Programs for Optometrists at Prime Steakhouses, Free of Charge.

On April 19, 2010, Relator Nevyas-Wallace received an email from Sales Manager Schlegel regarding a free business advisory meeting exclusively for optometrists that Allergan had scheduled for April 28, 2010. SAC ¶ 183. Schlegel wrote: "Attached please find an invitation to an OD [optometrist] specific program featuring Bob Teale. Would you feel comfortable forwarding this to your Optometric network. As you have found Bob's assistance with Nevyas Eye as beneficial, please inform them the value they will gain from attending this program. This discussion is not product related but a valuable resource that only Allergan provides and it directly can impact their practice. Additionally, office managers or key staff can attend." SAC ¶¶ 184-85. According to the invitation, the training session was scheduled for April 28, 2010, at 7:00 p.m., at Parker's Prime, a steak restaurant located in Newtown Square, Pennsylvania. SAC ¶ 186. No charge was associated with the event. SAC ¶ 187.

6. Teale Provided Relators with Free Financial and Web Site Analysis.

On or about April 28, 2010, Teale met with Relators in the office of Nevyas Eye Associates in Bala Cynwyd, Pennsylvania. SAC ¶ 188. During that meeting, Teale reviewed with Relators a detailed Excel spreadsheet entitled "Monthly Benchmarking Report Nevyas Eye Associates Bala (2)." SAC ¶ 189. The "Monthly Benchmarking" spreadsheet, which was prepared by Teale free-of-charge using one of the benchmarking templates from the *Allergan*

Access website, provided Relators with a comprehensive report on the financial health of the main office of their ophthalmological practice. SAC ¶ 190. The spreadsheet included analysis of the following financial categories: Net Collection Ratio; Operating Expense Ratio; Non-MD Payroll Ratio; Number of Full Time Equivalent (FTE) Support Staff Per FTE MD; Patient Encounters Per FTE MD; Net Collections Per FTE; Net Collections Per FTE MD; Net Collections Per Patient Encounter; Days Sales Outstanding; and Accounts Receivable Aging Analysis. SAC ¶ 190. Teale explained the spreadsheet, and offered recommendations to Relators for improving the financial performance of their ophthalmological practice. SAC ¶ 191. This was all provided to Relators free-of-charge. SAC ¶ 192.

During the meeting, Teale also presented Relators with a 68-page document entitled "Web Site Assessment — Prepared for: Nevyas Eye, Anita Nevyas-Wallace, M.D., Herbert Nevyas, M.D., Nevyas.com." SAC ¶ 193. According to the introduction of the document, "The Allergan Web Site Assessment program is part of our ongoing commitment to providing tools and resources related to successfully marketing and managing your practice. This assessment was completed specifically for your practice website, and contains your specific results, general comments and recommendations, as well as assessment tools for future use and reference." SAC ¶ 194. Teale explained in detail the "Web Site Assessment," and offered recommendations for improvements to the Relators' web site in order to optimize the marketing of their practice. SAC ¶ 195. Allergan, through its employee Teale, provided the "Web Site Assessment," analysis and advice to Relators free-of-charge. SAC ¶ 196.

C. Allergan Offers Valuable Kickbacks to Top Ophthalmologists Through *Allergan Access*.

Allergan's Territorial Manager Pete Pecoraro advised Relator Nevyas-Wallace, on March 26, 2009, that only the "top physicians' practices" are invited to take part in the *Allergan*

Access program, and that her practice was one of those top practices. SAC ¶¶ 207, 218-20. Relators became members of the *Allergan Access* website on or about September 3, 2009. SAC ¶ 220.

Allergan charges a fee of $895 for *Allergan Access*, and Relators paid one such fee of $895 to activate both of their memberships. SAC ¶ 220.[4] The fair market value of the comprehensive expert services offered on *Allergan Access* alone far exceeds the nominal $895 annual membership fee; eye care professionals across the United States spend far more on similar resources. SAC ¶¶ 208, 221-25. Allergan's own marketing and business advisory representatives confirmed to Relators that the extraordinary value of the *Allergan Access* website far exceeds the nominal $895 fee. SAC ¶ 228.

Allergan Access includes the following tools and resources, among others:

- Detailed print, radio, television and internet marketing materials, including complete marketing campaigns;
- Sophisticated financial analysis, benchmarking assessment tools, and guidance manuals;
- On-demand coding and billing assistance through the "Ask the Expert" feature of the website;
- A roster of 65 free online continuing education courses;
- Physician recruiting and contracting manuals, and contract templates;
- Human resources manuals and forms;
- Sophisticated payer evaluation tools, and contracting resources;
- Medicare Part D information;
- Patient education materials;
- Practice Feasibility Analyzers;
- Clinical Operations Resources; and

[4] The price for the services offered jumped dramatically in 2010, from $895 to between $1390 and $1690. SAC ¶¶ 278-83.

- Optical Shop Tools and Resources.

SAC ¶¶ 208, 212. Allergan retained BSM Consulting Group, one of the nation's foremost health care consulting firms, to develop, maintain, and operate *Allergan Access*. SAC ¶¶ 211, 213-15. The Complaint describes these services in detail but some of them are worth repeating here.

1. "Ask The Expert" Section of *Allergan Access*

The Corcoran Consulting Group, a renowned group of eye care practice management consultants, provides free expert advice through the *Allergan Access* website. The Corcoran Consulting Group, in 2010, normally charged ophthalmologists an hourly rate of at least $280 for its services, billable in one-tenth of an hour increments. SAC ¶¶ 226, 233, 238-39. The Corcoran Group provides on-demand expert answers to billing and coding questions submitted through the "Ask-The-Expert" Section of *Allergan Access* for no extra charge. SAC ¶¶ 226, 233-35.

2. "E-Learning" Section of *Allergan Access*

In the "E-Learning" Section of the *Allergan Access* website, members have free, unlimited access to continuing education courses in a wide range of subjects, including: Accredited Management Training; Accredited Technician Training; Staff training; Accredited Optician Training; and Business Office Training.[5] SAC ¶¶ 240, 241, 243. Similar on-line education courses can cost hundreds of dollars for each course. SAC ¶ 246.

On March 26, 2009, Allergan's Territorial Sales Manager Pecoraro told Relator Nevyas-Wallace that physicians can easily recover the $895 *Allergan Access* membership fee in short order because the technicians in their offices can get free continuing education credits

[5] The "Business Office Training" modules include courses such as: Fundamentals of Diagnosis Coding; How to Attract (Unwanted) Attention from Medicare; Reimbursement for New Technology; and Common Documentation and Coding Errors: Office Visits and Diagnostic Tests. SAC ¶ 245.

through the website, and that by using this feature alone, physicians would quickly recoup their $895 investment. SAC ¶ 229.[6]

3. "Financial Management" Section of *Allergan Access*

The "Financial Management" section of the *Allergan Access* website provides members with comprehensive resources and guidance relating to the management of an eye care practice, including: Practice Financial Health Assessments, Accounts Receivable Analytical Tools and Guides, Budget Tools, Sophisticated Financial Benchmarking Tools and Reports, Financial Management Tools, and Financial Assessment and Management Articles. SAC ¶ 247. This section also includes a variety of interactive "Financial Management Benchmarking Report Templates," which allow members to input financial information about their practices, generate detailed financial reports, and compare the performance of their practices with that of other practices nationwide. SAC ¶ 248. The "Tools" subheading of the website provides interactive tools, including an Accounts Receivable Management Report, allowing members to analyze accounts-receivable information and compare the results with industry benchmarks. Also included is a "Patient Visit Summary and Coding Analysis," which tracks patients' office visits and coding patterns and compares the results to CMS Utilization Data. SAC ¶¶ 249-50.

4. "Staff Management" Section of *Allergan Access*

In the "Staff Management" area of the *Allergan Access* website, members have access to comprehensive human resources guidance and advice, including: Human Resources

[6] Pecoraro's statements were confirmed by Allergan in an article published on the *Allergan Access* website entitled, "Case Study: Maximizing Use of the *Allergan Access* eLearning Center." SAC ¶ 230. This article describes the use of the E-Learning feature of *Allergan Access* by Pacific EyeCare of Poulsbo, a 51-employee ophthalmology practice in Washington State. *Id.* The article details how Pacific EyeCare benefitted from the E-Learning courses on the *Allergan Access* website, stating that Pacific EyeCare staff completed 411 E-Learning Courses in the first ten months of 2006 alone. *Id.* The article explains that "[o]n the *Allergan Access* website, the eLearning Center is without question the most popular feature." *Id.*

Self-Assessment; Training Guides; Sample Recruitment Forms; Employee Orientation Forms; Job Descriptions; Work Performance Review Forms; a Prototype Employee Policy and Procedure Manual; Employee Satisfaction Program; and Employee Counseling Forms. SAC ¶ 255. This section of the website also contains a number of useful forms related to personnel management, including a Confidential Employee Data Form, a Direct Deposit Sign-up Form, an Employee Paid Time Off Record, an Employee Wage and Benefit Statement, and a Payroll Status Change Form. SAC ¶ 256.

5. "MD Recruitment" Section of *Allergan Access*

Allergan Access includes an "MD Recruitment" section, containing resources designed to aid members in recruiting physicians into their practices. SAC ¶¶ 253-54. In this section, members can access sophisticated tools and guides related to physician recruiting and contracting, including: Physician Recruiting Self-Assessment Tools; Recruitment and Contracting Training Guides; Feasibility Assessment Tools; Contract Details; and the Online Job Fair. SAC ¶ 253. This section also includes template employment and confidentiality agreements, as well as detailed manuals and guidance relating to physician recruiting, contracting, and integration. SAC ¶ 254.

6. Additional Resources for *Allergan Access* Members

Through the *Allergan Access* website, selected eye care professionals also have free access to the consulting firm of J. Pinto & Associates, a health management consulting firm located in San Diego, California. SAC ¶¶ 221-23, 227, 267-70, 143, 168. J. Pinto & Associates normally charges ophthalmology practices an hourly rate of at least $295 per hour for its consulting services, and requires new clients to provide an upfront retainer fee of $5,000. SAC ¶¶ 227, 271. If travel to the client's offices is required, J. Pinto & Associates normally charges $2,950 per day, plus travel expenses. SAC ¶¶ 227, 271. Before becoming an *Allergan Access*

member, in approximately 2000, Relator Nevyas contacted J. Pinto & Associates to inquire about retaining them to provide consulting services to Nevyas Eye Associates. SAC ¶ 272. Relator Nevyas was informed by J. Pinto & Associates that they would require a retainer of approximately $15,000, plus additional charges for traveling to Relator Nevyas' office, before they would provide any consulting services. SAC ¶ 272.

D. Allergan Offers Kickbacks to Physicians Through its Speakers' Bureau

On Tuesday, May 12, 2009, Relator Nevyas-Wallace met with Allergan Territorial Sales Manager Matthew Schlegel in the office of Nevyas Eye Associates in Bala Cynwyd, Pennsylvania. SAC ¶ 286. Schlegel offered that Relator Nevyas-Wallace could become a member of Allergan's Speakers Bureau. SAC ¶ 287. Schlegel told her that she would have to negotiate with Allergan the amount of reimbursement that she would receive. SAC ¶ 288. Schlegel told Relator Nevyas-Wallace that in order to become a member of Allergan's Speakers' Bureau, she would need to be "a really good writer of prescriptions." SAC ¶¶ 288-89. This information was confirmed to Relator Nevyas-Wallace by another doctor at an Allergan Dry Eye Dinner meeting. SAC ¶ 291.

E. Allergan Offers Kickbacks to Ophthalmologists Through Its Sponsored Meetings and Dinners

Relators were invited to attend, and did attend, Allergan's Regional Advisory Board Meeting about the ophthalmic anti-inflammatory market, to be held on August 21-22, 2009 in New York, NY. SAC ¶¶ 292-93. Allergan provided each attendee with round-trip transportation (air travel, Amtrak ACELA, etc.), one night's hotel accommodation at The Benjamin (a luxury hotel located in the heart of Manhattan, where room rates begin at $599 per night), and meals throughout the program. SAC ¶¶ 295-96. In addition, each attendee would receive a $1,000 consultant fee and a $150 travel stipend. SAC ¶ 295. The agenda for the

meeting on Friday included only a two-hour "Welcome Reception" in the evening. On Saturday, the agenda included only: a breakfast from 7:30-8:00, a "General Session" from 8:00-12:30, and a lunch from 12:30-1:30. SAC ¶ 297.

Allergan representatives spent substantial time during the meeting delivering a marketing presentation on the benefits of a new formulation of Acular®, known as Acuvail®, that Allergan was planning to launch in the fall. SAC ¶ 301. According to a participant list distributed at the beginning of the Advisory Board Meeting, the approximately 22 eye care physicians who attended were from the following states: Connecticut, Florida, Maryland, New Jersey, New York, Ohio, Pennsylvania, and Tennessee. SAC ¶ 298. Each attendee received an Allergan Master Consulting Agreement to sign, which stated that, in exchange for the compensation received, the consultant would "give Allergan feedback and insight regarding NSAIDs and the current ophthalmic anti-inflammatory market." SAC ¶¶ 299-300. Allergan hosted the eye care professionals at its Regional Advisory Board meeting, at least in part, to induce them to prescribe Allergan's products. SAC ¶ 302.

F. Allergan's Offer to Fund Independent Research for Its Top Prescribers

Allergan has also offered to fund independent research to reward its top prescribers. SAC ¶ 303. On May 19, 2009, Allergan's Sales Manager Schlegel—rather than a member of Allergan's research and development staff—offered to fund Relator Nevyas-Wallace's independent research. SAC ¶ 304. Specifically, Schlegel told Relator Nevyas-Wallace that Allergan would be willing to fund a study that Dr. Nevyas-Wallace could design to compare the results of Allergan's Acular LS® versus a competing product in preventing cystoid macular edema following cataract surgery. SAC ¶ 304. Schlegel then discussed with Nevyas-Wallace how to propose such a study to Allergan. SAC ¶ 304.

G. The Purpose of Allergan's Programs is to Induce Prescriptions of Allergan's Products

All of Allergan's offerings described above are intended to induce eye care professionals to write prescriptions for Allergan's drugs. In fact, Allergan tracks the precise number of Allergan products prescribed by eye care professionals across the United States using prescription data that Allergan purchases from pharmacies and/or other consulting companies. SAC ¶ 100. Allergan utilizes this data, in part, to identify the eye care professionals it will target for its offerings, and to monitor the effectiveness of those offerings in increasing the number of Allergan products prescribed by those eye care professionals. SAC ¶ 101.

Allergan's programs have coincided with tremendous sales growth. SAC ¶ 32 (noting the increase in net sales of Allergan's Specialty Pharmaceutical segment from $2.319 billion in 2005 to $3.683 billion in 2009). Those programs, however, tainted physician decision-making in violation of the anti-kickback laws, and that growth has come at the expense of the public, which ultimately pays the bills for false claims submitted to federal and state health insurance programs.

III. PROCEDURAL HISTORY

Relators' Second Amended Complaint (the operative Complaint) was filed on September 27, 2010, and unsealed on December 16, 2013. Dkt. Nos. 15, 42. The government declined to intervene; but contrary to Allergan's suggestion, and as appellate courts consistently have held, the government's decision not to intervene in a False Claims Act ("FCA") case is not a commentary on the merits of a case or an indication of government disinterest. *United States ex rel. Spay v. CVS Caremark Corp.*, 913 F. Supp. 2d 125, 144 (E.D. Pa. 2012) ("As the United States Court of Appeals for the Third Circuit has yet to opine on this precise issue, this Court follows the overwhelming weight of authority from other circuits to find that no such

presumption [of lack of merit based on the government's decision not to intervene] should be imposed.").[7] By the same token, Allergan presumably does not intend for the Court to infer that Relators' case is meritorious simply because the government did not move to dismiss the action under 31 U.S.C. § 3730(c)(2)(A), as it is also entitled to do.

Allergan filed its original Motion to Dismiss Relators' Second Amended Complaint on April 1, 2014. One of its principal arguments was that the FCA's public disclosure bar deprived this Court of subject matter jurisdiction. In support of that argument, Allergan attached an exhibit that it believed to be publicly available portions of *Allergan Access*, or an advertisement for Allergan Access. *See* Dkt. No. 59. After Relators informed Allergan that the website attached to Allergan's original Motion was neither *Allergan Access* nor an advertisement for it, but instead was a completely different offering by an independent company, the parties filed a Consent Motion to Amend, Dkt. No. 60, and Allergan filed its Amended Motion to Dismiss, with accompanying Memorandum ("Def. Br."), on April 29, 2014. Dkt. No. 62.

IV. APPLICABLE PLEADING STANDARDS

A motion to dismiss pursuant to Rule 12(b)(6) challenges the legal sufficiency of the complaint. In assessing the complaint's sufficiency, the court must accept as true all well-pleaded facts and allegations, and must draw all reasonable inferences therefrom in favor of the

[7] *See also United States ex rel. Chandler v. Cook Cnty., Ill.*, 277 F.3d 969, 974 n.5 (7th Cir. 2002) ("There is no reason to presume that a decision . . . not to assume control of the suit is a commentary on its merits. The Justice Department may have myriad reasons for permitting the private suit to go forward."); *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1360 n.17 (11th Cir. 2006) (noting that the government's declination does not suggest that "the evidence of wrong doing [was] insufficient or the *qui tam* relator's allegations for fraud [were] without merit"); *United States ex rel. Williams v. Bell Helicopter Textron Inc.*, 417 F.3d 450, 455 (5th Cir. 2005) ("The [FCA] statute . . . does not require the government to proceed if its investigation yields a meritorious claim. Indeed, absent any obligation to the contrary, it may opt out for any number of reasons."); *United States ex rel. Berge v. Bd. of Trs. of the Univ. of Ala.*, 104 F.3d 1453, 1458 (4th Cir. 1997) (finding that the government's declination was "not an admission by the United States that it has suffered no injury in fact, but rather . . . a cost-benefit analysis").

plaintiff. *See Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (citing *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)); *United States ex rel. Bergman v. Abbott Labs.*, No. CIV A 09-4264, 2014 WL 348583, at *4 (E.D. Pa. Jan. 30, 2014). After accepting as true all well-pleaded facts and drawing all reasonable inferences in the plaintiffs favor, the court reviewing a motion to dismiss must determine whether the plaintiff has complied with Federal Rule of Civil Procedure 8 by "stat[ing] a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A complaint is facially plausible when the pleadings "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.*.

In addition to meeting the requirements of Rule 8, actions under the FCA must satisfy the heightened pleading standard of Federal Rule of Civil Procedure 9(b). *See United States ex rel. LaCorte v. SmithKline Beecham Clinical Lab.*, 149 F.3d 227, 234 (3d Cir. 1998). Courts in the Third Circuit apply Rule 9(b) with flexibility and have "cautioned against overemphasizing [Rule 9(b)'s] specificity requirement." *United States ex rel. Underwood v. Genentech, Inc.*, 720 F. Supp. 2d 671, 676 (E.D. Pa. 2010); *Gibbons v. Kvaerner Phila. Shipyard, Inc.*, No. 05-685, 2006 WL 328362, at *5 (E.D. Pa. Feb. 10, 2006) (same). Indeed, the Third Circuit has warned that "focusing exclusively on [Rule 9(b)'s] 'particularity' language is too narrow an approach and fails to take account of the general simplicity and flexibility contemplated by the rules." *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir. 1984) (internal citation and quotation marks omitted). Rather, "Rule 9(b) must be read with Federal Rule of Civil Procedure 8, which requires the plaintiff to allege a 'short and plain statement of the claim' and directs that averments in pleadings shall be 'simple, concise, and

direct.'" *Gibbons*, 2006 WL 328362, at *5 (quoting Fed. R. Civ. P. 8(a)(2)). In the Third Circuit, plaintiffs may satisfy Rule 9(b) with allegations of the "date, place, or time" of allegedly fraudulent conduct, though they "are free to use alternative means of injecting precision and some measure of substantiation into their allegations of fraud." *Seville*, 742 F.2d at 791.

V. ARGUMENT

Although the parties' combined briefing totals more than 125 pages, with no doubt more to come from Allergan, the case boils down to one simple question: have Relators alleged that when Allergan offered extremely valuable business consulting services to eye care professionals, one specific purpose of doing so was to induce those professionals to write prescriptions for Allergan's lucrative pharmaceutical products? Allergan's own employees answered this question by repeatedly touting the value of its business consulting services, and expressly requesting that Relators "show their appreciation" for that value by prescribing Allergan's drugs, particularly when there was a choice between Allergan's drugs and comparable products. SAC ¶¶ 207, 217-18, 231, 148, 169-71. Thus, Allergan violated the Anti-Kickback Statute ("AKS") and the FCA.

This postulate makes perfect sense and it should be no surprise that the law follows this common-sense formulation. If Allergan (a pharmaceutical manufacturer) can ultimately prove that it honestly believed that providing ophthalmologists and optometrists with the valuable ECBA and *Allergan Access* business services was not, in part, to induce prescriptions, then it may prevail at trial. This factual determination, however, cannot be resolved at the pleading stage. As set forth below, none of Allergan's attempts to obscure this critical issue and escape liability at this early stage of the case are well-founded, and its motion must be denied.

A. Allergan's AKS Violations Give Rise to FCA Liability.

Relators' legal theory is both straightforward and well-recognized: Allergan is liable under the FCA for causing claims for Medicare and Medicaid reimbursement to be submitted without disclosing that Allergan had tainted those claims by offering kickbacks in violation of the AKS, compliance with which is a condition of payment under the Medicare and Medicaid programs. Courts across the country, including within the Third Circuit, have repeatedly recognized this theory of FCA liability: "An FCA violation occurs . . . when a defendant submits or causes to be submitted a request for payment without disclosing that it is in violation of a regulation that affects its eligibility for payment." *Bergman*, 2014 WL 348583, at *7 (citing *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 314 (3d Cir. 2011)).

Indeed, the Third Circuit has long embraced the theory that AKS violations give rise to FCA liability. *See United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir. 2004). This is entirely consistent with "Congress' expressly stated purpose that the FCA should 'reach all fraudulent attempts to cause the Government to pay [out] sums of money or to deliver property or services.'" *Wilkins*, 659 F.3d at 306 (quoting S.Rep. No. 99–345, at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274, and citing *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968)). Kickbacks cause providers to make medical decisions based on "the amount of the kickbacks and rebates offered," not based on the patient's best interests or sound medical judgment. *United States v. Greber*, 760 F.2d 68, 71 (3d Cir. 1985) (quoting H.R. Rep. No. 95-393, *reprinted in* 1977 U.S.C.C.A.N. 3039, 3048-49).

Recognizing the serious threat kickbacks present to federal health insurance programs, Congress made the payment or receipt of kickbacks a felony. 42 U.S.C. § 1320a-7b(b). The government does not pay for claims tainted by kickbacks; otherwise, the government

would be "in the position of funding illegal kickbacks after the fact." *United States ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 616 (N.D. Ill. 2003).

Courts uniformly agree with the Third Circuit that AKS compliance is a condition of payment for federal health insurance programs, including Medicare and Medicaid. *See, e.g.*, *United States v. Rogan*, 517 F.3d 449, 452 (7th Cir. 2008) (illegal kickbacks are material to payment by Medicaid program); *McNutt ex rel. United States v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1260 (11th Cir. 2005) ("[C]ompliance with the [AKS] is necessary for reimbursement under the Medicare program"); *United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 54-55 (D. Mass. 2011) ("[C]ourts, without exception, agree that compliance with the Anti–Kickback Statute is a precondition of Medicare payment, such that liability under the False Claims Act can be predicated on a violation of the Anti–Kickback Statute.") (citing cases); *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., Inc.*, 565 F. Supp. 2d 153, 159 (D.D.C. 2008) ("Legion other cases" have held that AKS violations give rise to FCA liability).[8]

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[8] *See also, e.g., United States ex rel. Lisitza v. Johnson & Johnson*, 765 F. Supp. 2d 112, 127 (D. Mass. 2011) ("[AKS] compliance is not merely a condition of participation in federal health care programs, but is also material to the government's decision to pay any claim resulting from a kickback."); *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 12, 18 (D. Mass. 2007) ("the FCA is violated when a Medicaid claim is presented to the state government in violation of the Anti–Kickback statute."); *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp. 2d 35, 43 (D. Mass. 2000) (AKS violations sufficient to state a claim under the False Claims Act); *United States ex rel. Jamison v. McKesson Corp.*, No. 208CV214 SA DAS, 2009 WL 3176168, at * 12 (N.D. Miss. Sept. 29, 2009) *on reconsideration*, No. 2:08CV214-SA-DAS, 2010 WL 1223876 (N.D. Miss. Mar. 25, 2010) ("[F]ailure to comply with the kickback laws is, in and of itself, a false statement to the government."); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017, 1047 (S.D. Tex. 1998) (similar); *United States ex rel. Fry v. The Health Alliance of Greater Cincinnati*, No. 1:03–CV–00167, 2008 WL 5282139, at *12 (S.D. Ohio Dec. 18, 2008) ("The claims at issue in this case involve certification of compliance with the Anti–Kickback Statute, a condition of government payment."); *United States ex rel. Pogue v. Am. Healthcorp, Inc.*, 914 F. Supp. 1507, 1513 (M.D. Tenn. 1996) (allegation that "the government would not have paid the claims submitted by Defendants if it had been aware of the alleged kickback . . ." was sufficient to state FCA claim); *United States ex rel. Nehls v. Omnicare, Inc.*, No. 07 C 5777, 2011 WL 1059148, at *3 (N.D. Ill. Mar. 21, 2011) (AKS compliance is material to Medicaid program); *Mason v. Medline*, 731 F. Supp. 2d 730, 739 (N.D. Ill. 2010) (similar);

Despite this great weight of authority, Allergan contends that the "SAC fails to articulate a viable legal theory under the FCA." (Def. Br. at p. 11.) In support of its contention that the kickbacks alleged in this case do not give rise to FCA liability, Allergan pushes two primary arguments. First, Allergan argues that it is somehow immunized from FCA liability because the kickback-tainted claims were submitted by pharmacists, rather than by Allergan directly. But the FCA imposes liability not only on the party who submits the false claim. Rather, anyone who "*causes* to be presented" a fraudulent claim is liable. 31 U.S.C. § 3729(a)(1)(A) (emphasis added); *see also Schmidt*, 386 F.3d at 243-44 (defendant's liability "did not turn on whether the actual presenters were 'duped' or participated in the fraudulent scheme"). Second, after acknowledging, as it must, that compliance with the AKS is a condition of payment under the *Medicare* program (Def. Br. at p. 14), Allergan argues that the rule might be something different under the *Medicaid* program. Allergan, however, fails to explain why Medicaid—funded in part by the federal government (*see* 42 U.S.C. § 1396)—would be willing to pay kickback-tainted claims, while, as Allergan concedes, Medicare is not.

Neither of Allergan's attacks on Relators' theory of liability finds support in the text of the FCA, the AKS, or Third Circuit precedent. As set forth below, Allergan caused the government to pay claims tainted by Allergan's kickback violations, and those claims—whether

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United States v. Rogan, 459 F. Supp. 2d 692, 724 (N.D. Ill. 2006) ("[the AKS] clearly provide[s] that compliance with [its] terms is a condition of payment under the Medicaid programs. The United States would not have paid the claims if it had known the claims were false."); *United States ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 616 (N.D. Ill. 2003) ("Compliance with the AKS is thus central to the reimbursement plan of Medicare. To state otherwise would be to allow participation and reimbursement for supplies purchased illegally only because the claimant had the luck of not being caught and convicted in the first place."); *United States ex rel. Freedman v. Suarez-Hoyos*, 781 F. Supp. 2d 1270 (M.D. Fla. 2011); *United States ex rel. Barrett v. Columbia/HCA Health Care Corp.*, 251 F. Supp. 2d 28, 33 (D.D.C. 2003) ("compliance with the [AKS] would affect the government's decision to pay"); *United States ex rel. Ortega v. Columbia Healthcare, Inc.*, 240 F. Supp. 2d 8, 13 n. 5 (D.D.C. 2003) ("Compliance with these laws [the AKS and Stark] is a condition for reimbursement under Medicare . . .").

ultimately submitted by a pharmacist, or to the Medicaid program—are fraudulent under well-established FCA jurisprudence.

1. Allergan's AKS Violations Caused the Submission of Fraudulent Claims.

In *Wilkins*, the Third Circuit's most recent affirmation that AKS violations give rise to FCA liability, the court described the various theories of FCA liability. "There are two categories of false claims under the FCA: a factually false claim and a legally false claim." *Wilkins*, 659 F.3d at 305. "A claim is factually false when the claimant misrepresents what goods or services that it provided to the Government and a claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment." *Id.* "A legally false FCA claim is based on a 'false certification' theory of liability." *Id.* "There is a further division of categories of claims as the courts have recognized that there are two types of false certifications, express and implied." *Id.* "Under the 'express false certification' theory, an entity is liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds." *Id.* Under the "implied false certification" theory, "liability [ ] attaches 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.*

While these categories provide a structure for analyzing FCA claims, the precise labels are immaterial. *See, e.g., United States ex rel. Hendow v. Univ. of Phx.*, 461 F.3d 1166, 1172 (9th Cir. 2006) (the word "certification" has no "paramount and talismanic significance"). At bottom, the government is cheated whenever it is led to spend public money on claims it never intended to pay; such claims are not lawfully payable, and are therefore fraudulent.

(a) Allergan's AKS Violations Give Rise to FCA Liability Under an Implied False Certification Theory.

Relators have alleged that Allergan is liable under an implied false certification theory because it paid kickbacks to physicians and others to induce them to write prescriptions for Allergan's drugs. Similarly, the relators in *Wilkins* alleged that the defendant insurance companies paid kickbacks to physicians and others to induce people to join their programs. *Wilkins*, 659 F.3d at 300. The Third Circuit had little difficulty concluding that the relators had "clearly state[d] a claim for relief under an implied false certification of liability." *Id.* at 313. As the court explained, "[u]nder an implied false certification theory, instead of looking at the defendant's representations to the Government, the analysis focuses on the underlying contracts, statutes, or regulations themselves to ascertain whether they make compliance a prerequisite to the government's payment." *Id.* (quotations omitted.) Because "[c]ompliance with the AKS is clearly a condition of payment under Parts C and D of Medicare," the Third Circuit held that "violat[ing] the AKS while submitting claims for payment to a federal health insurance program" gives rise to FCA liability. *Id.* The court rejected the idea that such a theory of liability was too broad.

> Compliance [requires] a participant in a federal health care program to refrain from offering or entering into payment arrangements which violate the AKS, while making claims for payment to the Government under that program. We do not think this is an unreasonable requirement to impose on federal health care contractors, for as Justice Holmes once wrote: "Men must turn square corners when they deal with the Government." *Rock Island, A. & L.R. Co. v. United States*, 254 U.S. 141, 143, 41 S.Ct. 55, 56, 65 L.Ed. 188 (1920). And as the United States as *amicus curiae* points out, "[t]he Government does not get what it bargained for when a defendant is paid by CMS for services tainted by a kickback." *Amicus curiae* br. at 31.

Id. at 314.

The SAC, like the complaint in *Wilkins*, alleges that Allergan violated the AKS while causing claims to be submitted to federal health insurance programs. *See, e.g.*, SAC ¶ 325

("Claims that arise from Allergan's kickback scheme are false, and violate the False Claims Act, because they are the result of a kickback"). Accordingly, the SAC states a claim under the implied false certification theory of FCA liability. *Wilkins*, 659 F.3d at 314.

(b) Allergan's AKS Violations Also Give Rise to FCA Liability Under an Express False Certification Theory.

The Third Circuit has long held that AKS violations give rise to FCA liability under an express false certification theory. *Wilkins*, 659 F.3d at 312 (citing *United States ex rel. Kosenske v. Carlisle HMA Inc.*, 554 F.3d 88, 94 (3d Cir. 2009) and *Schmidt*, 386 F.3d at 243 ("A certificate of compliance with federal health care law is a prerequisite to eligibility under the Medicare program."). Relators have alleged that healthcare providers, including pharmacies, must certify that claims submitted for payment to federal health insurance programs comply with the AKS.

> I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal Anti-Kickback statute . . .

SAC ¶ 82; *see also* ¶ 83.[9] Relators also have alleged that, because Allergan paid kickbacks to eye-care professionals, the "underlying transaction" leading to the submission of claims for reimbursement for Allergan's drugs violated the AKS, and caused the certifications to be false. *Id.* These allegations suffice to state a claim under an express false certification theory. *Kosenske*, 554 F.3d at 94 ("Falsely certifying compliance with the Stark or Anti–Kickback Acts

[9] Allergan asserts, without citation, that the CMS forms cited in the SAC are "completely unrelated to the claims at issue here" because they are not completed by "retail pharmacies." (Def. Br. at p. 13.) Allergan's unsupported assertion would require a factual inquiry inappropriate at this stage. In any event, the Form CMS-855-S, which is quoted in the SAC, expressly includes "Pharmacy" and "Optometrist" in the list of "who should complete and submit this application." *See* http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855s.pdf (last visited May 14, 2014).

in connection with a claim submitted to a federally funded insurance program is actionable under the FCA.").

(c) Allergan's AKS Violations Render Claims for Reimbursement for Allergan's Drugs Factually False.

Even setting aside false certification theories, kickback-tainted claims are factually false because "the government does not get what it bargained for when a defendant is paid by CMS for services tainted by a kickback." *Wilkins*, 659 F.3d at 314 (quoting Br. for the United States Amicus Curiae, *United States ex rel. Wilkins v. United Health Grp., Inc.*, No. 10-2747, at 31 (U.S. Oct. 14, 2010)). While *Wilkins* did not examine whether kickback-tainted claims are factually false under the FCA, *Wilkins* did explain that "[a] claim is factually false when the claimant misrepresents what goods or services that it provided to the Government." *Id.* at 305. Because, as set forth above, compliance with the AKS is a material condition of payment, a kickback-tainted claim is a misrepresentation of what is being provided to the government—it is not what the government bargained for. *See United States v. Ruttenberg*, 625 F.2d 173, 177 (7th Cir. 1980) (the government is not required to pay claims tainted by kickbacks). Accordingly, the kickback-tainted claims that Allergan caused the government to pay are factually false.

2. Allergan's Attempts to Avoid FCA Liability for AKS Violations are Without Merit.

In the face of overwhelming authority holding that AKS violations give rise to FCA liability, Allergan makes only one attack on Relators' theory of liability with respect to Medicare claims: Allergan contends that its AKS violations are immunized because a pharmacist, rather than Allergan, submitted the kickback-tainted claims. With respect to Allergan's liability for the submission of false claims to the Medicaid program, it contends that

Medicaid—unlike Medicare—does not require compliance with the AKS as a condition of payment. Neither of Allergan's positions withstands scrutiny.

(a) Allergan is Liable Under the FCA for Causing Others to Submit Kickback-Tainted Claims.

Allergan contends that because pharmacists—not Allergan—submitted the kickback-tainted claims to government health insurance programs, Allergan is immune from FCA liability. (Def. Br. at pp. 15-17.) Allergan's argument ignores the plain statutory language which makes a person liable for *causing* the submission of a false claim, and is contrary to long-standing Third Circuit precedent.

In *Schmidt*, the relator alleged that the defendant, a medical device manufacturer, paid kickbacks to hospitals to induce additional purchases, and thereby caused the hospitals to submit false certifications that they "complied with all laws and regulations regarding the provision of health care services." 386 F.3d at 237-38; *id.* at 237 n.2. Those certifications are indistinguishable from the certifications at issue in this case. The district court dismissed the relator's complaint because the defendant did not itself submit any false certifications or claims to the government, and the relator failed to allege that the defendant ever saw, or certified the truthfulness of, the submitting party's certifications. *Id.* at 240. The Third Circuit reversed based on Supreme Court precedent, including *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943), and *United States v. Bornstein*, 423 U.S. 303 (1976):

> It does not appear from the opinion of the Court in either *Hess* or *Bornstein* that the party actually presenting the claims to the government was aware of the fraudulent conduct. This was not a matter material to the Court's analysis, however. Given the Court's view that the crucial issue was whether the defendants knowingly assisted in the presentation of false claims, the knowledge and conduct of the defendant were what mattered and the outcome did not turn on whether the actual presenters were "duped" or participated in the fraudulent scheme.

Schmidt, 386 F.3d at 243-44; *see also id.* at 244 ("[T]he District Court erred in concluding that someone other than the actual presenter cannot be responsible under the FCA in the absence of duping."). As in *Schmidt*, the knowledge and conduct of *Allergan* are what matters; the outcome does not turn on whether the *pharmacies* that actually presented the claims "were 'duped' or participated in the fraudulent scheme." *Schmidt*, 386 F.3d at 244.

Schmidt itself is consistent with long-standing Third Circuit precedent. *See United States v. Lagerbusch*, 361 F.2d 449, 450 (3d Cir. 1966) (where employee of government contractor cheated his employer, thus inflating costs that were passed on to government, the court found FCA liability: "We have no doubt that the False Claims Act covers such an indirect mulcting of the government."); *United States v. Rohleder*, 157 F.2d 126, 128 (3d Cir. 1946) (subcontractor who engaged in bid-rigging held liable under FCA even though prime contractor forwarded tainted bids to Navy "without suspicion" that they were rigged).

Allergan's out-of-context reading of *Wilkins* (Def. Br. at pp. 15-16)—relying on the court's general description of various FCA liability theories—ignores the Third Circuit's further description of the implied false certification theory of liability in which the court explained that: "A plaintiff can bring a claim under the FCA even without evidence that a claimant for Government funds made an express false statement in order to obtain those funds." *Wilkins*, 659 F.3d at 307. The court further explained that, "[u]nder an implied false certification theory, *instead of looking at the defendant's representations to the Government*, the analysis focuses on the underlying contracts, statutes, or regulations themselves to ascertain whether they make compliance a prerequisite to the government's payment." *Id.* at 313 (emphasis added). In other words, under *Wilkins*, like *Schmidt*, the relevant inquiry is *not* Allergan's "representation[] to the Government," but whether compliance with the AKS is a "prerequisite to the government's

payment." *Id.* And *Wilkins* answered that question: "Compliance with the AKS is clearly a condition of payment under Parts C and D of Medicare." *Id.*

Allergan's reliance on *United States ex rel. Rost*, 736 F. Supp. 2d 367 (D. Mass 2010), is misleading—the district court's holding in *Rost* cannot be reconciled with the First Circuit's later-issued opinions in *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 389 (1st Cir. 2011), and *New York v. Amgen Inc.*, 652 F.3d 103, 110-12 (1st Cir. 2011)—two opinions that are entirely consistent with the Third Circuit's holding in *Schmidt*. In *Hutcheson*, as in *Schmidt*, the relators alleged that a medical device manufacturer paid kickbacks to various doctors to use its devices, which in turn caused hospitals that had no knowledge of the underlying kickback scheme to submit claims to the government for services tainted by kickbacks. 647 F.3d at 378. The defendant in *Hutcheson* argued—just as Allergan does here—"that when a submitting entity expressly represents its own legal compliance, its representations cannot encompass a pre-condition of payment applicable to non-submitting entities." *Id.* at 389. The First Circuit, echoing the language of *Schmidt*, flatly rejected the defendant's argument:

> When the defendant in an FCA action is a non-submitting entity, the question is whether that entity knowingly caused the submission of either a false or fraudulent claim or false records or statements to get such a claim paid. The statute makes no distinction between how non-submitting and submitting entities may render the underlying claim or statements false or fraudulent.

Id. (*compare Schmidt*, 386 F.3d at 243-44). And, after examining *Hess* and *Bornstein*, the First Circuit rejected the proposition that Allergan advances here—that because the "pharmacists were unaware of any alleged kickbacks" (Def. Br. at pp. 16-17), Allergan is immune from FCA liability:

> These cases do not hold that a submitting entity's representations concerning its own conduct somehow immunize a non-submitting entity from liability under the 'causes' clauses of the FCA. Nor does Blackstone cite any other decision from the Supreme Court or this court that says that.

Id. at 390; *see also New York v. Amgen Inc.*, 652 F.3d at 110-12 (applying the same principles set forth in *Hutcheson* to Medicaid claims tainted by kickbacks).[10]

Aside from *Rost*, which does not reflect the law of its own circuit, Allergan relies only on *United States ex rel. Thomas v. Bailey*, No. 4:06CV00465 JLH, 2008 WL 4853630 (E.D. Ark. Nov. 6, 2008), an unpublished opinion followed only by *Rost* for the proposition that Allergan advances.

Standing opposed to *Rost* and *Thomas* is overwhelming authority, consistent with Third Circuit precedent, holding that the presence of an "innocent" intermediary in the government's reimbursement protocol cannot wash clean claims grounded in fraud. Indeed, the court in *United States ex rel. Fry v. Guidant Corp.*, No. 3:03-0842, 2006 WL 2633740, at *11-12 (M.D. Tenn. Sept. 13, 2006), relied exclusively on *Schmidt* in finding that a kickback scheme could give rise to FCA liability even where the party submitting the claim was innocent and unwitting. "As in *Zimmer*, the defendant in this case could be held liable under the FCA if it can be shown that it caused the hospitals' [unwitting] failure to comply with those regulations by concealing the existence of warranty credits." *Id.* More recently, in *Bergman*, the court denied a motion to dismiss an FCA claim involving a pharmaceutical manufacturer alleged to have paid kickbacks. Citing the relator's allegation, the court found that a "lack of kickbacks is a condition

[10] While Allergan, in a footnote, attempts to distance *Hutcheson* from Third Circuit precedent (Def. Br. at p. 16 n.8), *Hutcheson* is entirely consistent with *Schmidt*'s holding that "someone other than the actual presenter [can] be responsible under the FCA." *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244 (3d Cir. 2004). And *Hutcheson* is consistent with *Wilkins* in holding that "the federal Medicare program will not pay claims if the underlying transaction that gave rise to the claim violated the AKS." (*Compare United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 393 (1st Cir. 2011) *with United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 313 (3d. Cir. 2011).) Indeed, *Hutcheson* came to that conclusion after analyzing the very same certification language at issue in this case, *id.* at 392-93; *see also* SAC ¶ 82, and rejecting the proposition that a non-submitting entity, like Allergan, is immune from FCA liability because it does not submit the certification. *Hutcheson*, 647 F.3d at 393 (such a holding "would systematically excuse from FCA liability non-submitting entities who cause the submission of claims that fail to meet that stated precondition.").

of payment and that the kickbacks thus caused the submission of false claims for reimbursement." 2014 WL 348583 at *14.

Similarly, in *In re Pharm. Indus. Average Wholesale Price Litig.*, 478 F. Supp. 2d 164 (D. Mass. 2007), the court rejected the pharmaceutical company defendants' argument that they could not be liable under the FCA because doctors and pharmacists—not defendants—submitted the relevant claims to the government, finding that "the participation of doctors and pharmacists in the submission of Medi-Cal claims was not only a foreseeable and substantial factor in California's loss, but indeed it was an intended consequence of the alleged scheme of fraud." *Id.* at 175; *see also United States ex rel. Franklin v. Parke-Davis*, No. CIV.A. 96-11651PBS, 2003 WL 22048255, at *5 (D. Mass. Aug. 22, 2003) ("[T]he Court holds that Relator has presented evidence showing that it was foreseeable that Parke-Davis's conduct (including non-fraudulent promotion of off-label Neurontin uses) would ineluctably result in false Medicaid claims.") (citing *United States ex rel. Cantekin v. Univ. of Pittsburgh*, 192 F.3d 402, 416 (3d Cir. 1999) ("It is a basic principle of tort law that once a defendant sets in motion a tort, the defendant is generally liable for the damages ultimately caused, unless there are intervening causes.")).[11]

[11] *See also, e.g.*, *United States ex rel. Main v. Oakland City Univ.*, 426 F.3d 914, 916 (7th Cir. 2005) ("If a false statement is integral to a causal chain leading to payment, it is irrelevant how the federal bureaucracy has apportioned the statements among layers of paperwork."); *United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 378 (5th Cir. 2004) ("[A] person need not be the one who actually submitted the claim forms in order to be liable." (quoting *United States v. Mackby*, 261 F.3d 821, 827 (9th Cir. 2001))); *United States ex rel. Nehls v. Omnicare, Inc.*, No. 07 C 05777, 2013 WL 3819671 (N.D. Ill. July 23, 2013) (citing cases); *Mason v. Medline Indus., Inc.*, 731 F. Supp. 2d 730, 738 (N.D. Ill. 2010) ("The FCA places liability not only on persons who cause false claims to be submitted . . . but also on those who cause the claims . . . to be false in the first place."); *United States v. President & Fellows of Harvard Coll.*, 323 F. Supp. 2d 151, 186-87 (D. Mass. 2004) ("[A] defendant may be liable if it operates under a policy that causes others to present false claims to the government."); *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 238 F. Supp. 2d 258, 266 (D.D.C. 2002) ("An argument that the presentation of the claims was the work of another is unavailing as a means to avoid liability under the False Claims Act."); *United States v. Inc. Vill. of Island Park*, 888 F. Supp. 419, 440 (E.D.N.Y. 1995) ("When claims for payment on those mortgages are submitted by the innocent mortgagees, the fraudulent course of conduct pursuant to which the mortgages were approved emerge in 'full vigor' and become a part of those claims, which therefore constitute false claims within the meaning of the False Claims Act.

In short, because compliance with the AKS is a material condition of payment, claims tainted by kickbacks are fraudulent, and the FCA imposes liability on anyone who causes the submission of fraudulent claims to the government. *Wilkins*, 659 F.3d at 313; *Schmidt*, 386 F.3d at 244; 31 U.S.C. § 3729(a)(1)(A). The loophole Allergan attempts to create in an effort to escape this commonsense theory of liability would bestow a grant of FCA immunity on pharmaceutical companies that pay kickbacks to obtain government funds, and violate the text and spirit of the FCA. *See, e.g.*, 155 Cong. Rec. S10854 (Statement of Sen. Leahy) (explaining that the statute intended "to ensure that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil action under the False Claims Act, even when the claims are not submitted directly by the wrongdoers themselves."); *Cook Cnty., Ill. v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003) (in enacting the FCA "Congress wrote expansively, meaning 'to reach all types of fraud, without qualification, that might result in financial loss to the Government.'") (quoting *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968)). The Court should decline Allergan's invitation to create such a loophole.

(b) State Medicaid Programs Do Not Pay for Kickback-Tainted Claims

Allergan concedes that compliance with the AKS is a condition of payment under the Medicare program—in other words, Medicare will not pay for kickback-tainted claims. (Def. Br. at p. 14.) At the same time, Allergan contends that the Medicaid program *will* pay for kickback-tainted claims. This false distinction defies common sense and finds no support in Third Circuit precedent.

It is irrelevant that Lend–Mor, the lender who submitted the claims for mortgage subsidies is totally innocent.") (citing cases); *United States v. Teeven*, 862 F. Supp. 1200, 1223 (D. Del. 1992) ("The fact that the Defendants arguably neither made nor caused to be made any false statements or certifications to the Department of Education does not alter this conclusion. … The False Claims Act covers indirect mulcting of the government.").

As an initial matter, Allergan fails to provide any reasoned basis for treating the two programs differently. As the Third Circuit explained in *Wilkins*, "[t]he Government does not get what it bargained for when a defendant is paid by CMS for services tainted by a kickback." 659 F.3d at 314. Accordingly, "violat[ing] the AKS while submitting claims for payment to a *federal health insurance program*" gives rise to FCA liability. *Id.* (emphasis added); *see also Kosenske*, 554 F.3d at 94 ("Falsely certifying compliance with the Stark or Anti-Kickback Acts in connection with a claim submitted to a *federally funded insurance program* is actionable under the [FCA]" (emphasis added)). While *Wilkins* addressed Medicare claims, Medicaid, too, is a federal health insurance program.[12] And the AKS defines "federal health care program" to include the Medicaid program. 42 U.S.C. § 1320a-7b(f). There is no principled reason to suggest that Medicaid *does* get what it bargained for when it pays for services that are tainted by a kickback.

Not surprisingly, courts have had little difficulty concluding that compliance with the AKS is material to the government's decision to pay Medicaid claims, and that kickback-tainted claims submitted to Medicaid give rise to FCA liability. *See, e.g, United States ex rel. v. Boston Scientific Neuromodulation Corp.*, No. 2:11-CV-1210 SDW MCA, 2013 WL 2404816, at *5 (D.N.J. May 31, 2013) ("[C]ompliance with the Anti–Kickback Statute is material to the Government's decision to pay under Medicare and Medicaid."); *United States ex rel. Lisitza v. Johnson & Johnson*, 765 F. Supp. 2d 112, 127-128 (D. Mass. 2011) (kickbacks are material to government's decision to pay Medicaid claims) (citing *United States ex rel. Quinn v. Omnicare*, 382 F.3d 432, 443 (3d Cir. 2004) ("If a provider does not comply with the Medicaid regulations,

[12] Medicaid is a cooperative federal-state public assistance program established by Title XIX of the Social Security Act, under which federal matching funds are available to states that elect to pay for all or part of specified care and services furnished to needy individuals. *See* 42 U.S.C. §§ 1396-1396v.

. . . not only will the provider be ineligible to participate in the Medicaid programs, but Medicaid may seek to recover the money it paid to the provider for services covered by the claims.")); *In re Pharm.*, 491 F. Supp. 2d at 18 ("[T]he FCA is violated when a Medicaid claim is presented to the state government in violation of the Anti–Kickback statute.") (citing *Lagerbusch*, 361 F.2d at 449 (the FCA covers "indirect mulcting of the [federal] government")); *Rogan*, 517 F.3d at 452 (kickbacks are material to the validity of Medicare and Medicaid claims).[13]

Allergan insists that a "[s]tate-by-state and program-by-program analysis is critical because each state has a unique regulatory framework." To the contrary, like the United States, every state relevant to the SAC has enacted its own anti-kickback statute. *See* SAC ¶¶ 336 (CA); 344 (DE); 352 (FL); 360 (IL); 367 (IN); 376 (LA); 384 (MA); 392 (MI); 400 (MT); 490 (NV); 417 (NH); 425 (NJ); 433 (NM); 441 (NY); 449 (OK); 457 (RI); 465 (TX); 473 (VA); 481 (WI); 489 (DC). To the extent Allergan suggests that these statutes are insufficient to convey each state's intent to avoid paying for kickbacks because they do not "expressly state" that the provider must comply "in order to be paid," or because they are too "sweeping" (Def. Br. at p. 14), Allergan misunderstands Third Circuit precedent. Nothing in *Wilkins* suggests that an underlying statute must "expressly state" that compliance is a condition of payment. Such a rule, in the context of the AKS, would lead to an absurdity—after having declared kickbacks to be a

[13] *See also United States ex rel. Nehls v. Omnicare, Inc.*, No. 07 C 05777, 2013 WL 3819671, at *9 (N.D. Ill. July 23, 2013) ("compliance with the AKS . . . is a condition of reimbursement from Medicaid programs") (citing cases); *United States v. Ortho-McNeil Pharm., Inc.*, No. 03-C-8239, 2007 WL 2091185 (N.D. Ill. July 20, 2007) (same); *United States ex rel. Tyson v. Amerigroup Ill., Inc.*, No. 02-6074, 2005 WL 2667207, at *3 (N.D. Ill. Oct. 17, 2005) (same); *United States ex rel. Fry v. Health Alliance of Greater Cincinnati*, No. 03-00167, 2008 WL 5282139, at *12 (S.D. Ohio Dec. 18, 2008) (rejecting distinction between Medicare and Medicaid claims in holding that AKS violations give rise to FCA liability); *Mason v. Medline Indus. Inc.*, 731 F. Supp. 2d 730, 738 (N.D. Ill. 2010) (kickback-tainted claims submitted to Medicaid program are false claims); *United States ex rel. Pogue v. Diabetes Treatment Ctr. of Am.*, 565 F. Supp. 2d 153, 159 (D.D.C. 2008) (same).

crime, states that did not expressly disavow an obligation to pay for the fruits of that crime would be forced to fund it. *Bidani*, 264 F. Supp. 2d at 616.

In any event, *Schmidt* dispels any notion that the authority on which Allergan relies is applicable in the Third Circuit. In *Schmidt*, the relevant certification required the provider to certify compliance "with all laws and regulations regarding the provision of health care services." *Schmidt*, 386 F.3d at 237. Despite the absence of any "express statement" by the government that it would not pay claims that did not comply with that "sweeping" certification, the Third Circuit had no trouble concluding that the "complaint, to the extent it is based on Mercy's alleged false certification of compliance with federal health care law, states a claim upon which relief can be granted." *Id.* at 245.[14]

Allergan provides no reasoned basis for treating Medicaid claims any differently than Medicare claims—Relators have stated a claim based on Allergan's actions in causing the submission of kickback-tainted claims to the Medicaid program.

B. Relators Have Adequately Alleged Causation.

To properly plead causation in the AKS context under the FCA, a relator must allege only that the defendant's kickback scheme was a factor in rendering the claim false, and that the submission of that false claim was a normal consequence of that scheme. *Schmidt*, 386 F.3d at 244-45 (applying "ordinary causation principles from negligence law") (citing *United States ex rel. Cantekin v. Univ. of Pittsburgh*, 192 F.3d 402, 416 (3d Cir. 1999)).

In this case, Relators have alleged that Allergan's kickback scheme rendered claims for Allergan's drugs false, and that the submission of those false claims was "not only

[14] Even if more specific regulatory pronouncements were required for States to be able to avoid paying for kickback-tainted claims, each of the States relevant to this case have made such pronouncements. *See* Compilation of Medicaid Prohibitions of Payment of Claims Tainted by Kickbacks, attached hereto as Exhibit B (citing the relevant regulatory regimes of each State).

foreseeable, but an intended result of Allergan's illegal kickbacks." *See, e.g.*, SAC ¶ 319. As courts routinely hold, no more is required to sufficiently allege causation. *See United States ex rel. Simpson v. Bayer Corp.*, No. CIV.A. 05-3895 JLL, 2013 WL 4710587, at *14 (D.N.J. Aug. 30, 2013) (causation allegations sufficient where relator alleged a kickback scheme designed to induce prescriptions which "would inevitably" be submitted to the government); *Bergman*, 2014 WL 348583, at *13-14 (denying motion to dismiss; "when a relator alleges a kickback scheme large enough such that the submission of false claims is inevitable, then the relator has sufficiently alleged causation under 9(b).").[15]

Allergan's argument that the SAC fails to plead that Allergan caused a "financial loss to the government" (Def. Br. at p. 22), misses the mark because "[a] plaintiff need not allege that falsity caused an actual loss to the government." *Simpson*, 2013 WL 4710587, at *14; *see also United States ex rel. Int'l Bhd. of Elec. Workers, Local Union No. 98 v. Farfield Co.*, No. CIV.A. 09-4230, 2013 WL 3327505, at *4 (E.D. Pa. July 2, 2013) (citing cases) ("A party can be subject to FCA liability even where the government suffers no monetary injury."); *United States v. Educ. Mgmt. Corp.*, 871 F. Supp. 2d 433, 456 (W.D. Pa. 2012) ("[T]he Court does not agree that a plaintiff must demonstrate that the falsity caused an actual loss to the government.").

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[15] *See also In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21, 38-39 (1st Cir. 2013) ("Pfizer has always known that, because of the structure of the American health care system, physicians would not be the ones paying for the drugs they prescribed."); *United States ex rel. Booker v. Pfizer, Inc.*, No. CIV.A. 10-11166-DPW, 2014 WL 1271766, at *19 (D. Mass. Mar. 26, 2014) (relator sufficiently alleged causation even where pharmacies submitting claim were not the target of allegedly fraudulent marketing activities; "If the foreseeability of claims filed with state or federal programs is a question here, it is not one for the pleading stage.").

Allergan's citation to *United States ex rel. West v. Ctr. for Diagnostic Imaging, Inc.*, 787 F. Supp. 2d 1213, 1222 (W.D. Wash. 2011) is inapt. In *West*, the court found one of relators' kickback allegations implausible because the physicians who allegedly received free services did not know they were receiving them, and would not have been responsible for paying for them in any event. In this case, by contrast, Relators have alleged that Allergan actively promoted the value of the services it provided to eye care professionals who were responsible for paying for those services. *See, e.g.*, SAC ¶ 308.

In any event, the government *does* suffer a financial loss when it pays kickback-tainted claims—it does not get what it paid for. *Wilkins*, 659 F.3d at 314 ("[T]he government does not get what it bargained for when a defendant is paid by CMS for services tainted by a kickback.").[16] Through the Medicare and Medicaid programs, "[t]he government offers a subsidy (from the patients' perspective, a form of insurance), with conditions." *Rogan*, 517 F.3d at 453. One of those conditions is compliance with the AKS. *Id.* "When the conditions are not satisfied, nothing is due." *Id.* (affirming FCA judgment based on kickbacks even where defendant provided the care claimed in requests for reimbursement); *see also United States ex rel. Longhi v. United States*, 575 F.3d 458, 473 (5th Cir. 2009) ("In a case such as this, where there is no tangible benefit to the government and the intangible benefit is impossible to calculate, it is appropriate to value damages in the amount the government actually paid to the Defendants."); *cf. United States ex rel. Main v. Oakland City Univ.*, 426 F.3d 914, 917 (7th Cir. 2005) ("The statute provides for penalties even if (indeed, *especially* if) actual loss is hard to quantify."). In other words, the government suffers a loss whenever "the money appropriated for legitimate purposes [is] instead wasted on a false claim." *United States ex rel. Yesudian v. Howard Univ.*, 153 F.3d 731, 739 (D.C. Cir. 1998).

Accordingly, Relators need not prove—let alone allege—an increase in prescriptions for Allergan's drugs as a result of Allergan's kickback schemes. *Simpson*, 2013 WL 4710587, at *13-14 (relator need not plead "causal nexus" between kickbacks and claims submitted to government); *United States ex rel. Parikh v. Citizens Med. Ctr.*, No. 6:10-CV-64, 2013 WL 5304057, at *6-7 (S.D. Tex. Sept. 20, 2013) (relator is not required to plead that

[16] Accordingly, Allergan's citation to *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 184 (3d Cir. 2001), is unavailing. In *Hutchins*, the defendant submitted fraudulent bills for approval to a bankruptcy court. Because those bills would not have been paid by the government, they had no potential to cause the government any loss. *Id.* at 179, 184. In this case, by contrast, the very purpose of Allergan's scheme was to cause the government to pay money for its drugs.

"specific referrals were actually induced as a result of the kickbacks"). All claims tainted by Allergan's kickback scheme are false. *Rogan*, 517 F.3d at 453. And Relators have adequately alleged that Allergan caused kickback-tainted claims to be submitted to the government.

C. Relators Have Adequately Alleged that Allergan Violated the AKS.

The AKS makes it a felony to knowingly and willfully offer or pay any remuneration to induce a referral or purchase for which payment may be made under a federal health care program. 42 U.S.C. § 1320a-7b. Relators have alleged that Allergan did exactly that: Allergan knowingly and willfully offered valuable business services to induce eye care professionals to prescribe Allergan products. *See*, *e.g.*, SAC ¶ 203.

Designed to prevent medical professionals from choosing to order or prescribe goods or services based on something other than a patient's best interest, "[t]he statute is aimed at the inducement factor." *United States v. Greber*, 760 F.2d 68, 71 (3d Cir. 1985); *see also United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 29 (1st Cir. 1989) (the "gravamen of Medicare Fraud is inducement"). If any "one purpose" of the remuneration is to induce future referrals, the AKS is violated. *Greber*, 760 F.2d at 69. This is true even when the remuneration has other, legitimate purposes. *Id.* at 72 ([T]he Anti–Kickback Act is violated if one purpose of the payment tendered from hospital to physician is to induce future referrals, even if "the payments were also intended to compensate for professional services."). *Id.* at 72.[17]

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[17] *See also United States v. Borrasi*, 639 F.3d 774, 782 (7th Cir. 2011) (same); *United States v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000) ("[A] person who offers or pays remuneration to another person violates the Act so long as one purpose of the offer or payment is to induce Medicare or Medicaid patient referrals."); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998) (the AKS is violated whenever the benefits extended were partially to induce patient referrals); *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989) ("[T]he Medicare fraud statute is violated if 'one purpose of the payment was to induce future referrals.'") (quoting *United States v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985)); 66 Fed. Reg. 856, 918 (Jan. 4, 2001) ("If any one purpose of remuneration is to induce or reward referrals of Federal health care program business, the statute is violated.").

As Relators have alleged, one purpose—indeed, the primary purpose—of Allergan's business advisory programs was to induce eye care professionals to prescribe Allergan's drugs. Allergan repeatedly touted the value of its programs, and expressly requested that Relators "show their appreciation" for that value by prescribing Allergan's drugs, particularly when there was a choice between Allergan's drugs and comparable products. SAC ¶¶ 207, 217-18, 231, 148, 169-71. Allergan's conduct is thus precisely what Congress sought to eliminate, and criminalized, through the AKS. *Greber*, 760 F.2d at 71-72 (quoting *United States v. Hancock*, 604 F.2d 999, 1001 (7th Cir. 1979)).

And Allergan knew as much. Aside from being aware of the AKS as a member of the pharmaceutical industry, Allergan signed and agreed to abide by the guidance issued by the Pharmaceutical Research and Manufacturers of America ("PhRMA"), which expressly states that Allergan was not to offer "grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items . . . in exchange for prescribing products or for a commitment to continue prescribing products." SAC ¶ 91 (citing PhRMA Code II, Section 13, Exhibit A at p. 13). Yet Allergan offered precisely this type of remuneration in exchange for prescribing Allergan's drugs. Allergan's conduct was thus knowing and willful.

In response to such clear allegations of an AKS violation, Allergan attempts to defend its conduct by making three primary arguments: (1) that it did not pay "remuneration" under the AKS in connection with its speakers' bureau, sponsored meetings, or research funding (Def. Br. at pp. 27-28); (2) that it did not act with the requisite scienter (*id.* at pp. 17-21, 23-27); and (3) that its conduct was somehow protected by the First Amendment (*id.* at pp. 28-30). As set forth below, these defenses are without merit, especially on a motion to dismiss.

1. Allergan Paid "Remuneration" in Connection With All of Its Challenged Offerings, Including Its Speakers' Bureau, Sponsored Meetings, and Research Grants.

Allergan contends that Relators failed to properly plead remuneration because Relators did not allege that compensation paid to members of the speakers' bureau, attendees of sponsored meetings, or recipients of research funding was in excess of fair market value. (Def. Br. at p. 27.)[18] Allergan's "fair market value" defense is a red-herring. Relators have no obligation to prove—let alone allege—that the remuneration Allergan provided to eye care professionals was inconsistent with fair market value.

"Congress's intent in placing the term 'remuneration' in the statute in 1977 was to cover the transferring of *anything of value in any form or manner whatsoever*." Department of Health and Human Services, Office of Inspector General, Rules and Regulations, 42 C.F.R. Part 1001, 56 FR 35952-01 (Jul. 29, 1991) (emphasis added); *see also United States ex rel. Fry v. The Health Alliance of Greater Cincinnati*, 2008 WL 5282139, at *7-8 (S.D. Ohio Dec. 18, 2008) (remuneration includes "anything of value in any form whatsoever"). The Third Circuit has recognized the breadth of the term "remuneration":

> The text refers to "any remuneration." That includes not only sums for which no actual service was performed but also those amounts for which some professional time was expended. "Remunerates" is defined as "to pay an equivalent for service." Webster Third New International Dictionary (1966). By including such terms as kickbacks and bribes, the statute expands "remuneration" to cover situations where no service is performed. That a particular payment was a remuneration (which implies that a service was rendered) rather than a kickback, does not foreclose the possibility that a violation nevertheless could exist.

[18] Allergan appears to argue that "remuneration" was not adequately alleged only with regard to these "additional inducements." (Def. Br. at pp. 27-28.) To the extent it also contends that "remuneration" was not adequately alleged with regard to the ECBA and *Allergan Access* programs, that contention would fail for the same reasons set forth in this Section, and for the reasons stated in Sections V.C.2.b & d., below.

Greber, 760 F.2d at 71. Because "remunerates" is defined as "to pay an equivalent for service," a fair market value payment—*i.e.*, a payment of "equivalent" value—cannot "foreclose the possibility" of an AKS violation. *Id.* Indeed, in *Greber*, the Third Circuit never considered whether the alleged kickback—payments to a physician for professional services—was a fair market value payment despite the defendant's contention that the physician provided services in exchange for the payment. *Id.* at 71-72; *see also United States v. Borrasi*, 639 F.3d 774, 782 (7th Cir. 2011) (same). Thus, the relevant inquiry is *not* whether a payment was something more than "equivalent" value; rather, the relevant inquiry is whether one purpose of the payment was made to induce. *Greber*, 760 F.2d at 71 ("Even if the physician performs some service for the money received, the potential for unnecessary drain on the Medicare system remains. The statute is aimed at the inducement factor."); *see also Kosenske*, 2010 WL 1390661, at *9 (same); *Polk County v. Peters*, 800 F. Supp. 1451, 1454 (E.D. Tex. 1992) (same).[19]

In *Bay State Ambulance & Hosp. Rental Serv., Inc.*, 847 F.2d at 29, the court expressly rejected the contention that an AKS violation requires proof of a payment in excess of fair market value:

> The trial court did not err in not specifically instructing the jury that the government had to prove that the payments received were not reasonable for the actual work done. The gravamen of Medicare Fraud is inducement. Giving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient.

[19] While the statutory definition of "remuneration" references a "fair market value" payment, the definition is illustrative and inclusive (not exclusive): "The term 'remuneration' *includes* the waiver of coinsurance and deductible amounts (or any part thereof), and transfers of items or services for free or for other than fair market value. The term 'remuneration' does not include . . . . " 42 U.S.C. § 1320a–7a(i)(6) (emphasis added). Other statutory definitions in the same list, by comparison, are exclusive. *See, e.g.*, 42 U.S.C. § 1320a–7a(i)(2) ("The term 'claim' *means* an application for payments for items and services under a Federal health care program (as defined in section 1320a–7b(f) of this title)." (emphasis added.)).

The First Circuit further explained that the AKS's regulatory scheme does "not exempt *every* transaction in which the amount paid for services is an amount 'consistent with fair market value;' rather, it exempts only a small subset of such transactions." *Id.* at 31; *see also United States ex rel. Streck v. Allergan, Inc.*, 894 F. Supp. 2d 584, 597 (E.D. Pa. 2012) ("Plaintiff's Fourth Amended Complaint is devoid of facts that state the service fees paid under the contracts are a fair market value for the services rendered by wholesalers to Discount Defendants. That conclusion, however, is not fatal to Plaintiff's claims at this early pleading stage.").[20] As the OIG Guidance explains, "under the anti-kickback statute, neither a legitimate purpose for an arrangement (e.g., physician education), nor a fair market value payment, will necessarily protect remuneration if there is also an illegal purpose (i.e., the purposeful inducement of business)." OIG Compliance Program Guidance for Pharmaceutical Manufacturers ("OIG Guidance"), 68 Fed. Reg. 23731-01, at 23737 (May 5, 2003) (Exhibit C).

Accordingly, and contrary to Allergan's suggestion, Relators are not required to prove, or plead, that the remuneration Allergan paid was inconsistent with fair market value. Relators did, however, allege that speaker fees Allergan paid were negotiable, and that in order

[20] Further confirming that a fair market value payment, standing alone, does not immunize a transaction intended to induce referrals, many of the regulatory "safe harbors" to the AKS (none of which apply in this case) require a fair market value transaction *in addition* to other requirements. For example, to qualify for the "space rental" safe harbor, the parties must show that "[t]he aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties . . . " 42 C.F.R. § 1001.952(b). If a "fair market value" charge alone was enough to immunize a transaction, the safe harbor's other requirements—that the charge be set in advance and not determined in a manner that takes into account the volume or value of referrals—would be superfluous. *Id.*; *see also* 42 C.F.R. § 1001.952(a) (investment interests); 42 C.F.R. § 1001.952(c) (equipment rental); 42 C.F.R. § 1001.952(d) (personal services and management contracts); 42 C.F.R. § 1001.952(l) (increased coverage; reduced cost-sharing); 42 C.F.R. § 1001.952(r) (ambulatory surgical centers); 42 C.F.R. § 1001.952(u) (price reductions to managed care); and 42 C.F.R. § 1001.952(v) (ambulance replenishing). Moreover, to the extent that Allergan raises the concept of fair market value as a "safe harbor" to its AKS liability, Allergan bears the burden of proving that such a "safe harbor" applies. *See, e.g., United States v. Rogan*, 459 F. Supp. 2d 692, 715 (N.D. Ill. 2006) (burden is on defendant to establish his conduct was protected by an AKS safe harbor).

to qualify to receive those fees, one "would need to be 'a really good writer of prescriptions.'" SAC ¶¶ 288-89. Tying speaker fees to prescriptions demonstrates that "one purpose" of the speakers' bureau was to induce referrals of Allergan's drugs. *Greber*, 760 F.2d at 71. Whether Allergan also intended the fees as compensation for a legitimate service "does not foreclose the possibility that [an AKS] violation nevertheless could exist." *Id.* at 71.

With respect to the sponsored meetings, Relators alleged that attendees received a $1,000 consultant fee, a $150 travel stipend, and luxury hotel stays worth $599 per night. SAC ¶¶ 295-96. Attendees then "spent substantial time" listening to Allergan's marketing pitch for Allergan's Acuvail®. *Id.* ¶ 301. It is more than a fair inference that Allergan's payments to attendees were intended to induce prescriptions for Allergan's drugs. *See* OIG Guidance, 68 Fed. Reg. at 23738 (Exhibit C) ("Compensating physicians as 'consultants' when they are expected to attend meetings or conferences primarily in a passive capacity is suspect.").

Finally, with respect to Allergan's research grants, Relators have alleged that such grants were awarded to Allergan's top prescribers, and that they were offered not by Allergan's research team, but by Allergan's sales force. SAC ¶¶ 303-04. This funding activity, like Allergan's other offers of payment, demonstrates Allergan's intent to induce prescriptions. *See* OIG Guidance, 68 Fed. Reg. at 25735-36 (Exhibit C) ("[M]anufacturers should insulate research grant making from sales and marketing influences.").

In sum, Relators need not have alleged that Allergan's payments were in excess of fair market value. Relators need only allege that Allergan paid something of value to induce prescriptions for its products, and Relators have done so.

2. Relators Have Adequately Alleged Scienter.

Relators have alleged that Allergan "knowingly and willfully" offered valuable services and payments to induce eye care professionals to prescribe Allergan's drugs. *See, e.g.*,

SAC ¶ 203. Because "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally," these allegations alone are sufficient to survive a motion to dismiss. Fed. R. Civ. P. 9(b).

Nonetheless, Allergan attempts to attack the SAC by arguing that Relators failed to allege that Allergan acted "knowingly" under the FCA. (Def. Br. at p. 17-21.) The FCA "require[s] no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1). Instead, the FCA requires only that the defendant have "actual knowledge of the [relevant] information; 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)(B).

Allergan also contends that Relators failed to allege that Allergan acted "knowingly and willfully" under the AKS (Def. Br. at pp. 22-27). While the AKS, for purposes of obtaining a criminal conviction, requires a knowing *and* willful violation, 42 U.S.C. § 1320a-7b, "the AKS's scienter requirement, when used as a predicate for an FCA violation, is not a clear-cut issue." *United States ex rel. Nehls v. Omnicare, Inc.*, No. 07 C 05777, 2013 WL 3819671, at *10 (N.D. Ill. July 23, 2013). A number of courts have applied the "FCA scienter standard, as opposed to the heightened scienter requirement of 'knowingly and willfully.'" *Id.* (citing *Pogue*, 565 F. Supp. 2d at 167 ("[a] violation of the AKS under the FCA must have been made 'knowingly,' which can be proven by actual knowledge, deliberate ignorance, or reckless disregard.") (internal quotation marks omitted); *see also Kosenske*, 2010 WL 1390661, at *11 (same).

Under either standard, Relators have alleged more than enough to demonstrate scienter under the AKS. And under either standard, Allergan's state of mind is an "inherently fact-intensive inquiry that 'typically should not be decided' at the summary judgment stage,"

much less the motion to dismiss stage. *Cantekin*, 192 F.3d at 411 (explaining that in an FCA case, "we must heed the basic rule that a defendant's state of mind typically should not be decided on summary judgment"); *see also Hunt v. Cromartie*, 526 U.S. 541, 552 (1999) ("[I]t was error . . . for the District Court to resolve the disputed fact of motivation at the summary judgment stage."); *United States v. Wright*, 665 F.3d 560, 569 (3d Cir. 2012) ("Inferring mental state from circumstantial evidence is among the chief tasks of factfinders. We rely on the good sense of jurors (and, where applicable, trial judges) to distinguish intent from knowledge or recklessness where the direct evidence is necessarily scanty."). This Court should decline Allergan's invitation to assess the factual question of Allergan's intent on a motion to dismiss.

(a) Allergan's Feigned Ignorance of the Law is Irrelevant.

Allergan devotes three sentences to its contention that it did not know it could be liable under the FCA because claims for its drugs were ultimately submitted to the government by pharmacists. (Def. Br. at pp. 17-18 (discussing "[A]mbiguity surrounding the scope and impact of the pharmacist certifications [which] would undermine any allegation that Allergan knowingly caused false claims to be submitted.").) Allergan's contention amounts to a claim that it thought it would be okay to pay kickbacks to physicians to get the government to pay for its drugs because those claims would be laundered through the pharmacies, and the specific language in pharmacists' certifications was ambiguous. This feigned confusion should not be countenanced. As set forth above in Section V.A.2.a, the FCA unambiguously imposes liability on anyone who "causes" a false claim to be submitted. 31 U.S.C. § 3729(a)(1)(A). And, as the Third Circuit recognized, the Supreme Court has long held that "someone other than the actual presenter [can] be responsible under the FCA." *Schmidt*, 386 F.3d at 244.

Moreover, Allergan knew full well that it could not offer "grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items . . . in exchange

for prescribing products or for a commitment to continue prescribing products." SAC ¶ 91 (citing PHRMA Code II, Section 13, Exhibit A at 13). Allergan also knew that its inducements would cause claims for reimbursement to be submitted to the government. SAC ¶¶ 311-19. These allegations are more than sufficient to plead a knowing violation under the FCA. Contrary to Allergan's suggestion that the AKS is "highly technical" or a "detailed regulatory framework" (Def. Br. at p. 24 n.12), the "AKS is not a highly technical tax or financial regulation that poses a danger of ensnaring persons engaged in apparently innocent conduct. Indeed, the giving or taking of kickbacks . . . is hardly the sort of activity a person might expect to be legal . . . ." *United States v. Starks*, 157 F.3d 833, 838 (11th Cir. 1998) (citing *Bryan v. United States*, 524 U.S. 184, 193 (1998) ("the term 'knowingly' merely requires proof of knowledge of the facts that constitute the offense.").

Allergan's discussion of the "collective knowledge" theory is also irrelevant. (Def. Br. at p. 18.) Contrary to Allergan's suggestion, Relators are not trying to "expand the 'collective knowledge' theory" to include doctors and pharmacists. (*Id.*) Nor do they need to—"the knowledge and conduct of [Allergan] are what matter[] and the outcome [does] not turn on whether the actual presenters were 'duped' or participated in the fraudulent scheme." *Schmidt*, 386 F.3d at 243-44.

(b) Allergan's Feigned Confusion About What Constitutes Remuneration Should Be Disregarded.

Relying on two sentences—taken out of context—from OIG Guidance, Allergan claims that the services "Allergan allegedly provided are permissible" and that "its interpretation of the statute was reasonable rather than reckless, and this negates any allegation that Allergan *knowingly* caused the submission of false claims." (Def. Br. at pp. 19, 21.) Accepting Allergan's

position requires an *unreasonable* interpretation of applicable law, and an utter disregard for the overwhelming majority of the factual allegations in the SAC.

The guidance on which Allergan relies provides:

> Product Support Services. Pharmaceutical 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. Standing alone, services that have no substantial independent value to the purchaser may not implicate the anti-kickback statute. However, *if a manufacturer provides a service having no independent value (such as limited reimbursement support services in connection with its own products) in tandem with another service or program that confers a benefit on a referring provider (such as a reimbursement guarantee that eliminates normal financial risks), the arrangement would raise kickback concerns.* For example, the anti-kickback statute would be implicated if a manufacturer were to couple a reimbursement support service with a promise that a purchaser will pay for ordered products only if the purchaser is reimbursed by a federal health care program.

OIG Guidance, 68 Fed. Reg. at 25735 (emphasis added) (Exhibit C). At most, then, the OIG Guidance stands for the proposition that pharmaceutical manufacturers may provide certain support services "specifically tied to support of the purchased product" that have "no independent value."

Contrary to Allergan's contention, the remuneration alleged in the SAC bears almost no resemblance to "product support," and is certainly not of "no independent value." For example, the SAC alleges that Allergan's ECBAs provided consulting services regarding:

- Marketing strategy and implementation, including how to "expand and strengthen" an "Optometric referral network." SAC ¶¶ 103, 174.
- Financial/productivity analysis, including "revenue benchmarking, overhead costs benchmarking, and benchmarking the number of staff the Relators have in their offices compared to other practices across the Country." SAC ¶¶ 103, 161, 175, 181, 185, 189-91 (listing ten different financial reports).
- Practice valuation/governance, including information regarding "Maximizing the ROI from your most valuable resource." SAC ¶¶ 103, 185.

- Human resources, including advice regarding "the best way to terminate an employee," "how to reduce the amount of overtime" paid to employees, "how to restructure job responsibilities," and how to "handle the departure of a management employee." SAC ¶¶ 103, 167, 175.

- Practice efficiency, including "Clinical Operations Tips (Flow and Efficiency), information regarding "dealing with vendors, contracting with vendors and payors, managing an Optical shop," and "information on how the front desk should answer phone calls and greet and handle patients." SAC ¶¶ 103, 159, 175, 181, 185.

- Web development/search engine optimization/internet marketing, including a 68-page customized document entitled "Web Site Assessment." SAC ¶¶ 103, 193-96.

- Strategic planning, including "how to effectively manage a successful optometric practice." SAC ¶¶ 103, 162.

Allergan's sales manager, in promoting one of ECBA Teale's upcoming program, said the program "*is not product related* but a valuable resource that only Allergan provides and it directly can impact their practice." SAC ¶ 184. Allergan repeatedly told Relators that these services, far from being of no independent value, "were very valuable and would be quite expensive to obtain without Allergan." SAC ¶ 149. Moreover, Relators allege that Allergan provided these services, which Allergan claimed would "bring a sustainable competitive advantage," for free. SAC ¶ 108. Accordingly, there is simply no basis to conclude that Allergan's ECBA program was limited to "product support," or of "no substantial value."

The very same is true of the *Allergan Access* website, which featured:

- "E-Learning," including unlimited access to continuing education courses in Accredited Management Training; Accredited Technician Training; Staff training; Accredited Optician Training; and Business Office Training. SAC ¶¶ 240-46.

- "Financial Management," including tools that allow physicians to input their own practice's financial information; generate detailed financial reports; and compare or benchmark the financial performance of their practice with other practices nationwide. SAC ¶¶ 247-50.

- "MD Recruitment," including sophisticated guides, template employment agreements, and an online job fair. SAC ¶¶ 253-54.
- "Staff Management," including comprehensive employee and human resource guidance and advice. SAC ¶¶ 255-56.
- Marketing materials, including pre-printed, customizable advertising campaigns. SAC ¶ 257.
- Clinical Operations Resources, including recommendations, methods, and tools for improving patient scheduling and satisfaction. SAC ¶ 260.

All of these services were of "substantial value." *See* SAC ¶¶ 230-31 ("Teale confirmed to Relator Nevyas-Wallace . . . that Allergan's business advisory services offered through the *Allergan Access* website were very valuable and would be quite expensive without financial support from Allergan."); OIG Guidance, 68 Fed. Reg. at 23737 (Exhibit C) (providing services that "eliminate an expense that the physician would have otherwise incurred," and thus have independent value, is "problematic if the arrangement is tied directly or indirectly to the generation of federal health care program business for the manufacturer.").

In any event, these services cannot be viewed in isolation. The OIG Guidance discussing "product support" explains that when such services are provided "in tandem with another service or program that confers a benefit on a referring provider . . . , the arrangement would raise kickback concerns." OIG Guidance, 68 Fed. Reg. at 23735 (Exhibit C). Thus, even if some portion of Allergan's offerings were specifically tied to support of Allergan's products, and even if those particular offerings had no substantial independent value, they would still raise kickback concerns because they are tied to other services that do have independent value and that do confer a benefit on physicians.

Allergan's citation to *Streck*, 894 F. Supp. 2d at 598-600, is disingenuous and does not help its position. Allergan cites to the portion of *Streck* in which the court considered the actions of a subset of defendants and the fact that there was no statutory or regulatory guidance

for those defendants to consider. *Id*. at 600. Therefore, the court found that the plaintiffs had not alleged that those defendants acted recklessly. *Id*. at 600. But just pages earlier, with respect to other defendants for whose actions there *was* relevant guidance, the court denied Allergan's motion to dismiss and held that because there was specific statutory and regulatory guidance that the defendants allegedly failed to follow, the plaintiff had sufficiently alleged that the defendants acted at least recklessly. *Id*. at 598.

Similarly, *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47 (2007), does nothing to immunize Allergan's conduct on the basis of any supposedly "reasonable" interpretation of what the AKS allows—particularly on a motion to dismiss. As an initial matter, whether *Safeco* even applies outside of the context of the Fair Credit Reporting Act ("FCRA"), which has a different scienter standard than does the FCA and the AKS, is an open question. *Safeco* found that FCRA's scienter standard required a showing at least of recklessness. *See id*. at 57 (equating FCRA's "willfully fails to comply" standard with recklessness). By contrast, the FCA imposes liability not only for "reckless disregard," but also for "deliberate ignorance." As many courts have recognized, the FCA knowledge standard was expressly "'designed to address the problem of the 'ostrich-like' refusal to learn of information which an individual, in the exercise of prudent judgment, had reason to know.'" *Lamb Eng'g & Constr. Co. v. United States*, 58 Fed. Cl. 106, 110 (Fed. Cl. 2003) (quoting *UMC Elec. Co. v. United States*, 43 Fed. Cl. 776, 794 (1999), *aff'd*, 249 F.3d 1337 (Fed. Cir. 2001)).

But even if *Safeco* applies to FCA and AKS claims, it must be applied much differently on a motion to dismiss than on a motion for summary judgment. *See Korman v. Walking Co.*, 503 F. Supp. 2d 755, 761 (E.D. Pa. 2007) (finding the *Safeco* consideration of whether the defendant acted based on an plausible (albeit incorrect) interpretation of the statute

to be "inappropriate at the motion to dismiss stage"); *Smith v. HireRight Solutions, Inc.*, 711 F. Supp. 426, 435-36 (E.D. Pa. 2010) (holding the defendant's reliance on *Safeco* to be misplaced for a number of reasons, including the difference between the summary judgment standard and the motion to dismiss standard). At this stage of the case, on the merits, there is no basis on which the Court could find that Allergan "reasonably" interpreted the AKS to allow it to exchange *Allergan Access*, the ECBA services, and its other inducements for prescriptions for its drugs. In *Fry*, 2008 WL 5282139, at *10, the court faced a similar argument, which it easily rejected:

> The Court is not convinced that *Safeco* applies in the FCA context, but agrees that even if it does impose the requirement for the Court to make the legal determination whether Defendants' conduct was objectively reasonable, the conduct at question here [(exchanging referrals from doctors for giving them the opportunity to work in a specialty center of the hospital)] simply does not pass the smell test. Defendants can argue that their referral system fell within a grey area, but the fact is the allegations show benefits were accruing to doctors in exchange for referrals, that the system was challenged by those doctors being shut out, and it has been common knowledge since 1972 that remuneration for referrals is illegal. The Court rejects the argument that Defendants' conduct fell within such an ambiguous area of the law that the Complaint against them merits dismissal. Moreover, the Court is of the opinion that the question of Defendants' intent is a factual question properly within the province of the jury.

Ultimately, whether Allergan truly did not understand what it could offer as remuneration is a question of fact. At this stage, Relators' allegations, including that Allergan signed on to the PhRMA Code II, are enough to plead that Allergan knew it was not permitted to offer the remuneration it was offering, notwithstanding Allergan's newfound purported confusion about the OIG Guidance on this issue. Allergan's reliance on two sentences from OIG guidelines that bear no relation to the factual allegations of the SAC cannot immunize Allergan from AKS liability as a matter of law.

(c) Allergan's Supposed "Free" and "Open" Discussion About Its Website Does Not Negate Scienter.

Allergan's assertion that it openly discussed *Allergan Access* and the associated ECBA services is irrelevant as a matter of law. The AKS specifically contemplates that kickbacks may be made "overtly or covertly." 42 U.S.C. § 1320a-7b(b). Public advertising of kickbacks therefore cannot be legally sufficient to foreclose an adequate allegation of intent, because if it could, no overt kickbacks could violate the AKS.

In any event, Allergan *did not* publicly disclose its programs. To the contrary, *Allergan Access* was a "members only" club, and only "top prescribers" were invited. SAC ¶¶ 204-05, 206, 210, 217-18. The fact that Allergan publicly promoted the existence of these services was a necessary component of its scheme—without members, it would not exist. But Allergan's promotion does not suggest that it was acting in good faith which, in any event, is a question of fact. *See United States ex rel. Singh v. Bradford Reg'l Med. Ctr.*, 752 F. Supp. 2d 602, 643 (W.D. Pa. 2010) (denying both sides' motion for summary judgment, because the evidence submitted could allow a jury to find either way regarding whether the defendants had the requisite scienter).

(d) Relators Alleged that Allergan Intentionally Priced its Website Below Fair Market Value.

Allergan's contention that Relators failed to allege that Allergan "intended to price the [business] services below fair market value," is both irrelevant and inaccurate. (Def. Br. at p. 25-27.) First, as set forth in Section V.C.1, above, a "fair market value" payment does not immunize Allergan from liability. Just as Relators are not required to prove or allege that Allergan paid remuneration inconsistent with fair market value, Relators are not required to allege Allergan's intent to do so.

Nonetheless, Relators *did* allege, with great specificity, that *Allergan Access* was offered for far less than fair market value. *See, e.g.*, SAC ¶ 225 ("fair market value" of *Allergan Access* "far exceeds the $895 fee"); *id.* ¶ 224 ("fair market value" of limited components of *Allergan Access* "alone exceeds the nominal $895 fee"); *id.* ¶ 226 (unlimited billing advice available through *Allergan Access* otherwise offered at an hourly rate of at least $280).[21] And Relators alleged that Allergan provided ECBA services—which Allergan promoted as "bring[ing] a sustainable competitive advantage"—"*free of charge*." *Id.* ¶ 108 (emphasis added).

Moreover, as set forth in Section V.C.2.b., above, Allergan itself touted the fact that its offerings were worth far more that the cost. Further demonstrating Allergan's knowledge that its pricing was inappropriately low, shortly after receiving a government subpoena, Allergan dramatically altered the price and structure of its offerings. SAC ¶¶ 273-85. Allergan's abrupt change is inconsistent with a true belief that it was acting in conformity with applicable rules and regulations. Thus, contrary to Allergan's suggestion, Relators did allege specific facts demonstrating Allergan's intent to "to price the services below fair market value." (Def. Br. at p. 26.)[22]

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[21] Allergan argues that Relators' allegations regarding the services offered through *Allergan Access* by the Corcoran Group and J. Pinto & Associates are "inapt." (Def. Br. at p. 26.) Relators have alleged that these groups, who normally charge $280 or more per hour, provided unlimited services through the *Allergan Access* website that were included within the $895 annual fee. SAC ¶¶ 225-27, 233-38, 267-72. These allegations are certainly relevant to the fair market value of *Allergan Access*, which Allergan itself contends is somehow critical. But Allergan's dispute regarding the actual value underscores the fact that Allergan is asking this Court to undertake a factual inquiry into the value of the services Allergan offered. Such an inquiry is inappropriate on a motion to dismiss. And the same is true with respect to Allergan's argument that the calculation of the costs of their kickbacks should be compared to that of "cable television." (Def. Br. at p. 26.)

[22] Allergan attempts to suggest that Relators' allegations are made "on information and belief." (Def. Br. at pp. 26-27.) But Allergan cites only one such allegation, SAC ¶ 239, and Relators adequately allege a factual basis for that belief. *See* SAC ¶ 238 (explaining the factual basis for alleging that the "Ask-the-Expert" feature alone is worth more than $895).

While not necessary to allege an AKS violation, the fact that Allergan *did* provide services below fair market value is evidence that Allergan intended to induce referrals. *United States v. Lipkis*, 770 F.2d 1447 (9th Cir. 1985) ("we may infer that any excess paid over fair value is intended to induce referrals . . . "); *United States v. Rogan*, 459 F. Supp. 2d 692, 716, *aff'd*, 517 F.3d 449 (7th Cir. 2008) (same); *Pogue*, 565 F. Supp. 2d at 153 (same); *United States v. Norton*, No. 2:99CR10078, 2000 WL 33281703, at *4 (W.D. Va. Nov. 14, 2000) (same); *Am. Lithotripsy Soc. v. Thompson*, 215 F. Supp. 2d 23, 27 (D.D.C. 2002) ("Payment exceeding fair market value is in effect deemed payment for referrals"). Ultimately, the degree to which Allergan believed it was offering services at fair market value, is a question for the fact-finder, and inappropriate for consideration at the motion to dismiss stage. Relators have alleged more than enough to plausibly suggest that Allergan acted with the requisite scienter.

3. The First Amendment Rights of ECBAs Cannot Immunize Allergan from AKS Liability for Providing their Services for Free.

Allergan attempts to avoid AKS liability by characterizing its offerings as protected "free speech," rather than the valuable services they were, and contending that the First Amendment immunizes their conduct. But Allergan ignores a basic First Amendment principle: the right to "free speech" does not protect otherwise illegal conduct merely because such conduct can be characterized as "speech." Allergan's novel re-characterization of its offerings as "free speech" cannot immunize it from liability, because the purpose of Allergan's "speech" was to induce eye care professionals to write prescriptions for its products in violation of the AKS.

In *Gibony v. Empire Storage and Ice Co.*, 336 U.S. 490, 502 (1949), the Supreme Court confirmed this common sense First Amendment principle: "it has never been deemed an abridgement of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken,

written, or printed." In *Gibony*, the defendants argued that they could not be liable for violating an antitrust restraint statute because the conduct they had engaged in was otherwise peaceful picketing. *Id*. at 493-94. The Court rejected that argument and held that there was no authority to support "the contention that conduct otherwise unlawful is always immune from state regulation because an integral part of that conduct is carried on by display of placards by peaceful picketers." *Id*. at 498. Moreover, it was "clear that appellants were doing more than exercising a right of free speech or press. . . . They were exercising their economic power together with that of their allies to compel Empire to abide by union rather than by state regulation of trade." *Id*. at 503 (citation omitted).

As in *Gibony*, Allergan's conduct—even assuming any part of it constitutes protected speech—is not immune from regulation because it was otherwise unlawful. Allergan was "doing more than exercising a right of free speech"; it was providing something of value to induce prescriptions for its products. It is not the *content* of Allergan's speech that the AKS seeks to regulate; it makes no difference whether the ECBAs are speaking about best financial management practices or about physician recruiting. It is the intentional offering of valuable services in exchange for prescriptions that the AKS prohibits.

A similar challenge to the AKS on First Amendment grounds has been made, and rejected, before. In *United States v. Mathur*, No. 2:11-CR-00312-MMD, 2012 WL 4742833 (D. Nev. Sept. 13, 2012), report and recommendation adopted, No. 2:11-CR-00312-MMD, 2012 WL 4711960 (D. Nev. Oct. 3, 2012), the Court examined an indictment in which the defendant was said to have bribed physicians with money in exchange for their recommendations and referrals to him. The defendant challenged the indictment on First Amendment grounds, arguing that the physicians' recommendations were protected speech. The court cited *Gibony* and explained,

> Speech and writing "used as an integral part of conduct in violation of the valid criminal statute" is not protected by the First Amendment. *Gibony v. Empire Storage & Ice Co.*, 336 U.S. 490, 498. "[I]t has never been deemed an abridgment of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written or printed." *Id.* at 502 (citing *Fox v. Washington*, 236 U.S. 273, 277 (1915); *Chaplinsky v. New Hampshire*, 315 U.S. 568 (1942)). Proscribing bribery does not infringe on any First Amendment rights because it neither chills, nor is intended to chill, constitutionally-protected activities. *United States v. Dischner*, 974 F.2d 1502, 1511–12 (1992), *overruled on other grounds by United States v. Morales*, 108 F.3d 1031, 1035 (9th Cir. 1997).
>
> Solicitation is protected expression under the First Amendment. *See, e.g., Comite de Jornaleros*, 657 F.3d 936, 945 (9th Cir. 2011). However, the Anti–Kickback Act does not regulate speech protected by the First Amendment. *See Hanlester* [*Network v. Shalala*, 51 F.3d 1390] at 1398 [(9th Cir. 1995)]. Rather, it regulates the conduct of paying or offering to pay remuneration in return for Medicare or Medicaid referrals. *Id.* (stating "[t]he statute regulates only economic conduct"). The court finds that the Anti–Kickback Act is not facially overbroad. It is not a content-based regulation of speech.

Id. at *10. Applying these principles, the court held that the AKS was not unconstitutional as applied to the defendant's bribes to doctors in exchange for their recommendations. *Id.* at *11; *see also Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 514 (1972) ("It is well settled that First Amendment rights are not immunized from regulation when they are used as an integral part of conduct which violates a valid statute.") (citing *Gibony*); *Walker-Serrano ex rel. Walker v. Leonard*, 325 F.3d 412, 416 (3d Cir. 2003) ("conduct by the student, in class or out of it, which for any reason—whether it stems from time, place, or type of behavior—materially disrupts classwork or involves substantial disorder or invasion of the rights of others is, of course, not immunized by the constitutional guarantee of freedom of speech. . . .").

There are many instances in which the "creation" or "dissemination" of information is penalized either criminally or civilly, without running afoul of the First Amendment, because the underlying conduct otherwise violates the law. This is such a case.

D. Relators Have Pleaded Allergan's False Claims Act Violations With Particularity.

The SAC contains dozens of detailed allegations, pleaded with particularity, setting out Allergan's scheme, since at least 2002, to provide an elaborate set of business resources and other financial kickbacks to ophthalmologists and optometrists in order to induce them to prescribe Allergan eye care drugs—including, but not limited to Restasis®. As discussed above, the SAC specifies the contents and mechanics of the kickbacks that Allergan provided to eye care professionals, which included:

- valuable business consulting services provided by Allergan's Eye Care Business Advisory Group, SAC ¶¶ 102-205;
- sophisticated business resources and tools provided through the *Allergan Access* website, SAC ¶¶ 131-32, 142-48, 157-58, 169, 189-90, 206-85;
- fees paid to members of Allergan's "Speakers' Bureau", SAC ¶¶ 286-91;
- fully paid trips to sham "Advisory Board Meetings", SAC ¶¶ 292-302; and
- funding for eye care professionals' independent research, SAC ¶¶ 303-04.

The SAC also describes in detail that Allergan directed these kickbacks to select "top prescribers," whose prescriptions were closely tracked by Allergan. SAC ¶¶ 100-01, 115, 138, 145, 207-10, 217-18, 221-22, 246, 289-90, 294. The SAC further makes clear, through the statements by Allergan's own employees, Allergan's explicit purpose in providing these kickbacks—to induce the targeted ophthalmologists and optometrists to "show their appreciation" by prescribing Allergan products. SAC ¶¶ 148-51, 169-71, 204, 231, 284, 289-90, 308. These detailed allegations are sufficient to provide Allergan with fair notice to satisfy the pleading requirements of Federal Rules of Civil Procedure 9(b). *See United States ex rel. Budike*

v. PECO Energy, 897 F. Supp. 2d 300, 316 (E.D. Pa. 2012) ("Rule 9(b) is generally considered satisfied when a defendant has 'fair notice' of the charges against it"); *United States ex rel. Hunt v. Merck-Medco Managed Care, L.L.C.*, 336 F. Supp. 2d 430, 437 (E.D. Pa. 2004) ("[T]he court will be satisfied when, on the face of the pleadings it can fairly be said that a defendant is capable of mustering a full defense."); *Elysian Fed. Sav. Bank v. First Interregional Equity Corp.*, 713 F. Supp. 737, 757 (D.N.J. 1989) ("As long as the complaint sets forth enough information to provide factual support for plaintiff's allegations, it meets the [Rule 9(b)] standard."). Further, Rule 9(b) "is context specific and flexible and must remain so to achieve the remedial purpose of the False Claims Act." *United States v. Albinson*, No. CIV. 09-1791 DRD, 2010 WL 3258266, at *16 (D.N.J. Aug. 16, 2010).[23]

1. <u>The Alleged Deficiencies in Relators' Pleadings Raised by Allergan Are Irrelevant to Allergan's Notice of the Misconduct Alleged.</u>

Allergan does not contend that Relators' allegations are insufficient to put it on notice of the misconduct with which it is charged. Instead, Allergan primarily argues that the SAC does not satisfy Rule 9(b) because it does not identify "specific false claims" submitted to the government by physicians who received kickbacks from Allergan. (Def. Br. at pp. 30-33.) This argument is contrary to the relevant case law in this Circuit and improperly would require Relators to prove their case without the benefit of any discovery. *See, e.g., United States v.*

[23] The Third Circuit has specifically cautioned against a "narrow" focus on Rule 9(b)'s "'particularity' language" that "fails to take account of the general simplicity and flexibility contemplated by the rules," *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir. 1984), and has advised courts to "be sensitive to the fact that application of Rule 9(b) prior to discovery may permit sophisticated defrauders to successfully conceal the details of their fraud," *Craftmatic Sec. Litig. v. Kraftsow*, 890 F.2d 628, 645 (3d Cir. 1989) (internal quotation marks omitted). In the FCA context, Rule 9(b) "does not provide courts with a mandatory checklist of what must be included in the complaint." *United States v. Albinson*, No. CIV. 09-1791 DRD, 2010 WL 3258266, at *16 (D.N.J. Aug. 16, 2010). Therefore Rule 9(b) does not always "require date, time, and place allegations, provided that the plaintiff gives the defendants other means of precision and substantiation." *United States ex rel. Spay v. CVS Caremark Corp*, 913 F. Supp. 2d 125, 174 (E.D. Pa. 2012); *see also United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 188-89 (5th Cir. 2009).

Kensington Hosp., 760 F. Supp. 1120, 1126 (E.D. Pa. 1991) ("[F]ull particulars will have to be revealed during discovery."); *United States ex rel. Landsberg v. Levinson*, No. 03-1429, 2008 WL 2246308, at *1 (W.D. Pa. May 29, 2008) (same); *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 189 (5th Cir. 2009) ("[S]urely a procedural rule ought not be read to insist that a plaintiff plead the level of detail required to prevail at trial.").[24]

Here, the false claims themselves—reimbursement forms submitted to government health insurance programs such as Medicare or Medicaid—contain no information that would be useful in understanding the alleged misconduct.[25] Relators allege that Allergan provided kickbacks to eye care professionals in exchange for prescriptions. As discussed in Section V.A.1.a., above, claims for reimbursement from the government for prescriptions for Allergan eye care products by those professionals are *per se* false claims due to those kickbacks. While the identification of those claims obviously will be relevant to a damages calculation, it would not help to put Allergan on notice of the fraud that is claimed, nor would it aid in Allergan's defense of this action. *See, e.g., United States ex rel. Singh v. Bradford Reg'l Med. Ctr.*, No. 04-186 ERIE, 2006 WL 2642518, at *7 (W.D. Pa. Sept. 13, 2006) ("[W]e fail to see how requiring Relators to provide a single claim example would put Defendants in a better position to answer and defend against the claims."); *Underwood*, 720 F. Supp. 2d at 676; *Budike*, 897 F. Supp. 2d at 316; *Hunt*, 336 F. Supp. 2d at 437. Allergan makes no argument to the

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[24] Allergan argues that Relators were required to "delineate . . . the nature and scope of their efforts" to obtain, for example, information regarding specific false claims related to Allergan's kickbacks. *See* Def. Br. at pp. 32-33 n.16. But the requirement upon which Allergan relies expressly applies only to "essential information," *i.e.*, "information needed to plead with particularity." *See United States ex rel. Waris v. Staff Builders Inc.*, No. 96-1969, 1999 WL 179745, at *4 (E.D. Pa. Mar. 4, 1999). As discussed in this Section, none of the information about which Allergan complains is "essential" information."

[25] The same is true of other purportedly "critical elements" that Allergan contends were not included in the SAC, for example, the specific pharmacists involved and the dates on which the tainted prescriptions were written. (*See* Def. Br. at pp. 32-33.)

contrary, but merely seeks to apply Rule 9(b) in a mechanical and inflexible manner without regard to the nature of the fraud alleged. In substance, Allergan contends that identification of actual, specific false claims is a mandatory requirement for a Relator asserting an FCA violation. This is not the law. *See, e.g., United States ex rel. Schmidt v. Zimmer, Inc.*, No. Civ. A.00-1044, 2005 WL 1806502, at *2 n.2 (E.D. Pa. July 29, 2005) (noting that Rule 9(b) does not impose a "checklist of mandatory requirements").

In *Budike*, the court squarely rejected the argument that an FCA complaint is required to identify specific false claims with particularity. *Budike*, 897 F. Supp. 2d at 315-17, 319-20. The court held that the relator's allegations detailing the defendant's fraudulent *scheme* (in that case, to overcharge the government for power supplied to naval ships), satisfied Rule 9(b) because "the fraudulent conduct at issue does not rely on any specific claim." *Id.* at 320. In *Budike*, as in this case, requiring Relator to plead examples of false claims would not "put [defendant] in a better position to answer and defend against Relator's claims." *Id.* In both cases, the fraud alleged "does not turn on anything unique to an individual claim or anything that would be revealed from an examination of any claim." *Id.*[26] In *Underwood*, which, like the instant case, involved allegations of kickbacks paid by a pharmaceutical company, the court considered this same issue and reached the same conclusion: "There is no authority in this Circuit requiring such particularized pleading [of a specific false claim]." 720 F. Supp. 2d at 671-72. The court noted that the cases holding that relators were required to plead examples of false claims involved (1) allegations that the defendant itself had submitted the false claims

[26] Similarly, *United States ex rel. West v. Ctr. for Diagnostic Imaging*, 787 F. Supp. 2d 1213 (W.D. Wash. 2011), a case cited by Allergan, rejects the requirement that a Relator must plead specific false claims in a case like this one, where the falsity of the claims submitted to the government "does not turn on anything . . . that would be revealed from an examination of any claim" because the falsity is based upon "improper financial arrangements, which [do] not rely on any specific claim.'" 787 F. Supp. 2d at 1220-21 (alteration and internal quotation marks omitted).

directly to the government and (2) relators who had been employed by the defendant. *Id.* at 679. The court concluded that, at least when an FCA violation is based on false claims submitted by a third party, such as a doctor or pharmacy, requiring a relator "to identify in his complaint a specific false claim would effectively eliminate part of the False Claims Act," and would require "a level of proof not demanded to win at trial and significantly more than any federal pleading rule requires." *Id.*; *see also Bergman*, 2014 WL 348583, at *11 ("In order for FCA claims to survive 9(b), however, this District has found that a relator **does not** need to show a specific submitted false claim if the false claims are submitted by a third party and not the defendant." (emphasis in original)); *Simpson*, 2013 WL 4710587, at *13 ("Here, the alleged fraud or illegality is not tied to billing and is not premised upon submission of a false claim by Bayer itself, but rather submission by third parties."); *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 29 (1st Cir. 2009) (when relator alleges false claims submitted by third parties, relator may provide "factual or statistical evidence to strengthen the inference of fraud beyond possibility" without identifying specific false claims). The holdings of *Budike* and *Genentech* are consistent with the bulk of authority both in this district and elsewhere. *See, e.g.*, *Streck*, 894 F. Supp. 2d at 601-02; *Bergman*, 2014 WL 348583, at *10-14; *Singh*, 2006 WL 2642518, at *4-7; *United States ex rel. Landsberg v. Levinson*, No. 03-1429, 2006 WL 6936820, at *2-3 (W.D. Pa. Feb. 13, 2006); *Grubbs*, 565 F.3d at 185-93; *Duxbury*, 579 F.3d at 29; *Simpson*, 2013 WL 4710587, at *12-14[27]; *cf. Wilkins*, 659 F.3d at 308 (holding that a relator does

[27] The United States Government has previously indicated its disagreement with Allergan's position. As the U.S. Solicitor General recently explained in an *amicus curiae* submission to the Supreme Court:

> Subjecting *qui tam* relators to a per se rule requiring the identification of specific false claims is especially unwarranted because it attaches dispositive significance to the relator's awareness of details that in most instances are already known to the government. The government rarely if ever needs a relator's assistance to identify claims for payment that have been submitted to the United States. Rather, relators typically contribute to the

not need to "identify a specific claim for payment at the *pleading stage* of the case to state a claim for relief" under Rule 12(b)(6)).

While the SAC does not identify specific false claims, it does include "alternative means of injecting precision and some measure of substantiation into [his] allegations of fraud." *Underwood*, 720 F. Supp. 2d at 679; *see also Grubbs*, 565 F.3d at 190 (holding that Rule 9(b) is met by "alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted."); *United States ex rel. Jajdelski v. Kaplan, Inc.*, 517 F. App'x 534, 536 (9th Cir. 2013) (same). As discussed above, the SAC describes in detail Allergan's kickback program, the natural and intended consequence of which was to cause the submission of claims for reimbursement from federal health care programs, including Medicare and Medicaid. Relators identify the specific drug products for which kickback-tainted false claims are submitted to the government: the fourteen drugs that make up Allergan's Eye Care Pharmaceutical Product Line ("Eye Care Line"). SAC ¶ 33. Relators also allege the number of prescriptions actually written for drugs in Allergan's Eye Care Line for persons over sixty-five years of age, *id.* ¶ 34 (totaling over 2 million for just four drugs in approximately seven months), and allege that Restasis® (prescribed 514,000 times to persons over 65 from January 2008 to July 2008), is covered by government-funded health insurance plans, *id.* ¶¶ 34, 35. Relators further allege that Bob Teale, in a March 2009 presentation

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> government's enforcement efforts by bringing to light other information that shows those claims to be false. Requiring *qui tam* complaints to identify specific false claims thus would not meaningfully assist the government's enforcement efforts. To the contrary, the likely effect of such a requirement would be to discourage the filing of *qui tam* suits by relators . . . who would otherwise have the means and the incentive to expose frauds against the United States.

Br. for the United States as *Amicus Curiae*, *United States ex rel. Nathan v. Takeda Pharms. N.A., Inc.*, No. 12-1349, at *16 (U.S. Feb. 2014), attached as Ex. D.

discussing the revenue opportunities for physicians associated with treatment of dry eye (for which Allergan's Restasis® product is the only approved prescription therapy), *see id.* ¶¶ 119-33, specifically discussed the issue of the Medicare eligibility of the baby boomer generation, *id.* ¶ 119.

Further, though the SAC does not list the names of all eye care professionals who received Allergan's kickbacks, it nevertheless identifies these individuals using "alternative means of injecting precision." *See, e.g., Underwood,* 720 F. Supp. 2d at 679. Relators allege that kickbacks were provided to specific, well-defined groups of individuals, finite in number; for example, the clients of Allergan's ECBAs, the subscribers to the *Allergan Access* website, the members of Allergan's Speakers' Bureau, and the individuals invited to Allergan's Advisory Board Meetings. These individuals are selected by Allergan, *see, e.g.*, SAC ¶¶ 100-01, 210, 217, 218, 289, tracked by Allergan, *id.* ¶¶ 100-01, and belong to groups created by Allergan. Plainly, Allergan knows exactly who these individuals are. Its claim that it "would have no way of knowing" "the specific physicians . . . involved" is wholly disingenuous and should be rejected. (*See* Def. Br. at pp. 32-33.)

Tellingly, Allergan does not dispute that the eye care professionals who received kickbacks wrote prescriptions for Allergan products, and that some of these prescriptions were reimbursed through state and federal government health care programs. Courts have recognized in similar contexts that when a defendant's "scheme . . . is large enough in scope . . . [a]bsent extraordinary circumstances, the foreseeability that the drug would be billed to the Government by at least some prescribers can be presumed." *Underwood,* 720 F. Supp. 2d at 678 (alterations and internal quotation marks omitted); *see also Simpson,* 2013 WL 4710587, at *14 (Rule 9(b) satisfied by causation allegations regarding "illegal kickback scheme engineered to induce

medical providers to prescribe [defendant's products], which would inevitably cause false claims to be submitted to the government by healthcare providers."). Based upon Relators' allegations, including regarding the millions of prescriptions written for the Allergan drugs in question for patients over sixty-five years of age, it is inescapable that false claims were submitted to government health care programs as a result of Allergan's kickback scheme.[28]

In this action, whether Allergan violated the FCA by reason of its conduct described in the SAC will turn on whether Allergan in fact provided the business advisory services and other benefits to eye care professionals for the purpose of inducing those professionals to prescribe Allergan products. Identification of, for example, the claims submitted for kickback-tainted prescriptions, the pharmacies who submitted these claims, or the "specific Medicare or Medicaid claim forms" used will have no bearing on any of these issues. Rule 9(b) does not require a relator to plead these peripheral details.[29]

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[28] Contrary to Allergan's assertion (*see* Def. Br. at p. 32), a relator alleging FCA violations based on payment of kickbacks is not required to plead information regarding the extent to which Allergan's kickbacks influenced physicians' prescribing decisions. *United States ex rel. Simpson v. Bayer Corp.*, No. 05-3895 JLL, 2013 WL 4710587, at *13-14 (D.N.J. Aug. 30, 2013) (rejecting argument that relator must plead "causal nexus" between kickbacks and claims submitted to government); *United States ex rel. Parikh v. Citizens Med. Ctr.*, No. 6:10-CV-64, 2013 WL 5304057, at *6-7 (S.D. Tex. Sept. 20, 2013) (holding that relator is not required to plead that "specific referrals were actually induced as a result of the kickbacks"). Allergan cites no authority in support of this wholly unfounded proposition.

[29] The cases relied upon by Allergan are inapposite and/or readily distinguishable. In *United States ex rel. Waris v. Staff Builders, Inc.*, No. 96-1969, 1999 WL 179745 (E.D. Pa. Mar. 4, 1999), the relator claimed that the defendant had submitted false invoices to the government for consulting work that Relator had not in fact performed. 1999 WL 179745, at *1-2. Relator's only support for this contention was that the defendant had prepared an invoice for relator detailing reimbursable services that Relator had not provided and asked Relator to sign off on this false invoice. *Id.* at *1-2, 5. Relator refused this request, and was asked not to submit any further invoices. *Id.* at *1. Under these circumstances, this Court found that the allegations that any false invoices had been submitted to the government were "based on nothing more than speculation—and apparently implausible speculation at that." *Id.* at *5.

In *United States ex rel. Bartlett v. Tyrone Hosp., Inc.*, 234 F.R.D. 113 (W.D. Pa. 2006), the court found that "the Plaintiffs' description of any actual claims submitted for payment is somewhat vague and practically non-existent." 234 F.R.D. at 120-21. By contrast, it is not seriously disputed that, accepting the truth of Relators' allegations regarding Allergan's kickback scheme, claims for Allergan eye care drugs were submitted to Medicare and Medicaid. The *Bartlett* court further indicated that its holding was

2. Relators Sufficiently Allege the Nationwide Scope of Allergan's Kickback Scheme.

The SAC alleges, with particularity, a nationwide fraudulent scheme carried out by Allergan. In addition to Relators' allegations regarding their own experience, Relators allege that Allergan's scheme operates through Allergan's ECBA Group, a division of Allergan established at the corporate level, operating nationwide. SAC ¶¶ 102-10, 197-204. According to Allergan's own representative, Allergan employs approximately twelve ECBAs, each of whom provides similar services across the country. SAC ¶ 149. *See Spay*, 913 F. Supp. 2d at 178 n.34 (noting that "a nationwide false claims cause of action would not . . . be based on conjecture"

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based on a concern that a plaintiff's failure to allege reference dates or referring physicians involved in the alleged scheme "would not permit a defendant to defend against such a claim." *Id.* at 121; *see also United States ex rel. Singh v. Bradford Reg'l Med. Ctr.*, No. 04-186 ERIE, 2006 WL 2642518, at *7 (W.D. Pa. Sept. 13, 2006) (distinguishing unique "circumstances" of *Bartlett*). As discussed, no such concern exists with respect to Relators' allegations. Finally, the court specifically noted that the relators—unlike Relators in this case—were "insiders" and therefore had access to the alleged false claims. *Bartlett*, 234 F.R.D. at 122; *see also Singh*, 2006 WL 2642518, at *6-7 (discussing *Bartlett* and concluding, "[t]he *Bartlett* Court did not hold that Rule 9(b) requires specific identification of claims).

United States ex rel. Quinn v. Omnicare Inc., 382 F.3d 432 (3d Cir. 2004), involved the dismissal of an FCA claim at the *summary judgment* stage, and, as such, stands for the wholly unremarkable proposition that, following discovery, a False Claims Act relator must offer evidence of false claims in order to survive a motion for summary judgment. *Quinn*, 382 F.3d at 439-40 ("Without proof of an actual claim, there is no issue of material fact to be decided by a jury."); *see also United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 308 (3d Cir. 2011) (concluding that *Quinn* is irrelevant to FCA pleading requirements).

Finally, in *United States ex rel. Schmidt v. Zimmer, Inc.*, No. Civ.A.00-1044, 2005 WL 1806502 (E.D. Pa. July 29, 2005), the relator alleged that the defendant paid kickbacks to 1600 unidentified hospitals that were part of a purchasing cooperative, via a separate contract with each hospital, to induce the hospitals to purchase defendant's orthopedic equipment. *Schmidt*, 2005 WL 1806502, at *2. While specifically noting that Rule 9(b) did not require a "checklist of mandatory requirements," *id.* at *2 n.2, Judge Robreno dismissed the complaint, citing the relator's failure to identify a specific false claim and failure to identify which of the 1600 hospitals submitted false claims. *Schmidt*, 2005 WL 1806502, at *3. Subsequently, in *United States ex rel. Streck v. Allergan, Inc.*, 894 F. Supp. 2d 584 (E.D. Pa. 2012), (a case with which defendant is presumably familiar), Judge Robreno himself distinguished *Schmidt*, explaining that the relator in *Schmidt* had not merely failed to plead a specific false claim, but "also failed to provide any detail of the alleged kickback scheme and why it was unlawful." *Streck*, 894 F. Supp. 2d at 601-02. Judge Robreno further acknowledged that, since *Schmidt*, many courts have held that an FCA relator need not plead a specific false claim under Rule 9(b). *Id.* at 602.

when defendants have admitted that specific conduct is "consistent with their company-wide practices"). Relators further alleged that Mr. Teale himself was responsible for a large geographic territory. Mr. Teale represented that he was based in Virginia and responsible for parts of the East Coast, and presented to eye care professionals nationwide regarding the "assistance" that Allergan could offer physicians in their practices, SAC ¶¶ 118-20, 122-30, 133, and the benefits available through the *Allergan Access* website, *id.* ¶¶ 131-32.[30] Relators also describe the *Allergan Access* website, membership in which is offered to approximately 1,500 selected physicians "across the United States," *id.* ¶¶ 210, 218, for a fee that is well below market value, *id.* ¶¶ 218-31. And the SAC includes allegations about a specific practice in Washington, Pacific EyeCare of Poulsbo, which was part of the *Allergan Access* program, and indisputably received more than $895 in value from the *Allergan Access* services, as it completed over four hundred online courses in under a year. *Id.* ¶ 230.

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[30] The cases cited by Allergan on this issue are readily distinguishable as well. *In United States ex rel. Thomas v. Bailey*, No. 4:06CV00465JLH, 2008 WL 4853630 (E.D. Ark. Nov. 6, 2008), the relator alleged a "corporate policy, national in scope" to offer kickbacks to physicians in exchange for use of defendant's surgical products, but included no allegations whatsoever about any "nationwide corporate policy." 2008 WL 4853630, at *6 (noting that allegations of corporate kickback policy were based entirely upon anecdotal episodes, some hearsay, from sales reps of defendant's competitors).

In *United States ex rel. Wall v. Vista Hospice Care*, 778 F. Supp. 2d 709 (N.D. Tex. 2011), the court found all but one of relator's *federal* FCA claims to be insufficient under Rule 9(b), *see* 778 F. Supp. 2d at 715-23, and went on to dismiss relator's claims under the false claims laws of five states because relator (who was a corporate insider) had alleged *no basis whatsoever* for her conclusory allegations, made entirely "upon information and belief," that fraud occurred in any state other than Texas, where the relator worked, *see id.* at 723. By contrast, as summarized above, the SAC contains specific facts to support Relators' allegations that Allergan's conduct was nationwide in scope.

Finally, in *United States ex rel. West v. Ctr. for Diagnostic Imaging*, 787 F. Supp. 2d 1213 (W.D. Wash. 2011), the relator claimed that the defendant imaging facility violated the FCA by performing free or discounted angiography testing in order to induce physicians to refer MRI testing to the defendant. *See West*, 787 F. Supp. 2d at 1221-22. The court held that the specific allegations supporting this claim—apparently a single paragraph in the complaint—did not even satisfy Rule 12(b)(6), and were so vague and non-specific that they would not have satisfied Rule 9(b) even as to a single referring physician, much less a "broader scheme." *See West*, 787 F. Supp. 2d at 1221-22. The court also specifically noted that the relators in *West*, unlike the Relators in this action, were "high level insiders" who, as such, "should be able to provide specifics to support their claims." *Id.* at 1222.

As summarized above, Relators' allegations are not limited to the "Philadelphia metro area" or to Relators' eye care practice. (Def. Br. at pp. 34-35.) Rather, as confirmed by Allergan's own representatives, Allergan's ECBAs provided the same services to eye care professionals across the country, and the *Allergan Access* website was utilized by 1,500 selected physicians nationwide. Further, contrary to Allergan's suggestion, courts have regularly found that particularized allegations regarding a defendant's fraudulent conduct in one state or region are sufficient under Rule 9(b) to establish "a nationwide inference of fraud." *Spay*, 913 F. Supp. 2d at 174-75; *see also United States ex rel. Drennen v. Fresenius Med. Care Holdings, Inc.*, No. CIV.A. 09-10179-GAO, 2012 WL 8667597, at *1-2 (D. Mass. Mar. 6, 2012) (allegations of specific conduct combined with national billing practices sufficient satisfies Rule 9(b) with respect to nationwide scheme); *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 238 F. Supp. 2d 258, 268 (D.D.C. 2002) (nationwide kickback scheme adequately alleged though complaint identified only a single facility). This conclusion is entirely sensible, since a relator "cannot be expected to plead with particularity each and every false claim nationwide without the benefit of at least some discovery, as such information rests solely within Defendants' control." *Spay*, 913 F. Supp. 2d at 177; *see also Hunt*, 336 F. Supp. 2d at 437 ("A plaintiff 'cannot be expected to have personal knowledge of the details of corporate internal affairs' in corporate fraud cases." (quoting *In re Craftmatic Sec. Litig.*, 890 F.2d 628, 645 (3d Cir. 1989))). The Court should reject Allergan's contention that Relators have not alleged a nationwide fraudulent scheme and deny Allergan's motion to dismiss Relators' claims under states' false claims laws.

E. Allergan's Statute of Limitations and State Law Arguments

Allergan argues that the federal FCA claims (Count I) and the State FCA claims (Counts II through XXI) should be dismissed or restricted based upon its reading of the

applicable statute of limitations. (Def. Br. at pp. 35-36, 40-41.) It further contends that certain of the State FCA claims should be dismissed because: (1) the State FCA did not permit a Relator to proceed without the government's intervention in the case; and/or (2) the State FCA cannot be applied retroactively to false claims submitted prior to the effective date of that State FCA. (Def. Br. at pp. 37-39.) While not conceding that Allergan has properly characterized the relevant provisions of the FCA or the State FCA's, Relators will agree to limit their claims in this case as described below.

1. Statute of Limitations on the FCA and State FCA Claims

Relators agree that through this *qui tam* action they will seek to recover damages for the taxpayers under the FCA and the State FCAs for the time periods set forth in the table below:[31]

Jurisdiction (Count)	**Damages available for false claims submitted on or after:**[32]
Federal FCA (Count I)	November 12, 2003
California (Count II)	November 12, 1999 (all false claims alleged in SAC)
Delaware (Count III)	July 16, 2009
Florida (Count IV)	November 12, 2003
Illinois (Count V)	November 12, 2003
Indiana (Count VI)	July 1, 2005
Louisiana (Count VII)	November 12, 2003
Massachusetts (Count VIII)	November 12, 2003
Michigan (Count IX)	November 12, 2003
Montana (Count X)	May 1, 2005
Nevada (Count XI)	November 12, 2003

[31] While Relators agree to limit the damages sought from Allergan to the dates specified herein, Allergan's conduct prior to those dates will likely be relevant to claims and defenses at issue in this kickback case.

[32] As Allergan apparently recognizes, at the time the First Amended Complaint was filed, the False Claims Acts of California, New York, and Wisconsin were each governed by a ten-year statute of limitations. Accordingly, Relators' counts under these states' laws reach all false claims submitted by Allergan pursuant to the instant scheme, which began in 2002. *See* Cal. Gov't Code § 12654(a) (West 2013) (amended 2010, 2013); N.Y. State Fin. Law § 192 (McKinney 2010); Wis. Stat. § 893.981 (West 2007).

Jurisdiction (Count)	**Damages available for false claims submitted on or after:**[32]
New Hampshire (Count XII)	June 29, 2009
New Jersey (Count XIII)	March 13, 2008
New Mexico (Count XIV)	Relators agree to dismiss this claim in its entirety
New York (Count XV)	November 12, 1999 (all false claims alleged in SAC)
Oklahoma (Count XVI)	November 1, 2007
Rhode Island (Count XVII)	July 1, 2007
Texas (Count XVIII)	May 4, 2007
Virginia (Count XIX)	January 1, 2003
Wisconsin (Count XX)	November 12, 1999 (all false claims alleged in SAC)
D.C. (Count XXI)	November 12, 2003

2. State FCA Non-Intervention Provisions

Relators agree to dismiss their claim under the New Mexico FCA (Count XIV). In terms of their claims under the State FCAs of Delaware (Count III), New Hampshire (Count XII) and Texas (Count XVII), Relators agree to seek damages for the time periods specified above—which is the date on which each of those State FCAs was amended to permit a Relator to proceed with a non-intervened claim on behalf of state taxpayers. *See Bergman*, 2014 WL 348583, at *18-19 (holding that similar argument regarding non-intervention provisions did not limit false claims under the Delaware FCA that were submitted on or after July 16, 2009, or false claims under the Texas FCA that were submitted on or after May 4, 2007).[33]

3. Retroactivity of State FCAs

Relators agree that, through this *qui tam* action, they will seek to recover damages for the taxpayers under the State FCAs for the time periods set forth in the table above. Allergan erroneously asserts, however, that Relators' claims under the New York False Claims Act ("New York FCA") are barred prior to its effective date of April 1, 2007. In fact, New York's legislature, when enacting the New York FCA, unambiguously provided that the Act "shall apply

[33] The New Hampshire FCA was amended, effective June 29, 2009, to authorize the relator who initiated the proceeding to conduct the action, in the event that the State declines to intervene. N.H. Rev. Stat. § 167:61-c.

to claims filed or presented *before*, on or after [its effective date] April 1, 2007." 2007 N.Y. Sess. Laws (McKinney's) Ch. 58, S. 2108-c, § 93(5) (April 9, 2007) (emphasis added). Similarly, when amending the New York FCA in 2010, the legislature once again included language explicitly stating that its provisions apply to claims, records, or statements made or used "*prior to*" April 1, 2007. Ch. 379, § 13, 2010 McKinney's N.Y. Laws at 1165 (emphasis added). This language clearly satisfies the Supreme Court's test for determining whether a statute applies to conduct occurring before the statute's enactment. *See, e.g., Landgraf v. USI Film Prods.*, 511 U.S. 244, 280 (1994). Under this test, a Court must first determine if the legislature "has expressly prescribed the statute's proper reach." *Id.* If the legislature clearly expressed its intent that the statute have retroactive effect, the Court's inquiry ends there. *Id.* In light of the language quoted above, there can be no dispute that New York has unequivocally communicated its intent that its False Claims Act apply to claims made before its enactment on April 1, 2007. Other courts that have considered the retroactivity of the New York FCA have reached the same conclusion. *See, e.g.*, Transcript of Hearing Mot. to Dismiss, at 16-17, *United States ex rel. Mishra v. NYSARC*, 03-cv-7250 (S.D.N.Y. Mar. 20, 2009) ("[T]he [New York FCA] is explicitly retroactive . . . ."), attached hereto as Exhibit E; *United States ex rel. Assocs. Against Outlier Fraud v. Huron Consulting Grp., Inc.*, No. 09-cv-1800, 2010 WL 3467054, at *3 (S.D.N.Y. Aug. 25, 2010) (concluding that the New York FCA applied to claims filed before the April 1, 2007 enactment date); *see also Kuhali v. Reno*, 266 F.3d 93, 110-11 (2d Cir. 2001) (finding similar "before, on, or after" language to be an unambiguous expression of legislative intent to apply statute retroactively)*; cf. People ex rel. Schneiderman v. Sprint Nextel Corp.*, 970 N.Y.S.2d 164,

173-76 (N.Y. Sup. Ct. 2013) (retroactive application of 2010 amendments to New York FCA does not violate Ex Post Facto clause).[34]

F. Dismissal With Prejudice Is Not Warranted.

For the reasons set forth above, Defendant's Motion to Dismiss should be denied. However, if the Court does grant the motion, in full or in part, Relators respectfully request that such dismissal be with leave to file an amended complaint. The Third Circuit has instructed "that if a complaint is vulnerable to 12(b)(6) dismissal, a district court must permit a curative amendment, unless an amendment would be inequitable or futile." *Phillips*, 515 F.3d at 236. In the context of the FCA, a court errs where it denies leave to amend after one motion to dismiss, even if the relator amended the complaint once or more while the case was under seal. *See Frazier ex rel. United States v. Iasis Healthcare Corp.*, 392 Fed. App'x 535, 538 (9th Cir. 2010) (reversing district court's denial of leave to amend because court did not "give sufficient weight to the fact that the first two complaints were filed under seal and that the motion to dismiss the Second Amended Complaint was the first time that Frazier's claims were subject to a Rule 9(b)

[34] The cases cited by Defendants are inapposite. In both cases, the court never considered the language of the New York statute because the relator had *conceded* that the New York FCA was not retroactive. *See United States ex rel. Streck v. Allergan, Inc.*, 894 F. Supp. 2d 584, 605 (E.D. Pa. 2012) ("Plaintiff admits that none of the [state FCAs including the New York FCA] apply retroactively"); *United States ex rel. Bergman v. Abbott Labs.*, No. 09-4264, 2014 WL 348583, at *20 (E.D. Pa. Jan. 30, 2014) (noting that Relator conceded eleven of state FCA counts, including New York, on retroactivity grounds).

sufficiency analysis").[35] Here, this motion is the first time the Court is evaluating the sufficiency of Relators' claims. If the Court finds those claims lacking in any way, it should allow Relators the opportunity to submit an amended complaint.[36]

CONCLUSION

For all of the foregoing reasons, Relators respectfully request that Defendant's motion to dismiss be denied.

Respectfully submitted,

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[35] *See also United States ex rel. Grenadyor v. Ukranian Vill. Pharmacy, Inc.*, 895 F. Supp. 2d 872, 882 (N.D. Ill. 2012) ("Defendants argue that, with this being Relator's third try, the Court should dismiss with prejudice. However, the Court notes that this is the first complaint actually challenged by motions to dismiss. Because Defendants have only had to answer once, and because the Court does not believe amendment would necessarily be futile, it grants leave to replead."); *United States ex rel. West v. Ctr. for Diagnostic Imaging, Inc.*, 787 F. Supp. 2d 1213, 1225 (W.D. Wash 2011) ("Although this is plaintiffs' third amended complaint, this motion is the first time the sufficiency of the complaint has been adjudicated. Defendants will not suffer prejudice if leave to amend is granted. Plaintiffs will be granted leave to amend to augment their allegations."); *United States ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 785 (S.D. Tex. 2010) ("The relators have only amended once, before the filing of Medtronic's motion to dismiss. Medtronic does not argue that the relators' complaint is frivolous. This court grants the relators leave to amend.") (internal citations omitted).

[36] As the Court is aware, Allergan has already produced more than 130,000 pages of documents, directly related to the kickback allegations in this *qui tam* action, to the State of New York Office of Medicaid Inspector General ("OMIG") and the Commonwealth of Massachusetts Office of Attorney General. Dkt. No. 41, ¶¶ 4, 6. These documents were not produced by Allergan until *after* the operative SAC was filed. *Id.* Therefore, information contained in these Allergan documents, which are directly related to the kickback allegations in this case, has not been included in the operative SAC.

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EXHIBIT A

PhRMA CODE II

(Excerpted pursuant to Local Rule 5.1.2 (6))

Code on Interactions with Healthcare Professionals

PhRMA

Therefore, PhRMA adopts this updated and enhanced voluntary Code on relationships with U.S. healthcare professionals. This Code reflects and builds upon the standards and principles set forth in its predecessor, the PhRMA Code on Interactions with Healthcare Professionals that took effect on July 1, 2002. Like the 2002 edition, this Code addresses interactions with respect to marketed products and related pre-launch activities. PhRMA member companies' relationships with clinical investigators and other individuals and entities as they relate to the clinical research process are addressed in the PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results.

This updated Code will take effect in January 2009.

Items intended for the personal benefit of healthcare professionals (such as floral arrangements, artwork, music CDs or tickets to a sporting event) likewise should not be offered.

Payments in cash or cash equivalents (such as gift certificates) should not be offered to healthcare professionals either directly or indirectly, except as compensation for bona fide services (as described in Sections 6 and 7). Cash or equivalent payments of any kind create a potential appearance of impropriety or conflict of interest.

It is appropriate to provide product samples for patient use in accordance with the Prescription Drug Marketing Act.

11 Educational Items

It is appropriate for companies, where permitted by law, to offer items designed primarily for the education of patients or healthcare professionals if the items are not of substantial value ($100 or less) and do not have value to healthcare professionals outside of his or her professional responsibilities. For example, an anatomical model for use in an examination room is intended for the education of the patients and is therefore appropriate, whereas a DVD or CD player may have independent value to a healthcare professional outside of his or her professional responsibilities, even if it could also be used to provide education to patients, and therefore is not appropriate.

Items designed primarily for the education of patients or healthcare professionals should not be offered on more than an occasional basis, even if each individual item is appropriate.

12 Prescriber Data

Companies use non-patient identified prescriber data to facilitate the efficient flow of information to healthcare professionals. Such prescriber data, which does not identify individual patients, may serve many purposes, including enabling companies to: (a) impart important safety and risk information to prescribers of a particular drug; (b) conduct research; (c) comply with FDA mandated risk management plans that require drug companies to identify and interact with physicians who prescribe certain drugs; (d) track adverse events of marketed prescriptions drugs; and (e) focus marketing activities on those healthcare professionals who would most likely benefit from information about a particular drug.

Companies that choose to use non-patient identified prescriber data to facilitate communications with healthcare professionals should use this data responsibly. For example, companies should (a) respect the confidential nature of prescriber data; (b) develop policies regarding the use of the data; (c) educate employees and agents about those policies; (d) maintain an internal contact person to handle inquiries regarding the use of the data; and (e) identify appropriate disciplinary actions for misuse of this data.

In addition, companies should respect and abide by the wishes of any healthcare professional who asks that his or her prescriber data not be made available to company sales representatives. Companies may demonstrate this respect by following the rules of voluntary programs that facilitate prescribers' ability to make this choice.

13 Independence and Decision Making

No grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's prescribing practices.

14 Training and Conduct of Company Representatives

Pharmaceutical company representatives play an important role in delivering accurate, up-to-date information to healthcare professionals about the approved indications, benefits and risks of pharmaceutical therapies. These representatives often serve as the primary point of contact between the companies who research, develop, manufacture and market life-saving and life-enhancing medicines and the healthcare professionals who prescribe them. As such, the company representatives must act with the highest degree of professionalism and integrity.

Companies should ensure that all representatives who are employed by or acting on behalf of the companies and who visit healthcare professionals receive training about the applicable laws, regulations and industry codes of practice, including this Code, that govern the representatives' interactions with healthcare professionals. In addition, companies should train their representatives to ensure that they have sufficient knowledge of general science and product-specific information to provide accurate, up-to-date information, consistent with FDA requirements.

Companies should provide updated or additional training in all of these areas as needed for their representatives who visit healthcare professionals.

Companies should also assess their representatives periodically to ensure that they comply with relevant company policies and standards of conduct. Companies should take appropriate action when representatives fail to comply.

15 Adherence to Code

All companies that interact with healthcare professionals about pharmaceuticals should adopt procedures to assure adherence to this Code.

Companies that publicly announce their commitment to abide by the Code and who complete an annual certification that they have policies and procedures in place to foster compliance with the Code will be identified by PhRMA on a public web site. The certification must be signed by the company's Chief Executive Officer and Chief Compliance Officer. The web site will identify the companies who commit to abide by the Code; provide

EXHIBIT B

Compilation of Medicaid Prohibitions of Payment of Claims Tainted by Kickbacks

(Excerpted pursuant to Local Rule 5.1.2 (6))

California

Cal. Wel. & Inst. Code § 14107.11 (2014) (payments to providers to be suspended upon credible allegation of fraud); *id*. § 14107.2 (2014) (prohibiting kickbacks).

Delaware

Del. Code Ann. tit. 31, § 1005 (2014) (prohibits kickbacks in connection with claims to Medicaid)

District of Columbia

D.C. Code § 4-802 (2014) (prohibits kickbacks in connection with claims to Medicaid)

Florida

Fla. Stat. § 409.913(25)(a) (2013) ("The agency shall withhold Medicaid payments, in whole or in part, to a provider upon receipt of reliable evidence that the circumstances giving rise to the need for a withholding of payments involve fraud, willful misrepresentation, or abuse under the Medicaid program, or a crime committed while rendering goods or services to Medicaid recipients."); *id*. § 409.920(2)(a) (2013) (kickbacks are fraud).

Illinois

89 Ill. Adm. Code 140.35 (2013) (subjecting Medicaid providers to federal and state anti-kickback law).

Indiana

Ind. Code § 12-15-24-2 (2014) (prohibits kickbacks in connection with claims to Medicaid).

Ind. Code § 12-15-22-1 (2014) (authorizes Medicaid program to deny payment when provider has violated Medicaid law or rule).

405 Ind. Admin. Code § l-l-4(a)(6)(H) (the state's Medicaid office "may deny payment" of claims "aris[ing] out of... acts or practices" including violations of AKS).

Louisiana

La. Rev. Stat. Ann. § 46:438.2 (2013) (prohibits kickbacks in connection with claims to Medicaid.)

Louisiana General Information and Administration Provider Manual § 1.3, *available at* http://www.lamedicaid.com/provwebl/Providermanuals/manuals/GIA/GIA.pdf (authorizes denial of payment when providers have violated Medicaid laws, rules and policies).

Massachusetts

Mass. Gen. Laws ch, 118E, § 41 (2014) (prohibits kickbacks in connection with claims to Medicaid).

130 Mass. Code Regs. 450.249(B) (2014) (authorizes withholding of payment from providers that have violated Medicaid law).

Michigan

Mich. Comp. Laws § 400.604 (2014) (prohibits kickbacks in connection with claims to Medicaid).

Michigan Medicaid Provider Manual, § 16.2, available at http://www.mdch.state.mi.us/dch-medicaid/manuals/medicaidprovidermanual.pdf (defines fraud on Medicaid to include kickback activity).

Montana

Montana Code Ann. § 45-6-313(b) (prohibits kickbacks in connection with claims to Medicaid).

Montana Medicaid Provider Manual 2.8, *available at* http://medicaidprovider.hhs.mt.gov/pdf/providerreq.pdf (state may withhold payment if provider fails to abide by "federal and state laws," including AKS).

Nevada

Nev. Rev. Stat. 422.560(l)(c) (2013) (prohibits kickbacks for patient referrals in connection with claims to Medicaid).

Nevada Medicaid Services Manual § 102 p.9, *available at* http://www.dhcfp.state.nv.us/MSM/MSM%20Chapter%2004-15-14.pdf ("Prior to receiving reimbursement, providers must… comply with all federal, state and local statutes, rules and regulations relating to the services being provided.").

New Hampshire

N.H. Rev. Stat. Ann. § 167:61-aI.(i) (prohibits kickbacks in connection with claims to Medicaid.)

New Jersey

N.J. Stat. § 30:4D-17(c) (2014) (prohibits kickbacks in connection with claims to Medicaid).

New Mexico

New Mexico EDI Provider Trading Partner Agreement 6-7 (requiring compliance with Social Security Act - which includes the AKS - by providers billing Medicaid, and warning that non-compliance could result in withholding of payments), available at https://nmmedicaid.acs-inc.com/static/ProviderlnformationJ.htm.

New York

N.Y. Soc. Serv. Law § 366-d(2) (2014) (prohibits kickbacks in connection with claims to Medicaid).

Oklahoma

56 Okla. Stat. § 1005 (2013) (prohibits kickbacks in connection with claims to Medicaid).

56 Okla. Stat. § 1007 (2013) (imposes liability for full restitution and other penalties on those violating the Medicaid kickback law).

Rhode Island

R.I. Gen. Laws § 40-8.2-21 (2013) (authorizes denial of payment upon credible evidence that a provider has committed fraud on the Medicaid program); *id*. § 40-8.2-3 (2013) (kickbacks are fraud).

Texas

Tex. Hum. Res. Code § 32.039(b) (2013) (forbidding kickbacks); *id*. (c) (those who take or receive kickbacks are liable for "the amount paid as a result of the violation"); *id*. § 36.002(5) (prohibits kickbacks); *id*. § 36.052 (provides for restitution of amounts wrongfully paid by Medicaid for claims resulting from kickbacks).

Wisconsin

Wis. Stat. § 946.91(3) (kickbacks are fraud); Wis. Adm. Code § DHS 107.02 (2014) (payment will be rejected for claims that don't meet program requirements); *id*. § DHS 106.02(4) (2014) ("A provider shall be reimbursed only if the provider complies with applicable state and federal procedural requirements relating to the delivery of the service.").

Virginia

Va. Code Ann. § 32.1-315(A) (2014) (prohibits kickbacks in connection with claims to Medicaid).

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EXHIBIT C

OIG Compliance Program Guidance For Pharmaceutical Manufacturers ("OIG Guidance")

(Excerpted pursuant to Local Rule 5.1.2 (6))

68 FR 23731-01

NOTICES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

OIG Compliance Program Guidance for Pharmaceutical Manufacturers

Monday, May 5, 2003

***23731** AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice

SUMMARY: This Federal Register notice sets forth the recently issued Compliance Program Guidance for Pharmaceutical Manufacturers developed by the Office of Inspector General (OIG). Through this notice, the OIG is setting forth its general views on the value and fundamental principles of compliance programs for pharmaceutical manufacturers and the specific elements that pharmaceutical manufacturers should consider when developing and implementing an effective compliance program.

FOR FURTHER INFORMATION CONTACT: Mary E. Riordan or Nicole C. Hall, Office of Counsel to the Inspector General, (202) 619-2078.

SUPPLEMENTARY INFORMATION:

Background

Compliance program guidance is a major initiative of the OIG in its effort to engage the health care community in preventing and reducing fraud and abuse in federal health care programs. The purpose of the compliance program guidance is to encourage the use of internal controls to efficiently monitor adherence to applicable statutes, regulations and program requirements. In the last several years, the OIG has developed and issued compliance program guidance directed at the following segments of the health care industry: the hospital industry; home health agencies; clinical laboratories; third-party medical billing companies; the durable medical equipment, prosthetics, orthotics and supply industry; Medicare+Choice organizations offering coordinated care plans; hospices; nursing facilities; individual and small group physician practices; and ambulance suppliers.

Copies of these compliance program guidances can be found on the OIG Web site at http://oig.hhs.gov/fraud/complianceguidance.html.

Developing the Compliance Program Guidance for Pharmaceutical Manufacturers

On June 11, 2001, the OIG published a solicitation notice seeking information and recommendations for developing compliance program guidance for the pharmaceutical industry (66 FR 31246). In response to that solicitation notice, the OIG received eight comments from various outside sources. We carefully considered those comments, as well as previous OIG publications, such as other compliance program guidances and Special Fraud Alerts. In addition, we have taken into account past and ongoing fraud investigations conducted by the OIG's Office of Investigations and the Department of Justice, and have consulted with the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration). In an effort to ensure that all parties had a reasonable opportunity to provide input into a final product, draft compliance program guidance for the pharmaceutical industry was published in the Federal Register on October 3, 2002 (67 FR 62057) for further comments and recommendations.

Elements for an Effective Compliance Program

point for a manufacturer's legal review of its particular practices and for development of policies and procedures to reduce or eliminate potential risk.

a. Integrity of Data Used To Establish or Determine Government Reimbursement. Many federal and state health care programs establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable. A pharmaceutical manufacturer may be liable under the False Claims Act [7] if government reimbursement (including, but not limited to, reimbursement by Medicare and Medicaid) for the manufacturer's product depends, in whole or in part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly (as defined in the False Claims Act) failed to generate or report such information completely and accurately. Manufacturers may also be liable for civil money penalties under various laws, rules and regulations. Moreover, in some circumstances, inaccurate or incomplete reporting may be probative of liability under the federal anti-kickback statute.

Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or ***23734** other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues). Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements.

Given the importance of the Medicaid Rebate Program, as well as other programs that rely on Medicaid Rebate Program benchmarks (such as the 340B Program [8]), manufacturers should pay particular attention to ensuring that they are calculating Average Manufacturer Price and Best Price accurately and that they are paying appropriate rebate amounts for their drugs. [9]

In sum, pharmaceutical manufacturers are responsible for ensuring the integrity of data they generate that is used for government reimbursement purposes.

b. Kickbacks and Other Illegal Remuneration—A. General Considerations. Pharmaceutical manufacturers, as well as their employees and agents, should be aware of the federal anti-kickback statute and the constraints it places on the marketing and promotion of products reimbursable by the federal health care programs, including, but not limited to, Medicare and Medicaid. In the health care sector, many common business activities, including, for example, sales, marketing, discounting, and purchaser relations, potentially implicate the anti-kickback statute. Pharmaceutical manufacturers and their employees and agents should be aware that the anti-kickback statute prohibits in the health care industry some practices that are common in other business sectors. In short, practices that may be common or longstanding in other businesses are not necessarily acceptable or lawful when soliciting federal health care program business.

The anti-kickback statute is a criminal prohibition against payments (in any form, whether the payments are direct or indirect) made purposefully to induce or reward the referral or generation of federal health care business. The anti-kickback statute addresses not only the offer or payment of anything of value for patient referrals, but also the offer or payment of anything of value in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or ordering of any item or service reimbursable in whole or part by a federal health care program. The statute extends equally to the solicitation or acceptance of remuneration for referrals. Liability under the anti-kickback statute is determined separately for each party involved. In addition to criminal penalties, violators may be subject to civil monetary sanctions and exclusion from the federal health care programs. Under certain circumstances, a violation of the anti-kickback statute may give rise to liability under the False Claims Act.

Although liability under the anti-kickback statute ultimately turns on a party's intent, it is possible to identify arrangements or practices that may present a significant potential for abuse. Initially, a manufacturer should identify any remunerative relationship between itself (or its representatives) and persons or entities in a position to generate federal health care business for the manufacturer directly or indirectly. Persons or entities in a position to generate federal health care business include, for example, purchasers, benefit managers, formulary committee members, group purchasing organizations (GPOs), physicians and certain allied health care professionals, and pharmacists. The next step is to determine whether any one purpose of the remuneration may be to induce or reward the referral or recommendation of business payable in whole or in part by a Federal health care program. Importantly, a lawful purpose will not legitimize a payment that also has an unlawful purpose.

Although any arrangement satisfying both tests requires careful scrutiny from a manufacturer, the courts have identified several potentially aggravating considerations that can be useful in identifying arrangements at greatest risk of prosecution. In particular, manufacturers should ask the following questions, among others, about any problematic arrangements or practices they identify:

• Does the arrangement or practice have a potential to interfere with, or skew, clinical decision-making? Does it have a potential to undermine the clinical integrity of a formulary process? If the arrangement or practice involves providing information to decision-makers, prescribers, or patients, is the information complete, accurate, and not misleading?

• Does the arrangement or practice have a potential to increase costs to the federal health care programs, beneficiaries, or enrollees? Does the arrangement or practice have the potential to be a disguised discount to circumvent the Medicaid Rebate Program Best Price calculation?

• Does the arrangement or practice have a potential to increase the risk of overutilization or inappropriate utilization?

• Does the arrangement or practice raise patient safety or quality of care concerns?

Manufacturers that have identified problematic arrangements or practices can take a number of steps to reduce or eliminate the risk of an anti-kickback violation. Detailed guidance relating to a number of specific practices is available from several sources. Most importantly, the anti-kickback statute and the corresponding regulations establish a number of “safe harbors” for common business arrangements, including personal services and management contracts, 42 CFR 1001.952(d), warranties, 42 CFR 1001.952(g), discounts, 42 CFR 1001.952(h), employment, 42 CFR 1001.952(i), GPOs, 42 CFR 1001.952(j), and certain managed care and risk sharing arrangements, 42 CFR 1001.952(m), (t), and (u). Safe harbor protection requires strict compliance with all applicable conditions set out in the relevant safe harbor. Although compliance with a safe harbor is voluntary and failure to comply with a safe harbor does not mean an arrangement is illegal, many arrangements can be structured to fit in safe harbors, and we recommend that pharmaceutical manufacturers structure arrangements to fit in a safe harbor whenever possible. Other available guidance includes special fraud alerts and advisory bulletins issued by the OIG identifying and discussing particular practices or issues of concern and OIG advisory opinions issued to specific parties about their particular business arrangements. Parties may apply for an OIG advisory opinion using the procedures set out at 42 CFR part 1008. The safe harbor regulations (and accompanying Federal Register preambles), fraud alerts and bulletins, advisory opinions (and instructions for obtaining them), and other guidance are available on the OIG web site at http://oig.hhs.gov.

B. Key Areas of Potential Risk. The following discussion highlights several known areas of potential risk. The propriety of any particular arrangement can only be determined after a detailed examination of the attendant facts and circumstances. The identification of a given practice or activity as “suspect” or as an area of “risk” does not mean it is necessarily illegal or unlawful, or that it ***23735** cannot be properly structured to fit in a safe harbor. Nor does it mean that the practice or activity is not beneficial from a clinical, cost, or other perspective. Rather, the areas identified below are those areas of activity that have a potential for abuse based on historical law enforcement experience and that should receive close scrutiny from manufacturers. The discussion highlights potential risks under the anti-kickback statute arising from pharmaceutical manufacturers' relationships with three groups: purchasers (including those using formularies) and their agents; persons and entities in a position to make or influence referrals (including physicians and other health care professionals); and sales agents.

(1) Relationships with Purchasers and their Agents—(a) Discounts and Other Remuneration to Purchasers. Pharmaceutical manufacturers offer purchasers a variety of price concessions and other remuneration to induce the purchase of their products. Purchasers include direct purchasers (e.g., hospitals, nursing homes, pharmacies, some physicians), as well as indirect purchasers (e.g., health plans). Inducements offered to purchasers potentially implicate the anti-kickback statute if the purchased products are reimbursable to the purchasers, in whole or in part, directly or indirectly, by any of the federal health care programs. Any remuneration from a manufacturer provided to a purchaser that is expressly or impliedly related to a sale potentially implicates the anti-kickback statute and should be carefully reviewed.

Discounting arrangements are prevalent in the pharmaceutical industry and deserve careful scrutiny particularly because of their potential to implicate the Best Price requirements of the Medicaid Rebate Program. Because the Medicaid Rebate Program in many instances requires that states receive rebates based on the Best Price offered by a pharmaceutical manufacturer to other purchasers, manufacturers have a strong financial incentive to hide de facto pricing concessions to other purchasers to avoid passing on the same discount to the states. Because of the potential direct and substantial effect of such practices on federal health care program expenditures and the interest of some manufacturers in avoiding price concessions that would trigger rebates to the states, any remuneration from a manufacturer to a purchaser, however characterized, should be carefully scrutinized.

Discounts. Public policy favors open and legitimate price competition in health care. Thus, the anti-kickback statute contains an exception for discounts offered to customers that submit claims to the federal health care programs, if the discounts are properly disclosed and accurately reported. See 42 U.S.C. 1320a-7b(b)(3)(A); 42 CFR 1001.952(h). However, to qualify for the exception, the discount must be in the form of a reduction in the price of the good or service based on an arms-length transaction. In other words, the exception covers only reductions in the product's price. Moreover, the regulations provide that the discount must be given at the time of sale or, in certain cases, set at the time of sale, even if finally determined subsequent to the time of sale (i.e., a rebate).

Manufacturers offering discounts should thoroughly familiarize themselves, and have their sales and marketing personnel familiarize themselves, with the discount safe harbor at 42 CFR 1001.952(h) (and, if relevant, the safe harbors for price reductions in the managed care context, 42 CFR 1001.952(m), (t), and (u)). In particular, manufacturers should pay attention to the discount safe harbor requirements applicable to “sellers” and “offerors” of discounts. Under the safe harbor, sellers and offerors have specific obligations that include (i) informing a customer of any discount and of the customer's reporting obligations with respect to that discount, and (ii) refraining from any action that would impede a customer's ability to comply with the safe harbor. To fulfill the safe harbor requirements, manufacturers will need to know how their customers submit claims to the federal health care programs (e.g., whether the customer is a managed care, cost-based, or charge-based biller). Compliance with the safe harbor is determined separately for each party.

Product Support Services. Pharmaceutical 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. Standing alone, services that have no substantial independent value to the purchaser may not implicate the anti-kickback statute. However, if a manufacturer provides a service having no independent value (such as limited reimbursement support services in connection with its own products) in tandem with another service or program that confers a benefit on a referring provider (such as a reimbursement guarantee that eliminates normal financial risks), the arrangement would raise kickback concerns. For example, the anti-kickback statute would be implicated if a manufacturer were to couple a reimbursement support service with a promise that a purchaser will pay for ordered products only if the purchaser is reimbursed by a federal health care program.

Educational Grants. Pharmaceutical manufacturers sometimes provide grant funding for a wide range of educational activities. While educational funding can provide valuable information to the medical and health care industry, manufacturer grants to purchasers, GPOs, PBMs and similar entities raise concerns under the anti-kickback statute. Funding that is conditioned, in whole or in part, on the purchase of product implicates the statute, even if the educational or research purpose is legitimate.

Furthermore, to the extent the manufacturer has any influence over the substance of an educational program or the presenter, there is a risk that the educational program may be used for inappropriate marketing purposes.

To reduce the risks that a grant program is used improperly to induce or reward product purchases or to market product inappropriately, manufacturers should separate their grant making functions from their sales and marketing functions. Effective separation of these functions will help insure that grant funding is not inappropriately influenced by sales or marketing motivations and that the educational purposes of the grant are legitimate. Manufacturers should establish objective criteria for making grants that do not take into account the volume or value of purchases made by, or anticipated from, the grant recipient and that serve to ensure that the funded activities are bona fide. The manufacturer should have no control over the speaker or content of the educational presentation. Compliance with such procedures should be documented and regularly monitored.

Research Funding. Manufacturers often contract with purchasers of their products to conduct research activities on behalf of the manufacturer on a fee-for-service basis. These contracts should be structured to fit in the personal services safe harbor whenever possible. Payments for research services should be fair market value for legitimate, reasonable, and necessary services. Post-marketing research activities should be especially scrutinized to ensure that they are legitimate and not simply a pretext to generate prescriptions of a drug. Prudent manufacturers will develop contracting procedures that ***23736** clearly separate the awarding of research contracts from marketing. Research contracts that originate through the sales or marketing functions—or that are offered to purchasers in connection with sales contacts—are particularly suspect.

Pharmaceutical manufacturers sometimes provide funding to their purchasers for use in the purchasers' own research. In many cases, the research provides valuable scientific and clinical information, improves clinical care, leads to promising new treatments, promotes better delivery of health care, or otherwise benefits patients. However, as with educational grants, if linked directly or indirectly to the purchase of product, research grants can be misused to induce the purchase of business without triggering Medicaid Best Price obligations. To reduce risk, manufacturers should insulate research grant making from sales and marketing influences.

Other remuneration to purchasers. As already noted, any remuneration from a manufacturer provided to a purchaser that is expressly or impliedly related to a sale potentially implicates the anti-kickback statute and should be carefully reviewed. Examples of remuneration in connection with a sale include, but are not limited to, “prebates” and “upfront payments,” other free or reduced-price goods or services, and payments to cover the costs of “converting” from a competitor's product. Selective offers of remuneration (i.e., offers made to some but not all purchasers) may increase potential risk if the selection criteria relate directly or indirectly to the volume or value of business generated. In addition, manufacturers may contract with purchasers to provide services to the manufacturer, such as data collection services. These contracts should be structured whenever possible to fit in the personal services safe harbor; in all cases, the remuneration should be fair market value for legitimate, reasonable, and necessary services.

(b) Formularies and Formulary Support Activities. To help control drug costs while maintaining clinical appropriateness and quality of patient care, many purchasers of pharmaceutical products, including indirect purchasers such as health plans, have developed drug formularies to promote rational, clinically appropriate, safe, and cost-effective drug therapy. Formularies are a well-established tool for the effective management of drug benefits. The formulary development process—typically overseen by a committee of physicians, pharmacists, and other health care professionals—determines the drugs that are covered and, if tiered benefit levels are utilized, to which tier the drugs are assigned. So long as the determination of clinical efficacy and appropriateness of formulary drugs by the formulary committee precedes, and is paramount to, the consideration of costs, the development of a formulary is unlikely to raise significant issues under the anti-kickback statute.

Formulary support activities, including related communications with patients and physicians to encourage compliance, are an integral and essential component of successful pharmacy benefits management. Proper utilization of a formulary maximizes the cost-effectiveness of the benefit and assures the quality and appropriateness of the drug therapy. When provided by a PBM, these services are part of the PBM's formulary and benefit management function—a service provided to its customers—and

markedly different from its purchasing agent/price negotiator role. Most importantly, the benefits of these formulary support activities inure directly to the PBM and its customers through lower costs.

To date, Medicare and Medicaid involvement with outpatient drug formularies has been limited primarily to Medicaid and Medicare managed care plans. In light of the safe harbors under the anti-kickback statute for those managed care arrangements, the financial arrangements between health plans and pharmaceutical manufacturers or, where the pharmacy benefit is managed by a PBM, the arrangements among the three parties, have received relatively little scrutiny. However, as federal program expenditures for, and coverage of, outpatient pharmaceuticals increase, scrutiny under the anti-kickback statute has also increased. Several practices appear to have the potential for abuse.

• Relationships with formulary committee members. Given the importance of formulary placement for a manufacturer's products, unscrupulous manufacturers and sales representatives may attempt to influence committee deliberations. Any remuneration from a manufacturer or its agents directly or indirectly to person in a position to influence formulary decisions related to the manufacturer's products are suspect and should be carefully scrutinized. Manufacturers should also review their contacts with sponsors of formularies to ensure that price negotiations do not influence decisions on clinical safety or efficacy.

• Payments to PBMs. Any rebates or other payments by drug manufacturers to PBMs that are based on, or otherwise related to, the PBM's customers' purchases potentially implicate the anti-kickback statute. Protection is available by structuring such arrangements to fit in the GPO safe harbor at 42 CFR 1001.952(j). That safe harbor requires, among other things, that the payments be authorized in advance by the PBM's customer and that all amounts actually paid to the PBM on account of the customer's purchases be disclosed in writing at least annually to the customer. In addition, arrangements with PBMs that assume risk may raise different issues; depending on the circumstances, protection for such arrangements may be available under the managed care safe harbors at 42 CFR 1001.952(m), (t) and (u).

• Formulary placement payments. Lump sum payments for inclusion in a formulary or for exclusive or restricted formulary status are problematic and should be carefully scrutinized.

In addition, some manufacturers provide funding for purchasers' or PBMs' formulary support activities, especially communications with physicians and patients. While the communications may indirectly benefit the manufacturer, the primary economic beneficiary is typically the formulary sponsor. In other words, the manufacturer's dollars appear to replace dollars that would or should be spent by the sponsor. To the extent the manufacturers' payments are linked to drug purchases directly or indirectly, they potentially implicate the anti-kickback statute. Among the questions that should be examined by a manufacturer in connection with these activities are: Is the funding tied to specific drugs or categories? If so, are the categories especially competitive? Is the formulary sponsor funding similar activities for other drug categories? Has funding of PBM activities increased as rebates are increasingly passed back to PBM customers?

(c) Average Wholesale Price. The “spread” is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the “spread,” it controls its customer's profit. ***23737**

Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at “95 percent of average wholesale price.” 42 U.S.C. 1395u(o). Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.

If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike bona fide discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the “spread” to induce customers to purchase its product.

In the light of this risk, we recommend that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process. Furthermore, manufacturers should review their marketing practices. The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute. Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product.

(2) Relationships with Physicians and Other Persons and Entities in a Position to Make or Influence Referrals. Pharmaceutical manufacturers and their agents may have a variety of remunerative relationships with persons or entities in a position to refer, order, or prescribe—or influence the referral, ordering, or prescribing of—the manufacturers' products, even though the persons or entities may not themselves purchase (or in the case of GPOs or PBMs, arrange for the purchase of) those products. These remunerative relationships potentially implicate the anti-kickback statute. The following discussion focuses on relationships with physicians, but the same principles would apply when evaluating relationships with other parties in a position to influence referrals, including, without limitation, pharmacists and other health care professionals.

Manufacturers, providers, and suppliers of health care products and services frequently cultivate relationships with physicians in a position to generate business for them through a variety of practices, including gifts, entertainment, and personal services compensation arrangements. These activities have a high potential for fraud and abuse and, historically, have generated a substantial number of anti-kickback convictions. There is no substantive difference between remuneration from a pharmaceutical manufacturer or from a durable medical equipment or other supplier—if the remuneration is intended to generate any federal health care business, it potentially violates the anti-kickback statute.

Any time a pharmaceutical manufacturer provides anything of value to a physician who might prescribe the manufacturer's product, the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent to induce or reward referrals. For example, if goods or services provided by the manufacturer eliminate an expense that the physician would have otherwise incurred (i.e., have independent value to the physician), or if items or services are sold to a physician at less than their fair market value, the arrangement may be problematic if the arrangement is tied directly or indirectly to the generation of federal health care program business for the manufacturer. Moreover, under the anti-kickback statute, neither a legitimate purpose for an arrangement (e.g., physician education), nor a fair market value payment, will necessarily protect remuneration if there is also an illegal purpose (i.e., the purposeful inducement of business).

In light of the obvious risks inherent in these arrangements, whenever possible prudent manufacturers and their agents or representatives should structure relationships with physicians to fit in an available safe harbor, such as the safe harbors for personal services and management contracts, 42 CFR 1001.952(d), or employees, 42 CFR 1001.952(i). An arrangement must fit squarely in a safe harbor to be protected. In addition, arrangements that do not fit in a safe harbor should be reviewed in light of the totality of all facts and circumstances, bearing in mind the following factors, among others:

• Nature of the relationship between the parties. What degree of influence does the physician have, directly or indirectly, on the generation of business for the manufacturer? Does the manufacturer have other direct or indirect relationships with the physician or members of the physician's group?

• Manner in which the remuneration is determined. Does the remuneration take into account, directly or indirectly, the volume or value of business generated (e.g., is the remuneration only given to persons who have prescribed or agreed to prescribe the manufacturer's product)? Is the remuneration conditioned in whole or in part on referrals or other business generated? Is there any service provided other than referrals?

• Value of the remuneration. Is the remuneration more than trivial in value, including all gifts to any individual, entity, or group of individuals? [10] Do fees for services exceed the fair market value of any legitimate, reasonable, and necessary services rendered by the physician to the manufacturer?

• Potential federal program impact of the remuneration. Does the remuneration have the potential to affect costs to any of the federal health care programs or their beneficiaries or to lead to overutilization or inappropriate utilization?

• Potential conflicts of interest. Would acceptance of the remuneration diminish, or appear to diminish, the objectivity of professional judgment? Are there patient safety or quality of care concerns? If the remuneration relates to the dissemination of information, is the information complete, accurate, and not misleading?

These concerns are addressed in the PhRMA Code on Interactions with Healthcare Professionals (the “PhRMA Code”), adopted on April 18, 2002, which provides useful and practical advice for reviewing and structuring these relationships. (The PhRMA Code is available through PhRMA's Web site at http://www.phrma.org.) Although compliance with the PhRMA Code will not protect a manufacturer as a matter of law under the anti-kickback statute, it will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements. ***23738**

The following paragraphs discuss in greater detail several common or problematic relationships between manufacturers and physicians, including “switching” arrangements, consulting and advisory payments, payments for detailing, business courtesies and other gratuities, and educational and research activities.

• Switching” arrangements. As noted in the OIG's 1994 Special Fraud Alert (59 FR 65372; December 19, 1994), product conversion arrangements (also known as “switching” arrangements) are suspect under the anti-kickback statute. Switching arrangements involve pharmaceutical manufacturers offering physicians or others cash payments or other benefits each time a patient's prescription is changed to the manufacturer's product from a competing product. This activity clearly implicates the statute, and, while such programs may be permissible in certain managed care arrangements, manufacturers should review very carefully any marketing practices utilizing “switching” payments in connection with products reimbursable by federal health care programs.

Consulting and advisory payments. Pharmaceutical manufacturers frequently engage physicians and other health care professionals to furnish personal services as consultants or advisers to the manufacturer. In general, fair market value payments to small numbers of physicians for bona fide consulting or advisory services are unlikely to raise any significant concern. Compensating physicians as “consultants” when they are expected to attend meetings or conferences primarily in a passive capacity is suspect.

Also of concern are compensation relationships with physicians for services connected directly or indirectly to a manufacturer's marketing and sales activities, such as speaking, certain research, or preceptor or “shadowing” services. While these arrangements are potentially beneficial, they also pose a risk of fraud and abuse. In particular, the use of health care professionals for marketing purposes—including, for example, ghost-written papers or speeches—implicates the anti-kickback statute. While full disclosure by physicians of any potential conflicts of interest and of industry sponsorship or affiliation may reduce the risk of abuse, disclosure does not eliminate the risk.

At a minimum, manufacturers should periodically review arrangements for physicians' services to ensure that: (i) The arrangement is set out in writing; (ii) there is a legitimate need for the services; (iii) the services are provided; (iv) the

compensation is at fair market value; and (v) all of the preceding facts are documented prior to payment. In addition, to further reduce their risk, manufacturers should structure services arrangements to comply with a safe harbor whenever possible.

Payments for detailing. Recently, some entities have been compensating physicians for time spent listening to sales representatives market pharmaceutical products. In some cases, these payments are characterized as “consulting” fees and may require physicians to complete minimal paperwork. Other companies pay physicians for time spent accessing web sites to view or listen to marketing information or perform “research.” All of these activities are highly suspect under the anti-kickback statute, are highly susceptible to fraud and abuse, and should be strongly discouraged.

Business Courtesies and Other Gratuities. Pharmaceutical companies and their employees and agents often engage in a number of other arrangements that offer benefits, directly or indirectly, to physicians or others in a position to make or influence referrals. Examples of remunerative arrangements between pharmaceutical manufacturers (or their representatives) and parties in a position to influence referrals include:

• Entertainment, recreation, travel, meals, or other benefits in association with information or marketing presentations; and

• Gifts, gratuities, and other business courtesies.

As discussed above, these arrangements potentially implicate the anti-kickback statute if any one purpose of the arrangement is to generate business for the pharmaceutical company. While the determination of whether a particular arrangement violates the anti-kickback statute depends on the specific facts and circumstances, compliance with the PhRMA Code with respect to these arrangements should substantially reduce a manufacturer's risk.

Educational and Research Funding. In some cases, manufacturers contract with physicians to provide research services on a fee-for-service basis. These contracts should be structured to fit in the personal services safe harbor whenever possible. Payments for research services should be fair market value for legitimate, reasonable, and necessary services. Research contracts that originate through the sales or marketing functions—or that are offered to physicians in connection with sales contacts—are particularly suspect. Indicia of questionable research include, for example, research initiated or directed by marketers or sales agents; research that is not transmitted to, or reviewed by, a manufacturer's science component; research that is unnecessarily duplicative or is not needed by the manufacturer for any purpose other than the generation of business; and post-marketing research used as a pretense to promote product. Prudent manufacturers will develop contracting procedures that clearly separate the awarding of research contracts from marketing or promotion of their products.

In addition, pharmaceutical manufacturers also provide other funding for a wide range of physician educational and research activities. Manufacturers should review educational and research grants to physicians similarly to educational and research grants to purchasers (described above). As with grants to purchasers, the OIG recognizes that many grant-funded activities are legitimate and beneficial. When evaluating educational or research grants provided by manufacturers to physicians, manufacturers should determine if the funding is based, in any way, expressly or implicitly, on the physician's referral of the manufacturer's product. If so, the funding plainly implicates the anti-kickback statute. In addition, the manufacturer should determine whether the funding is for bona fide educational or research purposes. Absent unusual circumstances, grants or support for educational activities sponsored and organized by medical professional organizations raise little risk of fraud or abuse, provided that the grant or support is not restricted or conditioned with respect to content or faculty.

Pharmaceutical manufacturers often provide funding to other sponsors of continuing medical education (CME) programs. Manufacturers should take steps to ensure that neither they, nor their representatives, are using these activities to channel improper remuneration to physicians or others in a position to generate business for the manufacturer or to influence or control the content of the program. [11] In addition, manufacturers and sponsors of educational programs should be mindful of the relevant rules and regulations of the Food and Drug Administration. Codes of conduct promulgated by the CME industry may provide a useful starting point for manufacturers when reviewing their CME arrangements.

(3) Relationships with Sales Agents. In large part, a pharmaceutical manufacturer's commitment to an effective fraud and abuse compliance program can be measured by its ***23739** commitment to training and monitoring its sales force. A pharmaceutical manufacturer should: (i) Develop a regular and comprehensive training program for its sales force, including refresher and updated training on a regular basis, either in person or through newsletters, memoranda, or the like; (ii) familiarize its sales force with the minimum PhRMA Code standards and other relevant industry standards; (iii) institute and implement corrective action and disciplinary policies applicable to sales agents who engage in improper marketing; (iv) avail itself of the advisory opinion process if it has questions about particular practices used by its sales force; and (v) establish an effective system for tracking, compiling, and reviewing information about sales force activities, including, if appropriate, random spot checking.

In addition, manufacturers should carefully review their compensation arrangements with sales agents. Sales agents, whether employees or independent contractors, are paid to recommend and arrange for the purchase of the items or services they offer for sale on behalf of the pharmaceutical manufacturer they represent. Many arrangements can be structured to fit in the employment or personal services safe harbor. Arrangements that cannot fit into a safe harbor should be carefully reviewed. Among the factors that should be evaluated are:

• The amount of compensation;

• The identity of the sales agent engaged in the marketing or promotional activity (e.g., is the agent a “white coat” marketer or otherwise in a position of exceptional influence);

• The sales agent's relationship with his or her audience;

• The nature of the marketing or promotional activity;

• The item or service being promoted or marketed; and

• The composition of the target audience.

Manufacturers should be aware that a compensation arrangement with a sales agent that fits in a safe harbor can still be evidence of a manufacturer's improper intent when evaluating the legality of the manufacturer's relationships with persons in a position to influence business for the manufacturer. For example, if a manufacturer provides sales employees with extraordinary incentive bonuses and expense accounts, there may well be an inference to be drawn that the manufacturer intentionally motivated the sales force to induce sales through lavish entertainment or other remuneration.

c. Drug Samples. The provision of drug samples is a widespread industry practice that can benefit patients, but can also be an area of potential risk to a pharmaceutical manufacturer. The Prescription Drug Marketing Act of 1987 (PDMA) governs the distribution of drug samples and forbids their sale. 21 U.S.C. 353(c)(1). A drug sample is defined to be a unit of the drug “that is not intended to be sold * * * and is intended to promote the sale of the drug.” 21 U.S.C. 353(c)(1). Failure to comply with the requirements of PDMA can result in sanctions. In some circumstances, if the samples have monetary value to the recipient (e.g., a physician) and are used to treat federal health care program beneficiaries, the improper use of samples may also trigger liability under other statutes, including the False Claims Act and the anti-kickback statue.

Pharmaceutical manufacturers should closely follow the PDMA requirements (including all documentation requirements). In addition, manufacturers can minimize their risk of liability by: (i) Training their sales force to inform sample recipients in a meaningful manner that samples may not be sold or billed (thus vitiating any monetary value of the sample); (ii) clearly and conspicuously labeling individual samples as units that may not be sold (thus minimizing the ability of recipients to advertently or inadvertently commingle samples with purchased product); and (iii) including on packaging and any documentation related to the samples (such as shipping notices or invoices) a clear and conspicuous notice that the samples are subject to PDMA and

may not be sold. Recent government enforcement activity has focused on instances in which drug samples were provided to physicians who, in turn, sold them to the patient or billed them to the federal health care programs on behalf of the patient.

C. Designation of a Compliance Officer and a Compliance Committee

1. Compliance Officer

Every pharmaceutical manufacturer should designate a compliance officer to serve as the focal point for compliance activities. [12] This responsibility may be the individual's sole duty or added to other management responsibilities, depending upon the size and resources of the company and the complexity of the task. If the individual has additional management responsibilities, the pharmaceutical manufacturer should ensure that the individual is able to dedicate adequate and substantive time and attention to the compliance functions. Similarly, if the compliance officer delegates some of the compliance duties, he or she should, nonetheless, remain sufficiently involved to fulfill the compliance oversight function.

Designating a compliance officer with the appropriate authority is critical to the success of the program, necessitating the appointment of a high-level official with direct access to the company's president or CEO, board of directors, all other senior management, and legal counsel. The compliance officer should have sufficient funding, resources, and staff to perform his or her responsibilities fully. The compliance officer should be able to effectuate change within the organization as necessary or appropriate and to exercise independent judgment. Optimal placement of the compliance officer within the organization will vary according to the particular situation of a manufacturer. [13]

Coordination and communication with other appropriate individuals or business units are the key functions of the compliance officer with regard to planning, implementing or enhancing, and monitoring the compliance program. The compliance officer's primary responsibilities should include:

• Overseeing and monitoring implementation of the compliance program; [14]

• Reporting on a regular basis to the company's board of directors, CEO or president, and compliance committee (if applicable) on compliance matters and assisting these individuals or groups to establish methods to reduce the company's vulnerability to fraud and abuse;

• Periodically revising the compliance program, as appropriate, to respond to changes in the company's needs and applicable federal health care program requirements, identified weakness in the compliance program, or identified systemic patterns of noncompliance;

• Developing, coordinating, and participating in a multifaceted educational and training program that focuses on the elements of the compliance program, and seeking to ensure that all affected employees and management understand and comply with pertinent federal and state standards;

• Ensuring that independent contractors and agents, particularly those agents and contractors who are involved in sales and marketing activities, are aware of the requirements of the company's compliance program with respect to sales and marketing activities, among other things;

• Coordinating personnel issues with the company's Human Resources/ ***23740** Personnel office (or its equivalent) to ensure that the List of Excluded Individuals/Entities [15] has been checked with respect to all employees and independent contractors;

• Assisting the company's internal auditors in coordinating internal compliance review and monitoring activities;

EXHIBIT D

Brief for The United States as Amicus Curiae
(United States ex rel. Nathan v. Takeda Pharm. N.A. Inc.)

(Excerpted pursuant to Local Rule 5.1.2 (6))

No. 12-1349

In the Supreme Court of the United States

UNITED STATES EX REL. NOAH NATHAN, PETITIONER

v.

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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such complaints are inadequate would hinder the ability of *qui tam* relators to perform the role that Congress intended them to play in the detection and remediation of fraud against the United States. See U.S. Amicus Br. at 16-17, *Ortho Biotech Prods., L.P.* v. *United States ex rel. Duxbury*, No. 09-654 (May 19, 2010). *Qui tam* complaints are often filed by the defendants' current and former employees. Such relators may be privy to detailed information indicating that their employers are engaged in fraud against the United States, and may be well-positioned to provide valuable assistance to the government's anti-fraud efforts, even if they are not privy to the details of the defendants' billing activities.

In *Lusby*, for example, an engineer who had worked for a government contractor alleged that his former employer had falsely represented that its aircraft engines met the government's specifications. See 570 F.3d at 853-854. And in *Grubbs*, a physician alleged that other doctors at his hospital had sought to recruit him into a scheme to bill the government for services they had not provided. See 565 F.3d at 191-192. Both relators came forward with detailed, plausible allegations of fraud. Yet under a per se rule requiring *qui tam* complaints to identify specific false claims, both suits would have been dismissed because neither relator was familiar with the minutiae of his employer's billing. Because a prospective relator is unlikely to be privy to such details unless she "works in the defendant's accounting department," a rule demanding the details of specific false claims would "take[] a big bite out of *qui tam* litigation." *Lusby*, 570 F.3d at 854.

Subjecting *qui tam* relators to a per se rule requiring the identification of specific false claims is especially unwarranted because it attaches dispositive significance to the relator's awareness of details that in most instances are already known to the government. The government rarely if ever needs a relator's assistance to identify claims for payment that have been submitted to the United States. Rather, relators typically contribute to the government's enforcement efforts by bringing to light other information that shows those claims to be false. Requiring *qui tam* complaints to identify specific false claims thus would not meaningfully assist the government's enforcement efforts. To the contrary, the likely effect of such a requirement would be to discourage the filing of *qui tam* suits by relators—like those in *Grubbs* and *Lusby*—who would otherwise have the means and the incentive to expose frauds against the United States.

2. The proper application of Rule 9(b) in the FCA context is thus a significant issue. If one or more courts of appeals continue to adhere to the rigid view that petitioner attributes to the court below (but see pp. 13-14, *supra*), this Court's intervention may be warranted in a case where application of that approach appears to be outcome-determinative. This case, however, is not a suitable vehicle in which to take up the question. The court below correctly held that petitioner's complaint failed to satisfy Rule 9(b) and *Iqbal* because it does not plausibly allege that false claims were presented to the government. Petitioner's suit therefore could not go forward under the pleading standard adopted by any court of appeals.

a. Petitioner contends (Pet. 19-20; Reply Br. 3-4 & n.2) that the court of appeals found his complaint

insufficient only because that court adopted an inflexible rule requiring *qui tam* relators to identify specific false claims. But the court of appeals did not adopt that per se rule. To the contrary, it required only "'some indicia of reliability' * * * to support the allegation that an actual false claim was presented to the government." Pet. App. 8a (quoting *Clausen*, 290 F.3d at 1311). The court stated that a relator must identify specific false claims only where the "defendant's actions, as alleged and as reasonably inferred from the allegations, *could* have led, but *need not necessarily* have led, to the submission of false claims." *Id.* at 10a. Although this articulation of the pleading standard differs from the phrasing used by other circuits, it does not require that every *qui tam* complaint plead the details of specific false claims.[6]

The court of appeals' rejection of a per se rule is further confirmed by the balance of its opinion. If the court had followed the decisions demanding that a relator plead "representative examples" of specific

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[6] Petitioner contends (Reply Br. 5) that, by requiring a relator to identify specific false claims whenever a defendant's conduct would not "necessarily" have led to the submission of false claims, the court of appeals improperly elevated *Iqbal*'s plausibility requirement to a demand that relators "prov[e] falsity." But the court below did not require such proof; rather, it rejected petitioner's complaint because petitioner had failed to "plausibly allege" the presentation of false claims. Pet. App. 2a, 13a. The court of appeals explained, moreover, that a relator's complaint is sufficient if the defendant's actions "as alleged *and as reasonably inferred from the allegations*" would "necessarily have led[] to the submission of false claims." *Id.* at 10a (emphasis altered). That formulation suggests that petitioner's complaint would have satisfied the court's standard if petitioner had alleged facts sufficient to support a reasonable inference that false claims were submitted.

EXHIBIT E

Transcript of Hearing of Motion to Dismiss

(Excerpted pursuant to Local Rule 5.1.2 (6))

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,	:	03-CV-7250
Plaintiff,	:	
v.	:	
NYSARC, et al.,	:	500 Pearl Street New York, New York
Defendants.	:	March 20, 2009

TRANSCRIPT OF HEARING REGARDING MOTION TO DISMISS
BEFORE THE HONORABLE SIDNEY H. STEIN
UNITED STATES DISTRICT JUDGE

APPEARANCES:

For the Plaintiff:	STATE OF NEW YORK NEW YORK ATTORNEY GENERAL'S OFFICE BY: JACOB BERGMAN, ESQ. U.S. ATTORNEY GENERAL'S OFFICE BY: REBECCA MARTIN, ESQ.
For the Defendants:	MALCOLM J. HARKINS, III, ESQ. JAMES F. SEGROVES, ESQ. Proskauer Rose, LLP 1001 Pennsylvania Avenue NW Washington, D.C. 20004-2533
For Jitendra Nath Mishra:	TIMOTHY MCINNIS, ESQ. Law Office of Timothy J. McInnis 521 Fifth Avenue - Suite 1700 New York, New York 10175
Court Transcriber:	RUTH ANN HAGER TypeWrite Word Processing Service 211 N. Milton Road Saratoga Springs, New York 12866

Proceedings recorded by electronic sound recording,
transcript produced by transcription service

expressly condition payment for MSC services on face-to-face meetings. The vendor SC manual provides "A vendor's monthly billing must be substantiated by a face-to-face visit with the person documented in the service coordinator's monthly notes. If a person is away, e.g. on vacation and no face-to-face visit takes place, the MSC vendor cannot bill for MSC for those months." See the vendor MSC manual at 5-1. Therefore, Mishra has alleged viable state and federal claims under theory of implied false certification pursuant to the False Claims Acts.

(F) Lack of health and safety safeguards. Later alleges a final fraudulent scheme stating that NYSARC failed to comply with requirements that it maintain health and safety safeguards as components of habilitation plans. Complaint 66 to 68.

In Mishra's opposition to this motion, however, he concedes that the allegation is "potentially dismissible" under Mike's v. Strauss. The cited guidelines do not condition payment of Medicaid claims on maintenance of these safeguards and I do agree that the complaint does not plead a claim for factually or legally false certification and I dismiss this claim.

In sum so far, Mishra has pled claims on which relief can be granted pursuant to the state and federal claims for day services that NYSARC billed to Medicaid but that did

not provide for duplicative billing for full-day habilitation and prevocation services and for false certification of MSC services for months in which the MSC coordinator did not meet face to face with the consumer.

I now will briefly turn to the remaining arguments which, as I said in the beginning really, don't have any merit.

IV. NYSARC argues that a violation of a state rather than federal requirement is insufficient to violate the federal act of the plain language of the federal act makes no such distinction and other courts have -- that have considered this issue have rejected it. See U.S. v. Rogan, 549 F. Supp. 2d 692, 708 (Northern District of Illinois 2006). Affirmed 517 F.3d 449 (7th. Cir. 2008); U.S. ex rel. Quinby Omni Care, Inc., 382 F.3d 432, 442-43 (3d. Cir. 2004). Mishra's allegations that NYSARC violated state rules governing Medicaid reimbursement are sufficient to support a claim pursuant to the False Claims Act.

V. Retroactivity of the state act. NYSARC tries to argue that the New York False Claims Act is not retroactive. The statute is explicitly retroactive. New York False Claims Act 2007 New York Session Law, Chapter 58 S2108-C of April 9, 2007 states that Section 39 of the New York NYSARC False Claims Act "shall apply to claims filed or presented prior to, o or after April 1, 2007." It doesn't matter that the

provision concerning retroactivity is not officially codified in the New York State Finance Law. And the Court has to give the statute specifically stated retroactive affect. See Lands Graffy USI [Ph.], 511 U.S. 244, 280 1994. The state statute is retroactive and relators claims pursuant to it are appropriate.

VI. *Qui tam* provisions of the federal and state claims are constitutional. This has really been litigated rather thoroughly. U.S. ex rel. Farrell v. SKF USA, Inc., 32 F. Supp. 2d. 617, 618 (Western District of New York 1999) collecting cases states "Numerous courts have addressed the issue of whether *qui tam* plaintiffs are officers of the United States within the meaning of the appointments clause of the U.S. Constitution and have held beyond question that they are not." The relator claims that the *qui tam* provisions violates the appointments clause, the claim has no merit. That's true also of the New York False Claims Act. That statute does not violate principals of separation of powers. See U.S. ex rel. Krinlevy, Krinlevy United Technologies Corp., 985 F.2d 1148, 1155 (2d. Cir. 1993). That's a federal citation but the same logic applies to the state *qui tam* provision because the language of the statutes are the same.

VII. Retaliation. Mishra also alleges that NYSARC retaliated against him by harassing, suspending, and ultimately firing him after he raised questions concerning its

allegedly fraudulent billing practices. Complaint 73 to 79. Section 3703(h) in the False Claims Act provides a cause of action for "any employee who is discharged, demoted, suspended, threatened or harassed or in any other manner discriminated against by his or her employer because of lawful acts done by the employee in furtherance of an action under the FCA including investigation for, initiation of, testimony for or assistance in this action." 31 U.S.C. 3730(h) and New York State Finance Law 191(1).

Contrary to NYSARC's argument, retaliation claims are not subject to Rule 9(b)'s heightened pleading standard. Every circuit court that has addressed this, I must say -- not including the Second Circuit -- has held that Rule 9(b) does not apply. For example, U.S. ex rel. Marlar v. BWXTY 12, LLC, 525 F.3d 439, 448-50 (Sixth Cir. 2008); Mendiondo -- that's M-e-n-d-i-o-n-d-o -- v. Centinela -- that's C-e-n-t-i-n-e-l-a -- Hospital Medical Center, 521 F.3d 1097, 1103 (Ninth Circuit 2008); United States ex rel. Karvelas, K-a-r-v-e-l-a-s, v. Melrose Wakefield Hospital, 360 F.3d 220, 238, Note 23, (First Circuit 2004), thus applying Twombly and Rule 8, general standard of notice pleading to Mishra's claims for retaliation, which is what I'm doing here.

So let's look at that under those pleading standards. The complaint does plead a claim for retaliation. "To sustain an action under Section 3730(h) a plaintiff has to