



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.

SEP 27 2010

MICHAEL E KUNZ, Clerk By Dep. Clerk

Civil Action No. 09-432

: Hon. Thomas N. O'Neill, Jr.

: JURY TRIAL DEMANDED

Plaintiffs,

ALLERGAN, INC.

Defendant

v.

COMPLAINT FILED UNDER SEAL

SECOND AMENDED QUI TAM COMPLAINT

Qui tam plaintiffs/relators Herbert J. Nevyas, M.D. and Anita Nevyas -Wallace, M.D. through their attorneys Pietragallo Gordon Alfano Bosick & Raspanti, LLP, and Goldberg Kohn, LTD, on behalf of the United States of America, the State of California, the State of Delaware, the State of Florida, the State of Illinois, the State of Indiana, the State of Louisiana, the Commonwealth of Massachusetts, the State of Michigan, the State of Montana, the State of New Jersey, the State of New Mexico, the State of New York, the State of Oklahoma, the State of

Rhode Island, the State of Texas, the Commonwealth of Virginia, the State of Wisconsin, and the District of Columbia (collectively "the States and the District of Columbia"), for their Second Amended Qui Tam Complaint against defendant Allergan, Inc., based upon their direct and personal knowledge, allege as follows:

I. <u>INTRODUCTION</u>

This is an action to recover damages and civil penalties on behalf of the 1. United States of America, the States, and the District of Columbia, arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used or presented by defendant Allergan, Inc. ("Allergan") and/or its agents, employees and co-conspirators in violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729 et seg., as amended ("the FCA" or "the Act") and its state-law counterparts: the California False Claims Act, Cal. Govt Code § 12650 et seq.; the Delaware False Claims and Reporting Act, 6 Del. C. § 1201 et seq.; the Florida False Claims Act, Fla. Stat. Ann. § 68.081 et seq.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1-8; the Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5-1 et seq.; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1 et seq.; the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5A et seq.; the Michigan Medicaid False Claim Act, M.C.L. §400.601 et seq.; the Montana False Claims Act, Mont. Code Ann. § 17-8-401 et seq.; the Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.010 et seq.; the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. §167:61-b et seq.; the New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-1 et seq.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 et seq.; the New York False Claims Act, N.Y. State Fin. Law § 187 et seq.; the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 §5053.1 et seq; the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 et seq.; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. § 36.001 et seq.; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 et seq.; the Wisconsin False Claims for Medical Assistance Act, 121 Wis. Stat. § 20.931; and the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. § 2-308.0 and § 2-308.14 et seq.

- 2. Defendant has, since at least approximately 2002, conducted an unlawful kickback scheme to induce eye care professionals to prescribe Allergan products, in violation of the federal Anti-Kickback Statutes, and analogous state laws and statutes.
- 3. Defendant Allergan's scheme involves offering and providing substantial, illegal financial inducements to ophthalmologists and optometrists, as described in more detail below, include:
 - A. Free on-demand, expert business advisory services, offered through Allergan's nationwide network of Eye Care Business Advisors;
 - B. Membership in the state-of-the-art *Allergan Access* website, which provides physicians selected by Allergan with comprehensive business services, including, but not limited to: sophisticated financial analysis and benchmarking assessment tools; payer and reimbursement analysis and benchmarking tools; human resource guidance and tools; physician recruitment and contracting guidance and tools; on-demand expert billing and coding advice; and a full suite of on-line continuing education courses for technicians and staff. The fair-market-value of

- these expert services far exceeds the nominal annual membership fee for access to Allergan's exclusive website; and
- C. Membership in Allergan's lucrative speaker's bureau, which is reserved for those physicians who are described by Allergan as "really good writers of prescriptions,".
- 4. As a direct result of Defendant's improper practices, federal and state health insurance programs including, but not limited to, Medicare, Medicaid, MediCal, TennCare, CHAMPUS/TRICARE, CHAMPVA and the Federal Employee Health Benefits Program ("FEHBP") have been caused to pay false or fraudulent claims for reimbursement of the Defendant's prescription drugs that resulted from Defendant's illegal kickbacks.
- 5. The False Claims Act was originally enacted during the Civil War, and was substantially amended in 1986. Congress amended the Act to enhance the Government's ability to recover losses sustained as a result of fraud against the United States after finding that fraud in federal programs was pervasive and that the Act, which Congress characterized as the primary tool for combating government fraud, was in need of modernization.
- 6. Congress intended that the amendments to the False Claims Act create incentives for individuals with knowledge of fraud against the government to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit legal resources to prosecuting fraud on the Government's behalf.
- 7. The Act provides that any person who knowingly submits, or causes the submission of a false or fraudulent claim to the U.S. Government for payment or

approval is liable for a civil penalty of up to \$11,000 for each such claim, plus three times the amount of the damages sustained by the Government. Liability attaches when a defendant knowingly seeks payment, or causes others to seek payment, from the Government that is unwarranted.

- 8. The Act allows any person (known as a "Relator") having information about a false or fraudulent claim against the Government to bring an action for himself and the Government, and to share in any recovery. The Act requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit.
- 9. Should the Government elect not to join in the suit, the Act provides that the Relator "shall have the right to conduct the action." 31 U.S.C. § 3730(c)(3). The United States, and/or the States involved in this case, may elect to intervene at a later date as additional evidence is obtained. 31 U.S.C. § 3730(c)(3).
- 10. Any recovery in the action goes to the federal and/or state government. The Act, however, provides that the Relator shall receive an award of between 25 percent and 30 percent of the Governments' proceeds of the action. 31 U.S.C. § 3730(d)(2). In addition, the Relator is entitled to receive from the Defendant an amount for reasonable attorney's fees, costs and expenses. <u>Id</u>.
- 11. Based on these provisions, qui tam Plaintiffs seek through this action to recover on behalf of the United States and those States, all of which authorize similar qui tam actions, damages and civil penalties arising from the named Defendant's making or

causing to be made false or fraudulent records, statements and/or claims in connection with its illegal kickbacks related to its prescription drugs.

- 12. Although Defendant did not directly submit claims for prescription drugs to federal and state health insurance programs, it knew, and/or reasonably foresaw, 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.
- 13. Defendant is therefore liable under the federal False Claims Act and analogous state False Claims Acts for causing the submission of thousands of claims for prescriptions that were not eligible for reimbursement because those claims resulted from illegal kickbacks that were offered and/or supplied by Allergan to the Ophthalmologists and Optometrists who ordered those prescriptions.

II. PARTIES

A. Relators Herbert J. Nevyas, M.D. and Anita Nevyas-Wallace, M.D.

- 14. Plaintiffs/Relators Herbert J. Nevyas, M.D. and Anita Nevyas–Wallace,M.D. are residents of Pennsylvania and citizens of the United States.
- 15. Dr. Herbert J. Nevyas is a board-certified ophthalmologist, licensed to practice medicine under the laws of Pennsylvania, New Jersey, and Florida.
- 16. Since 1964, Relator Herbert J. Nevyas, M.D. has been in private practice. Currently, he is a principal in Nevyas Eye Associates, which specializes in medical and surgical ophthalmology through offices in Bala Cynwyd, PA, Philadelphia, PA, and Marlton, N.J. Nevyas Eye Associates' Bala Cynwyd location houses a dedicated LASIK surgery suite and the Delaware Valley Laser Surgery Institute, a fully accredited ambulatory surgery center, with two operating rooms, and two minor surgery suites.

- 17. Dr. Herbert J. Nevyas earned a B.A. from the University of Pennsylvania, and his medical degree from University of Pennsylvania School of Medicine. Following his internship at Jefferson Medical College Hospital, and post-graduate studies at the Institute of Ophthalmology of the University of London and Moorfields Eye Hospitals, London, UK. Relator Herbert J. Nevyas, M.D. served his residency in Ophthalmology at the Hospital of the University of Pennsylvania.
- 18. Dr. Nevyas served in the United States Army Reserve Medical Corps, from 1962 to 1966.
- 19. Relator Nevyas is a member of the Phi Beta Kappa Honor Society, and the recipient of the Oliver Memorial Prize in Ophthalmology University of Pennsylvania School of Medicine.
- 20. Dr. Nevyas is a current and former member of many local, national, and international professional scientific societies, and he is presently a Fellow of the American Academy of Ophthalmology, a founding member of the American Society for Cataract and Refractive Surgery, a Fellow of the Society of Eye Surgeons, a member of the American Medical Association, and a member of the esteemed International Society of Refractive Surgeons.
- 21. Dr. Nevyas has written and lectured extensively throughout the United States on ophthalmic disease and surgery.
- 22. Dr. Nevyas has served on the faculty of the department of ophthalmology at the University of Pennsylvania, and served as the Chief of the Division of Ophthalmology at the Medical College of Pennsylvania. Former faculty appointments include: Jefferson Medical College (through Wills Eye Hospital); Temple University

School of Medicine (through Wills Eye Hospital); Hahnemann Hospital College; and the University of Pennsylvania School of Medicine. Presently, Dr. Nevyas has a teaching appointment at Drexel University College of Medicine.

- 23. Relator Anita Nevyas-Wallace, M.D. is a board-certified ophthalmologist, licensed to practice medicine under the laws of Pennsylvania and New Jersey.
- 24. Since 1988, Dr. Nevyas-Wallace has been in private practice with the Nevyas Eye Associates, specializing in medical and surgical ophthalmology.
- 25. Relator Nevyas-Wallace, M.D. earned a B.S. from the University of Pennsylvania, and her medical degree from the University of Pennsylvania School of Medicine. Relator Nevyas-Wallace, M.D. served her residency in Ophthalmology at the University of Pennsylvania, Scheie Eye Institute, and a fellowship in Anterior Segment Ophthalmic Surgery at the Medical College of Pennsylvania.
- 26. Relator Nevyas-Wallace received honors as a University Scholar and Benjamin Franklin Scholar at the University of Pennsylvania, and she also received the American Society of Cataract and Refractive Surgery "Best Paper of Session" Award, on two occasions.
- 27. Dr. Nevyas-Wallace is a member of many local, national, and international professional scientific societies, including the American Society of Cataract and Refractive Surgery, the International Society of Refractive Surgery, the Society for Excellence in Eyecare, the Pennsylvania Academy of Ophthalmology, the Outpatient Ophthalmic Surgery Society, Surgical Eye Expeditions International, and Women in Ophthalmology. She is a Clinical Associate of the University of Pennsylvania Department of Ophthalmology.

28. Relator Nevyas-Wallace has lectured, and continues to lecture, extensively on refractive and cataract surgery.

B. Defendant Allergan, Inc.

- 29. Defendant Allergan, Inc. ("Allergan") is an international biopharmaceutical company, incorporated under the laws of the state of Delaware, and headquartered at 2525 Dupont Drive, Irvine, CA 92612.
- 30. Defendant Allergan's primary business activity in the United States relates to discovering, developing, and commercializing specialty pharmaceutical, medical device, and over-the-counter products for the ophthalmic, neurological, medical dermatological, breast aesthetics, obesity intervention, urological and other specialty markets.
- 31. Defendant Allergan operates its business in two segments: (1) Specialty Pharmaceuticals; and (2) Medical Devices.
- 32. Defendant Allergan's Specialty Pharmaceutical segment generated net sales of: \$2.319 Billion in 2005; \$2.638 Billion in 2006; \$3.105 Billion in 2007; \$3.502 Billion in 2008; and \$3.683 Billion in 2009
- 33. Within its Specialty Pharmaceutical Segment, Defendant Allergan's Eye Care Pharmaceutical Product Line 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. The Eye Care Pharmaceutical Product Lines includes, but is not limited to, the following prescription 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®

Allergy Products: Alocril®, Elestat®.;

34. Defendant Allergan sells a substantial amount of the products within its

Eye Care Pharmaceutical Product Line to persons in the United States over 65 years of

age. For example, between January and July of 2008, the numbers of prescriptions

written for certain of Defendant Allergan's Eye Care Pharmaceutical products, for

persons in the United States over 65 years of age, were as follows:

Lumigan: 1,074,000 prescriptions

Zymar: 591,000 prescriptions

Restasis: 514,000 prescriptions

Acular LS: 355,000 prescriptions

In the area of Chronic Dry Eye, Defendant Allergan's product Restasis is 35.

the first and currently the only prescription therapy for the treatment of chronic dry eye

worldwide.

36. Chronic Dry Eye, according to Defendant Allergan, is a painful and

irritating condition involving abnormalities and deficiencies in the tear film initiated by a

variety of causes. Until the approval of Restasis in December 2002, physicians generally

used lubricating tears as a temporary measure to provide palliative relief of the symptoms

of chronic dry eye.

- 37. Because of its status as the exclusive prescription therapy for chronic dry eye, Restasis is covered by most private and government funded health insurance plans, including, but not limited to, Medicare, the Federal Employee Health Benefits Program, and the Medicaid programs of each of the States named in this Second Amended Complaint.
- 38. Restasis is Allergan's best selling eye care product. 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.

III. <u>JURISDICTION AND VENUE</u>

- 39. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S. C. § 1367, 42 U.S.C. §1320-7b(b), and 31 U.S.C. § 3732, the last of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3720. Under 31 U.S.C. § 3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint. Relators, moreover, would qualify under that section of False Claims Act as an "original source" of the allegations in this Second Amended Qui Tam Complaint even had such a public disclosure occurred.
- 40. The Court has subject matter jurisdiction over Defendant's violations of the California False Claims Act, Cal. Govt Code § 12650 et seq.; the Delaware False Claims and Reporting Act, 6 Del. C. § 1201 et seq.; the Florida False Claims Act, Fla. Stat. Ann. § 68.081 et seq.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1-8; the Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5-1 et seq.; the Louisiana Medical Assistance Programs Integrity Law, La.

Rev. Stat. Ann. § 46:439.1 et seq.; the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5A et seq.; the Michigan Medicaid False Claim Act, M.C.L. §400.601 et seq.; the Montana False Claims Act, Mont. Code Ann. § 17-8-401 et seq.; the Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.010 et seq.; the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. §167:61-b et seq.; the New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-1 et seq.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 et seg.; the New York False Claims Act, N.Y. State Fin. Law § 187 et seg.; the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63 §5053.1 et seq; the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 et seq.; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. § 36.001 et seq.; the Virginia Fraud Against Taxpavers Act, Va. Code Ann. § 8.01-216.1 et seq.; the Wisconsin False Claims for Medical Assistance Act, 121 Wis. Stat. § 20.931; and the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. § 2-308.0 and § 2-308.14 et seq., pursuant to 31 U.S.C. § 3732(b) because Defendant's violations of the State False Claims Acts and the federal FCA arise out of a common nucleus of operative fact. See also 31 U.S.C. § 3732(b) (granting district courts jurisdiction over any action brought under the laws of any state for the recovery of funds paid by a state if the action arises from the same transaction or occurrence as an action brought under the federal FCA).

41. This Court has personal jurisdiction and venue over the Defendant pursuant to 28 U.S.C. §§ 1391(b) and 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because the Defendant has minimum contacts with the United States. Moreover, the Defendant can be found in, resides and transacts business in and throughout the Eastern District of Pennsylvania.

42. Venue is proper in this District pursuant to 31 U.S. C. § 3731(a) because the Defendant can be found in and transacts business in the Eastern District of Pennsylvania. At all times relevant to this Second Amended Qui Tam Complaint, the Defendant regularly conducted substantial business within the Eastern District of Pennsylvania, maintained employees and offices in Pennsylvania and made significant sales within Pennsylvania. In addition, statutory violations as alleged herein, occurred in this district.

IV. <u>BACKGROUND ON FEDERAL & STATE-FUNDED HEALTH</u> <u>INSURANCE PROGRAMS</u>

A. Medicare Program

- 43. In 1965, Congress enacted Title XVIII of the Social Security Act, which established the Medicare Program to provide health insurance for the elderly and disabled. Medicare is a health insurance program for: people age 65 or older; people under age 65 with certain disabilities; and people of all ages with end-stage renal disease (permanent kidney failure requiring dialysis or a kidney transplant).
- 44. Medicare now has three parts: Part A; Part B, and the recently enacted Part D Program.
- 45. Medicare Part A (Hospital Insurance) helps cover inpatient care in hospitals, including critical access hospitals, and skilled nursing facilities (not custodial or long-term care). Medicare Part A also helps cover hospice care and some home health care.
- 46. Medicare Part B (Medical Insurance) helps cover doctors' services and outpatient care, as well as other medical services not covered by Part A. Part B also helps pay for covered health services and supplies when they are medically necessary.

- 47. Medicare Part D (Prescription Drug Plan) provides beneficiaries with assistance in paying for out-patient prescription drugs
- 48. Payments from the Medicare Program come from a trust fund known as the Medicare Trust Fund which is funded through payroll deductions taken from the work force, in addition to government contributions. Over the last forty years, the Medicare Program has enabled the elderly and disabled to obtain necessary medical services from medical providers throughout the United States.
- 49. The Medicare Program is administered through the United States Department of Health and Human Services ("HHS") and, specifically, the Centers for Medicare and Medicaid Services ("CMS"), an agency of HHS.
- 50. Much of the daily administration and operation of the Medicare Program is managed through private insurers under contract with the federal government.
- 51. Under Medicare Part A, contractors serve as "fiscal intermediaries," administering Medicare in accordance with rules developed by the Health Care Financing Administration ("HCFA").
- 52. Under Medicare Part B, the federal government contracts with insurance companies and other organizations known as "carriers" to handle payment for physicians' services in specific geographic areas. These private insurance companies, or "Medicare Carriers", are charged with and responsible for accepting Medicare claims, determining coverage, and making payments from the Medicare Trust Fund.
- 53. Under Medicare Part D, Medicare beneficiaries must affirmatively enroll in one of many hundreds of Part D plans ("Part D Sponsors") offered by private companies that contract with the federal government. Part D Sponsors are charged with

and responsible for accepting Medicare Part D claims, determining coverage, and making payments from the Medicare Trust Fund.

- 54. The principal function of both intermediaries and carriers is to make payments for Medicare services, and to audit claims for those services, to assure that federal funds are spent properly.
- 55. To participate in Medicare, providers must assure that their services are provided economically and only when, and to the extent they are medically necessary. Medicare will only reimburse costs for medical services that are needed for the prevention, diagnosis, or treatment of a specific illness or injury.

B. Medicaid Program

- 56. Medicaid was created in 1965, at the same time as Medicare, when Title XIX was added to the Social Security Act. The Medicaid program aids the states in furnishing medical assistance to eligible needy persons, including indigent and disabled people. Medicaid is the largest source of funding for medical and health-related services for America's poorest people.
- 57. Medicaid is a cooperative federal-state public assistance program which is administered by the states.
- 58. Funding for Medicaid is shared between the federal government and those state governments that choose to participate in the program. Federal support for Medicaid is significant. For example, the federal government provides 50% of the funding for New Jersey Medicaid, the remaining 50% of funds is received from the state.

- 59. Title XIX of the Social Security Act allows considerable flexibility within the States' Medicaid plans and therefore, specific Medicaid coverage and eligibility guidelines vary from state to state.
- 60. However, in order to receive federal matching funds, a state Medicaid program must meet certain minimum coverage and eligibility standards. A state must provide Medicaid coverage to needy individuals and families in five broad groups: pregnant women; children and teenagers; seniors; people with disabilities; and people who are blind. In addition, the state Medicaid program must provide medical assistance for certain basic services, including inpatient and outpatient hospital services.

C. Other Federal Health Care Programs

- 61. In addition to Medicaid and Medicare, the federal government reimburses a portion of the cost of prescription drugs under several other federal health care programs, including but not limited to CHAMPUS/TRICARE, CHAMPVA and the Federal Employees Health Benefit Program.
- 62. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veteran Affairs, is a health care program for the families of veterans with a 100 percent service-connected disability. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for hundreds of thousands of federal employees, retirces, and survivors.

V. APPLICABLE LAW

A. Federal Anti-Kickback Statute

- 63. Enacted in 1972, the main purpose of the federal Anti-Kickback Statute, 42 U.S.C. §13207b(b), is to protect patients and federal health care programs from fraud and abuse by curtailing the corrupting influence of money on health care decisions.
- 64. When a company pays kickbacks to a doctor in order to induce him/her to use the company's products, it fundamentally compromises the integrity of the doctor-patient relationship. Government-funded healthcare programs, such as Medicare and Medicaid, rely upon physicians to decide what treatment is appropriate and medically necessary for patients, and, therefore, payable by that healthcare program. As a condition of its reimbursement, government healthcare programs require that the physicians must render their services without the conflict of receipt of a kickback.
- 65. Many states, including those States identified as Plaintiffs herein, have enacted similar prohibitions against illegal inducements to health care decision-makers.
- 66. The federal Anti-Kickback Statute and analogous state laws make it a crime to knowingly and willfully offer, pay, solicit or receive any remuneration to induce a person:
- (1) to refer an individual to a person for the furnishing of any item or service covered under a federal health care program; or
- (2) to purchase, lease, order, arrange for or recommend any good, facility, service, or item covered under a federal health care program.
 42 U.S.C. §1320a-7b(b)(1) and (2).

- 67. The term "any remuneration" encompasses any kickback, bribe, or rebate, direct or indirect, overt or covert, in cash or in kind. 42 U.S.C. §1320a-7b(b)(1).
- 68. Violations of the federal Anti-Kickback Statute must be knowing and willful. 42 U.S.C. §1320a-7b(b)(1).
- 69. The federal Anti-Kickback Statute has been interpreted by the United States Court of Appeals for the Third Circuit, as well as other federal courts, to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. See United States v. Greber, 760 F.2d 68 (3d Cir.), cert denied, 474 U.S. 988 (1985).
- 70. Proof of an explicit *quid pro quo* is not required to show a violation of the Anti-Kickback Statute.
- 71. In addition to the various laws and regulations all pharmaceutical companies are required to follow, the Government also offers industry guidance in an effort to police the marketing activities of the pharmaceutical industry.
- 72. For instance, the Office of the Inspector General of the Department of Health and Human Services ("HHS-OIG"), in April 2002, issued its Compliance Program Guidance for Pharmaceutical Manufacturers, a document meant to provide an overview of the fundamental elements of a pharmaceutical manufacturer compliance plan, and identifies and discusses specific risk areas.
- 73. HHS-OIG has stated that "[a]nytime 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 tangible benefit to the

physician with the intent to induce or reward referrals." HHS-OIG Guidance to Pharmaceutical Manufacturers, issued April 2002, p. 28.

- 74. A violation of the federal Anti-Kickback Statute constitutes a felony punishable by a maximum fine of \$25,000, imprisonment up to five years, or both. Any party convicted under the federal Anti-Kickback Statute *must* be excluded (*i.e.*, not allowed to bill for any services rendered) from Federal health care programs for a term of at least five years. 42 U.S.C. § 1320a-7(a)(1).
- 75. Even without a conviction, if the Secretary of HHS finds administratively that a provider has violated the federal Anti-Kickback Statute, the Secretary may exclude that provider from federal health care programs for a discretionary period, and may impose administrative sanctions of \$50,000 per kickback violation. 42 U.S.C. §1320a-7(b).
- 76. HHS has published safe harbor regulations that define practices that are not subject to prosecution or sanctions under the federal Anti-Kickback Statute because such practices would unlikely result in fraud or abuse. See 42 C.F.R. §1001.952. However, only those arrangements that precisely meet all of the conditions set forth in the safe harbor are afforded safe harbor protection. None of the practices at issue here meet these safe harbor regulations.
- 77. Compliance with the Anti-Kickback Statute is a condition of payment under the Medicare and Medicaid programs, and that condition applies regardless of which entity is submitting the claim to the government.
- 78. Claims that arise from a kickback scheme violate the False Claims Act for two separate and distinct reasons: (1) claims seeking payment for services or

prescriptions tainted by kickbacks are "factually false" because compliance with the Anti-Kickback Statute is a condition of payment; and (2) health care providers must certify in their provider enrollment agreement that they will comply with the Anti-Kickback Statute as a condition of payment.

- 79. First, claims that result from a kickback scheme are per se false because the Anti-Kickback Statute prohibits the government from paying for services or pharmaceuticals tainted by kickbacks. No further express or implied false statement is required to render such infected claims false, and none can wash the claim clean.
- 80. The False Claims Act imposes liability where a defendant knowingly causes such tainted claims to be presented to the Medicare. Medicaid or other government funded healthcare programs.
- 81. Second, as a prerequisite to participating in federally-funded health care programs, providers must certify (expressly or, through their participation in a federally-funded health care program, impliedly) their compliance with the federal Anti-Kickback Statute.
- Physicians, hospitals, and pharmacies enter into Provider Agreements with CMS in order to establish their eligibility to seek reimbursement from the Medicare Program. As part of that agreement, without which physicians, hospitals and pharmacies may not seek reimbursement from Federal Health Care 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.

Form CMS-855A (for institutional providers); Form CMS-855I (for physicians and non-physician practitioners; Form 855-S (for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Suppliers).

- 83. Moreover, as a prerequisite to participating in the various state Medicaid programs, providers must certify (expressly or, through their participation in the state-funded health care program, impliedly) their understanding of and compliance with both the federal Anti-Kickback Statute and applicable state anti-kickback laws.
- 84. Even in the absence of an express certification of Compliance, a party that submits a claim for payment impliedly certifies compliance with all conditions of payment, i.e., that it is properly payable.
- 85. Consequently, if a party pays a kickback to induce the prescribing of a particular daug, it renders false the submitter's implied or express certification of compliance that the resulting claim complies with the requirements of the Anti-kickback Statute.
- 86. On March 23, 2010, as part of the Affordable Healthcare for America Act, the Anti-Kickback Statute was amended to clarify that all claims resulting from a violation of the Anti-Kickback Statute are a violation of the federal False Claims Act. 42 U.S.C. § 1320a-7(b)(g). The amendment to the Anti-Kickback Statute codified the long standing law within the Third Circuit Court of Appeals that a violation of the Anti-Kickback Statute renders a claim false under the federal False Claims Act. See e.g., United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235 (3d Cir. 2004).

B. The PhRMA Code

- 87. The Pharmaceutical Research and Manufacturers of American ("PhRMA") represents research-based pharmaceutical and biotechnology companies throughout the United States, including Defendant Allergan.
- 88. PhRMA issued guidance, which took effect July 1, 2002, relating to interactions with healthcare professionals ("PHRMA Code I").
- 89. PhRMA issued an updated and enhanced guidance on relationships with United States healthcare professionals, which took effect January 2009 ("PHRMA Code II").
- 90. Defendant Allergan is a signatory to, and has agreed to abide by, the PHRMA Code II.
- 91. 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." PHRMA Code II, Section 13 (Independence and Decision Making).
- 92. The PHRMA Code II further provides, in relevant part, that: "Payments in cash or cash equivalents (such as gift certificates) should not be offered to healthcare professionals either directly or indirectly... cash or equivalent payments of any kind create a potential appearance of impropriety or conflict of interest." PHRMA Code II, Section 10 (Prohibition of Non-Educational and Practice-Related Items).

93. Defendant Allergan's scheme, as described herein, of offering and providing substantial, illegal financial inducements to Ophthalmologists, including Relators, and to Optometrists, to induce them to prescribe Allergan's Ophthalmic Medications violates federal and state Anti-Kickback Statutes, federal and state False Claims Acts, and the principles embodied in the PHRMA Code II.

V. <u>FRAUD ALLEGATIONS</u>:

A. Allergan Provides Improper Financial Remunerations To Ophthalmologists and Optometrists To Induce Them To Prescribe Allergan's Ophthalmic Medications, In Violation Of The Anti-Kickback Statute.

1. Overview of Allergan's Improper Financial Inducements

- 94. Allergan's revenue from its Eye Care Pharmaceutical Product Lines depends heavily upon the decision by Ophthalmologists and Optometrists to prescribe Allergan products to their patients, instead of products sold by one of Allergan's competitors.
- 95. In the case of Restasis, which is the only approved prescription medication for chronic dry eye, Allergan's revenue from Restasis depends heavily upon the decision of Ophthalmologists and Optometrists to prescribe Restasis to their patients, instead of using one of the many over-the-counter methods of treating chronic dry eye. These over-the-counter alternatives are substantially cheaper than Restasis, which cost approximately \$190.40 per month in 2006. Moreover, Allergan maintains that most patients will need to continue using Restasis indefinitely in order to treat their dry eyes.
- 96. Since approximately 2002, Allergan has offered, and continues to offer, substantial, illegal financial inducements to Ophthalmologists, including Relators, and to

Optometrists, to induce them to prescribe or use Allergan's Ophthalmic Medications, including, but not limited to, Restasis and other Allergan ophthalmic products.

- 97. Allergan's improper financial inducements for Ophthalmologists and Optometrists include, but are not limited to:
 - (a) Free, On-Demand Business Advisory Services from Allergan's Eye Care
 Business Advisor Group;
 - (b) Memberships in the exclusive Allergan Access Website; and
 - (c) Offers to join Allergan's Speakers' Bureau.
- 98. One purpose of Allergan's improper financial inducements is to induce Ophthalmologists and Optometrists to prescribe Allergan medications, including, but not limited to, Restasis.
- 99. Allergan's offer and provision of these financial inducements to Ophthalmologists and Optometrists in an effort to induce them to prescribe Allergan medications is a violation of the federal Anti-Kickback Statute, as well as similar State Anti-Kickback Statutes.
- 100. Allergan, upon information and belief, tracks the precise number of Allergan products prescribed by Ophthalmologist and/or Optometrist across the United States, through prescription data that Allergan purchases from pharmacies and/or other consulting companies (hereafter "prescription tracking data").
- 101. Allergan, upon information and belief, utilizes this prescription tracking data, in part, to identify the Ophthalmologists and Optometrists who will be offered the illegal financial inducements described herein, and also to monitor the results that those

financial inducements have on the number of Allergan products prescribed by those Ophthalmologists and Optometrists.

(a) Allergan Offers Valuable Kickbacks to Ophthalmologists and Optometrists Through its Eye Care Business Advisor Group

- 102. Allergan has, since at least 2002, offered valuable kickbacks to Ophthalmologists and Optometrists through a division of its company known as the "Eye Care Business Advisory Group."
- 103. Allergan's Eye Care Business Advisor Group provides valuable business advisory and consulting services free of charge to Ophthalmologists and Optometrists across the United States. These free business advisory services include, but are not limited to:
 - Marketing strategy and implementation,
 - Financial/productivity analysis,
 - Practice valuation/governance,
 - Human resources,
 - Practice efficiency,
 - Web development/search engine optimization/internet marketing, and
 - Strategic planning.
- 104. Allergan's Eye Care Business Advisor Group is, upon information and a belief, a part of Allergan's Business Advisor Group, which is headed by William Voyles, Director, Allergan Business Advisor Group.
- 105. Allergan's Eye Care Business Advisor Group employs at least 12 to 15 "Eye Care Business Advisors," each of whom is assigned a specific geographic region in the United States. Allergan's Eye Care Business Advisors are instructed to provide

valuable business advisory and consulting services free of charge to select Ophthalmologists and Optometrists in their assigned geographic area.

- 106. Allergan's Eye Care Business Advisors have substantial experience in the healthcare industry, some having worked in the industry for more than 30 years. Many of the Eye Care Business Advisors have advanced degrees and/or certifications, including Masters in Business Administration and Certified Ophthalmic Executive. Additionally, many of Allergan's Eye Care Business Advisors have prior experience as product sales representatives with Allergan or other pharmaceutical manufacturers.
- 107. According to marketing literature issued by Allergan in 2007, "The Allergan Eye Care Business Advisory Group designs, develops, and delivers practice management resources that bring a sustainable competitive advantage to its customers."
- 108. Allergan provides these valuable "practice management resources that bring a sustainable competitive advantage" to Ophthalmologists and Optometrists free of charge to induce them to prescribe Allergan medications.
- 109. Allergan's Eye Care Business Advisor Group, as described in more detail below, offered and provided to Relators valuable business advisory and consulting services free of charge. In exchange for these free business advisory and consulting services, Allergan explicitly requested that Relators prescribe Allergan products.
- 110. Allergan's provision of valuable business advisory services to Ophthalmologists and Optometrists across the United States, free of charge, violates the federal Anti-Kickback Statute, and analogous state laws.

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

- 111. On January 21, 2009, Relators received an invitation from Allergan Territory Sales Manager Matthew Schlegel inviting them to attend a Dry Eye Dinner held on March 16, 2009, at the restaurant Maia, located in Villanova, Pennsylvania.
- 112. Relators were among 16-20 eye care professionals (predominantly ophthalmologists) who attended the event.
- 113. The Allergan representatives in attendance at the Dry Eye Dinner included marketing representatives Matt Schlegel and Pete Pecoraro, J. Scott Youmans, Area Manager Dry Eye/External Disease, and Bob Teale ("Teale"), Allergan Eye Care Business Advisor.
- 114. The featured speaker at the March 16, 2009 Dry Eye Dinner was Bob Teale, Allergan's Senior Eye Care Business Advisor, and a key member of Allergan's Eye Care Business Advisor Group.
- 115. During the cocktail reception, the Relators spoke with Teale, who said he was familiar with the Relators, and knew that they had a very large eye care practice, and that he was happy they attended the dinner.
- 116. During the Dry Eye Dinner, Teale told Relator Nevyas that he had been working for Allergan for eight years, and that he had worked as an Eye Care Business Advisor for four years.
- 117. Teale is a Certified Ophthalmic Executive, with more than 30 years experience in the healthcare industry. 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.

- 118. Teale also told Relator that he is based out of Virginia, and that his territory includes parts of the East Coast of the United States. Teale further stated that he makes the same presentation that he delivered on March 16, 2009 to eye care professionals all across the United States.
- 119. Teale began his presentation by discussing when the baby boomer population would be expected to reach Medicare eligibility, the percentage of the population that has untreated dry eye, and that many dry eye patients suffer from allergies.
- 120. During his presentation at the Dry Eye Dinner, Teale spent considerable time explaining to the eye care professionals present the ways in which Allergan could assist physicians in marketing their practices as dry eye treatment centers, and thereby, substantially increase the revenues of their respective ophthalmologic practices.
- 121. Allergan's encouragement and support for physicians to build a successful "Dry Eye" practice also directly and substantially benefits Allergan because, as discussed above, Allergan's product Restasis® is the first and currently the only prescription therapy approved in the United States for the treatment of chronic dry eye.
- 122. 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.
- 123. One of the slides Teale used showed various diagnoses and billing codes that physicians could use when treating dry eye patients. Referring to this slide, Teale told the assembled physicians that treating "X" number of dry-eye patients each year

would generate hundreds of thousands of dollars in additional revenues for the physicians' practices.

- 124. Teale further stated that Allergan could provide the eye care professionals present at the Dry Eye Dinner with strategies and tools to build a Dry Eye Center of Excellence, including, but not limited to: scripts, marketing letters, and patient quizzes.
- 125. Teale's marketing strategies included calling patients who had not been seen in 48 months and marketing the practice as a "Dye Eye Center for Excellence." Teale offered "scripts" for physicians to use when discussing their dry eye practice with patients. Teale also discussed a quiz Allergan had developed to be given to every patient in an effort to identify those who might be candidates for dry eye treatment.
- 126. Becoming a "Dry Eye Center for Excellence," according to Allergan's Teale, did not involve a formal certification or accreditation, but instead involved becoming sensitive to patient complaints about dry eye and responding with aggressive treatment. Teale focused on how the physicians could identify, market, and target potential dry-eye patients.
- 127. Allergan's Teale also suggested reviewing existing patient files to identify patients with certain diagnoses codes, including allergy codes, and contact them for the treatment of dry eye.
- 128. During Allergan's Dry Eye Dinner, Teale also instructed the physicians to send letters to other physicians (rheumatologists, family practice physicians and gynecologists), many of whom see patients who might have dry eye but are not treating them. Teale offered to provide form letters, and Allergen's handouts for the Relators included one such letter.

- 129. Teale's presentation at the Allergan Dry Eye Dinner focused on how the physicians could maximize their business revenues by treating dry eye patients.
- 130. Teale's message was that aggressive treatment of dry eye patients, including marketing their practice as a "Dry Eye Center of Excellence," could generate significant additional annual practice revenues. Teale used the terms "Return on Investment" and "Financial Benchmarking" throughout his presentation.
- 131. Teale also spent substantial time during the Dry Eye Dinner describing the business tools the physicians could obtain through *Allergan Access*, a restricted website supported by Allergan that is available to select physicians at a cost of approximately \$800 (actually \$895) per year.
- 132. Teale further explained that *Allergan Access* provided physician practices with marketing plans, sample advertisements and promotions (including dry-eye specific ads), business office policy and procedure manuals.
- 133. During the March 16, 2009 Dry Eye Dinner, Teale also offered to provide education and training to the physicians' office staff, either at a lunch or dinner event that Allergan would arrange.
- 134. At the end of the evening, Teale asked if Nevyas-Wallace had access to a network of optometrists and, when she replied that she did, Teale offered to provide education and training to the optometrists.
- 135. Optometrists represent a substantial source of revenue for Allergan. Optometrists are the eye care professional who many patients see first for a variety of eye conditions, and for regular check-ups. In a majority of states, including Pennsylvania, Optometrists are authorized to write prescriptions for ophthalmic drugs, including

Restasis® and many of the other products in Defendant Allergan's Eye Care Pharmaceutical Product Line.

- 136. Teale also told Relator Nevyas-Wallace that the optometrists in her network could obtain free answers to billing and coding questions by having Nevyas-Wallace pose their questions to *Allergan Access*, and then provide the answers to the optometrists.
- 137. 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 offered, described and provided by Bob Teale.
- 138. On March 17, 2009, the next day following the Dry Eye Dinner, Allergan Territory Sales Manager Matthew Schlegel emailed Relator Nevyas-Wallace thanking her for attending the Dry Eye Dinner. In that email, Schlegel stated "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."
- 139. On March 17, 2009, the next day following the Dry Eye Dinner, Allergan's Senior Eye Care Business Advisor Bob Teale emailed Relators a description of the services offered by the business advisory group at Allergan. 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."

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

- 140. On September 18, 2009, at Allergan's request, Relators Nevyas and Nevyas-Wallace met with Allergan Senior Eye Care Business advisor Teale at the Bala Cynwyd office of Nevyas Eye Associates.
- 141. The meeting was scheduled as a result of a series of communications from Teale to Dr. Nevyas-Wallace requesting an opportunity to discuss the types of services that Allergan's Business Advisor Group could provide to the Relators' practice.
- 142. During the September 18, 2009 meeting, Teale discussed in detail the valuable business advisory and consulting services that are available through the *Allergan Access* website.
- 143. In describing the value of the consulting services Allergan provides to its top physicians, Allergan's Teale described these consultants as "the best people under contract" to assist the physicians members of the *Allergan Access* website. Teale informed the Relators that these top-notch consultants include the BSM Consulting Group, as well as The Corcoran Group and John Pinto.
- 144. At this same meeting, Teale told the Relators that through *Allergan Access*, Allergan has made these expert advisors available to assist the physician members of *Allergan Access* and that these advisors experts are available "at any time" they are needed by the Relators and the other *Allergan Access* members.
- 145. At this same September 18, 2009 meeting, Allergan's Teale discussed in detail certain aspects of the business advisory services that Allergan provides to selected prescribers through its *Allergan Access* website, including: "e-learning," the on-line

continuing education services; the "payer assessment" tools; the "financial benchmarking" tools; and the "Dry Eye Recall Program."

- 146. Allergan's Teale suggested that every member of Relators' practice take advantage of free on-line training, which is available for virtually every member of an ophthalmology practice: technicians, opticians, business office employees, and office staff. Teale highlighted that technicians could receive JCAHPO (Joint Commission on Allied Health Personnel in Ophthalmology) credits through free training available on Allergan Access. Teale offered to instruct Relators' employees to use this service.
- 147. Regarding the "Dry Eye Recall program," section of the *Allergan Access* website, Teale explained this could result in increased income to the Relators' practice from an initial dry eye visit, three follow-up visits, and any additional conditions which could be treated, i.e., cataracts.
- 148. During the September 18, 2009 meeting, Teale repeatedly told the 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.
- 149. Allergan's Teale also told the Relators that "none of this would be possible" without Allergan, and that Allergan paid Teale's salary. Teale added that Allergan employs approximately 12 Eye Care Business Advisors nationwide and that each provides similar services to Ophthalmologists across the country.
- 150. During the September 18, 2009 meeting, Allergan's Teale repeatedly told the Relators that he would expect them to "show their appreciation" for Allergan's business advisory services by prescribing Allergan's products. Teale further added that if

another company and Allergan made similar products, the Relators should prescribe the Allergan product.

- 151. Teale also offered to provide the Relators with "patient consents" that Allergan had retained attorneys to develop. After the meeting, he forwarded these documents by email to Relator Nevyas-Wallace.
- 152. At the September 18, 2009 meeting, Allergan's Teale offered to sponsor a dinner for the Relators' employees at a local hotel. Teale offered to pay for the room and the dinner and to give a presentation on customer service. Relators tentatively scheduled this event for October 12, 2009.
- 153. Finally, at the September 18, 2009 meeting, Allergan's Teale also wanted to schedule a meeting with Relators' staff to review in greater detail the Allergan business advisory services and the free on-line continuing education. Relators tentatively set this meeting for October 13, 2009.
- 154. Allergan did not require Relators to pay any fee for the valuable business advisory services provided and/or described by Bob Teale on September 18, 2009.

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

- 155. On October 12, 2009 Allergan Senior Eye Care Business Advisor Bob Teale gave a presentation to the staff of Nevyas Eye Associates, at their offices in Bala Cynwyd, Pennsylvania.
- 156. Teale had offered, during the September 18, 2009 meeting with Relators, to make such a presentation to the staff of Nevyas Eye Associates.

- 157. Teale first met with the office managers of Nevyas Eye Associates. During that meeting, Teale discussed the continuing education portion of the *Allergan Access* Website. In particular, Teale discussed the process for getting all of the Nevyas Eye Associates' employees signed up for the free continuing education website.
- 158. Teale offered his assistance in helping the Nevyas' employees to select the appropriate continuing education courses for their particular specialty. Teale told the Nevyas office managers that the Nevyas Eye Associates' employees should sign up for and take as many of the free e-learning continuing education courses as soon as possible.
- 159. After meeting with the Nevyas' office managers, Teale gave a presentation to approximately 35 to 40 members of the staff of the Nevyas Eye Associates. During that presentation, Teale spoke at length about the importance of customer service, and ways to deliver excellent customer service, including, but not limited to information on how the front desk staff should answer phone calls and greet and handle patients.
- 160. Following the presentation to the staff of Nevyas Eye Associates, Teale spoke privately with Relators for approximately one hour in the conference room of the office building complex of Nevyas Eye Associates.
- 161. Teale talked at length about the bench marking assistance that Allergan could provide to the Relators. Teale said that he could help their practice generate reports and help them benchmark their practice versus other Ophthalmological practices across the United States. The benchmarking included many different areas, including coding benchmarking, revenue benchmarking, overhead costs benchmarking, and benchmarking the number of staff the Relators have in their offices compared to other practices across the Country.

- 162. Teale also proposed that the Relators arrange a dinner for local Optometrists, and that during this meeting Teale would give a detailed lecture on business advisory and consulting issues. In particular, Teale said that his lecture would cover how to effectively manage a successful optometric practice.
- 163. Teale further told Relators that they, not Teale, should invite the Optometrists to the dinner meeting, which was tentatively scheduled for December 8, 2009, so that the Optometrists would understand that Relators were the ones responsible for arranging the valuable, free business advisory and consulting services. Teale stated that proceeding in this manner would allow Allergan to help Relators expand and strengthen their Optometric referral network.
- 164. Teale also stated that, in addition to the December 8, 2009 meeting, Allergan could provide other business advisory services to Relators' referring Optometrists. In particular, Teale said that Allergan would provide billing and coding assistance and answers to the Relators' referring Optometrists, so long as the optometrists first called Relators with the questions.
- and coding questions to Teale and to the "Ask the Expert" section of the *Allergan Access* website. Teale explained that Relators could then pass back to the Optometrists the answers to their billing and coding questions. Teal emphasized that the purpose of giving Optometrists business advisory services in this manner was so that Allergan could help Relators build and strengthen their own referrals from Optometrists.

- 166. 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.
- 167. Teale also gave Relators advice on a number of additional issues. For example, Teale gave Relators a script on the best way to terminate an employee. Teale also gave Relators advice on how to reduce the amount of overtime they are paying to employees. Teale also gave Relators advice on how to restructure job responsibilities within their office to handle the departure of a management employee.
- 168. Relator Nevyas-Wallace stated during the meeting that she really did not know much about the business side of running a practice, to which Teale responded that he and John Pinto are available to help Dr. Nevyas-Wallace at any time.
- 169. Teale emphasized that none of the Eye Care Business Advisory services he was providing, or that was available on the *Allergan Access* website, would be possible without the financial support from Allergan, and also would not be possible without Relators supporting Allergan.
- 170. 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. Teale also said that if there is a choice between comparable products that Relators should show their appreciation to Allergan for the business advisory services by choosing the Allergan product.
- 171. Teale also stated that he was the sole breadwinner in his family, and that he wanted to keep his job, and he would personally appreciate it if Relators would show

their appreciation for the valuable business advisory services by prescribing Allergan products.

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

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

- 173. On January 19, 2010, Allergan Senior Eye Care Business Advisor Bob Teale gave a presentation to a group of approximately 30 Optometrists who refer patients to Relators' Ophthalmology practice, Nevyas Eye Associates. The meeting took place at The Tavern, a restaurant located in Bala Cynwyd, Pennsylvania.
- 174. Teale had suggested, during his meeting with Relators on October 12, 2009, making this presentation to allow Allergan to help Relators expand and strengthen their Optometric referral network. Although this meeting had been tentatively scheduled for December 8, 2009, it was ultimately rescheduled for January 19, 2010.
- Optometrists on the topic of What You Should Know About Managing an Optometric Practice. 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 the correct number of employees, and benchmarking your Optometric practice.

- 176. Allergan did not charge Relators, or any of the attending Optometrists, for the valuable business advisory presentation made by Allergan Senior Eye Care Business Advisor Bob Teale on January 19, 2010.
- 177. Following the presentation, Teale emailed Relator Nevyas-Wallace, thanking her for the opportunity to speak to Relators' referring Optometrists. Teale stated "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"
- Nevyas-Wallace received an email from Allergan's Territory Sales Manager Matt Schlegel. In that email, Schlegel stated, in relevant part: "The purpose of this email is to follow-up on last night's OD diner 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."
- 179. In his January 20, 2010 email, 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. Schlegel further stated that: "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."
- 180. On January 27, 2010, Relator Nevyas-Wallace emailed Teale to accept his offer to speak again at a meeting of Optometrists who might refer patients to Nevyas Eye

Associates, scheduled for May 2, 2010. Relator Nevyas-Wallace asked Teale to provide the title of the presentation he would deliver at that meeting.

- 181. On January 29, 2010, Teale emailed Relator Nevyas-Wallace stating that he would present on either of the following subjects, "Optical Shop Enhancement," or "Financial Benchmarking an Optometric Practice." Teale later confirmed that his presentation would last approximately 45 minutes.
- 182. Due to an apparent family vacation, Bob Teale later told Relator Nevyas-Wallace that he would be unable to deliver his presentation to the referring Optometrists on May 2, 2010. Teale stated that he would, however, be interested at speaking at a future meeting.

5. Allergan Territory Sales Manager Schlegel Asks Relators to Invite their Referring Optometrists to a Free Business Advisory Meeting

- 183. On April 19, 2010, Relator Nevyas-Wallace received an email from Allergan Territory Sales Manager Matthew Schlegel regarding a free business advisory meeting for Optometrists only that Allergan had scheduled for April 28, 2010.
- 184. In his April 19th email, Schlegel stated: "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."
- 185. The invitation attached to Schlegel's email states "You are cordially invited to attend an Allergan Practice Management Training Session." According to the

invitation, the Training Session, entitled "Things to Know When Managing an Optometric Practice," includes such topics as: "Clinical Operations Tips (Flow and Efficiency);" "Maximizing the ROI [Return on Investment] from your most valuable resource;" "Financial Benchmarks;" and "Customer Service."

- 186. 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.
- 187. Neither the invitation, nor Schlegel's April 19th email to Relator Nevyas-Wallace, stated that those Optometrists who attended the Practice Management Training Session and accompanying dinner would be required to pay a fee. Instead, it appears that the Practice Management Training Session and dinner were offered to Relators' referring Optometrists free-of-charge.

6. Teale Provides Relators with Free Financial and Web Site Analysis and Advice

- 188. On or about April 28, 2010, Teale met with Relators in the office of Nevyas Eye Associates in Bala Cynwyd, Pennsylvania.
- 189. During that meeting, Teale reviewed with Relators a detailed excel spreadsheet entitled "Monthly Benchmarking Report Nevyas Eye Associates Bala (2)."
- 190. The "Monthly Benchmarking" spreadsheet, which was prepared by Teale using one of the benchmarking templates included on the *Allergan Access* website, provided Relators with a comprehensive report on the financial health of the main office of their Ophthalmological practice. 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."

- 191. During the meeting on or about April 28, 2010, Teale explained in detail the excel spreadsheet he had prepared for Relators, and Teale offered recommendations to Relators for improving the financial performance of their Ophthalmological practice.
- 192. Allergan, and its employee Teale, provided the comprehensive "Monthly Benchmarking" report, financial analysis and advice to Relators free-of-charge.
- 193. During the meeting, on or about April 28, 2010, Teale also presented Relators with a 68-paged document entitled "Web Site Assessment Prepared for: Nevyas Eye, Anita Nevyas-Wallace, M.D., Herbert Nevyas, M.D., Nevyas.com."
- 194. According to the introduction of the "Web Site Assessment: "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."
- 195. During the meeting on or about April 28, 2010, Teale explained in detail the "Web Site Assessment," and he offered recommendations for improvements to the Relators' web site in order to optimize the marketing of their Ophthalmological practice.
- 196. Allergan, and its employee Teale, provided the "Web Site Assessment," analysis and advice to Relators free-of-charge.

- 5. The Free Business Advisory Services Allergan Provides to Ophthalmologists and Optometrists Through its Eye Care Business Advisory Group Constitute an Illegal Kickback
- 197. Allergan has stated publicly that its business is manufacturing and selling pharmaceuticals, biologics and medical devices.
- 198. Allergan is not, and does not claim to be, in the business of providing practice management and business advisory services "that bring a sustainable competitive advantage" to Ophthalmologists and Optometrists.
- 199. Nonetheless, since at least 2002, Allergan has provided valuable practice management and business advisory services to Ophthalmologists and Optometrists across the country through the Allergan Eye Care Business Advisor Group. These valuable practice management and business advisory services include, but are not limited to, the services that Allergan's Eye Care Business Advisor Teale provided to Realtors and their Ophthalmology practice.
- 200. Allergan provides these valuable practice management and business advisory services to Ophthalmologists and Optometrists free of charge.
- 201. Allergan provides these free practice management and business advisory services to Ophthalmologists and Optometrists who decide, on a daily basis, whether or not to prescribe Allergan products to their patients.
- 202. Allergan's revenue from its Eye Care Pharmaceutical Product Line depends heavily upon Ophthalmologists and Optometrists deciding to prescribe Allergan products to their patients.
- 203. Allergan knowingly and willfully offers and provides these valuable practice management and business advisory services to Ophthalmologists and

Optometrists free of charge to induce them to prescribe Allergan products to their patients.

- 204. Allergan's purpose in providing these illegal financial inducements was clearly exemplified by Allergan's Senior Eye Care Business Advisor, when he told Relator, on October 12, 2009, that he wanted Relators to show their appreciation for the valuable business advisory services that Allergan provided to them by prescribing Allergan products.
- 205. Prescribing Ophthalmologists and Optometrists who received Allergan's illegal inducements directed referrals of patients in federally-funded health care programs to Allergan's products in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) and similar state anti-kickback laws.

(b) Allergan Offers Valuable Kickbacks to Ophthalmologists and Optometrists Through its Restricted Website, Allergan Access

- 206. *Allergan Access*, is an Allergan restricted, members-only website, with the internet address of www.bsmconsulting.com/allergan-eye.
- 207. Allergan's Territory Sales 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 selected for membership in the *Allergan Access* program.
- 208. Allergan provides select physicians, through *Allergan Access*, with a unique, valuable online suite of practice management tools and resources developed specifically for ophthalmology practices, including, but not limited to:
 - Physician recruiting and contracting guidance, manuals, and contract templates;

- Sophisticated financial analysis and benchmarking assessment tools, and guidance manuals;
- Employee and human resources manuals and forms;
- Sophisticated payer evaluation and benchmarking tools;
- Payer contracting resources;
- Detailed print, radio, television and internet marketing materials and manuals, including complete marketing campaigns;
- Complete roster of 65 free online continuing education courses;
- Medicare Part D information;
- Patient education materials;
- Free on-demand coding and billing assistance (through the "Ask the Expert" feature of the website offered with the assistance of The Corcoran Group);
- Practice Feasibility Analyzers;
- Clinical Operations Resources; and
- Optical Shop Tools and Resources.
- 209. According to the *Allergan Access* website, it provides the selected eye care professionals with an "online suite of practice management tools and resources developed specifically for ophthalmology practices."
- 210. Allergan restricts membership in the *Allergan Access* website to those Ophthalmologists whom Allergan alone selects to have the privilege of using this extraordinary, valuable suite of practice management tools and resources.

1. Allergan Retained the BSM Consulting Group to Develop the Allergan Access Website

- 211. Allergan retained the BSM Consulting Group, headquartered in Nevada, to develop, maintain, and operate the *Allergan Access* website.
- 212. The *Allergan Access* website for eye care professionals has been operating since late 2002 or early 2003.
- 213. According to the BSM website, since 1978 BSM has continually furnished expert assistance to an ever-expanding list of clients in the health care industry, earning an international reputation as one of the foremost health care consulting firms. BSM helps its clients cope with the financial, operations and strategic challenges of a dramatically changing market.
- 214. BSM claims that its clients benefit from the services of retained consultants who specialize in the development of client media projects (from written materials to audio/visual projects), certified public accountants who provide support in the financial areas of practice valuation, trend analysis, financial benchmarking, and human resource management.
- 215. BSM also provides its clients with extensive support through technology services dedicated to Internet web design. BSM claims to be one of the nation's leading eye care consulting firms and they specialize in the application of eLearning technology to management and training programs for health care professionals.
- 216. In addition to *the Allergan Access* website aimed at eye care professionals, BSM has developed other specialty-specific interactive *Allergan Access* websites including: medical aesthetics, dermatology (no longer available as of 2009); bariatric; future focus: and a separate website for its European operations.

2. Allergan Marketing Representatives Offer Relators Membership in the Restricted Allergan Access Website

- 217. Allergan's Territory Sales Manager Pete Pecoraro stated to Relator Nevyas-Wallace, on March 26, 2009, that Allergan frequently turned physicians away who requested to partake in *Allergan Access* and that there were already too many physicians using *Allergan Access*.
- 218. Teale informed Relator Nevyas-Wallace, on September 18, 2009, that there are approximately 1,500 physicians across the United States who have been enrolled in the "special program" which gives them access to the valuable business advisory services included on the *Allergan Access* website.
- 219. Relators were invited by Allergan, through its employees Matthew Schlegel (Allergan Territory Sales Manager), Peter Pecoraro (Allergan Territory Sales Manager) and Bob Teale (Allergan Senior Eye Care Business Advisor) to become members of the *Allergan Access* website.
- 220. Relators became members of the *Allergan Access* website on or about September 3, 2009. Relators paid one fee of \$895 to activate both of their memberships in the *Allergan Access* website.
 - 3. The Allergan Access Website is an Illegal Kickback Because Allergan Provides Referring Physicians with Valuable Services Which Far Exceed the \$895 Membership Fee
- 221. The *Allergan Access* website provides the physicians selected by Allergan with comprehensive consulting and advisory services that are worth far more than the \$895 annual membership fee for access to the *Allergan Access* website.
- 222. Allergan, upon information and belief, also offers membership in, and/or access to the resources of, the *Allergan Access* website to select Optometrists. On

September 18, 2009, Allergan Senior Eye Care Business Advisor Bob Teale told Relators that Allergan would provide billing and coding assistance and answers, through the "Ask-the-Expert section of the *Allergan Access* website, to the Relators' referring Optometrists, so long as the optometrists first called Relators with the questions.

- 223. Physicians' practices across the United States spend substantial sums of money, far greater than \$895, for access to the comprehensive expert practice management and sophisticated financial tools, guidance, and resources provided by Allergan to select physicians, via the *Allergan Access* website.
- 224. The fair market value of either the free continuing education courses, or the on-demand expert billing and coding assistance (through the "Ask-the-Expert" feature), alone exceeds the nominal \$895 fee paid by those physicians selected by Allergan for membership in *Allergan Access*.
- 225. The fair market value of the all of the comprehensive services offered on Allergan Access, including, but not limited to: sophisticated financial management and benchmarking tools, payer management and benchmarking tools, human resource tools, physician recruitment tools and contracts, customizable media campaigns, on-demand expert billing and coding answers, and comprehensive on-line continuing education courses, far exceeds the \$895 fee paid by those physicians selected by Allergan for membership in *Allergan Access*.
- 226. One of the many consultants who provide the expert advisory content and services through the *Allergan Access* network, The Corcoran Consulting Group, normally charges ophthalmology practices an hourly rate of \$280 per hour for its services, billable in one-tenth of an hour increments. The hourly rate for the founder of The Corcoran

Consulting Group, Kevin Corcoran, is even higher than \$280 per hour. The Corcoran Consulting Group provides expert answers to billing and coding questions submitted through the "Ask-The-Expert" Section of the *Allergan Access* website.

- 227. Another of the many consultants who provide the expert advisory content and services through the *Allergan Access* network, J. Pinto & Associates, normally charges ophthalmology practices an hourly rate of \$295 per hour for its services, and requires new clients to provide an upfront retainer of \$5,000. If travel is required, J. Pinto & Associates normally charges clients \$2,950 per day, plus all travel expenses.
- 228. Allergan's own marketing and business advisory representatives confirmed to Relators that the extraordinary value of the tools and resources included within the *Allergan Access* website far exceeds the nominal \$895 fee paid by those top physicians granted membership in *Allergan Access*.
- 229. On March 26, 2009, Allergan's Territory 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 office can get free continuing education credits on *Allergan Access*, and that by using this feature alone, physicians would quickly recoup their \$895 investment.
- 230. The statements by Allergan's Territory Sales Manager Pecoraro were confirmed by Allergan in an article published on the *Allergan Access* website, entitled ""Case Study: Maximizing Use of the Allergan Access eLearning Center." This article features a case study regarding the use of the eLearning feature of the *Allergan Access* website by Pacific EyeCare of Poulsbo, a 51-employee ophthalmology practice in Washington State. According to the article, Pacific EyeCare first subscribed to the

Allergan Access website on June 1, 2004. The article details how Pacific EyeCare benefitted from the eLearning courses on the Allergan Access website. In particular, the article states that Pacific EyeCare staff had completed 411 eLearning Courses in first ten months of 2006 alone. Moreover, the article states that "[o]n the Allergan Access website, the eLearning Center is without question the most popular feature." This article demonstrates the frequency with which physicians utilize the eLearning feature of Allergan Access, and confirms the statements that Allergan's Territory Sales Manager Pecoraro made to Relators.

231. Allergan further confirmed to Relator Nevyas-Wallace, on September 18, 2009 and October 12, 2009, 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. Teale further stated, on October 12, 2009, that the business advisory services provided on the Allergan Access website, also would not be possible without Relators supporting Allergan, and using Allergan products.

4. Overview of the Highly Valuable Business Services that Allergan Provides to Physicians in the Allergan Access Website

232. The *Allergan Access* website is organized into the following main topic sections, each with multiple subparts and subpages containing detailed information, tools, and resources: eLearning Overview; Student Registration; Student Login; Administrator's Tools; Staff Certification; Course Listing; Ask the Expert; Quick Reference Guides; Glossary of Terms; Articles; Surveys; Professional Links; Marketing; Practice Websites; Patient Education; Patient Newsletters; Financial Management; Staff Management; Clinical Operations; Optical Services; MD Recruitment; Payer Contracting; Medicare Part D; Cataract; Dry Eye; Glaucoma; and Aesthetic Services.

(a) "Ask The Expert" Section of Allergan Access

- 233. In the "Ask-The-Expert" area of the *Allergan Access* website, members are provided on-demand access to answers to their billing and coding questions from The Corcoran Consulting Group, renowned eye care practice management consultants.
- 234. The "Ask the Expert" feature allows members to ask billing and coding questions using the "Submit Question" form. The instructions state that the member's questions will be "reviewed and answered by a member of our team of experts within 5 to 7 business days."
- 235. The "Ask-The-Expert" Section of the Allergan Access website also provides members with an archive of over 2,100 billing and coding questions and answers from the Corcoran Consulting Group.
- 236. According to their website, the Corcoran Group is a practice management consulting firm specializing in reimbursement issues for ophthalmology and optometry.
- 237. The Corcoran Group's operations span the United States, with offices located in South Carolina, Georgia, Ohio, Pennsylvania, Texas, and with the headquarters located in San Bernardino, California.
- 238. For physicians who are not selected by Allergan for membership in the Allergan Access website, which includes unlimited access to advice from the Corcoran Group, the Corcoran Group provides billing and coding advice on the open-market for a substantial fee. According to its website and consulting agreement, the Corcoran Group charges approximately \$280 per hour in increments of 0.1 hours, for these types of consulting services.

239. Upon information and belief, the fair market value of the "Ask-the-Expert" feature alone with its on-demand answers from renowned experts in ophthalmological billing and coding issues, far exceeds the nominal \$895 fee paid by physicians who are specially selected by Allergan to join Allergan Access.

(b) "E-Learning" Section of Allergan Access

- 240. In the "E-Learning" Section of the Allergan Access website, members have unlimited access to continuing education courses in a wide range of subjects through Allergan's eLearning Library.
- 241. Allergan has arranged the continuing education classes in the *Allergan*Access eLearning Library as "modules" related to areas of learning, which include:
 - CCE-accredited Management Training;
 - JCAHPO-accredited Technician Training;
 - Staff training;
 - ABO-Accredited Optician Training; and
 - Business Office Training.
- 242. Each module contains the course description, class materials, an on-line examination which is immediately graded, and upon successful completion, the appropriate certification of continuing education credit.
- 243. Until it abruptly changed the *Allergan Access* website on April 1, 2010, Allergan provided approximately 65 continuing education courses (which are frequently updated) to its top practices including, but not limited to, JCAHPO-(Joint Commission on Allied Health Personnel in Ophthalmology) accredited courses for technicians.

- 244. The eLearning modules in the subject of "JCAHPO-accredited Technician Training" include courses on such topics as: Administrative/Practice Management; Glaucoma; Ophthalmic Knowledge; Ophthalmic Skills/Instruments: Ultrasound; Ophthalmic Skills/Instruments: Contact Lenses; Refractive and Cataract Surgery; Cornea; Ocular/Systemic Disease; Surgical: General; and Retina.
- 245. The eLearning modules in the subject of "Business Office Training" include courses on such topics 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.
- 246. Other on-line education courses for ophthalmic technicians can cost hundreds of dollars for each course. Allergan, however, provides its select, top-physicians, with unlimited access to a comprehensive catalogue of continuing education courses as part of the membership in the *Allergan Access* website.

(c) "Financial Management" Section of Allergan Access

- 247. In the area "Financial Management," the *Allergan Access* website provides its members with comprehensive practice management guidance, including, but not limited to:
 - Practice Financial Health Assessments,
 - Accounts Receivable Analytical Tools and Guides,
 - Accounts Receivable Self Assessment Tools,
 - Training Guides,
 - Budget Tools,
 - Sophisticated Financial Benchmarking Tools and Reports,

- Financial Management Tools,
- Feasibility Analyzer Tools,
- a Business Office Policy and Procedure Manual, and
- Financial Assessment and Management Articles.
- 248. The "Financial Management" section of the *Allergan Access* website, under the subheading "Financial Management Benchmarking Report Templates," also provides members with the following interactive "Financial Management Benchmarking Report Templates": Clinic: Three-Year Historical Benchmarking Report; Clinic: Monthly Benchmarking Report; ASC: Three-Year Historical Benchmarking Report; ASC: Monthly Benchmarking Report; Optical: Monthly Benchmarking Report. These financial benchmarking reports allow physicians to input their own practice's financial information; generate detailed financial reports; and compare or benchmark the financial performance of their practice versus other physicians' practices nationwide.
- 249. The "Financial Management" section of the Allergan Access website, under the subheading "Financial Management Tools," also provides members with the following interactive tools: Provider Scheduler Analysis; Accounts Receivable Management Report; Provider Productivity Reports; and Patient Visit Summary and Coding Analysis by Provider.
- 250. The "Accounts Receivable Management Report" analyzes monthly gross charges, adjustments, collections, and accounts receivable aging information, and compares results to industry benchmarks. The Patient Visit Summary and Coding Analysis tracks office visits and coding patterns by provider for all new and established patients, and compares the results to CMS Utilization Data.

(d) "Payer Contracting" Section of Allergan Access

- 251. In the area of "Payer Contracting" the *Allergan Access* website also provides its members with sophisticated payer management tools and payer evaluation tools, including, but not limited to:
 - Evaluating Payer Contracting Training Guide,
 - Payer Contract Analyzer Tools,
 - Payer Fee Request Form,
 - Checklist for Evaluating Payer Performance, and
 - Related Articles.
- 252. The "Payer Contracting" section of the Allergan Access website, under the subheading " Payer Analyzer Tools" contains the following statement: "The Payer Contract Analyzer is designed to allow you to compare payment rates on your third-party contracts against Medicare reimbursement levels. The report also provides a comparison of collections by CPT code for the individual payers you are evaluating."

(e) "MD Recruitment" Section of Allergan Access

- 253. In the area of "MD Recruitment," the *Allergan Access* website provides its members with sophisticated physician recruiting and contracting guides and tools, including:
 - Physician Recruitment Self-Assessment Tools,
 - Recruitment and Contracting Training Guides,
 - Feasibility Assessment Tools,
 - Contract Details,
 - Transition Details,

- Online Job Fair, and
- Recruitment Articles.
- 254. The "MD Recruitment" section of the *Allergan Access* website also provides members with template employment agreements, template confidentiality agreements, and detailed guidance and manuals regarding the physician recruiting, contracting, and integration process.

(f) "Staff Management" Section of Allergan Access

- 255. In the area of "Staff Management," the *Allergan Access* website provides its members with comprehensive employee and human resource guidance and advice, including, but not limited to:
 - Human Resources Self-Assessment,
 - Training Guides,
 - Sample Recruitment Forms,
 - Employee Orientation Forms,
 - Job Descriptions,
 - Work Performance Review Forms,
 - Prototype Employee Policy and Procedure Manual,
 - Employee Satisfaction Program,
 - Employee Counseling Forms,
 - Other Personnel Forms, and
 - Related Articles.
- 256. The "Staff Management" section of the Allergan Access website, under the subheading "Other Personnel Forms," also provides members with the following

forms created by Allergan Access to help physicians obtain and document staff personnel files: Confidential Employee Data Form; Direct Deposit Sign-Up Form; Employee Paid Time Off Record; Employee Wage and Benefits Statement; Extended Leave Request; Payroll Status Change; Time Off Request; and Time Sheet.

(g) "Marketing" Section of Allergan Access

- 257. In the area of "Marketing," the *Allergan Access* website provides its members with comprehensive marketing campaigns, strategies and advice, including, but not limited to:
 - Marketing Overview
 - Self Assessment Tool,
 - Marketing Plan,
 - Marketing Budget,
 - Tracking Reports,
 - Staff Management (including job descriptions),
 - Direct Mail (Pre-printer, customizable campaigns),
 - Sample Ads (Pre-printed, customizable print ads)
 - Radio Advertising (Campaigns and Scripts),
 - Patient Correspondence, and
 - Related Articles.
- 258. The "Marketing" section of the Allergan Access website, under the subheading "Tracking Reports," also provides members with sophisticated tracking reports that can be used to check the progress of various marketing initiatives, including:

 Telephone Lead Tracking Reports/General Inquiries, Telephone Lead Tracking

Reports/Specific Marketing Campaigns, Cost per Lead Analysis, General Inquiries, and Cost per Lead Analysis/Specific Marketing Campaign.

259. The "Marketing" section of the Allergan Access website also provides members with marketing tools and pre-printed, customizable marketing campaigns tailored to specific patient markets, including: dry eye; glaucoma; cataract; and aesthetic services.

(h) "Clinical Operations" Section of Allergan Access

- 260. In the area of "Clinical Operations," the *Allergan Access* website provides its members with comprehensive practice management tools and guidance, including, but not limited to:
 - Patient Flow and Efficiency Self-Assessment,
 - Patient Satisfaction Program,
 - Patient Scheduling Methods,
 - Scheduling Tips and Recommendations,
 - Scheduling Assessment Tool,
 - Flow and Efficiency Red Flags,
 - Flow and Efficiency Benchmarks,
 - Template Patient Forms, and
 - Related Articles.
- 261. The "Clinical Operations" section of the Allergan Access website, under the subheading "Template Patient Forms," also provides members with various patient forms, including: Authorization and Consent Forms, Clinical Chart Forms, and Patient Letters.

(i) "Optical Services" Section of Allergan Access

- 262. In the Optical Services area, the *Allergan Access* website provides its members with sophisticated optical practice management and benchmarking tools and guidance, including, but not limited to:
 - Optical Services Self-Assessment Tools,
 - Optical Benchmarking Report Templates,
 - Patient Forms,
 - Optical Patient Satisfaction Programs,
 - Clinical Referral Techniques,
 - Optical Management Reports,
 - Links to Related Websites, and
 - Related Articles.

(j) "Dry-Eye" Section of Allergan Access

- 263. In the area of "Dry Eye," the *Allergan Access* website provides its members with comprehensive marketing campaigns, strategies and advice to build a successful dry-eye practice, including, but not limited to:
 - Staff Training Tools,
 - Patient Recall Program (with guidance manuals and marketing scripts),
 - Patient Satisfaction Survey,
 - Patient Seminars,
 - Patient Forms,
 - Billing Guidance, and

- Marketing Materials (including pre-printed, customizable campaigns).
- 264. The "Dry Eye" section of the Allergan Access website provides members with a comprehensive Dry Eye Recall Program Manual, which recommends that physicians, as part of their recall program, conduct a computer search of their patient database to patients with the following "ICD-9" codes, or diagnosis codes: 375.15 Tear Film Insufficiency, Unspecified Dry Eye Syndrome; 370.33 Keratoconjunctivitis Sicca, Not Specified as Sjorgen's; and 710.2 Sicca Syndrome Keratoconjunctivitis Sicca Sjorgen's.
- 265. Allergan's encouragement and support for physicians to build a successful "Dry Eye" practice directly and substantially benefits Allergan because, as discussed above, Allergan's product Restasis® is the first and currently the only prescription therapy approved in the United States for the treatment of chronic dry eye. Restasis® is also Allergan's top selling pharmaceutical product.

(k) "Cataract" Section of Allergan Access

- 266. In the area of "Cataract," the *Allergan Access* website provides its members with comprehensive marketing campaigns, strategies and advice to build a successful cataract practice, including, but not limited to:
 - Financial tools,
 - Marketing,
 - Patient Education,
 - Co-management,
 - Clinical Operations,
 - Chart Forms,

- Staff Training,
- Patient Counseling, and
- Related Links.

(l) Additional Resources for Allergan Access Members

- 267. Through the *Allergan Access* website, the selected eye care professionals also have access to the consulting firm of J. Pinto & Associates.
- 268. According to its website, J. Pinto & Associates is a health management consulting firm, located in San Diego, California.
- 269. J. Pinto & Associates has, for the past 15 years, focused nearly exclusively on ophthalmic practices, ranging from modest solo practices to high-volume LASIK and cataract market leaders and teaching centers. The company website boasts that the owner, John Pinto, "take[s] pride in turning around ophthalmology practices and in helping ambitious refractive and cataract surgeons build practices of distinction."
- 270. J. Pinto & Associates works with ophthalmology practices across the United States with annual "run rates" ranging from under \$1 million to \$80 million.
- 271. J. Pinto & Associates normally charges ophthalmology practices an hourly rate of \$295 per hour for its consulting services, and requires new clients to provide an upfront retainer fee of \$5,000. If travel to the client's offices is required, J. Pinto & Associates charges clients \$2,950 per day, plus its travel expenses.
- 272. Relator Nevyas contacted J. Pinto & Associates, in approximately 2000, to inquire about retaining them to provide consulting services to Nevyas Eye Associates.

 Relator 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.

5. Allergan's Abruptly Discontinued Key Sections of the *Allergan Access* Website After it Received a Government Subpoena

- 273. On February 18, 2010, Relators Herbert Nevyas and Anita Nevyas-Wallace received an email from Allergan's Senior Eye Care Business Advisor Bob Teale informing them that, effective April 1, 2010, Allergan would be discontinuing the following sections of the Allergan Access website: all eLearning courses that offer continuing education (CE) credit; support or answer certain subject matter via the "Ask the Expert" tool; and some human resource (HR) material.
- 274. The three sections of the Allergan Access website that Allergan decided to abruptly discontinue, with a little more than 30 days notice, provided the 1,500 physician members with valuable billing, coding, and human resource tools and guidance, and a full suite of on-line continuing education courses. The value of these three sections of the Allergan Access website alone far exceeded the \$895 fee that physicians paid for access to this entire restricted website.
- 275. Allergan's stated explanation for its decision to abruptly discontinue these three valuable sections of the Allergan Access website was: "The updated PhRMA Code on Interactions with Healthcare Professionals that took effect in January 2009 prompted Allergan to review many aspects of our pharmaceutical business, which included the ECBA [Eye Care Business Advisory] program."
- 276. Allergan, therefore, claims that it decided to discontinue these three valuable sections of the *Allergan Access* website, with a little more than 30 days notice, based solely upon the PhRMA Code II, which took effect more than one year earlier.

- 277. Allergan failed to mention in its February 18, 2010 email announcement from Bob Teale that, approximately one month earlier, Allergan received a subpoena from a state Attorney General questioning the Allergan Access website, including, but not limited to: the creation, content, and marketing of the website; and the fair market value of the tools, guidance and services offered to physicians on that website.
- 278. On March 24, 2010, Relator Nevyas received an email from Bruce S. Maller, President and CEO of BSM Consulting. Maller's email, which is addressed "Dear Allergan Access Member," states, in relevant part:

"You recently received a letter from Joe Schultz, Senior Vice President of Allergan U.S. Eye Care about the transition of certain content, including eLearning courses and Ask the Expert to a new BSM managed website. We are pleased to introduce you to BSM ConnectionTM for Ophthalmology, which will be launched on April 1, 2010.

The transition to BSM *Connection*TM for Ophthalmology should be seamless. We have retained your existing username and password, as well as the usernames and passwords for all employees in your practice who are registered as students in our eLearning Center.

As Joe mentioned, effective April 1, and until the expiration of your current Allergan *Access*[®] membership, you will have access to the new BSM *Connection*TM website. For a period of 60 days following the expiration of your current membership you will have an opportunity to purchase an annual subscription to BSM *Connection*TM for Ophthalmology for a "one time" special price of \$695. Effective April 1, the annual membership price for new subscribers will be \$995.

279. On September 1, 2010, Relator Nevyas received an email letter from Allergan's Senior Eye Care Business Advisor Bob Teale regarding Nevyas' subscription to the *Allergan Access* website. In that email, which was addressed "Dear Allergan Access Member," Teale states:

Effective April 1, 2010 we launched a new Allergan *Access*® practice management program. The new program offers a comprehensive package of practice management tools and business consulting services that can be tailored to meet your needs. As part of the new program, I would conduct a more in-depth needs assessment in order to identify and prioritize key areas of opportunity and determine the types of services that best meet your needs.

The annual fee for this program is \$695. This fee covers my time to support implementation of the basic package of services. For most customers this will include completion of the initial practice assessment, staff training, and implementation of one or more practice management programs, such as our online patient satisfaction survey and website assessment programs.

- 280. Effective April 1, 2010, the *Allergan Access* website is no longer located at the web address <u>www.bsmconsulting.com/allergan-eye</u>, as it had been since approximately 2002. Since April 1, 2010, the *Allergan Access* website has moved to a new web address, <u>www.allerganaccess.com</u>, which was created on or about March 2, 2010. The web address <u>www.allerganacces.com</u> is registered to Defendant Allergan.
- 281. Although Allergan has moved Allergan Access to a new web address, it continues to retain BSM Consulting to develop and manage the *Allergan Access* website.
- 282. As a result of the changes to *Allergan Access* abruptly announced by Allergan on February 18, 2010, *Allergan Access* members will, in the future, be required to pay between \$1,390 and \$1,690 to receive the same business advisory services they received, since approximately 2002, for a nominal fee of \$895.
- 283. Ophthalmologists, including Relators, could not obtain the same valuable business acroisory and practice management services provided by Allergan, the through Allergan Access website, for \$1,690, let alone the nominal \$895 fee charged between 2002 and April 2010.

- 284. Moreover, Allergan Eye Care Business Advisor Teale told Relators, on September 18, 2009 and October 12, 2009, 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.
- 285. Allergan has, since 2002, provided these valuable business advisory and practice management services to Ophthalmologists and Optometrists to induce them to prescribe Allergan products to their patients, and thereby generating substantial sales revenue for Allergan.

(c) Allergan Offers Kickbacks to Physicians Through its Speakers' Bureau

- 286. On Tuesday, May 12, 2009, Relator Nevyas-Wallace met with Allergan Territory Sales Manager Matthew Schlegel in the office of Nevyas Eye Associates in Bala Cynwyd, Pennsylvania.
- 287. During this meeting, Allergan's Territory Sales Manager Schlegel offered that Dr. Nevyas Wallace could become a member of Allergan's Speakers Bureau.
- 288. Schlegel told Dr. Nevyas Wallace on May 12th that she would have to negotiate with Allergan the amount of reimbursement that she would receive for being a member of the Speakers' Bureau. In addition, she would have to tell Allergan how often she wanted to speak.
- 289. During this same meeting, Schlegel told Dr. 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."
- 290. Defendant's offer to place Dr. Nevyas-Wallace on Allergan's paid speakerpanel if she were "a really good writer of prescriptions," indicates that Allergan uses its

speaker panel as one form of financial inducement to physicians for prescribing Allergan products.

291. On June 25, 2009, Relator Nevyas Wallace attended an Allergan Dry Eye Dinner meeting. During this meeting, Dr. Brandon Ayres, a member of Allergan's Speakers' Bureau, told Relator Nevyas-Wallace that he usually gives speeches a few times a month for the Allergan Speakers' Bureau, but that Allergan would like him to do them constantly. Dr. Ayres stated that Allergan pays him \$1,000 per speech. Dr. Ayres revealed, however, that the fees paid to Allergan's Speakers' Bureau members vary greatly depending on the speaker and associated travel. Dr. Ayres told Dr. Nevyas-Wallace that she would have to negotiate with Allergan for her compensation.

(d) Additional Inducements Allergan has Offered to Relators

- (1) Allergan Offers Kickbacks to Ophthalmologists Through its Sponsored Meetings and Dinners
- 292. On or about June 8, 2009 Relators received an invitation to 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.
- 293. On July 30, 2009, Relator Nevyas received an email on behalf of Allergan confirming his attendance at the August 21-22, 2009 Regional Advisory Board meeting. Attached to Dr. Nevyas' confirmation were many email confirmations addressed to other eye care professionals regarding a May 8-9, 2009 Regional Advisory Board meeting, which was also to be held at The Benjamin, New York City.
- 294. These eye care professionals, whom Allergan had invited to the May 8-9, 2009 Advisory Board Meeting, were, upon information and belief, from large-volume ophthalmology practices across the Eastern and into the Midwest United States,

including: Florida; Georgia; Maryland; New Jersey; New York; Ohio; Pennsylvania; Tennessee; and Virginia.

295. The terms for each attendee to the May 8-9, 2009 Regional Advisory Board Meeting were identical to the Relators' terms for the August 21-22, 2009 event: Allergan would provide each attendee with round-trip transportation (air travel, Amtrak ACELA, etc.), one night's hotel accommodation at The Benjamin, and meals throughout the program. In addition, each attendee will receive a \$1,000 consultant fee and a \$150 travel stipend.

296. Relators attended the August 21-22, 2009 Advisory Board meeting, which Allergan held at The Benjamin, a luxury hotel located in the heart of Manhattan, where room rates begin at \$599 per night.

297. The agenda for the Regional Advisory Board Meeting was as follows:

Friday, August 21	7:00-9:00	Welcome Reception
Saturday, August 22	7:30-8:00 8:00-12:30 12:30-1:30	Breakfast General Session Lunch and Departures

- 298. According to a Participant List distributed at the beginning of the Advisory Board Meeting, the approximately 22 eye care professionals (physicians) who attended or participated were eye care professionals from the following states: Connecticut; Florida; Maryland; New Jersey; New York; Ohio; Pennsylvania; Tennessee.
- 299. When the Relators arrived in New York, they received an Allergan Master Consulting Agreement for their execution. Upon information and belief, each attendee at the Regional Advisory Group Meeting executed the same Allergan Master Consultant Consulting Agreement presented to the Relators.

- 300. Allergan's Master Consulting Agreement stated that, in exchange for the compensation received, the consultant shall "give Allergan feedback and insight regarding NSAIDs and the current ophthalmic anti-inflammatory market."
- 301. In keeping with representations made during the earlier June 25, 2009 Dry Eye Dinner by Allergan's Territory Sales Manager Schlegel, Allergan representatives at the August 2009 Advisory Board Meeting spent substantial time 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.
- 302. Allergan hosted the eye care professionals at its Regional Advisory Board meeting, at least in part, to induce them to prescribe Allergan's products.

(2) Allergan's Offer to Fund Independent Research for its Top Prescribers

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

B. <u>Allergan's Inducements Violate the Federal and State Anti-Kickback Statutes</u>

- 305. Allergan has, as described above, knowingly engaged in a sustained, multi-faceted campaign to provide financial remuneration to Ophthalmologists and Optometrists in order to induce them to prescribe and recommend Allergan products, in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) and similar state anti-kickback laws.
- 306. Allergan's illegal financial inducements to Ophthalmologists and Optometrists, as described in more detail above, include:
 - A. Free on-demand, expert business advisory services, offered through Allergan's nationwide network of Eye Care Business Advisors;
 - B. Membership in the *Allergan Access* website, which provides physicians selected by Allergan with comprehensive, expert financial, reimbursement, consulting and advisory services the fair-market-value of which far exceeds the nominal \$895 annual membership fee for access to that exclusive website; and
 - C. Membership in Allergan's lucrative speaker's bureau, which is reserved for those physicians who are "really good writers of prescriptions.".
- 307. Allergan has provided, and continues to provide, these illegal, valuable financial remunerations to physicians across the United States, to induce and/or reward those physicians to prescribe Allergan products to their patients, including patients insured by Medicare, Medicaid, and other federal and state health care programs.
- 308. Allergan's purpose in providing these illegal financial inducements was clearly exemplified by Allergan's Senior Eye Care Business Advisor, when he told

Relator, on October 12, 2009, that he wanted Relators to show their appreciation for the valuable business advisory services that Allergan provided to them by prescribing Allergan products.

309. Prescribing Ophthalmologists and Optometrists who received Allergan's illegal inducements directed referrals of patients in federally-funded health care programs to Allergan's products in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) and similar state anti-kickback laws.

C. Allergan Caused the Submission of False or Fraudulent Claims to Federal And State Health Insurance Programs

- 310. As described above, Allergan, between at least 2002 to the present, knowingly violated the federal Anti-Kickback Statute and similar state anti-kickback laws.
- 311. When Allergan intentionally decided to employ these illegal kickbacks to promote their Eye Care Pharmaceutical Product Line, it knew or should have known that pharmacists and physicians would routinely and necessarily file false and fraudulent claims with the federal government and state governments when they sought federal and state reimbursement for Allergan's eye care pharmaceutical products.
- 312. Medicaid and Medicare claims for the payment of Allergan's eye care pharmaceutical products induced by illegal kickbacks are submitted to the United States and/or the States by the pharmacists who fill the patients' prescriptions. In most or all cases, the pharmacist does not know whether the prescription has been induced by a kickback. Nonetheless, because such prescriptions are not eligible for federal or state reimbursement, submission of such a claim for reimbursement constitutes a false or fraudulent claim under the federal False Claims Act, 31 U.S.C. § 3729, and the States'

analogous false claims statutes. And, those who knowingly cause such false or fraudulent claims to be filed, as Allergan has through its illegal kickback practices, are liable under the federal False Claims Act, 31 U.S.C. § 3729, and the States' analogous false claims statutes.

- 313. Allergan knew that kickback-induced prescriptions were not eligible for federal and state health care program reimbursement. Notwithstanding its knowledge that prescriptions for Allergan's eye care pharmaceutical products induced by kickbacks were not eligible for federal and state reimbursement, Allergan knowingly undertook such illegal kickback practices to increase the prescription of its eye care pharmaceutical products.
- 314. Allergan's illegal kickbacks caused the submission of false or fraudulent claims to federal and state health insurance plans.
- 315. Allergan substantially benefitted from all of the false and fraudulent claims described herein.
- 316. Each prescription that was written as a result of Defendant's illegal inducements represents a false or fraudulent record or statement. And, each claim for reimbursement for illegally induced prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment, in violation of the Federal False Claims Act and analogous State False Claims statutes.
- 317. Claims that arise from Allergan's kickback scheme are false, and violate the False Claims Act, because they are the result of a kickback no further express or implied false statement is required to render such infected or tainted claims false, and none can wash the claim clean.

- 318. Although no express or implied false statement is required, claims infected or tainted by Allergan's illegal kickbacks do contain false statements of compliance with the Anti-Kickback statute. In particular, a party that submits a claim for payment to Medicare or Medicaid impliedly certifies compliance with all conditions of payment, i.e., that it is properly payable. As discussed above, a condition of payment of any claim submitted to Medicare or Medicaid is that the claim did not result from a financial transaction that violated the Anti-Kickback Statute. Consequently, Allergan's payment of kickbacks to induce Ophthalmologists to prescribe Allergan's eye care pharmaceutical products (including *Restasis*) renders false the submitter's implied or express certification of compliance that resulting claim complies with the requirements of the Anti-Kickback Statute.
- 319. The submission of false claims was not only foreseeable, but an intended result of Allergan's illegal kickbacks.

Count I Federal False Claims Act 31 U.S. C. §§ 3729(a)(1) and (a)(2)

- 320. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 319 of this Second Amended Complaint.
- 321. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S. C. § 3729, et seq., as amended.
- 322. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

- 323. By virtue of the acts described above, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Government to approve or pay such false and fraudulent claims.
- 324. Allergan provided illegal remuneration to prescribing eye care professionals to induce improper referrals for Defendant's ophthalmic prescription drugs to beneficiaries of federally-funded health care programs in violation of the federal Anti-Kickback Statute.
- 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 no further express or implied false statement is required to render such infected claims false, and none can wash the claim clean.
- 326. Defendant's violations of the federal Anti-kickback Statute give rise to liability under the federal False Claims Act.
- 327. Defendant violated the federal False Claims Act by submitting, or causing to be submitted, claims for reimbursement from federal health care programs, including Medicare and Medicaid, knowing that those claims were ineligible for the payments demanded due to federal Anti-Kickback Statute violations associated with illegal remuneration paid to prescribing eye care professionals.
- 328. Each prescription that was written as a result of the Defendant's illegal inducements represents a false or fraudulent record or statement.
- 329. Each claim for reimbursement for illegally induced prescriptions submitted to a federal health insurance program represents a false or fraudulent claim for payment.

- 330. Relators cannot at this time identify all of the false claims for payment that were caused by Defendant's conduct. The false claims were presented by thousands of separate entities, across the United States, and over many years. Relators have no control over, or dealings with, such entities and have no access to the records in their possession.
- 331. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by defendant, paid and continues to pay the claims that are non-payable as a result of Defendant's illegal kickbacks, and therefore false under this federal FCA.
- 332. By reason of the Defendant's acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Federal health insurance programs have paid many thousands of claims, amounting to many hundreds of millions of dollars, for prescriptions that were illegally induced by Defendant.
- 333. All of the Defendant's conduct described in this Second Amended Complaint was knowing, as that term is used in the federal False Claims Act.

Count II California False Claims Act Cal Govt Code § 12651(a)(1) and (2)

- 334. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 333 of this Second Amended Qui Tam Complaint.
- 335. This is a claim for treble damages and penalties under the California False Claims Act.
- 336. By virtue of the acts described above, the Defendant has violated and continues to violate California laws prohibiting the payment or receipt of bribes or

kickbacks, namely Cal Bus. & Prof. Code § 650, Cal. Welfare & inst. Code § 14107.2, and Cal. Health & Safety Code § 445.

- 337. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.
- 338. By virtue of the acts described above, Defendant knowingly made, used or caused to be made or uses false records and statements, and omitted material facts, to induce the California State Government to approve or pay such false and fraudulent claims.
- 339. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continued to pay the claims that are non-payable as a result of the Defendant's illegal inducements.
- 340. By reason of the Defendant's acts, the State of California has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.
- 341. The State of California is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

Count III Delaware False Claims and Reporting Act 6 Del C. § 1201(a)(1) and (2)

342. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 341 of this Second Amended Qui Tam Complaint.

- 343. This is a claim for treble damages and penalties under the Delaware False Claims and Reporting Act.
- 344. By virtue of the acts described above, the Defendant has violated and continues to violate Delaware law prohibiting the payment or receipt of bribes or kickbacks, namely Del. Code Ann. tit. 31 §§ 1005, 1007, and 1008.
- 345. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.
- 346. By virtue of the acts described above, Defendant knowingly made, used or caused to be made or uses false records and statements, and omitted material facts, to induce the Delaware State Government to approve or pay such false and fraudulent claims.
- 347. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continued to pay the claims that are non-payable as a result of Defendant's illegal inducements.
- 348. By reason of the Defendant's acts, the State of Delaware has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.
- 349. The State of Delaware is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

Count IV Florida False Claims Act Fla. Stat. Ann. § 68.082(2)

- 350. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 349 of this Second Amended Qui Tam Complaint.
- 351. This is a claim for treble damages and penalties under the Florida False Claims Act, Fla. Stat. § 68.082(2)
- 352. By virtue of the acts described above, Defendant has violated and continues to violate Florida law prohibiting the payment or receipt of bribes or kickbacks, namely Fla. Stat. §456.054 and Fla. Stat. § 409.920.
- 353. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.
- 354. By virtue of the acts described above, Defendant knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Florida State Government to approve or pay such false and fraudulent claims.
- 355. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendants, paid and continues to pay the claims that are non-payable as a result of Defendant's illegal inducements.
- 356. By reason of the defendant's acts, the State of Florida has been damaged, and continued to be damaged, in a substantial amount to be determined at trial.

357. The State of Florida is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

Count V Illinois Whistleblower Reward and Protection Act 740 Ill. Comp. Stat. § 175/3(a)(1) and (2)

- 358. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 357 of this Second Amended Qui Tam Complaint.
- 359. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward and Protection Act.
- 360. By virtue of the acts described above, Defendants has violated and continues to violate the 305 ILCS 5/8A-3(b) of the Illinois Public Aid Code (Vendor Fraud and Kickbacks).
- 361. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.
- 362. By virtue of the acts described above, Defendant knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Illinois State Government to approve or pay such false and fraudulent claims.
- 363. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by Defendant, paid and continues to pay the claims that are non-payable as a result of Defendant's illegal inducements.

- 364. By reason of the Defendant's acts, the State of Illinois has been damaged, and continued to be damaged, in a substantial amount to be determined at trial.
- 365. The State of Illinois is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

Count VI Indiana False Claims and Whistleblower Protection Act IC 5-11-5.5-2(b)(1), (2), and (8)

- 366. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 365 of this Second Amended Qui Tam Complaint.
- 367. By virtue of the acts described above, Defendant has violated and continues to violate Indiana law prohibiting the payment or receipt of bribes or kickbacks, namely Ind. Code §12-15-24-2.
- 368. This is a claim for treble damages and penalties under the Indiana False Claims and Whistleblower Protection Act.
- 369. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.
- 370. By virtue of the acts described above, Defendant knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Indiana State Government to approve or pay such false and fraudulent claims.
- 371. By virtue of the acts described above, Defendant knowingly caused or induced another person to perform an act described in IC 5-11-5.5-2(b)(1) and/or (2).

- 372. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendant, paid and continues to pay the claims that are non-payable as a result of the Defendant's illegal inducements.
- 373. By reason of the defendant's acts, the State of Indiana has been damaged, and continued to be damaged, in a substantial amount to be determined at trial.
- 374. The State of Indiana is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

Count VII

Louisiana Medical Assistance Programs Integrity Law La. Rev. Stat. Ann. § 46:439.1-4, 46:440.1-4

- 375. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 374 of this Second Amended Qui Tam Complaint.
- 376. By virtue of the acts described above, the Defendant has violated and continues to violate Louisiana law prohibiting the payment or receipt of bribes or kickbacks, namely La. Rev. Stat. Ann. §37.1745.
- 377. This is a claim for treble damages and penalties under the Louisiana Medical Assistance Programs Integrity Law.
- 378. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.
- 379. By virtue of the acts described above, Defendant knowingly made, used or caused to be made or used false records and statements, and omitted material facts to

induce the Louisiana State Government to approve or pay such false and fraudulent claims.

- 380. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendant, paid and continues to pay the claims that are non-payable as a result of Defendant's illegal inducements.
- 381. By reason of the defendant; acts, the State of Louisiana has been damaged, and continued to be damaged, in a substantial amount to be determined at trial.
- 382. The State of Louisiana is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

Count VIII Massachusetts False Claims Act Mass. Gen. Laws ch. 12 § 5B(1) and (2)

- 383. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 382 of this Second Amended Qui Tam Complaint.
- 384. By virtue of the acts described above, the Defendant has violated and continues to violate Massachusetts law prohibiting the payment or receipt of bribes or kickbacks, namely Mass. Gen. Laws Ch. 175H, §3.
- 385. This is a claim for treble damages and penalties under the Massachusetts False Claims Act.
- 386. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Commonwealth of Massachusetts for payment or approval.

- 387. By virtue of the acts described above, Defendant knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Commonwealth of Massachusetts to approve or pay such false and fraudulent claims.
- 388. The Commonwealth of Massachusetts, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendant, paid and continues to pay the claims are non-payable as a result of Defendant's illegal inducements.
- 389. By reason of the defendant's acts, the Commonwealth of Massachusetts has been damaged, and continued to be damaged, in a substantial amount to be determined at trial.
- 390. The Commonwealth of Massachusetts is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

Count IX Michigan Medicaid False Claim Act M.C.L. §400.603, 400.606, and 400.607

- 391. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 390 of this Second Amended Qui Tam Complaint.
- 392. By virtue of the acts described above, the Defendant has violated and continues to violate Michigan law prohibiting the payment or receipt of bribes or kickbacks, namely Mich. Comp. Laws §752.1004.
- 393. This is a claim for treble damages and penalties under the Michigan Medicaid False Claim Act.

- 394. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Michigan State Government for payment or approval.
- 395. By virtue of the acts described above, Defendant knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Michigan State Government to approve or pay such false and fraudulent claims.
- 396. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendant, paid and continues to pay the claims that are non-payable as a result of Defendant's illegal inducements.
- 397. By reason of the defendant's acts, the State of Michigan has been damaged, and continued to be damaged, in a substantial amount to be determined at trial.
- 398. The State of Michigan is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

Count X Montana False Claims Act Mont. Code Ann. § 17-8-403(1) and (2)

- 399. Relators reallege and incorporate by reference the allegations contained in paragraphs I through 398 of this Second Amended Qui Tam Complaint.
- 400. By virtue of the acts described above, the Defendant has violated and continues to violate Montana law prohibiting the payment or receipt of bribes or kickbacks, namely Montana Code Ann. §45-6-313.

401. This is a claim for treble damages and penalties under the Montana False

Claims Act.

402. By virtue of the acts described above, defendant knowingly presented or

caused to be presented, false or fraudulent claims to the Montana State Government for

payment or approval.

403. By virtue of the acts described above, Defendant knowingly made, used or

caused to be made or used false records and statements, and omitted material facts to

induce the Montana State Government to approve or pay such false and fraudulent

claims.

404. The Montana State Government, unaware of the falsity of the records,

statements and claims made, used, presented or caused to be presented by defendant, paid

and continues to pay the claims are non-payable as a result of Defendant's illegal

inducements.

405. By reason of the defendant's acts, the State of Montana has been damaged,

and continued to be damaged, in a substantial amount to be determined at trial.

406. The State of Montana is entitled to the maximum penalty of \$11,000 for

each and every false or fraudulent claim, record or statement made, used, presented or

caused to be made, used or presented by Defendant.

Count XI

Nevada False Claims Act

Nev. Rev. Stat. Ann. § 357.040.1(a) and (b)

407. Relators reallege and incorporate by reference the allegations contained in

paragraphs 1 through 406 of this Second Amended Qui Tam Complaint.

- 408. This is a claim for treble damages and penalties under the Nevada False Claims Act.
- 409. By virtue of the acts described above, the Defendant has violated and continues to violate Nevada law prohibiting the payment or receipt of bribes or kickbacks, namely Nev. Rev. Stat. §191.905.
- 410. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.
- 411. By virtue of the acts described above, Defendant knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Nevada State Government to approve or pay such false and fraudulent claims.
- 412. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendant, paid and continues to pay the claims that are non-payable as a result of Defendant's illegal inducements.
- 413. By reason of the defendant's acts, the State of Nevada has been damaged, and continued to be damaged, in a substantial amount to be determined at trial.
- 414. The State of Nevada is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

Count XII New Hampshire False Claims Act N.H. Rev. Stat. Ann. §167:61-b.1(a) and (b)

- 415. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 414 of this Second Amended Qui Tam Complaint.
- 416. This is a claim for treble damages and penalties under the New Hampshire False Claims Act.
- 417. By virtue of the acts described above, the Defendant has violated and continues to violate New Hampshire law prohibiting the payment or receipt of bribes or kickbacks, namely N.H. Rev. Stat. Ann. §167:61-a.
- 418. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the New Hampshire State Government for payment or approval.
- 419. By virtue of the acts described above, Defendant knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the New Hampshire State Government to approve or pay such false and fraudulent claims.
- 420. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendant, paid and continues to pay the claims that are non-payable as a result of Defendant's illegal inducements.
- 421. By reason of the Defendant's acts, the State of New Hampshire has been damaged, and continued to be damaged, in a substantial amount to be determined at trial.

422. The State of New Hampshire is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

Count XIII New Jersey False Claims Act N.J. Stat. Ann. § 2A:32C-3(a) and (b)

- 423. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 422 of this Second Amended Qui Tam Complaint.
- 424. This is a claim for treble damages and penalties under the New Jersey False Claims Act.
- 425. By virtue of the acts described above, defendant has violated and continues to violate the New Jersey Anti-Kickback Statute, N.J.S.A.§ 30:40D-17.
- 426. By virtue of the acts described above, defendant knowingly presented or caused to be presented, false or fraudulent claims to the New Jersey State Government for payment or approval.
- 427. By virtue of the acts described above, Defendant knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the New Jersey State Government to approve or pay such false and fraudulent claims.
- 428. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendant, paid and continues to pay the claims that are non-payable as a result of Defendant's illegal inducements.

- 429. By reason of the defendant's acts, the State of New Jersey has been damaged, and continued to be damaged, in a substantial amount to be determined at trial.
- 430. The State of New Jersey is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

Count XIV New Mexico Medicaid False Claims Act N.M. Stat. Ann. § 27-14-4A and C.

- 431. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 430 of this Second Amended Qui Tam Complaint.
- 432. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act.
- 433. By virtue of the acts described above, the Defendant has violated and continues to violate New Mexico law prohibiting the payment or receipt of bribes or kickbacks, namely N.M. Stat. Ann. §30-44-7.
- 434. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.
- 435. By virtue of the acts described above, Defendant knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the New Mexico State Government to approve or pay such false and fraudulent claims.
- 436. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendant, paid

and continues to pay the claims that are non-payable as a result of Defendant's illegal inducements.

- 437. By reason of the Defendant's acts, the State of New Mexico has been damaged, and continued to be damaged, in a substantial amount to be determined at trial.
- 438. The State of New Mexico is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

Count XV New York False Claims Act N.Y. State Fin. Law § 189.1(a) and (b)

- 439. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 438 of this Second Amended Qui Tam Complaint.
- 440. This is a claim for treble damages and penalties under the New York False Claims Act.
- 441. By virtue of the acts described above, the Defendant has violated and continues to violate New York law prohibiting the payment or receipt of bribes or kickbacks, namely N.Y. Soc. Serv. Law §366-d.
- 442. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval.
- 443. By virtue of the acts described above, Defendant knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the New York State Government to approve or pay such false and fraudulent claims.

- 444. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by Defendant, paid and continues to pay the claims that are non-payable as a result of Defendant's illegal inducements.
- 445. By reason of the Defendant's acts, the State of New York has been damaged, and continued to be damaged, in a substantial amount to be determined at trial.
- 446. The State of New York is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

Count XVI Oklahoma Medicaid False Claims Act Okla. Stat. tit. 63 §5053.11 et seq.

- 447. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 446 of this Second Amended Qui Tam Complaint.
- 448. This is a claim for treble damages and penalties under the Oklahoma Medicaid False Claims Act.
- 449. By virtue of the acts described above, the Defendant has violated and continues to violate Oklahoma law prohibiting the payment or receipt of bribes or kickbacks, namely Okla. Stat. tit. 56, §§1005-1006.
- 450. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval.
- 451. By virtue of the acts described above, Defendant knowingly made, used or caused to be made or used false records and statements, and omitted material facts to

induce the Oklahoma State Government to approve or pay such false and fraudulent claims.

- 452. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendant, paid and continues to pay the claims that are non-payable as a result of Defendant's illegal inducements.
- 453. By reason of the Defendant's acts, the State of Oklahoma has been damaged, and continued to be damaged, in a substantial amount to be determined at trial.
- 454. The State of Oklahoma is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

Count XVII Rhode Island False Claims Act R.I. Gen. Laws § 9-1.1-3(a)(1) and (2)

- 455. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 454 of this Second Amended Qui Tam Complaint.
- 456. This is a claim for treble damages and penalties under the Rhode Island False Claims Act.
- 457. By virtue of the acts described above, the Defendant has violated and continues to violate Rhode Island law prohibiting the payment or receipt of bribes or kickbacks, namely R.I. Gen Laws § 5-48.1-3; R.I. Gen. Laws § 40-8.2-3.
- 458. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Rhode Island State Government for payment or approval.

- 459. By virtue of the acts described above, Defendant knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Rhode Island State Government to approve or pay such false and fraudulent claims.
- 460. The Rhode Island State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendant, paid and continues to pay the claims that are non-payable as a result of Defendant's illegal inducements.
- 461. By reason of the Defendant's acts, the State of Rhode Island has been damaged, and continued to be damaged, in a substantial amount to be determined at trial.
- 462. The State of Rhode Island is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

<u>Count XVIII</u> Texas Medicaid Fraud Prevention Act Tex. Hum. Res. Code Ann. § 36.002(1), (2), (4) B and (7)

- 463. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 462 of this Second Amended Qui Tam Complaint.
- 464. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Act.
- 465. By virtue of the acts described above, the Defendant has violated and continues to violate Texas law prohibiting the payment or receipt of bribes or kickbacks, namely Tex. Occ. Code Ann. §102.001.

- 466. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.
- 467. By virtue of the acts described above, Defendant knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Texas State Government to approve or pay such false and fraudulent claims.
- 468. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendant, paid and continues to pay the claims that are non-payable as a result of Defendant's illegal inducements.
- 469. By reason of the Defendant's acts, the State of Texas has been damaged, and continued to be damaged, in a substantial amount to be determined at trial.
- 470. The State of Texas is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

Count XIX Virginia Fraud Against Taxpayers Act Va. Code Ann. § 8.01-216.3A.1 and 2

- 471. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 470 of this Second Amended Qui Tam Complaint.
- 472. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

- 473. By virtue of the acts described above, the Defendant has violated and continues to violate Virginia law prohibiting the payment or receipt of bribes or kickbacks, namely Va. Code Ann. § 26-20-4 and § 26-20-9.
- 474. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Commonwealth of Virginia for payment or approval.
- 475. By virtue of the acts described above, Defendant knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Commonwealth of Virginia to approve or pay such false and fraudulent claims.
- 476. The Commonwealth of Virginia, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendant, paid and continues to pay the claims that are non-payable as a result of Defendant's illegal inducements.
- 477. By reason of the Defendant's acts, the Commonwealth of Virginia has been damaged, and continued to be damaged, in a substantial amount to be determined at trial.
- 478. The Commonwealth of Virginia is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

Count XX Wisconsin False Claims for Medical Assistance Act 121 Wis. Stat. § 20.931

- 479. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 478 of this Second Amended Qui Tam Complaint.
- 480. This is a claim for treble damages and penalties under the Wisconsin False Claims for Medical Assistance Act.
- 481. By virtue of the acts described above, the Defendant has violated and continues to violate Wisconsin law prohibiting the payment or receipt of bribes or kickbacks, namely W.S.A. § 49.49(2).
- 482. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Wisconsin State Government for payment or approval.
- 483. By virtue of the acts described above, Defendant knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the Wisconsin State Government to approve or pay such false and fraudulent claims.
- 484. The Wisconsin State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendant, paid and continues to pay the claims that are non-payable as a result of Defendant's illegal inducements.
- 485. By reason of the Defendant's acts, the State of Wisconsin has been damaged, and continued to be damaged, in a substantial amount to be determined at trial.

486. The State of Wisconsin is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

Count XXI District of Columbia Procurement Reform Amendment Act D.C. Code Ann. § 2-308.14 (a)(1) and (2)

- 487. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 486 of this Second Amended Qui Tam Complaint.
- 488. This is a claim for treble damages and penalties under the District of Columbia Procurement Reform Amendment Act.
- 489. By virtue of the acts described above, the Defendant has violated and continues to violate the law of the District of Columbia prohibiting the payment or receipt of bribes or kickbacks, namely D.C. Code Ann. § 4-802.
- 490. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.
- 491. By virtue of the acts described above, Defendant knowingly made, used or caused to be made or used false records and statements, and omitted material facts to induce the District of Columbia Government to approve or pay such false and fraudulent claims.
- 492. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by defendant, paid and continues to pay the claims that are non-payable as a result of Defendant's illegal inducements.

- 493. By reason of the Defendant's acts, the District of Columbia has been damaged, and continued to be damaged, in a substantial amount to be determined at trial.
- 494. The District of Columbia is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

Prayer

WHEREFORE, qui tam Plaintiffs pray for judgment against the Defendant as follows:

- that Defendant ceases and desists from violating 31 U.S. C. § 3729 et seq.,
 and the equivalent provisions of the States and the District of Columbia's statutes as set forth above;
- 2. that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the United States has sustained because of Defendant's actions, plus a civil penalty of not less than \$5,000 and not more than \$11,000 for each violation of 31 U.S.C. § 3729;
- 3. that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of California has sustained because of Defendant's actions, plus a civil penalty of \$10,000 for each violation of Cal. Govt Code § 1265(a);
- 4. that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Delaware has sustained because of Defendant's actions, plus a civil penalty of \$11,000 for each violation of 6 Del. C. § 1201(a);

- 5. that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Florida has sustained because of Defendant's actions, plus a civil penalty of \$10,000 for each violation of Fla. Stat. Ann. § 68.082(2);
- 6. that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Illinois has sustained because of Defendant's actions, plus a civil penalty of \$10,000 for each violation of 740 Ill. Comp. Stat. § 175/3(a);
- 7. that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Indiana has sustained because of Defendant's actions, plus a civil penalty of \$10,000 for each violation of IC § 5-11-5.5-2(b);
- 8. that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Louisiana has sustained because of Defendant's actions, plus a civil penalty of \$10,000 for each violation of La. Rev. Stat. Ann. §§ 46:439.1-4 and 46:440.1-4;
- 9. that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the Commonwealth of Massachusetts has sustained because of Defendant's actions, plus a civil penalty of \$10,000 for each violation of Mass. Gen. L. Ch. 12 § 5B;
- 10. that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Michigan has sustained because of

Defendant's actions, plus a civil penalty of \$10,000 for each violation of M.C.L. §§ 400.603, 400.606, and 400.607

- that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Montana has sustained because of Defendant's actions, plus a civil penalty of \$10,000 for each violation of Mont. Code Ann. § 17-8-403(1) and (2);
- 12. that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Nevada has sustained because of Defendant's actions, plus a civil penalty of \$10,000 for each violation of Nev. Rev. Stat. Ann. § 357.040(1)(a), (b);
- 13. that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of New Hampshire has sustained because of Defendant's actions, plus civil penalties for each violation of N.H. Rev. Stat. Ann. §167:61-b.1(a) and (b);
- that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of New Jersey has sustained because of Defendant's actions, plus civil penalties for each violation of N.J. Stat. Ann. § 2A:32C-3(a) and (b);
- 15. that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of New Mexico has sustained because of Defendant's actions, plus civil penalties for each violation of N.M. Stat. Ann. § 27-14-4A and C [N.M. Stat. Ann. § 27-2F-4];

- 16. that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of New York has sustained because of Defendant's actions, plus civil penalties of \$12,000 for each violation of N.Y. State Fin. § 189.1;
- that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of Defendant's actions, plus a civil penalty of \$10,000 for each violation of Okla. Stat. tit. 63 §5053.11 et seq.
- 18. that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Rhode Island has sustained because of Defendant's actions, plus a civil penalty of \$10,000 for each violation of R.I. Gen. Laws § 9-1.1-3(a)(1) and (2);
- 19. that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Texas has sustained because of Defendant's actions, plus a civil penalty of \$10,000 for each violation of Tex. Hum. Res. Code Ann. § 36.002(1), (2), (4) B and (7);
- 20. that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the Commonwealth of Virginia has sustained because of Defendant's actions, plus a civil penalty of \$10,000 for each violation of Va. Code Ann. § 8.01-216.3A.1 and 2;
- 21. that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Wisconsin has sustained because of

Defendant's actions, plus a civil penalty of \$10,000 for each violation of 121 Wis. Stat. § 20.931;

- that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the District of Columbia has sustained because of Defendant's actions, plus a civil penalty of \$10,000 for each violation of D.C. Code Ann. § 2-308.14(a)(1)and (2);
- 23. that <u>qui tam</u> Plaintiffs be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act, and the equivalent provisions of the States and District of Columbia statutes set forth above;
- 24. that <u>qui</u> <u>tam</u> Plaintiffs be awarded all costs of this action, including attorneys' fees and expenses; and
- 25. that all Plaintiffs recover such other relief as the Court deems just and proper.

Demand for Jury Trial

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, qui tam Plaintiffs hereby demand a trial by jury.

PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP

By:_

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Dated: September 23, 2010