

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	
ex rel. DONALD R. GALMINES,	:	
	:	
BRINGING THIS ACTION ON BEHALF	:	
OF THE UNITED STATES OF AMERICA	:	
THE STATES OF HAWAII, ILLINOIS,	:	Civil Action No. 06-3213
INDIANA, LOUISIANA, MICHIGAN,	:	
TENNESSEE, and THE COMMONWEALTHS	:	
OF MASSACHUSETTS AND VIRGINIA,	:	Judge Gene E.K. Pratter
	:	
Plaintiffs and Relator,	:	
	:	
v.	:	
	:	
NOVARTIS PHARMACEUTICALS	:	
CORPORATION,	:	
	:	
Defendant.	:	

**FOURTH AMENDED COMPLAINT FOR VIOLATIONS
OF THE FALSE CLAIMS ACT**

I. INTRODUCTION

1. Qui tam Relator Don Galmines brings this action on his own behalf and on behalf of the United States of America and a number of states to recover damages and penalties under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, against Defendant Novartis Pharmaceuticals Corporation (Novartis). The violations arise out of requests for payment submitted to Medicaid, Medicare, TRICARE, and other federally-funded government healthcare programs for a prescription medication, Elidel[®], which Novartis illegally marketed for use in infants and for other unapproved purposes.

2. This complaint details several related areas of illegal conduct by Novartis which was intended to and did cause submission of millions of false claims in violation of the False Claims Act. These claims include fraudulent schemes by Novartis to increase the market share of one of its prescription drug products by means of an aggressive campaign to promote its prescription topical immunomodulator cream, Elidel[®], for off-label use in the treatment of children under the age of two, for first-line use, and for chronic use. The Complaint also alleges that false claims to state Medicaid programs resulted from violations of the anti-kickback provisions of the State False Claims Acts of Michigan, Virginia, Illinois, Indiana, Massachusetts and Louisiana.

3. This amended complaint varies from the Third Amended Complaint only in the addition of details regarding the continuation of Novartis's off-label marketing through at least April 2009 and the continuation of its false claims to state Medicaid programs due to violations of anti-kickback statutes through at least mid-2007.

II. JURISDICTION AND VENUE

4. This action arises under 31 U.S.C. § 3729 *et seq.*, commonly known as the False Claims Act.

5. This court has subject-matter jurisdiction pursuant to 31 U.S.C. § 3732 (a) and 28 U.S.C. § 1331, and has personal jurisdiction over the defendant because the defendant does business in and with the Eastern District of Pennsylvania.

6. Venue lies under 28 U.S.C. 1391 (b) and (c) and 31 U.S.C. 3732 (a) because Novartis operates and transacts business within this district and many of the facts forming the basis of this Complaint occurred within said district.

7. Relator also brings this action on behalf of several states and the Commonwealths of Massachusetts and Virginia under their respective *qui tam* state laws. These laws are the Hawaii False Claims Act, HRS 661-21 *et seq.*; the Illinois Whistleblower Reward and Protection Act, 740 ILCS. §175/1-8; the Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5; the Louisiana Medical Assistance Programs Integrity Law, RS 46.437.1 *et seq.*; the Massachusetts False Claims Law, Mass Gen. Laws ch. 12, § 5A-O; the Michigan Medicaid False Claims Act, MCL 400.601 *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code 71-5-181 *et seq.*; and the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.* Jurisdiction over these state-law-based claims is predicated upon 28 U.S.C. § 1367(a) and 31 U.S.C. § 3732(b), and, as the Court deems appropriate, the doctrine of pendent jurisdiction.

8. The facts and circumstances which give rise to Novartis's violations of the False Claims Act have not been publicly disclosed in a criminal, civil, or administrative hearing, nor in any congressional, administrative, or General Accounting Office report, hearing, audit, or investigation, nor in the news media.

9. Relator is the original source of the information upon which this complaint is based, as that phrase is used in the False Claims Act and other laws at issue herein.

10. Relator provided disclosure of the allegations of this matter to the United States, and the States of California, Florida, Hawaii, Illinois, Indiana, Louisiana, Michigan, Nevada, Texas, and Tennessee, the Commonwealths of Massachusetts and Virginia, and the District of Columbia prior to the filing.

10(a). On or about July 5, 2006, counsel for relator spoke personally with Assistant United States Attorney Kathleen Meriwether, Esq., who at the time was an Assistant United States Attorney serving in the Office of the United States Attorney for the Eastern District of Pennsylvania with cognizance over False Claims Act matters involving defendant Novartis, provided her with an overview of the facts to be alleged in this matter, and offered to make Relator Donald Galmines available for an in-person or telephonic interview prior to the filing of the complaint.

10(b). On July 13, 2006, relator, by counsel, sent by electronic mail a factually-complete draft of the complaint to Ms. Meriwether, confirming that a False Claims Act action was to be filed regarding those facts and offering to provide any requested additional information.

10(c). Relator also provided disclosure of the allegations of this matter to all affected States prior to the filing of the complaint.

10(d). On July 17, 2006, relator, by counsel, sent by electronic mail a factually-complete draft of the complaint, together with a letter explaining that the information was being provided as a pre-filing *qui tam* disclosure, to appropriate representatives of the States of California, Florida, Hawaii, Illinois, Indiana, Louisiana, Michigan, and Tennessee, and the Commonwealths of Massachusetts and Virginia. Assistant United States Attorney Meriwether also was sent that July 17, 2006, electronic mail message.

10(e). On July 20, 2006, relator, by counsel, sent by electronic mail a factually-complete draft of the complaint to appropriate representatives of the State of Nevada and the District of Columbia.

III. PARTIES

11. The real parties in interest to the claims set forth herein are the United States of America, and the States of Hawaii, Illinois, Indiana, Louisiana, Michigan, and Tennessee, and the Commonwealths of Massachusetts and Virginia.

12. Relator Donald R. Galmines is a resident of Illinois and a citizen of the United States. Relator was employed by Novartis as a Senior Sales Consultant in its Dermatology/Respiratory Division from April 2001 through May, 2006. Throughout his career at Novartis, Relator was involved extensively in the marketing and sales of Elidel[®], which was launched by Novartis in early 2002. Mr. Galmines was “District MVP” in 2001 and 2003.

13. Defendant Novartis is a division of Novartis AG, a global pharmaceutical company created in 1996 from the merger of two Swiss companies, CIBA-Geigy AG and Sandoz AG. Novartis AG is headquartered in Basel, Switzerland, has operations in over 140 countries around the world, and employs approximately 81,000 people. Novartis’s United States operations are headquartered in East Hanover, New Jersey.

IV. THE REGULATORY ENVIRONMENT

A. THE REGULATION OF PRESCRIPTION DRUG SALES AND MARKETING ACTIVITIES IN THE UNITED STATES

14. The United States Food, Drug and Cosmetic Act (FDCA) establishes the framework for regulation of, *inter alia*, the sales and marketing activities of pharmaceutical manufacturers in the United States, including the introduction of new drugs into interstate commerce.

15. Under the FDCA, new drugs cannot be distributed into interstate commerce unless and until the manufacturer has demonstrated to the Food and Drug Administration (FDA) that the drug is safe and effective for each of its intended uses, and the FDA has approved the drug to be sold for those uses. 21 U.S.C. § 355 (a) and (d).

16. While the “medical practice exception” allows an individual physician to prescribe a drug for a use other than one for which it is approved, the FDA prohibits a drug manufacturer from marketing or promoting a drug for non-approved uses. 21 U.S.C. § 331(d), 355(a). Consistent therewith, a drug manufacturer’s sales representatives are prohibited from initiating discussions with medical professionals regarding any off-label use of the drug. While physicians may prescribe a drug for unapproved uses, the FDCA prohibits drug manufacturers from marketing to physicians and other health-care professionals for such purposes.

17. The dissemination of information or materials by a pharmaceutical manufacturer of any unapproved or off-label use constitutes unlawful promotional advertising or misbranding of the drug and violates the FDCA.

18. Reasons for the prohibition of off-label marketing and promotion by drug manufacturers include, without limitation, the following: (1) off-label promotion diminishes or eliminates the drug manufacturer’s incentive to study the use of its drug and obtain definitive safety and efficacy data; (2) off-label promotion harms patients as the result of unstudied uses that lead to adverse results, or are ineffective; (3) off-label

promotion diminishes the use of evidenced-based medicine; and (4) such promotion erodes the efficacy standard in medicine.

B. Omitted

19. Omitted

20. Omitted

21. Omitted

22. Omitted

23. Omitted

C. REIMBURSEMENT CRITERIA USED BY GOVERNMENT-FUNDED HEALTH CARE PROGRAMS

24. The federal government pays for prescription drug benefits under a variety of health care programs. One of these programs is Medicaid, which provides health care coverage, including prescription drug benefits, for the poor and disabled. The Medicaid program, which is administered by the Center for Medicare and Medicaid Services (CMS), is funded in part by the federal government. Other government-funded health care programs that pay for prescription drugs include Medicare, CHAMPUS/Tricare, the Veteran's Health Administration, Federal Employees' Health Benefits Program, and the Indian Health Bureau.

25. While each government-funded health program varies in its reimbursement criteria, none of the programs pay for medications that are not FDA approved, not prescribed for a medically accepted indication, or that are prescribed as a result of false or misleading information disseminated by the pharmaceutical manufacturer. In

addition, none of the government-funded health care programs willingly pay for prescription drugs the prescribing of which was the result of, or was influenced by, unlawful inducements from or unlawful marketing activities by the drug company.

V. ALLEGATIONS OF FACT

A. Atopic Dermatitis

26. Atopic dermatitis (the most common form of a group of diseases known as “eczema”) is a predominately-pediatric remitting-and-relapsing disease, believed to have a significant genetic component, which affects ten to twenty percent of the general population in the United States. “Atopic” indicates that the condition has allergenic features, and “dermatitis” means an inflammation of the skin. The prevalence of the condition increased throughout the twentieth century, with a dramatic increase in prevalence among those born after 1970. An estimated 35,000,000 Americans suffer from atopic dermatitis.

27. The symptoms of atopic dermatitis typically are evident in early childhood, with 65% of patients exhibiting symptoms in their first year and 90% of patients exhibiting symptoms before age five. Lesions typically appear on an infant’s face and scalp and, once the child begins to crawl, lesions are commonly seen on the knees and elbows.

28. Lesions, often called flares, appear to be the result of bacterial infection interacting with the atopic dermatitis.

29. Once lesions appear, “first-line” (preferred) treatment for atopic dermatitis consists of the use of skin emollients and short courses of topical corticosteroids.

B. Elidel®

30. As a consequence of the increasing prevalence of atopic dermatitis in pediatric populations and the real and perceived side-effects of treatment with topical corticosteroids, defendant Novartis developed the drug at issue in this case, Elidel® (pimecrolimus 1% in cream suspension).

31. Pimecrolimus is in a family of drugs known as topical immunomodulators (“TIMs”) because they suppress T cell and mast cell activation, inhibiting inflammatory cytokine release. Cytokines are the neurotransmitters responsible for triggering immune-system responses. Thus their inhibition in turn inhibits the reaction which becomes atopic dermatitis.

32. Novartis sought FDA approval of Elidel® by filing, on or about December 15, 2000, New Drug Application (“NDA”) No. 21-302.

33. NDAs are submitted by drug manufacturers who wish to secure FDA approval of their drugs.

34. FDA approval is a precondition to marketing any drug sold in the United States, and is also a precondition for reimbursement of any drug by Medicare, Medicaid, and all other public-payor health care systems in the United States.

35. In NDA 21-302, Novartis sought approval for the use of Elidel® as a treatment for atopic dermatitis in patients older than three months.

36. FDA promptly advised Novartis that “the NDA is minimally fileable” because studies were ongoing; advised that “[d]evelopment of the drug product during

the review cycle is not the best approach;” and cautioned that “the label that may result may be more restrictive than envisioned.” These admonitions are set out in a February 1, 2001 “Memorandum of Telecon” by FDA Medical Officer Susan Walker, M.D.

37. Dr. Walker further advised Novartis on or about February 1, 2001 that its NDA included “a. incomplete safety and efficacy data to review for ages less than two years (open trials) [and] b. incomplete long term safety data (open trials).”

38. As it studied the Elidel[®] NDA, FDA became concerned with several aspects of the drug’s adverse-effect profile, and especially those related to malignancy.

39. On or about February 15, 2001, FDA directed Novartis to provide information regarding background rates of occurrence for several forms of neoplastic lesions observed in Wistar rat studies of Elidel[®] (Wistar rats are the prevalent rat strain used in animal studies of pharmaceutical products).

40. On or about July 10, 2001, FDA directed Novartis to provide information regarding metastatic carcinoma, thyroid and thymus effects, and follicular cell carcinoma and adenoma observed in mouse and rat studies of Elidel[®].

41. On or about August 8, 2001, FDA directed Novartis to provide “an analysis or discussion regarding the effect of Elidel[®] cream on the developmental immunology of pediatric patients, especially in children <2 years of age” and “an analysis regarding the effect of Elidel[®] on growth velocity in children exposed to the drug, especially in children less than 2 years of age.” FDA also directed Novartis to provide information regarding

the 14 cases of lymphadenopathy (lymph-node swelling) observed in the Elidel[®] clinical trial.

42. The FDA's Medical Review of Elidel[®] concluded that in both double-blind and open-label clinical testing, Elidel[®] exhibited a "poor safety profile in infants." The Medical Review for NDA 21-302 states that "[t]he open-label phase supports the poor safety profile in infants of ASM 1% cream [Elidel[®]], as in most cases, infants who were on ASM 1% cream in the open-label phase who had been on vehicle [placebo] in the double-blind phase began to experience the same, if not higher rate of occurrence of these same adverse events as those who had been on ASM 1% cream in the double-blind phase." In other words, when infants who were tested on placebo were switched to Elidel[®], their rate of adverse side-effects increased.

43. The Medical Review team also concluded that "there is a clear correlation between the increase in these adverse events and the use of ASM 1% cream [Elidel[®]] in infants." The adverse events identified in the Medical Review included, among numerous others, upper respiratory tract infection; nasopharyngitis; otitis media; gastroenteritis; viral upper respiratory infection; pyrexia; teething; diarrhea; and restlessness.

44. The Medical Review concluded: "The increased incidence of systemic infection that occurs in infants over 6 weeks in the ASM 1% [Elidel[®]] arm as compared to vehicle [placebo], along with the increased incidence that is observed over a 6 month period, suggests that the safety profile for ASM 1% cream is sufficiently poor in this population to justify not recommending its use in infants to treat atopic dermatitis."

45. Under the category of “Safety Outcomes,” the Medical Review reiterated that Novartis’s clinical trials “support . . . the position that infants have a significant increase in infection such that in this reviewer’s opinion warrant that ASM 1% cream not be used in this [3-23 month] age group for atopic dermatitis.”

46. The Medical Review team further stated that “subjects in the ASM 1% arm continue to have a greater incidence of adverse events including nasopharyngitis, URIs, otitis media, pyrexia, bronchitis, tonsillitis, influenza, teething, cough, irritability, chickenpox, vomiting, rhinitis, asthma, dermatitis contact, and conjunctivitis. [The data] also demonstrates that there are adverse events that are now statistically significant in their occurrence in infants on ASM 1% cream after use over a 6 months period as compared to vehicle that were not present in the short-term 6 week vehicle controlled trial. These include viral rash (4.4% vs. 0), lower respiratory tract infection [pneumonia (3.9% vs. 0)], eye infection (2.5% vs. 0), pharyngitis 5 (2.5% vs. 0), respiratory tract infection NOS (2.5% vs. 0), toothache (2.9% vs. 0), rhinorrhea (3.9% vs. 0), wheezing (3.9% vs. 0), hypersensitivity (8.3% vs. 2.2%), and irritability (2.5% vs. 0).

47. The Safety Conclusion of the Medical Review is that “[i]nfants treated with ASM 1% cream had a clinically significant higher incidence of infections and adverse events than did their counterparts treated with vehicle in the double-blind studies, both short term (6 weeks) and long term study (6 months)” and notes that “the open-label phase of the short-term trial further illustrates this concern of infection in infants. Not only did the incidence of some infections rise in the infants who had been on ASM 1%

cream in the double-blind phase but infants who had been on vehicle began to experience the same increases in infection when placed on ASM 1%.”

48. As a consequence of the Medical Review, FDA proposed labeling information for Elidel[®] which did not include study data regarding infants 3-24 months.

49. By letter dated November 28, 2001, Novartis Associated Director for Drug Regulatory Affairs James L. Martino wrote to Dr. Jonathan Wilkin, FDA Director of the Division of Dermatologic and Dental Drug Products, Office of New Drugs. In that letter, Mr. Martino acknowledged FDA’s concerns regarding the safety profile of Elidel[®] in infants, but asserted that it should be permitted to include data about the use of Elidel[®] in infants “[i]n keeping with the spirit of FDA’s efforts to encourage clinical studies in children[.]”

50. On or about December 14, 2001, the FDA granted marketing approval of defendant’s product Elidel[®] as indicated for second-line therapy of mild to moderate atopic dermatitis in patients aged two and older. The second-line indication means that usage was to be limited to those patients for whom standard, approved treatments (*i.e.*, emollients and intermittent topical hydrocortisone) were ineffective or contraindicated, particularly in cases of hydrocortisone allergy.

51. The FDA specifically restricted its approval of Elidel[®] to exclude its use in treatment of patients younger than two. The FDA found that children younger than two had a disproportionately higher incidence of adverse events in both the short term (six weeks) and long term (six months) trials.

52. As a result of the FDA's action, it was illegal for Novartis to market Elidel[®] for use in patients under the age of two.

53. FDA acceded to Novartis's request to allow the label to include information regarding study results in infants, but in no way agreed that Novartis could use those data to support a marketing campaign for Elidel[®] in the infant population.

54. As a result of the labeling approval granted Novartis by FDA, Novartis began marketing Elidel[®] in three package sizes, each of which has its own National Drug Control "NDC" number. Sizes, NDC numbers, and retail prices are:

30-gram tube	00078-0375-46	\$86.59
60-gram tube	00078-0375-49	\$184.99
100-gram tube	00078-0375-63	\$246.99

C. Off-Label Physician Marketing of Elidel[®] At Novartis's Insistence

55. Shortly after the FDA approval, Novartis began an aggressive marketing campaign to spur use of Elidel[®] in the treatment of atopic dermatitis. The marketing of Elidel[®] included schemes to convince health care providers, including pediatricians and dermatologists, that Elidel[®] could be safely used (1) in infants younger than two years of age; (2) as a first-line treatment; and (3) chronically. All three are non-approved indications.

56. Over the years of marketing Elidel, Novartis's marketing continued through nuanced variations of these off-label uses. For example, to encourage off-label use in infants, Novartis instructed representatives to detail articles that maintained off-label use was safe or effective. Novartis representatives also told physicians that Novartis was

seeking an FDA indication for under 2 use. To encourage off-label first-line treatment, Novartis continually advocated Elidel as safer or more effective than steroids. It also continued to encourage use at first signs or symptoms. To encourage use of Elidel for chronic eczema, Novartis encouraged that Elidel be used to control eczema and for patients to use Elidel long-term, until all the symptoms are gone.

57. Mr. Galmines was never informed of any of the FDA's negative findings and conclusions with respect to the safety of Elidel®.

58. Novartis representatives, including Mr. Galmines, were given pre-launch training in how to detail Elidel® to physicians. On or about January 18, 2002, Mr. Galmines was instructed by a Novartis Sales Trainer named Lisa, whose last name he does not recall, that "Elidel® should replace all mid-level steroid usage, including poison ivy, rosacea, seborrheic dermatitis."

59. Sales Trainer Lisa further instructed Mr. Galmines that if a physician asked whether it was appropriate to use Elidel® on infants younger than age two, he was to say "Doctor, what else would you use? Surely not steroids!"

60. Before and at the time of product launch, Mr. Galmines also was trained by Novartis personnel to respond to questions regarding the use of Elidel® in infants by saying that because the FDA allowed Novartis to put data regarding clinical results in infants in the package insert, it "must be safe."

61. Mr. Galmines was not advised that he should advise physicians that the infant-population data were included in the insert because Novartis advocated its inclusion to spur further research.

62. Within weeks of FDA approval, Lawrence F. Eichenfield, M.D., a pediatric dermatologist who received compensation as a consultant to Novartis and also received research funding from Novartis, made public statements supporting the manufacturer's claim that tests indicated pimecrolimus was safe and efficacious in infants as young as three months old. Dr. Eichenfield was quoted in various national publications as stating that "[t]he FDA has only approved pimecrolimus for the same age groups as tacrolimus [another topical immunosuppressant] . . . but it may be that the dermatologic community will be comfortable using pimecrolimus in children less than two."

63. In May 2002, shortly after Dr. Eichenfield's aggressive promotion of Elidel[®] for treatment of atopic dermatitis in infants, a Novartis-funded report of a Novartis-funded clinical study was announced by Dr. Alexander Kapp of Hannover, Germany, and other European and South African researchers which asserted that Elidel[®] was safe and effective in infants between three months and two years of age. The article, entitled "Long-term management of atopic dermatitis in infants with topical pimecrolimus, a nonsteroid anti-inflammatory drug," compared treatment of atopic dermatitis in infants with Elidel[®] against treatment with a placebo. It found that Elidel[®] worked better than the placebo, but did not test Elidel[®] against topical corticosteroids, the first-line therapy for atopic dermatitis.

64. The Novartis-sponsored Kapp article asserted that there “should be no restriction regarding treatment duration on the basis of safety considerations,” but failed to identify or acknowledge the many safety risks determined by the FDA to pervade the clinical trials which Novartis submitted in support of its NDA.

65. Notwithstanding the FDA’s refusal to grant Novartis the indication it requested for the use of Elidel[®] in infancy, Novartis immediately undertook a public relations campaign touting the Kapp article as proof that Elidel[®] should be used in infants.

66. An August 13, 2002 Novartis press release described Dr. Kapp’s results in detail, but made no mention of Novartis’s sponsorship of the study.

67. In March 2002, in contemplation of product launch, Mr. Galmines was again directed by the Elidel[®] trainer named Lisa that he was to push Elidel[®] to replace all moderate-strength topical corticosteroid use, to include poison ivy, rosacea, and seborrheic dermatitis. He was told to respond to questions about use in infants by asserting that it must be safe because the FDA allowed the infant data to be printed.

68. Elidel[®]’s product launch occurred in March 2002. The launch was not as successful as Novartis hoped.

69. In the months after the launch, Novartis, through, among others, District Manager Karl Burnitz, strongly exhorted Relator Galmines and other pharmaceutical representatives employed by the company to engaged in off-label marketing of Elidel[®] in at least three different ways: First, to push sales of Elidel[®] for use in infants under

two years of age. Second, to push sales of Elidel[®] as a first-line, rather than second-line, therapy. Third, to encourage physicians to prescribe Elidel[®] for chronic, rather than short-term, intermittent use.

70. All three of these marketing strategies show up in Novartis's printed material for Elidel[®]. For example, visual-aid booklets or "vis aids" used from late 2002 into 2004 included references to the Kapp study's findings regarding the percentage of an infant's body surface which could "safely" be coated with Elidel[®], stating that in infants 3-23 months of age, up to 92% of the body surface could be covered with Elidel[®] with negligible effects on blood serum levels.

71. Mr. Galmines was consistently ordered to engage in vigorous marketing of Elidel[®] for off-label use even though his superiors knew it was improper. On or about September 25, 2002, he was instructed by District Manager Karl Burnitz to carry two promotional binders in his car, one which contained only approved detail pieces and a second which included off-label literature. Mr. Burnitz explained that by so doing, Mr. Galmines could provide the approved binder if he was ever approached by "the FDA."

72. A May 16, 2002 Novartis press release regarding Dr. Kapp's report was headlined "Elidel[®] cream offers new non-steroid approach to treating atopic eczema in babies and sensitive skin areas" and asserts that Novartis "plan[s] to hold further discussions with the Food and Drug Administration in the USA this year regarding the use of Elidel[®] in infants under 2 years of age."

73. In June 2002, Mr. Galmines attended a week-long "Phase 2" training session at Novartis's corporate office in New Jersey. The primary topics of training were the presentation of nonapproved clinical articles, including the Kapp article, and the use of Elidel® on infants under two years of age and as a first-line therapy.

74. An August 13, 2002 Novartis press release discussing the Kapp article quoted Novartis consultant Dr. Eichenfield as advising that "[t]hese results indicate that Elidel® may offer significant therapeutic advantages over other treatment strategies in the long-term management of chronic eczema in infants and young children. A steroid-free therapy like Elidel® provides a new alternative for this difficult-to-treat young patient group."

75. An October 6, 2003 Novartis press release reprised its touting of the Kapp study, which it referred to as a "new study." The press release asserts that treatment of infants with "Elidel® improved parents' quality of life." This press release remains available through the "Press" archive at Novartis's web site.

76. A November 18, 2004 Novartis press release asserted that a "Study explores whether long-term treatment of eczema with Elidel® could reduce risk of asthma by halting 'atopic march.'" The release discusses (1) the use of Elidel® in infants 3-18 months; (2) the use of Elidel® "as early as possible to prevent flare-ups;" and (3) the "long-term" use of Elidel®.

77. An October 14, 2005 Novartis press release touted a study which tested, again against a placebo, the use of Elidel® "at the first sign of symptoms of disease."

78. “Vis aids” rolled out in 2004 and used up to and during 2006 included the admonition to “[u]se Elidel® twice daily at the **first signs or symptoms** of a flare and through resolution” (emphasis and capitalization in original), which patently markets the product as a first-line treatment. The same Elidel® “vis aid” urges physicians to “[t]reat early with Elidel® for long-term control” and urges that patients “[u]se Elidel® at the first signs or symptoms of flare recurrence through resolution to control eczema.” Further suggesting first-line use, the “vis aid” urges use of Elidel® “[w]hen you want or need to avoid corticosteroids for your mild to moderate eczema patients” and identifies “**first signs and symptoms**” as being “[a] hint of itchiness,” “[a] spot of redness,” “[t]he slightest bump,” and “[t]he tiniest tingle.” The literature further relegates the actual first-line treatment--topical corticosteroids—to situations where “a patient presents with or experiences severe or uncontrolled flare” of her eczema.

79. Its 2007 visual aid also encouraged use at the first signs and symptoms. Sales representatives were instructed to detail this message such that the key takeaway was to use Elidel from the first sign of a flare until all the symptoms were gone. This is off-label as Elidel is not indicated for first-line use, for prevention, or for continuous use. Moreover, even though Novartis cannot claim it knows how the actual mechanism of action of Elidel works, it misleadingly instructed its representatives to make sure another key takeaway was that Elidel targets the cells involved in skin inflammation.

80. When Elidel® was launched, Mr. Galmines was ordered to answer the “age indication” question by saying “[r]ight now, Elidel® is indicated down to age two, but

the FDA has allowed us to put our infant data in our Product Information.” This instruction was provided by Mr. Galmines’s District Manager, Karl Burnitz, as well as other managers and Sales Trainers.

81. He was also taught to say that Novartis was continuing to pursue an under age 2 indication. These practices continued past July 2006, and on information and belief, they continued until Novartis stopped marketing Elidel in 2009.

82. Mr. Galmines also was instructed to focus attention on the perceived problems and adverse publicity surrounding “steroids,” even though none of the clinical testing of Elidel® compared its safety and efficacy to that of the topical corticosteroids which are the first-line treatment for atopic dermatitis. This marketing technique took advantage of what Dr. Jonathan Wilken, who was from 1994 to 2005 Director of Dermatology and Dental Products at FDA, has called “topical corticosteroid phobia in patients with atopic dermatitis.”

83. Novartis’s exploitation of consumer fears of using corticosteroids continued throughout the time period, with “steroid-free” continuing to be used on Novartis’s website as late as 2011.

84. Shortly after the Kapp article was published, reprints of it were made available to the Elidel® sales force. Mr. Galmines was repeatedly instructed to detail the Kapp reprint directly to physicians, including pediatricians. Such instructions were given by, among others, Mr. Burnitz. Up to the date of his resignation from Novartis, Mr. Galmines was able to order reprints of the Kapp article in quantities of 200 per month from a Novartis office which then drop-shipped the articles to his home.

85. Mr. Galmines estimates that he has detailed physicians with reprints of the Kapp article on more than 100 occasions while in the presence of his manager, Karl Burnitz.

86. Novartis instructed its sales representatives to actively detail Dr. Kapp's article, as well as other off-label articles it sponsored, with physicians. These practices continued past July 2006, and on information and belief, they continued until Novartis stopped marketing Elidel in 2009.

87. On or about November 5, 2002, Mr. Burnitz instructed Mr. Galmines that if he was not using all unapproved reprints in his detailing of Elidel[®], he was "leaving business on the table."

88. In January 2003, Mr. Galmines prepared a detail piece titled "The Atopic Triad Theory." The "Atopic Triad" is a term applied to atopic dermatitis, allergic rhinitis (hay fever), and asthma.

89. The basis for the "Atopic Triad" detail piece was the Kapp article. It overtly referenced both first-line treatment and treatment of infants 3—23 months of age. Mr. Galmines's manager, Mr. Burnitz, took Mr. Galmines's detail, put his name and the name of another manager on it and rolled it out as a regional initiative.

90. Other unapproved reprints included articles by Novartis-supported authors, doctors Vincent Ho, Ulrich Wahn and Michael Meurer. Dr. Ho's article, entitled "Safety and Efficacy of Nonsteroid Pimecrolimus Cream 1% in the treatment of Atopic Dermatitis," discussed off-label use in infants. Dr. Wahn's article, entitled "Efficacy and Safety of Pimecrolimus Cream in the Long-Term Management of Atopic Dermatitis in

Children,” discussed off-label first-line therapy, as well as preventative long-term use, in children. Dr. Meurer’s article, entitled “Pimecrolimus Cream in the Long-Term Management of Atopic Dermatitis in Adults: a Six-month Study,” discussed off-label first-line use, as well as long-term and preventative use.

91. Relator was instructed by Novartis to detail messages from the above articles. These practices continued past July 2006, and on information and belief, they continued until Novartis stopped marketing Elidel in 2009.

92. By April 15, 2003, defendant Novartis asserted that Elidel[®] was “the number-one branded prescription treatment for eczema in the US.” Novartis reported 2003 U.S. sales at \$205,000,000 and \$235,000,000 worldwide, up 147% from 2002 worldwide sales. Sales for the first half of 2004 were \$172,000,000, of which \$137,000,000 reflected sales within the United States, and 2004 sales totaled approximately \$279,000,000 in the U.S. and \$349,000,000 worldwide. In 2005, sales fell to \$192,000,000 in the U.S. and \$270,000,000 worldwide. Global sales reached \$179,000,000 in 2006, \$176,000,000 in 2007, and \$152,000,000 in 2008. In 2011, Novartis divested itself of Elidel.

93. Through the end of 2005, total public-payor expenditures on Elidel[®] were approximately \$248,266,936.25. Between 2006 and 2009, public payor expenditures were at least an additional \$108,663,122.73.

94. Mr. Galmines’s success with the marketing of Elidel[®] was rewarded with a trip to New Orleans in May, 2003, at which he trained sales representatives from all U.S. regions how to detail physicians based on “The Atopic Triad Theory.” The “Atopic

Triad Theory” is the same topic discussed in Novartis’s November 2004 press release discussing the “atopic march.”

95. At that national sales meeting, the Sales Trainer Lisa stated to Mr. Galmines that the sales representatives who were doing the best with Elidel® were selling off-label and for infant uses.

96. Also at the meeting, several workshops were held to discuss the topic of responding to questions about the age indication for Elidel®. Representatives were instructed to advise physicians that kids were “practically bathed in Elidel®” with no effect on their blood-serum levels.

97. By the end of 2004, more than 1.2 million prescriptions had been written directing the dispensing of Elidel® for use on patients younger than two years of age. FDA Pediatrics Advisory Committee member Thomas B. Newman, M.D., M.P.H., has referred to these prescriptions as “clearly off-label.”

98. In 2003, Novartis devoted \$79.7 million to direct-to-consumer advertising of Elidel®.

99. At a district-wide sales meeting in Orlando, Florida on or about January 30, 2004, Mr. Burnitz instructed all sales personnel under his supervision to use the Kapp reprint to detail Elidel® to physicians for use in infants under two, and told them “not to worry” about detailing the Kapp piece, because the “chances of getting caught were a million to one.”

100. Novartis routinely instructed Mr. Burnitz to engage in off-label marketing of Elidel[®], and did so in writing. For example, in November 2004, Mr. Burnitz was given a Business Development Report which identified as his primary Trimester Goal to develop “Elidel[®] 1st line for mild to moderate LT [Long Term] prevention.” Thus, the primary requirement imposed upon him by Novartis was to market Elidel[®] for off-label use inconsistent with the approved labeling.

101. In a presentation to the financial community on or not long after January 15, 2004, Novartis Chief Financial Officer Raymond Breu referred to Elidel[®] as a “Blockbuster” drug based on, among other factors, “effective positioning and messaging,” “strong field force execution,” and “effective DTC” (“Direct to Consumer” advertising).

102. In January 2005, defendant’s Elidel[®] Senior Product Manager was recognized as one of the Top 25 DTC (“Direct to Consumer”) drug marketing executives in the United States by the publication *DTC Perspectives*.

103. Mr. Galmines attended a national sales meeting during the week of May 9, 2005. At that meeting, he was strictly instructed to target Elidel[®] sales to pediatricians, to assert that Elidel[®] was safe for infants, and to heavily detail the Kapp reprint. He was instructed to advise physicians that infants with 92% body coverage of Elidel[®] for a year showed negligible blood-serum levels.

104. Novartis’s goal, articulated in its 2004 marketing plan, was that Elidel would be the gold standard for long-term treatment and prevention of atopic disease. As late as 2007 and 2008, Novartis continued to use its marketing to aspire to these

same off-label uses. For instance, one top directive for 2007 was to position Elidel for sensitive skin in order to capture the long term atopic disease management market and to continue to advocate early use of the drug. Marketing continued to focus on the sensitive skin messaging for 2008 as a way to strengthen Elidel's value over topical corticosteroids. Once again by positioning Elidel against steroids, Novartis looked to bend the second-line indication by stating it was whenever a physician "wanted" to avoid steroids.

105. Mr. Galmines was orally reprimanded by Mr. Burnitz on or about February 28, 2006 because Mr. Galmines's detail bag did not contain two unapproved details, including the Kapp article. This occurred following a meeting with Dr. Paul Miller, a pediatrician who asked Mr. Galmines about prescribing Elidel[®] for use on patients younger than two years old. Mr. Burnitz reprimanded Mr. Galmines for advising Dr. Miller that he should not write such prescriptions.

106. Novartis carefully tracked the prescription-writing habits of all physicians detailed by Mr. Galmines and all other Novartis representatives, and assigned Mr. Galmines lists of doctors upon whom he was to call. Mr. Galmines was specifically instructed by Mr. Burnitz and others to detail all doctors for all three off-label indications.

107. Relator also was instructed to exhort physicians whom he detailed to write prescriptions for the largest-size (100-gram) tube of Elidel[®], which retails for \$246.99, because by so doing they could save their patients co-payments associated with repeated prescriptions.

108. Novartis continued to engage in off-label marketing of Elidel[®] to physicians through at least April 2009 and directly to the public until 2011. For example, Novartis published a website, <http://www.treat-eczema-now.com>, which asserted through at least June 4, 2006, that “There are two topical prescription drugs for eczema that do not contain steroids. These are called topical immunomodulators or TIMs. Both are effective in treating the itch and rash of eczema. Neither causes certain side effects, such as thinning of the skin (atrophy), stretch marks (striae), spider veins, or discoloration of the skin.” No mention was made of the fact that Elidel[®] is not appropriate for first-line use or of the FDA’s black-box warning against using Elidel[®] on infants.

109. As of July 2011, the website continued to exhort: “Don’t wait until eczema symptoms turn into a flare-up! At the first signs or symptoms, you can use Elidel to control it” despite the fact that Elidel is not approved for first-line use or for prevention. As of October 2011, the website continued to advocate that Elidel could control mild to moderate eczema and to “fight eczema right where it starts.” It continued to describe Elidel as “steroid-free.”

110. Novartis published a 30-page book, The Eczema Survival Guide, which, until at least 2006, was available at www.treat-eczema-now.com. While the front cover of the Survival Guide indicates that it is published by the “National Eczema Association for Science and Education in conjunction with Novartis Pharmaceuticals,” the back cover of the book states that it is ©2004 Novartis.” The Survival Guide discusses the fact that 60% of those with eczema develop symptoms before age 1, and discusses Elidel[®] in the same language as Novartis’s website without discussing the

inappropriateness of Elidel® for first-line use or the FDA's black-box warning against using it on infants. The Eczema Survival Guide was also available on the national Eczema Association's website until at least March 16, 2008.

111. The National Eczema Association is a 501(c)(3) corporation to which Novartis was the largest single contributor in 2004 and one of two "Diamond Benefactors" who, in 2003, contributed more than \$50,000 of the Association's \$207,000 in corporate donations. Novartis continued contributions to the NEASE through 2009.

D. Elidel®'s Cancer-related Black-box Warning

112. The concern exhibited by FDA during the Elidel® approval process regarding the risk of malignancy associated with prolonged use and use in infants of topical immunosuppressants resurfaced in the form of an October 30, 2003 meeting of the Pediatric Subcommittee of FDA's Anti-Infective Drugs Advisory Committee. Reasoning that there is no such thing as an acceptable increased cancer risk, the Subcommittee "felt that long term studies would be needed in situations [such as topical immunosuppressants] where there is evidence of systemic absorption and systemic effects with potential for serious and long-term complications."

113. On December 15, 2004, FDA issued a Postmarketing Safety Review discussing clinical-trial and postmarketing reports of malignancy-related events associated with use of Elidel®. The postmarketing review focused on the question whether the immuno-suppression mechanism of Elidel® and another topical immunosuppressant created a risk of cancer.

114. On February 15, 2005, a hearing was held before the FDA Advisory Committee regarding the safety of Elidel® for children. The topic of the hearing was identified as “Potential Cancer Risk in Children From the Use of Topical Immunosuppressants.”

115. At the hearing, Dr. Norman Fost, M.D., M.P.H., an FDA consultant, Professor of Pediatrics, and Vice Chairman of the Department of Medical History and Bioethics at the University of Wisconsin, commented on the off-label use of Elidel® as follows: “[I]t’s clear that the products we [are] discussing today are being used on a wide scale outside of the package insert. Clearly they are being used on the zero to two age range and for many, many patients for whom they are not being used as a second-line drug. This is the story of the FDA. This is the SSRI story, the Vioxx story. Approval is sought for a very narrow indication from which you really can’t make very much money and then somehow a way is found to get it to be used on a very wide scale outside of the indication.”

116. At the hearing, FDA’s Dr. Marilyn Pitts, Pharm.D., stated that when drug usage stratified by age was evaluated, 14% of Elidel® prescriptions were written off-label for infants under two years of age. Dr. Pitts further said that from December 2001 until November 2004, “slightly more than 8.7 million prescriptions [of Elidel®] were dispensed in the United States.” Thus, at least 1,218,000 prescriptions were written between December 2001 and November 2004 for use of Elidel® on infants under two.

117. In 2005, 2,463,000 prescriptions were written for Elidel[®]. If the percentage written off-label for infants held true, an additional 345,000 such prescriptions were written.

118. Comparison of Novartis's reported income from Elidel[®] with the number of prescriptions reported indicates that the average revenue to Novartis per prescription approximates \$100. If so, then Novartis has recognized approximately \$150,000,000 in income from Elidel[®] prescriptions to infants under two years of age. This does not take into account those revenues realized from off-label sales based on first-line usage and chronic or sustained usage. Mr. Galmines estimates that such usage reflects 50% or more of the remaining prescriptions.

119. At the hearing, Dr. Carle Paul, Novartis's Elidel[®] Medical Director, stated to the Advisory Committee that Novartis did not engage in off-label marketing of Elidel[®]. Specifically, when asked if Novartis was "doing anything to discourage off-label use," Paul said "Of course. As we encourage label use, we discourage off-label use." Dr. Paul further stated to the FDA that "[t]he promotional activities with Elidel[®] are done according to the label. We make sure that the way the products attribute are communicated according to its label."

120. Dr. Paul's statements to the FDA Advisory Committee were either knowingly false or made with reckless indifference to their truth or falsity.

121. Following the Advisory Committee hearing, FDA's Pediatric Committee recommended that a "black box" warning be added to Elidel[®]'s approved labeling because of concern that Elidel[®] causes cancer in children or with prolonged use. So-

called because of the heavy black line which surrounds the warning contained therein, a black-box warning is the most serious of five levels of warnings which FDA can require on a label. A black box warning indicates that a prescription drug can cause serious or life-threatening side-effects.

122. The FDA's black-box warning advises doctors to weigh the risks and benefits of these drugs in adults and children and to consider the following:

- Elidel[®] is approved for short-term and intermittent eczema treatment in people who have not responded to or are intolerant of other eczema treatments.

- Elidel[®] is not approved for use in children younger than two years old. The long-term effect of Elidel[®] on the developing immune system in infants and children is not known. In clinical trials, infants and children younger than two years of age treated with Elidel[®] had a higher rate of upper respiratory infections than those treated with a placebo cream.

- Elidel[®] should be used only for short periods of time, not continuously. The long-term safety of these products is unknown.

- Children and adults with a weakened immune system should not use Elidel[®].

- Use the minimum amount of Elidel[®] needed to control the patient's symptoms. The animal data show that the risk of cancer increases with increased exposure to Elidel[®].

123. The FDA-ordered black-box warning squarely addresses each and every one of the three off-label marketing schemes embraced by Novartis since the product was launched: Use in infants; first-line use; and long-term use.

124. After the black-box warning directive was issued, the Joint Council of Allergy, Asthma and Immunology (a combined body of the American Academy of

Allergy, Asthma and Immunology and the American College of Allergy, Asthma and Immunology) issued a “Dear Colleague” letter indicating that

These topical agents, which are indicated for the short term or intermittent long term treatment of atopic dermatitis, were developed for use as second-line therapy when conventional therapies are inadvisable, ineffective or not tolerated.

“Because of a perception by patients and physicians that they are safer than steroid preparations, they have increasingly been used as first-line therapy.

125. Since Elidel[®]'s package insert was modified to include the FDA-ordered black box warning, sales of Elidel[®] have dropped substantially. 2005 sales were \$250,284,000, down 30% from 2004. Novartis attributes a similar drop in 2006 to “a change in prescribing information.”

126. On or about January 27, 2006, Karl Burnitz and Novartis Manager Thomas Michaels stated that the “real reason” for the Elidel[®] black-box warning was that 20% of prescriptions for the drug were written off-label to children under two years of age. However, Mr. Burnitz and Mr. Michaels continued encouraging off-label promotion.

127. At this same meeting Mr. Galmines spoke with several representatives regarding the legality of detailing reprints. 90% of those he spoke with still thought that it was acceptable to detail the Kapp and Meuer reprints to physicians.

128. On or about February 28, 2006, Mr. Burnitz told Mr. Galmines that Elidel is as safe for infants as placebo; that there is “absolutely no reason” for doctors to be worried; and that the FDA that should be worried that Novartis is going to sue them for the unprecedented black box for Elidel. When Mr. Galmines asked Mr. Burnitz why he

could no longer order the Kapp Clinical Study, Mr. Burnitz told him that while Novartis did not want it used, Burnitz could still provide more copies to him. On the same day, Mr. Burnitz chastised Mr. Galmines for not having two non-approved detail pieces in his bag to show Dr. Paul Miller, a pediatrician, and for telling Dr. Miller not to prescribe Elidel to infants. One of the articles Mr. Burnitz directed Mr. Galmines to use was a Reuters piece entitled "Pimecrolimus cream safe for infants with eczema." The other article was from Memorial Hospital entitled "Topical Calcineurin Inhibitor (Protopic/Elidel) Update, February 2006."

129. At a follow up hearing on March 22, 2010, Novartis testified that off-label prescriptions had dropped. However, an average of approximately 10% of overall prescriptions between 2005 and 2009 were still for children under age 2. Government payors reimbursed prescriptions of Elidel for off-label beneficiaries would have been over \$18 million for this time period. One committee member, Dr. Leon Dure, commented: "There are still a lot of pediatricians that are prescribing these drugs, and it did drop from 2004 to 2008. ... but we've still got a large number of kids on off-label drugs." Committee member Dr. Kathleen Neville commented: "a large percentage of the cases were from use of children less than 2 years and a year longer than duration. So while that may have been placed in the black box, obviously, it seems to me, it's not having the intended impact."

E. Omitted

130. Also as part of its off-label marketing campaign, Novartis provided cash and noncash payments to physicians to both induce and reward them for prescribing

Elidel[®]. Novartis tracked the prescribing habits of physicians and rewarded high-volume prescribers by way of cash payments and gifts to those physicians. Novartis used numerous schemes to provide kickbacks to physicians as a reward for prescribing Elidel[®] within the States of Illinois, Indiana, Virginia, Michigan, Massachusetts and Louisiana in violation of the prohibitions under the law of those states against paying kickbacks.

131. In order to solicit physicians to prescribe Elidel[®] for off-label uses, Novartis sponsored seminars and provided gifts to physicians to guarantee their attendance. These gifts included meals, bottles of wine, and pre-paid travel arrangements.

132. Mr. Burnitz instructed Mr. Galmines to offer Dr. Dolar Koya, a family-practice physician with offices in Aurora, Illinois, an all-expenses-paid trip to France for Elidel[®] “speaker training.” Dr. Koya accepted, and stated to Mr. Burnitz, quoting or closely paraphrasing, “[m]y patients will use whatever I tell them to. I know how the system works—you take care of me and I’ll take care of you.”

133. Physicians who were considered to have potential for ordering a high number of off-label Elidel[®] prescriptions were actively recruited by Novartis with the promise of receiving “honoraria” in return for prescribing the medication.

134. During seminars regarding the use of Elidel[®], Novartis representatives planted physicians or sales representatives in the audience to ask questions of the (usually compensated) speaker regarding off-label use of the medication. This scheme was done in order to make attendees aware of the off-label uses of the product and to recruit those physicians to prescribe the medication for off-label use.

135. When physicians used slides to discuss Elidel[®], the slides were subject to preapproval by Mr. Galmines and/or Mr. Burnitz, and were expected to include off-label discussion.

136. Novartis maintained records on physicians who were detailed and the number of Elidel[®] prescriptions written by each. Then, under the guise of “consultant services” or “speaking fees,” Novartis selected a number of physicians throughout the United States to receive payments for speaking about off-label uses for Elidel at seminars.

137. Most if not all speakers were high-volume prescribers or “heavy writers” of Elidel[®], and Mr. Galmines was expressly instructed by Mr. Burnitz on, among other occasions, January 13, 2003, to recruit speakers in Illinois based solely on their ability to write large numbers of off-label prescriptions for Elidel[®].

138. These compensation packages were paid by Novartis to reward physicians for prescribing Elidel[®] and to solicit other physicians to use the medication, to include off-label uses. Relator Galmines personally arranged for many such seminars, and was directed to do so by District Manager Burnitz. The payments were usually in the amount of \$1,000.00 or more, and were made throughout the years 2002, 2003, 2004, 2005, and 2006. Such payments were made to physicians in Illinois, and violated the Illinois anti-kickback statute.

139. By way of example, on or about April 24, 2005, Mr. Galmines paid \$1,500 to Dermatologist Dr. Omeed Memar for discussing Elidel[®] with two residents, using no slides. The focus of the meeting was the detailing of Elidel[®] by Mr. Galmines and two

other Novartis sales representatives, Heather Handell and Adam, whose last name may be Cratar. These events took place in Illinois.

140. Relator knows, from discussions with other representatives, that such practices occurred nationwide.

141. Novartis sales representatives and members of Novartis management, to include Mr. Galmines and District Manager Karl Burnitz, arranged payments to physicians for seminars which never actually took place. Relator was never required to turn in attendance lists or in any other way document that a seminar actually took place.

142. Relator knows, from discussions with other representatives, that such practices occurred nationwide. Mr. Burnitz has a national list of approved Elidel[®] speakers which includes approximately 700 names—more than the total number of Elidel[®] sales representatives. Novartis used the paid-speaker process to deputize huge numbers of physicians as off-label detailers of Elidel.

143. On February 11, 2003, in the course of Mr. Galmines's 2002 performance evaluation, Mr. Burnitz advised Mr. Galmines to let him know which scheduled speaker programs he should attend, and which he shouldn't attend because they were not actually going to occur. Mr. Galmines followed this instruction.

144. Physicians who were paid speaking fees for seminars which never took place included Dr. David J. Coynik, a dermatologist with offices in Chicago; Dr. Dolar Koya, a family-practice physician with offices in Aurora, Illinois; and Dr. Michael Bukhalo, a dermatologist with offices in Arlington Heights, Illinois.

145. After the completion of the seminars which did occur, Novartis tracked the prescribing habits of the attendees to determine whether it was successful in getting the physicians to change their prescription habits by prescribing Elidel for off-label uses.

146. A third way that Mr. Galmines was directed to use speaker programs to funnel Novartis kickbacks to high-volume prescribers was to have other physicians in the speaker's own practice attend the seminar to boost attendance. By using this artifice, Mr. Galmines was able to funnel thousands of dollars to Dr. Rudolfo Sarmiento, a pediatrician practicing in Lombard, Illinois.

147. At the direction of his manager, Mr. Galmines hosted and paid for dinners in Illinois at expensive restaurants for physicians who prescribed large amounts of Elidel[®] for off-label uses. These dinners occurred regularly, and Mr. Galmines knows that all sales representatives were expected to engage in such activities.

148. On or about October 18, 2005, Mr. Galmines hosted a dinner at Louie's Chophouse in a Chicago suburb for Dr. Thomas Blondon, two doctors in his practice, and four or five nurses. The dinner cost about \$1,000, and the only discussion of Elidel[®] was detailing activity by Mr. Galmines, primarily for off-label uses.

149. On or about November 16, 2002, Mr. Galmines hosted a dinner for Dr. Sarmiento, his family, and his staff at Magnum's restaurant. The bill was approximately \$1,000. No other physicians attended.

150. On or about July 28, 2005, Mr. Galmines hosted a dinner for Dr. Sarmiento, his family, and his staff at Magnum's restaurant. Dinner for 10 or 11 people cost between \$1,000 and \$1,500. No education or training was provided.

151. On or about April 28, 2005, Mr. Galmines hosted a dinner for Dr. Sarmiento and his staff at Sal & Cavao Restaurant. The bill was approximately \$750. No training or education was provided.

152. On or about August 25, 2005, Mr. Galmines hosted a dinner for Dr. Sarmiento and members of his practice at Magnum's restaurant. No slides were used and the dinner was primarily an opportunity to detail off-label uses of Elidel.

153. Mr. Galmines was instructed to use "preceptorships" as a way to funnel money to physicians in exchange for their support of Elidel®. In a "preceptorship" as that term is used in the pharmaceutical-marketing arena, a drug representative trails a physician in his office for a few hours and pays the doctor.

154. On or about April 22, 2002 and on or about July 11, 2002, Mr. Galmines attended "preceptorships" with Dr. David Coynik, a dermatologist in Peru, Illinois. Dr. Coynik was paid \$500 for each visit. He stated to Mr. Galmines, quoting or closely paraphrasing, that "as long as you pay me I'll prescribe Elidel® by the truckload."

155. Defendant's payments and provision of gifts to physicians for the purpose of influencing them and others to write more prescriptions for Elidel® violated the Indiana, Illinois, Virginia, Michigan, Massachusetts and Louisiana anti-kickback statutes, and all claims submitted to the Medicaid programs in those States as a sequel to those payments and gifts were false claims.

156. District Manager Burnitz referred to his attitude regarding the FDA and its regulations as "the Golden Rule," and he often repeated it to Mr. Galmines: "Them who holds the gold makes the rules, and the FDA doesn't hold the gold, Novartis does."

157. After the Black Box caused prescriptions to drop, one of Novartis's top strategic priorities was to continue to utilize speaker programs to market Elidel, and increased funds to do so. In 2006, Novartis planned for money spent on Regional Events to drive market share by focusing on the top tier physicians. Novartis had concluded that each speaker program generated 7.3 prescriptions. Therefore, Novartis created a plan to train 800 speakers in early 2006 as a key to the overall success of Elidel. Similarly, in 2007, Novartis had similar objectives, including allocation of \$700,000 for Elidel in the first semester of 2007 for Regional Event programs. Novartis's plan for 2008 continued to include utilizing Key Opinion Leaders and physician education as a promotional lever and a key tactic.

158. Speakers at Regional Events received anywhere between \$500 and \$2000 from Novartis to speak. Novartis continued to provide payments to these speakers through at least mid-2007, and on information and belief, continued in 2008. For example, in Texas alone, Novartis spent \$197,000 on speaker honoraria in 2006 and \$15,000 through the first four months of 2007.

159. After Mr. Galmines's employment with Novartis ended, Mr. Galmines called on other dermatologists as a representative of Graceway. Dr. Paul Revis, a dermatologist, mentioned to Mr. Galmines that Novartis would take him golfing. Another dermatologist whom Mr. Galmines knew to be a heavy Elidel writer, Dr. Bruce Kolton, demanded five-star restaurant deliveries for lunch. Mr. Galmines expects that he demanded the same treatment from Novartis.

V. CLAIMS

**COUNT I: VIOLATIONS OF THE
UNITED STATES CIVIL FALSE CLAIMS ACT**

160. The allegations of paragraphs 1-143 are realleged as if fully set forth herein.

161. The False Claims Act, 31 U.S.C. § 3729(a)(1) and (2), imposes liability upon, *inter alia*, those who knowingly cause to be presented to an officer or employee of the United States, to include state Medicaid systems as federal grantees under 31 U.S.C. § 3729(c), false claims for payment or approval. It also imposes liability on those who conspire to get false claims paid. 31 U.S.C. § 3729(a)(3).

162. Defendant Novartis deliberately engaged in a concerted, vigorous, and cynical campaign to market its prescription drug Elidel® for uses which were specifically disapproved by the United States Food and Drug Administration and for uses which posed significant safety and health risks to infants and others to whose skin Elidel® was applied.

163. Claims for payment to federally-financed healthcare systems, to include at least Medicaid, Medicare, and Tricare, which resulted from Novartis's knowingly-illegal and immoral marketing campaign pushing the use of Elidel® in infants, as first-line treatment for atopic dermatitis, and for chronic use, were false claims.

164. The false claims referenced in the foregoing paragraph were caused to be presented by Novartis, in violation of 31 U.S.C. §3729(a)(1).

165. Novartis's representations to physicians regarding these illegal uses of Elidel[®] constituted false statements which Novartis intended would get false claims paid, in violation of 31 U.S.C. § 3729(a)(2).

166. Omitted

167. Omitted.

168. Because the United States would not have paid for prescriptions of Elidel which it knew to have been the result of illegal marketing, the United States has been harmed in an amount equal to the value paid by the United States, directly or indirectly through State or Commonwealth Medicaid programs, for such prescriptions.

169. The United States Government has been damaged as a result of Novartis's conduct in violation of the False Claims Act in an amount to be determined at trial.

COUNT II: OMITTED

170. Omitted.

171. Omitted.

172. Omitted.

173. Omitted.

174. Omitted.

175. Omitted.

176. Omitted.

177. Omitted.

178. Omitted.

179. Omitted.

180. Omitted.

COUNT III: OMITTED

181. Omitted.

182. Omitted.

183. Omitted.

184. Omitted.

185. Omitted.

186. Omitted.

187. Omitted.

188. Omitted.

189. Omitted.

190. Omitted.

191. Omitted.

COUNT IV: OMITTED

192. Omitted.

193. Omitted.

194. Omitted.

195. Omitted.

196. Omitted.

197. Omitted.

198. Omitted.

199. Omitted.

200. Omitted.

201. Omitted.

202. Omitted.

COUNT V: Omitted

203. Omitted.

204. Omitted.

205. Omitted.

206. Omitted.

207. Omitted.

208. Omitted.

209. Omitted.

210. Omitted.

211. Omitted.

212. Omitted.

213. Omitted.

214. Omitted.

COUNT VI: VIOLATIONS OF THE HAWAII FALSE CLAIMS ACT

215. The allegations of paragraphs 1-143 are realleged as if fully set forth herein.

216. This is a qui tam action brought by Relator Don Galmines on behalf of himself and the State of Hawaii to recover treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*

217. Haw. Rev. Stat. § 661-21(a) provides liability for any person who:

- (1) knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval; [or]
- (2) knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;

218. Novartis violated Haw. Rev. Stat. § 661-21(a) and knowingly caused false claims to be made, used and presented to the State of Hawaii from at least 2002 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA,, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs.

219. The State of Hawaii, by and through the Hawaii Medicaid program and other state health care programs, and unaware of Novartis's fraudulent schemes, paid the claims submitted by health care providers and third party payers in connection therewith.

220. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Hawaii in connection with Novartis's fraudulent schemes.

221. Had the State of Hawaii known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis's schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payers in connection with those schemes.

222. As a result of Novartis's violations of Haw. Rev. Stat. § 661-21(a) the State of Hawaii has been damaged.

223. This Court is requested to exercise supplemental jurisdiction pursuant to 28 U.S.C. § 1367(a) and 31 U.S.C. § 3732(b) or pendent jurisdiction over this state-law claim as it is predicated upon the same facts as the federal claim asserted in Count I, and so forms part of the same case or controversy.

**COUNT VII: VIOLATIONS OF THE
ILLINOIS WHISTLEBLOWER REWARD & PROTECTION ACT**

224. The allegations of paragraphs 1-143 are realleged as if fully set forth herein.

225. This is a *qui tam* action brought by Relator Don Galmines on behalf of the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175/1 *et seq.*

226. 740 ILCS 175/3(a) provides liability for any person who:

- (1) knowingly presents, or causes to be presented, to an officer or employee of the State or a member of the Guard a false or fraudulent claim for payment or approval;

- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State:
- (3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

227. 305 ILCS 5/8A-3(b) of the Illinois Public Aid Code (Vendor Fraud and Kickbacks) prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Illinois Medicaid program.

228. Novartis violated 305 ILCS 5/8A-3(b) by engaging in the conduct described herein.

229. Novartis furthermore violated 740 ILCS 175/3(a) and knowingly caused false claims to be made, used and presented to the State of Illinois by its deliberate and systematic violation of federal and state laws, including the FDCA and the Illinois Vendor Fraud and Kickback statute, 305 ILCS 5/8A-3, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

230. The State of Illinois, by and through the Illinois Medicaid program and other state healthcare programs, and unaware of Novartis's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

231. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief,

also an express condition of payment of claims submitted to the State of Illinois in connection with Novartis's conduct. Compliance with applicable Illinois statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Illinois.

232. Had the State of Illinois known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis's conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would have not paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

233. As a result of Novartis's violations of 740 ILCS 175/3(a) and 305 ILCS 5/8A-3, the State of Illinois has been damaged.

234. This Court is requested to exercise supplemental jurisdiction pursuant to 28 U.S.C. § 1367(a) and 31 U.S.C. § 3732(b) or pendent jurisdiction over this state-law claim as it is predicated upon the same facts as the federal claim asserted in Count I, and so forms part of the same case or controversy.

**COUNT VIII: INDIANA FALSE CLAIMS
AND WHISTLEBLOWER PROTECTION ACT**

235. The allegations of paragraphs 1-143 are realleged as if fully set forth herein.

236. This is a qui tam action brought by Relator Don Galmines on behalf of the State of Indiana to recover double damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5 *et seq.*

237. Indiana code 5-11-5.5.2 provides liability for any person who knowingly or intentionally:

- (1) presents a false claim to the state for payment or approval;
- (2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state; or
- (3) conspires with another person to perform an act described above.

238. In addition IC 12-17.6-6-12 prohibits the solicitation, offering or receipt of a kickback or bribe in connection with the furnishing of items or services or the making or receipt of payment.

239. Novartis violated IC 12-17.6-6-12 by engaging in the conduct described herein.

240. Novartis furthermore violated IC 5-11-5-5.2 and knowingly caused false claims to be made, used and presented to the State of Indiana from 2002 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA and IC 12-17.6-6-12, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs.

241. The State of Indiana, by and through the Indiana Medicaid program and other state health care programs, and unaware of Novartis's fraudulent schemes, paid

the claims submitted by health care providers and third party payers in connection therewith.

242. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Indiana in connection with Novartis's fraudulent schemes.

243. Had the State of Indiana known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis's schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payers in connection with those schemes.

244. As a result of Novartis's violations of IC 5-11-5.2 and IC 12-17.6-6-12, the State of Indiana has been damaged.

245. This Court is requested to exercise supplemental jurisdiction pursuant to 28 U.S.C. § 1367(a) and 31 U.S.C. § 3732(b) or pendent jurisdiction over this state-law claim as it is predicated upon the same facts as the federal claim asserted in Count I, and so forms part of the same case or controversy.

COUNT IX: LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

246. The allegations of paragraphs 1-143 are realleged as if fully set forth herein.

247. This is a *qui tam* action brought by Relator Don Galmines on behalf of

himself and the State of Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, Louisiana RS 46:437.1 *et seq.*

248. Louisiana RS 46:438.3 provides that:

- (1) No person shall knowingly present or cause to be presented a false or fraudulent claim;
- (2) No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance program funds;
- (3) No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.

249. In addition, Louisiana RS 46:438.2(A) prohibits the solicitation, receipt, offering or payment of any financial inducements, including kickbacks, bribes, rebates, etc. directly or indirectly, overtly or covertly, in cash or in kind, for furnishing health care goods or services paid for in whole or in part by the Louisiana medical assistance programs.

250. Novartis violated RS 46:438.2(A) from at least 2002 to the present by engaging in the fraudulent schemes described herein.

251. Novartis furthermore violated RS 46:438.3 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Louisiana from at least 2002 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act and RS 438.2(A), and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded

health care programs.

252. The State of Louisiana, by and through the Louisiana Medicaid program and other state health care programs, and unaware of Novartis's fraudulent schemes, paid the claims submitted by health care providers and third party payers in connection therewith.

253. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Louisiana in connection with Novartis's fraudulent schemes.

254. Had the State of Louisiana known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis's schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would not have paid the claims submitted by health care providers and third party payers in connection with those schemes.

255. As a result of Novartis's violations of Louisiana RS 46:438.3 the State of Louisiana has been damaged.

256. This Court is requested to exercise supplemental jurisdiction pursuant to 28 U.S.C. § 1367(a) or pendent jurisdiction over this state-law claim as it is predicated upon the same facts as the federal claim asserted in Count I, and so forms part of the same case or controversy.

COUNT X: VIOLATIONS OF THE MASSACHUSETTS FALSE CLAIMS ACT

257. The allegations of paragraphs 1-143 are realleged as if fully set forth herein.

258. This is a *qui tam* action brought by Relator Don Galmines on behalf of himself and the State of Massachusetts for treble damages and penalties under Massachusetts False Claims Act, Mass. Gen. Laws Ann. Chap. 12 § 5(A) et seq.

259. Mass. Gen Laws Ann. Chap. 12 § 5B provides liability for any person who:

- (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth, or any political subdivision thereof;
- (3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim; or
- (4) is a beneficiary of an inadvertent submission of a false claim to the commonwealth or political subdivision thereof, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reasonable time after discovery of the false claim.

260. In addition, Mass. Gen. Laws Ann. Chap. 118E § 41 prohibits the solicitation, receipt or offering of any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any good, service or item for which payment may be made in whole or in part under the Massachusetts Medicaid program.

261. Novartis violated Mass. Gen. Laws Ann. Chap. 118E § 41 by engaging in the conduct described therein.

262. Novartis furthermore violated Mass. Gen. Laws Ann. Chap. 12 § 5B and knowingly caused hundreds of thousands of false claims to be made, used and/or presented to the State of Massachusetts by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Mass. Gen. Law Ann. Chap. 118E § 41 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

263. The State of Massachusetts, by and through the Massachusetts Medicaid program and other state healthcare programs, and unaware of Novartis's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

264. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Massachusetts in connection with Novartis's conduct. Compliance with applicable Massachusetts statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Massachusetts.

265. Had the State of Massachusetts known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis's conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would

not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

266. As a result of Novartis's violations of Mass. Gen. Laws Ann. Chap. 12 § 5B, the State of Massachusetts has been damaged.

267. This Court is requested to exercise supplemental jurisdiction pursuant to 28 U.S.C. § 1367(a) or pendent jurisdiction over this state-law claim as it is predicated upon the same facts as the federal claim asserted in Count I, and so forms part of the same case or controversy.

**COUNT XI: VIOLATIONS OF THE
MICHIGAN MEDICAID FALSE CLAIMS ACT**

268. The allegations of paragraphs 1-143 are realleged as if fully set forth herein.

269. This is a qui tam action brought by Relator Don Galmines on behalf of himself and the State of Michigan to recover treble damages and civil penalties under the Michigan Medicaid Fraud Claims Act, MCL 400.601 *et seq.*

270. MCL 400.603 - 607 provides liability for any person who:

- (1) knowingly makes or causes to be made a false statement or false representation of a material fact in an application for medicaid benefits;
- (2) enters into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another to obtain the payment or allowance of a false claim under the social welfare act; or
- (3) makes or presents or causes to be made or presented to an employee or officer of this state a claim under the social welfare act.

271. MCL 400.604 prohibits the solicitation or receipt of any remuneration, including any kickback or bribe made in connection with the furnishing of goods or services for which payment is or may be made in whole or in part pursuant to a program established under Act No. 280 of the Public Acts of 1939.

272. Novartis violated MCL 400.604 by engaging in the conduct described herein.

273. Novartis furthermore violated MCL 400.603-607 and knowingly caused false claims to be made, used and/or presented to the State of Michigan from 2002 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA and MCL 400.604, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs.

274. The State of Michigan, by and through the Michigan Medicaid program and other state health care programs, and unaware of Novartis's fraudulent schemes, paid the claims submitted by health care providers and third party payers in connection therewith.

275. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Michigan in connection with Novartis's fraudulent schemes.

276. Had the State of Michigan known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with

Novartis's schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and or misleading information, it would not have paid the claims submitted by health care providers and third party payers in connection with those schemes.

277. As a result of Novartis's violations of 400.603-607, the State of Michigan has been damaged.

278. This Court is requested to exercise supplemental jurisdiction pursuant to 28 U.S.C. § 1367(a) and 31 U.S.C. § 3732(b) or pendent jurisdiction over this state-law claim as it is predicated upon the same facts as the federal claim asserted in Count I, and so forms part of the same case or controversy.

COUNT XII: OMITTED

279. Omitted.

280. Omitted.

281. Omitted.

(1) Omitted.

(2) Omitted.

(3) Omitted.

(4) Omitted.

282. Omitted.

283. Omitted.

284. Omitted.

285. Omitted.

286. Omitted.

287. Omitted.

288. Omitted.

289. Omitted.

COUNT XII: OMITTED

290. Omitted

291. Omitted

292. Omitted

293. Omitted

294. Omitted

295. Omitted

296. Omitted

297. Omitted

298. Omitted

299. Omitted

300. Omitted

COUNT XIV: OMITTED

301. Omitted

302. Omitted

303. Omitted

304. Omitted

305. Omitted

- 306. Omitted
- 307. Omitted
- 308. Omitted
- 309. Omitted
- 310. Omitted
- 311. Omitted

COUNT XV: TENNESSEE FALSE CLAIMS ACT

312. The allegations of paragraphs 1-143 are realleged as if fully set forth herein.

313. This is a qui tam action brought by Relator Don Galmines on behalf of himself and the State of Tennessee to recover treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et. seq.*

314. Tenn. Code Ann. § 71-5-182 provides liability for any person who:

1. presents, or causes to be presented to the state, a claim for payment under the Medicaid program knowing such claim is false or fraudulent;
2. makes, uses, or causes to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false; or
3. conspires to defraud the State by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent.

315. Novartis violated Tenn. Code Ann. § 71-5-182 and knowingly caused false claims to be made, used and presented to the State of Tennessee from at least 2002 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA, and by virtue of the fact that none of the claims submitted in connection with

its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs.

316. The State of Tennessee, by and through the Tennessee Medicaid program and other state health care programs, and unaware of Novartis's fraudulent schemes, paid the claims submitted by health care providers and third party payers in connection herewith.

317. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Tennessee in connection with Novartis's fraudulent schemes.

318. Had the State of Tennessee known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis's schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and/or misleading information, it would have not paid the claims submitted by health care providers and third party payers in connection with those schemes.

319. As a result of Novartis's violation of Tenn. Code Ann. § 71-5-182(a)(1), the State of Tennessee has been damaged.

320. This Court is requested to exercise supplemental jurisdiction pursuant to 28 U.S.C. § 1367(a) and 31 U.S.C. § 3732(b) or pendent jurisdiction over this state-law claim as it is predicated upon the same facts as the federal claim asserted in Count I, and so forms part of the same case or controversy.

COUNT XVI: OMITTED

- 321. Omitted.
- 322. Omitted.
- 323. Omitted.
- 324. Omitted.
- 325. Omitted.
- 326. Omitted.
- 327. Omitted.
- 328. Omitted.
- 329. Omitted.
- 330. Omitted.

**COUNT XVII: COMMONWEALTH OF VIRGINIA
FRAUD AGAINST TAXPAYERS ACT**

- 331. The allegations of paragraphs 1-143 are realleged as if fully set forth herein.
- 332. This is a qui tam action brought by Relator Don Galmines on behalf of himself and the Commonwealth of Virginia to recover treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Article 19.1, § 8.01-216.1 *et seq.*
- 333. Virginia Art. 19.1, §§ 8.01-216.3 provides liability for any person who:
 - (1) knowingly presents, or causes to be presented, to an officer or employee of the Commonwealth, a false or fraudulent claim for payment or approval;
 - (2) knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth; or

- (3) conspires to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid.

334. Virginia Code § 32.1-315 prohibits the solicitation, receipt or offering or payment of any remuneration, including any kickback, bribe, or rebate, in cash or in kind to any person to induce such person to purchase, lease, order, or arrange for or recommend purchasing, leasing or ordering any goods, facility, service or item for which payment may be made in whole or in part under medical assistance.

335. Novartis violated Virginia Code 32.1-315 by engaging in the conduct described herein.

336. Novartis violated Virginia Code 8.01-216.3 and knowingly caused false claims to be made, used and presented to the State of Virginia from 2002 to the present by its deliberate and systematic violation of federal and state laws, including the FDCA and Virginia Code 32.1-315, and by virtue of the fact that none of the claims submitted in connection with its fraudulent schemes were even eligible for reimbursement by the government-funded health care programs.

337. The Commonwealth of Virginia, by and through the Virginia Medicaid program and other state health care programs, and unaware of Novartis's fraudulent schemes, paid the claims submitted by health care providers and third party payers in connection therewith.

338. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief,

also an express condition of payment of claims submitted to the Commonwealth of Virginia in connection with Novartis's fraudulent schemes.

339. Had the Commonwealth of Virginia known that Novartis was violating the federal and state laws cited herein and/or that the claims submitted in connection with Novartis's schemes failed to meet the reimbursement criteria of the government-funded health care programs or were premised on false and or misleading information, it would not have paid the claims submitted by health care providers and third party payers in connection with those schemes.

340. As a result of Novartis's violations of Virginia Article 19.1, § 8:01-216.3, the Commonwealth of Virginia has been damaged.

341. This Court is requested to exercise supplemental jurisdiction pursuant to 28 U.S.C. § 1367(a) and 31 U.S.C. § 3732(b) or pendent jurisdiction over this state-law claim as it is predicated upon the same facts as the federal claim asserted in Count I, and so forms part of the same case or controversy.

VI. PRAYER FOR RELIEF

WHEREFORE, on Count I, Relator requests:

1. That the Court enter judgment against Novartis in an amount equal to three times the amount of damages the United States Government has sustained because of Defendants' actions, plus a civil penalty of \$11,000 for each action in violation of 31 U.S.C. § 3729, and the costs of this action, with interest, including the costs to the United States Government for its expenses related to this action;

2. Omitted

3. That Relator be awarded an amount for collecting the civil penalty and damages of 30% of the proceeds of this action or the settlement of any such claim;

4. That Relator be awarded all costs, attorneys' fees, and litigation expenses;

5. That the United States Government and Relator receive all relief, both at law and in equity, to which they may reasonably appear entitled.

On all remaining Counts, Relator requests:

1. That the Court enter judgment against Novartis in the maximum amount of damages available under each state or commonwealth False Claims Act over which the Court accepts jurisdiction, to include any multipliers provided in such Acts;

2. That the Court enter judgment against Novartis for the maximum amount of civil penalties in favor of those states or commonwealths whose False Claims Acts provide for such relief, together with such state's or commonwealth's costs of this action;

3. That Relator be awarded, under each state or commonwealth False Claims Act, the maximum share permitted by law of all amounts recognized by such state or commonwealth as a consequence of this action;

4. That Relator be awarded all costs, attorneys' fees, and litigation expenses;

5. That each state or commonwealth and Relator receive all relief, both at law and in equity, to which they may reasonably appear entitled.

Respectfully submitted,

/s/ Frederick M. Morgan, Jr.
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CERTIFICATE OF SERVICE

I certify that copies of this document were served on all counsel who have appeared through the Court's ECF system on March 12, 2015:

/s/ Frederick M. Morgan, Jr.
Frederick M. Morgan, Jr.